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Government of Uttar Pradesh

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R.D.S. E-STAMP VENDER SHCIL ACC. No. UP14267604 Sign. Mob: 9532997410 SADAR TEHSIL, LUCKNOW

Certificate No.	:	IN-UP04319804617799V
Certificate Issued Date	:	09-May-2023 03:21 PM
Account Reference	:	NEWIMPACC (SV)/ up14267604/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14267604031305401092 00V
Purchased by	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Description of Document	:	Article 4 Affidavit
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Second Party	:	SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SC
Stamp Duty Paid By	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

NOTARY VIJAY KUMAR DWIVEDI, ADV. GOVT OF (INDIA) NOTARIAL

NOTARY VIJAY KUMAR DWIVEDI ADV. GOVT OF (INDIA)

SWORN & VERIFIED BEFORE ME
9/5/2023
...UMAR DWIVEDI
...Advocate & Notary
Reg. ...66 Expiry 24-8-2025
Mob. ...13783222

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

R.D.S. E-STAMP VENDER * SADAR TEHSIL, LUCKNOW * SHCIL ACC. Code 87604 Sign..... Mob:9532997410

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Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

NOTARY * VIJAY KUMAR DWIVEDI, Adv. * GOVT OF (INDIA) NOTARIAL NOTARIAL

Please write or type below this line

NOTARY * VIJAY KUMAR DWIVEDI, Adv. * GOVT OF (INDIA)

SWORN & VERIFIED BEFORE ME 9/5/2023

VIJAY KUMAR DWIVEDI

Advocate & Notary

Reg. No. 5666 Expiry 24.8.2025

Mob. 9919733222

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (hereinafter called the 'MOU') is made at Lucknow on this ..... day of ..... month... ..... of 2023;

BETWEEN

Dr. Ram Manohar Lohia Institute of Medical Sciences, Lucknow, which has its office at Vibhuti Khand, Gomti Nagar, Lucknow, Uttar Pradesh, hereinafter referred to as **"First Party"** which expression shall, unless it be repugnant to or inconsistent with the context or meaning thereof, be deemed to mean and include its successors and permitted assigns through its authorised signatory..... who is authorised to sign and execute this document

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, having its office at Rae Bareli Road, Lucknow, hereinafter referred to as **"Second Party"**, which expression shall, unless it be repugnant to or inconsistent with the context or meaning thereof, be deemed to mean and include its successors and permitted assigns.

Whereas First Party and Second Party have come together to enter into a collaborative understanding, **AND WHEREAS** the parties herein desires to enter into a MOU setting forth services to be provided by the collaborative;

NOW, THEREFORE, the parties mutually intended, agreed and consented to the following terms in pursuance of a common intent to promote and develop as under:

GENERAL

This MOU is not a legal commitment and shall not be construed as a legal contract. Rather, this MOU expresses the intention of the parties to provide mutual collaboration through procedures set forth herein to the maximum extent possible.

OBJECTIVES

The purpose of this MOU is to set forth the terms and conditions, scope of work and responsibilities of the parties associated with their collaboration on arranging the testing anti HLA antibodies in the department of Nephrology of Second Party at the time of deceased kidney transplantation at the First Party Institution.

Sign.... 3/5/23
VIJAY KUMAR DWIVEDI
Advocate & Notary
Regn. No.a Expiry 24.6.2025
Mob. No 16733x80

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

AND WHEREAS, the First Party is a registered centre (ME-3/2016/HOTA renewed via ME-3/2021/HOTA for performing renal transplantation since year 2016, and is desirous of starting deceased donor renal transplantation program in the near future.

AND WHEREAS, it is the statutory requirement that once a kidney is allocated to prospective recipient(s) at First Party Institution (Dr.RMLIMS) by the State Organ & Tissue Transplant Organisation (SOTTO) Uttar Pradesh, prior to receipt of donor kidney, waitlisted patient(s) from Dr.RMLIMS will need to be tested for anti-HLA antibodies by flow cytometric cross match technique, the expertise for which is available in-house at Department of Nephrology, SGPGIMS, Lucknow

NOW it is agreed between the Parties as follows :

1. That once it is decided that one donor kidney is allocated to a patient registered at Dr.RMLIMS, and the proposed recipient(s) have been called and blood samples have been drawn, the same shall be transported to the Department of Nephrology, SGPGIMS, Lucknow for performing flow-cytometric cross match.

2. That once the results of the above mentioned test(s) are available, the recipient will be finalized for organ transplantation.

3. That both the parties shall conform to the guidelines for research, good clinical practice and medical ethics.

4. That apart from the charges incurred in performing the said tests at Department of Nehprology, SGPGIMS there will be no further financial implications to this understanding. All the cost incurred for the tests, will borne by the patient(s).

5. That both the parties shall be liable for the acts and omissions of its own employees and agents with respect to this MOU and shall save the other institution harmless in relation to losses or damages, if any.

6. Neither institution shall be liable for the acts and omissions of any third party, if any, with respect to this MOU.

7. Any notice to be given under this MOU shall be in writing and shall be deemed to have been duly and properly served upon the party hereto if delivered by e-mail or speed post.

8. None of the parties shall do or cause to be done anything derogatory to the reputation of the other.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

9. This MOU shall be effective from the date of signing by both the parties and will be valid for the five years which may be extended for a suitable period as mutually agreed between the parties.

10. In the event of any dispute relating to the interpretations or performance of this MOU arising between the parties, both parties will settle the dispute amicably through the Head of Organisations. However all disputes are subject to the jurisdiction of Court of Lucknow, U.P.

11. This MOU may be terminated by either party on prior notice of 30 days in writing.

12. Unless agreed otherwise or as set out in a separate specific project agreement, the parties acknowledge and accept that each party is bound to apply its own internal policies including those relating to intellectual property ownership and its use.

13. Both the parties shall not reproduce each other's logo without obtaining the prior consent of the other.

IN WITNESS WHEREOF, th duly authorised representatives of the participating Institutions have here to executed and se their hand by their signature below.

On behalf of Dr. RMLIMS, Lucknow

29.04.2023

Signature

Name

On behalf of SGPGIMS, Lucknow

26/5/23

Signature

Name

Signature of Witnesses

1.

2.

9/5/23

Sign
VI
PI
Regn
Mob 9918733222

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Certificate No.	:	IN-UP42937547995208V
Certificate Issued Date	:	01-Mar-2023 11:08 AM
Account Reference	:	NONMPACC (SV)/ up14730704/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14730704899685791Q4V
Purchased by	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Description of Document	:	Article 6 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Second Party	:	Not Applicable
Stamp Duty Paid By	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Stamp Duty Amount(Rs.)	:	10 (Ten only)

NOTARY
R.C. VERMA
ADV. & NOTARY
Lucknow U.P. INDIA
Regd. No. 1/2003

Sworn and verified
before me

R.C. VERMA
ADV. & NOTARY
Lucknow U.P. INDIA
Regd. No. 1/2003

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – MoU (RP)

Dr. Ram Manohar Lohia Institute of Medical Sciences Lucknow has applied for seeking accreditation with NBE in the specialty of Clinical Hematology. The applicant hospital does not have adequate exposure in the areas of Hematopoietic Stem Cell Transplantation.

As per NBE requirements, comprehensive training shall be provided by the hospital as per prescribed DNB/DrNB curriculum in the specialty. To ensure the same, the applicant hospital has undertaken a Memorandum of Understanding (MoU) with Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow which is recognized for DM Programme in the specialty of Clinical Hematology and where the above mentioned exposure is available.

As per the MOU, the trainees of the applicant hospital shall be rotated to the above mentioned hospital under MOU as per following externship plan:

Areas wherein exposure is inadequate in the applicant hospital	Proposed hospital for externship of trainees (Specify Name & complete address)	Duration of rotational posting (in weeks/months)
Hematopoietic Stem Cell Transplantation	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, UP, INDIA	3 months

The above said externship shall be governed by following terms and conditions:

	Terms & Conditions for Externship	Hospital submission
1.	The rotation shall be Hands on experience and not mere observer ship.)	Yes, the rotation will provide 'Hands On' experience in the field of stem cell transplant
2.	How does the applicant hospital propose to monitor the training of the candidates as part of the proposed MoU?	Faculty of applicant hospital (Dr RMLIMS, Lucknow) will monitor training progress of candidate weekly (Saturday) by evaluating the logbook and assessing the learning achievements.
3.	Who shall bear the stipend of the candidate during this period of training outside the hospital in another accredited institute?	Applicant hospital (Dr. RMLIMS, Lucknow) will bear the stipend of the candidate during training period.
4.	What shall be the status of theses supervision?	Thesis supervision will be continued during this period by maintaining the records of patients proforma, sample collections and follow up. Review of thesis work will also be done once a week (Saturday) by physical meeting with thesis candidate.
5.	How will the thesis supervisor and guide of the candidate provide teaching and mentoring support during this period?	Thesis supervisor and guide of the candidate will provide teaching and mentoring support during this period by calling candidate on every Saturday to the applicant hospital (Dr RMLIMS, Lucknow)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

		which is only 15Km away from externship hospital (SGPGIMS, Lucknow). After the thesis review monitoring of the training will be done as specified in S. No. 7
6.	Nature of responsibilities of the respective hospitals that shall deploy the candidate for the appropriate period of providing training.	Hands on training of all procedures involved in the Stem Cell Transplant patient management followed by weekly appraisal/Logbook review of the training will be done both by the applicant (Dr RMLIMS, Lucknow) as well as externship hospital (SGPGIMS, Lucknow).
7.	*Validity of MoU*: The MOU shall be effective w.e.f. 1st December 2022 and shall remain valid till 31st December 2025	

Date: 24th November 2022

Place: Lucknow

GOVT. OF UTTAR PRADESH NOTARY R. C. VERMA Adv. & NOTARY Lucknow U.P. India Regd. No. 21764/2009

A. Nityanand

Signature & Stamp of Head of the Institute
(Applicant Hospital)

Director
Dr. Ram Manohar Lohia
Institute of Medical Sciences
Vibhuti Khand, Gomti Nagar, Lucknow

Signature & Stamp of Head of the Institute
(Hospital under MOU)

Prof Radha Krishan Dhiman
Director
Sanjay Gandhi Postgraduate Institute
of Medical Sciences, Lucknow-226014

SIGNATURE ATTESTED

R.C. VERMA
Adv. & NOTARY
Collectorate Court
Lucknow U.P. India
Regd. No. 21764/2009

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(69)

MIDLAND
HEALTHCARE & RESEARCH CENTER
(A UNIT OF APOORVA MEDICARE PVT. LTD.)

13/4/23

To,
Director,
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow.

Subject : Observership for DNB candidates of Midland Healthcare, Lucknow .

Sir,

This is to present a MOU regarding the DNB programme for Urology at Midland Healthcare & Research Center. As per our request for the MOU where your Respectful Institute which is recognized for the Mch programme will allow our DNB candidates for externship for a month each in Renal transplantation and Paediatric Urology in third year of the candidate .

We humbly request your approval for the Observership for the candidates.

Thanking you,

Aditya Pratap Singh
Director,
Midland Healthcare & Research Center,
Lucknow.

10/Apr/2023

SGPGIMS, Lko.
RSD CELL (E-OFFICE)
Computer No. 58244
Date 11.04.2023
Time 9:55 AM

F.I.R

11/4/23

To,
HOD Urology
& Renal Trans.
Comment/ Plea

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Certificate No.	:	IN-UP80936710186269V
Certificate Issued Date	:	10-Apr-2023 03:20 PM
Account Reference	:	NEWIMPACC (SV)/ up14587504/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14587504561493235239991V
Purchased by	:	MIDLAND HEALTHCARE RESEARCH CENTER
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	MIDLAND HEALTHCARE RESEARCH CENTER
Second Party	:	SANJAY GANDHI POSTGRADUATE INSITUTE OF MEDICAL SCI
Stamp Duty Paid By	:	MIDLAND HEALTHCARE RESEARCH CENTER
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

MEMORANDUM OF UNDERSTANDING FOR EXTERNSHIP OF DNB TRAINEES

The present Memorandum of Understanding (MoU) is being signed between:
'Hospital 1' **Midland Healthcare& Research Center, Lucknow.**
and

'Hospital 2'**Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow.**

Whereas in terms of the applicable rules and regulations of the NBEMS and in order to ensure comprehensive training of the candidate, as per the prescribed DNB/DrNB curriculum in the concerned specialty (Urology), the present MoU is being signed between Hospital 1 and Hospital 2.

Whereas Hospital 1 has applied for accreditation with the NBEMS for the DNB program in the Specialty of Urology, but does not have adequate exposure in Renal Transplant.

SIGNATURE ATTESTED

And whereas Hospital 2 is recognized /accredited for the MCh. program in the Specialty of Urology and the above mentioned exposureis available.

Collectorate Code

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

And whereas the trainees of the above mentioned Hospital 1 shall be rotated to the above mentioned Hospital 2 for externship for 01 month as per the following plan:

Areas wherein exposure is inadequate in the Hospital 1	**Name and Complete Address for proposed Hospital 2**	**Duration of rotational posting (in weeks / months)**
Renal Transplantation	**Department of Urology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow.**	1Month
Sub-Speciality area of Urology (Paediatric Urology)	**Department of Urology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow.**	1Month

And whereas the abovementioned externship shall be governed by following terms and conditions:

1. That the rotation shall be hands on experience and not mere observership.

2. That **Midland Healthcare& Research Center, Lucknow** shall bear the stipend of the candidate during theperiod of externshi in Hospital 2.

3. That the supervision of thesis shall be done by the Hospital 1 during the period of externship.

4. Hospital 1 and Hospital 2 both agree that failure to comply with any of the aforementioned conditions may lead to withdrawal of accreditation by the NBEMS and / or a recommendation to the NMC for the withdrawal of recognition granted to the said hospital / institution.

That the present MoU shall be effective from 01/04/2023 and shall remain valid till 31/03/2029.

Date :-

Place:-

Midland Healthcare & Research Centre

Signature and Stamp
Of HOI of Hospital 1

DIRECTOR
S.G.P.G.I.M.S., Lko.

SIGNATURE ATTESTED
10/4/2023
Collectorate Court
Lucknow U.P. INDIA
Regd No 31/04/2000

Signature and Stamp
of HOI of Hospital 2

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH GA 778980

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (in short MOU) is made at LUCKNOW and entered into as of this .16th. day of February, in the year, 2023 (hereinafter called the 'Effective Date').

BETWEEN

THE INTEGRAL UNIVERSITY (IU), Lucknow, Uttar Pradesh (hereinafter referred to as the 'University') through its duly authorized by U.P. Act No.9, 2004 of the Uttar Pradesh State Government and incorporated under Uttar Pradesh Private Universities Act 2019 (U.P. Act no.12 of 2019). The University is duly approved by the University Grants Commission (UGC) under sections 2(f) and 12B of the UGC Act, 1956, Medical Council of India, Pharmacy Council of India, Indian Nursing Council, Council of Architecture, Bar Council of India, Indian Association of Physiotherapists, National Council for Teacher Education, UP State Medical Faculty. Integral University is accredited by NAAC and recognized as a Scientific & Industrial Research Organization (SIRO) by the Department of Scientific & Industrial Research, Ministry of Science & Technology, Government of India represented by Vice Chancellor, Registrar, Director, Admissions & Academics (authorized signatory) (which expression shall, unless it be repugnant to or inconsistent with the context or meaning thereof, be deemed to mean and include its successor and permitted assigns), Integral University of the first party.

AND

THE SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS), Lucknow, (hereinafter referred to as the 'PGI'), a Body Corporate State Medical

Prof. Radha Krishan Dhiman
Registrar
Sanjay Gandhi PGIMS, Lucknow

Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

E. To promote framing of joint research projects in diseases of public health importance.

F. Joint organization of seminars, workshops, short-term CMEs and other academic activities

G. Faculty members/scientists from both institutes may be invited to deliver guest lectures, and other academic deliberations for benefit of students and faculty members.

H. To support the visit of students and faculty members for utilization of library facilities on reciprocal basis.

BACKGROUND

1.03. Both the parties see the benefits of this project, have a desire to pursue the project and have determined that each brings unique expertise and experience necessary to accomplish the object outlined hereinabove -

CO-ORDINATION AND FUNDING

1.04. In order to carry out and fulfill the objectives of this MOU, each party may appoint (an) appropriate person (s) to represent its institution and co-ordinate the implementation of activities. They will meet regularly with prior notice to each other to discuss the progress and activities. A specific plan would be worked out for each activity, setting forth detailed arrangements for collaboration. The terms and conditions for each visit including purpose, funding if any will be worked out between the institutions. Terms of any financial arrangements will be subject to agreement and will be worked out on case to case basis.

CONFIDENTIALITY

1.05. Each party agrees that it shall not, at any stage, after initiating or executing the activities of this MOU, disclose any information relating to these activities or the affairs of business or method of carrying on the business of the other party without consent of the parties. The terms of confidentiality and mode of disclosure shall be as per the mutually acceptable terms.

LEGALITY OF MOU

1.06.

i. Both parties assume that this MOU does not go against the laws of the land.

ii. This MOU will be functional from the effective date and will have an initial duration of 5 years and may be reviewed for possible renewal for further period as mutually agreed.

ETHICS APPROVAL

1.07. Where the nature of a research project undertaken by the visiting scholar requires human or animal ethics approval, the Host Institution will ensure that an appropriate approval is obtained from the competent forum to be determined on project to project basis.

INTEGRAL UNIVERSITY LUCKNOW-INDIA

Prof. Kalyan Krishan Dhiman
Director
Institute

Lt Gen Makrand Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

AMENDMENTS

3.04. All modifications, additions, omissions, review, revision and amendments to this MOU must be mutually agreed to by the parties in writing in accordance with the law of the land.

EXTENSION OF MOU

3.05. The MOU may be extended for further period provided the parties agree upon and can provide the necessary resources.

TERMINATION

5.01. This MOU may be terminated by either party on ninety days' prior notice in writing.

5.02. Termination of the MOU shall prevent the selection of additional visiting scholars but the PARTIES shall honour all commitments to the visiting scholars already accepted or participating in the programme on the date of termination.

INTELECTUAL PROPERTY

6.01 Both parties i.e. Integral University and PGI agree to respect intellectual property rights in all matters of each of the parties.

6.02 The visiting scholar shall acknowledge the host institution in any of its publication (s) related to work done during the exchange programme.

6.03. Unless agreed otherwise or as set out in a separate specific project agreement, the parties acknowledge and accept that each party is bound to apply its own internal policies including those relating to intellectual property ownership and its use.

6.04. Both the parties shall not reproduce each other's logo without obtaining the prior consent of the other.

IN WITNESS WHEREOF, the duly authorized representatives of the participating Institutions have here to execute and set their hands by their signature below:

Prof. Javed Mussarat
Vice-Chancellor
Integral University
Lucknow

VICE CHANCELLOR
INTEGRAL UNIVERSITY
LUCKNOW

Prof. Radha Krishan Dhiman
Director
Sanjay Gandhi Postgraduate Institute
Of Medical Sciences, Lucknow-226014

Prof. R. K. Dhiman
Director
Sanjay Gandhi Postgraduate Institute of
Medical Sciences, Lucknow

Witness :

Prof. Mohammed Haris Siddiqui
Registrar
Integral University, Lucknow

Witness :

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

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e-Stamp

Signature
Acc Name:- Mohd Kamar
Acc Code:- UP14014104
Acc Addr:- Sector 37 Noida Mob-9650885051
Firm No. 104 Tehsil & Distt. Dadri G.B. Nagar U.P

Certificate No.	:	IN-UP942505968464400U
Certificate Issued Date	:	19-May-2022 01:20 PM
Account Reference	:	NEWIMPACC (SV)/ up14014104/ GAUTAMBUDDH NAGAR 1/ UP-GBN
Unique Doc. Reference	:	SUBIN-UPUP14014104799416681710611U
Purchased by	:	POSTGRADUTE INSTITUTE OF CHILD HEALTH
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	POSTGRADUTE INSTITUTE OF CHILD HEALTH
Second Party	:	SANJAY GANDHI POST GRADUTE INSTITUTE OF MEDICAL SC
Stamp Duly Paid By	:	POSTGRADUTE INSTITUTE OF CHILD HEALTH
Stamp Duly Amount(Rs.)	:	100 (One Hundred only)

NOTARY PUBLIC BALKRISHNA DIXIT G.B. NAGAR (U.P.) Regd. No. 7767 GOVT. OF INDIA

NOTARY PUBLIC BALKRISHNA DIXIT G.B. NAGAR (U.P.) Regd. No. 7767 GOVT. OF INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This MoU made on this _____ of _____ between Post graduate Institute of Child Health, Sector 30, Noida- 201301 (An Autonomous Institute under the Government of Uttar Pradesh) of the one part.

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India (hereinafter called SGPGIMS, Lucknow which expression shall where the context so admits, include its successors and permitted assigns) of the second part.

Each PGICH, Noida and SGPGIMS, Lucknow here under are also referred to separately as the ("Party") or together as ("Parties")

Background

i. PGICH, Noida and SGPGIMS, Lucknow will share interests in teaching training, skill building and research in the area of Biomedical Research and basic sciences.

ii. The two Parties have identified that a stronger relationship between them is mutually beneficial and wish to establish a more formal relationship with each other.

1. Commencement and Duration

1.1. This Memorandum of Understanding ("MoU") shall take effect on the date of signing and shall continue for a period of 05 years unless terminated earlier in accordance with the provisions of Clause 7.

2. Scope of the MOU

2.1. The areas of agreement outlined in this MoU are described to facilitate more detailed and specific negotiations between the parties which may lead to the preparation and signing of one or more formal agreements between PGICH, Noida and SGPGIMS, Lucknow. Unless specifically noted herein, this MoU is not intended to be of legal force and effect in any manner whatsoever. This MoU shall not create a legal relationship between the parties.

3. Broad Areas for Cooperation

3.1. PGICH, Noida and SGPGIMS, Lucknow will discuss the possibility of cooperation in the following areas:

a. Joint Research projects

b. Training of Post Graduate students of PGICH at SGPGIMS as per the norms of the institute and vice versa.

c. Organizing joint seminars and conferences

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

d. Joint publications as a result of collaborative research

e. Faculty interaction between two organizations

f. Any collaborative efforts that both may deem fit from time to time.

g. Collaborative efforts in social outreach programs

3.3. Representatives of the Parties may agree to review the operation of this MoU from time to time.

4. Joint Contributions

4.1. Potential areas for collaborative research will be identified and recorded in subsequent research specific agreement(s) that set out appropriate and relevant contributions by the Parties. This may include-

a. Access to its research laboratories and assist in development of projects involving the parties

b. Joint submission of research proposals to national and international organizations to obtain support for their common research objectives

c. PGICH, Noida, and SGPGIMS, Lucknow shall work specifically in the areas defined in Para (i) and Para 3.1.

4.2. The parties acknowledge that all specific financial arrangements proposed must be negotiated and will depend upon the availability of funds and organization approvals

5. Confidentiality and Privacy

5.1. PGICH, Noida and SGPGIMS, Lucknow recognize that they will come into possession of information which the other considers to be confidential, including Personal information ("Personal Information" means information and opinion recorded in any form about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion). Each of PGICH, Noida and SGPGIMS, Lucknow covenants and agrees that it shall not, at any time, disclose to any third party, any confidential information of another party without first having obtained the prior written consent of the other party.

5.2. The provisions of this Clause 5 are intended to and shall be binding upon the parties upon the signing of the MoU and shall survive the termination or expiry of this MoU

6. Intellectual Property

NOTARY PUBLIC BALKRISHNA DIXIT G.B. NAGAR (U.P.) Regd. No. 7157 GOVT. OF INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.1 "Intellectual Property" means and includes all copyright, all rights in relation to inventions (including patent rights), plant varieties, registered and unregistered trademark, registered and unregistered designs and all other rights resulting from intellectual activity in the scientific, industrial, literary or artistic fields.

5.1 Each party shall retain all rights to all existing intellectual property belonging to it and contributed by it ("Background IP") at the commencement of each Research Project arising under this agreement.

5.3. If any IPR issue emerges as a result of joint research, then a specific IPR addendum will be jointly agreed upon

7. Termination

7.1. Either of PGICH, Noida and SGPGIMS, Lucknow may terminate this MoU by written notice to the other party. A minimum period of six months notice will be required form a party wishing to terminate the MoU, or such shorter period as the parties may agree upon in writing.

7.2. The termination of this MoU shall not affect the implementation of activities that have been undertaken prior to such termination, unless agreements pertaining to such activities explicitly provide for such termination.

8. Amendments and Supplementary Agreements

8.1. The parties may agree to amend this MoU at any time by further memoranda in writing executed by the duly authorized officer(s) of each party.

8.2. The parties shall wherever necessary enter into written agreements to facilitate collaborative activities arising from this MoU. Such agreement will specify the details of agreed activities and programs, including the contribution and responsibilities of the parties, funding, intellectual property provision, confidentiality, risk allocation and indemnity obligations of each party.

9. Use of Name and Logo

9.1. No party shall use, nor permit any person or entity to use, the name or logo (or any variation thereof) of another party without first obtaining prior written consent from the other party. The parties intend that this provision shall be binding upon them and shall survive the termination or expiry of this MoU.

NOTARY PUBLIC
BALKRISHNA DIXIT
G.B. NAGAR (U.P.)
Regd. No. 7167
GOVT. OF INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

[illegible] PGIMER	[illegible] SGPGIMS, Lucknow
Signature	Signature
Name:	Name:
Designation:	Designation:
Seal:	Seal:
Date:	Date:
Witnesses	Witnesses
1.	1.
2.	2.

This agreement is executed in the following four parts-

1. Ext's Lucknow Medical College, Lucknow
2. King George's Medical University, Lucknow
3. SGPGIMS, Lucknow
4. RML, Lucknow.

NOTARY PUBLIC BALKRISHNA DIXIT G.B. NAGAR

ATTESTED
BALKRISHNA DIXIT
Advocate (Notary)
U. No. 7167
G.B. NAGAR (U.P.)

19 MAY 2022

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Certificate No.	:	IN-UP38860504821501V
Certificate Issued Date	:	20-Feb-2023 11:37 AM
Account Reference	:	NEWIMPACC (SV)/ up14756204/ BAKSHI KA TALAB/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14756204716488692522O4V
Purchased by	:	CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Second Party	:	SGPGIMS LUCKNOW
Stamp Duty Paid By	:	CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

NOTARY Suresh Kumar Adv. & Notary Distt. Lucknow Reg. No. 31(89) 09 GOVT. OF U.P. INDIA

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

"A Randomized Double Blind Placebo Control Clinical Study to Evaluate the Immunomodulatory Effect of Swarnprashan in Moderately Malnourished Children"

SIGNATURE ATTESTED

SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Majar Dev...
Niwaj Ganj Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Between

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES (CCRAS)

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS), LUCKNOW

This memorandum of understanding (MoU) entered into and executed on date..... between **Central Council for Research in Ayurvedic Sciences** (hereinafter referred to as **"CCRAS"**), a society registered under the Societies Registration Act 1860, having its office at 61-65, Opp. 'D" Block, Institutional Area, Janakpuri, New Delhi which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include its nominees, istrators, legal representatives executors, successors in interest / business, and permitted assigns, of the of the First part

And

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow (hereinafter referred to as SGPGIMS) which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include its nominees, istrators, legal representatives, executors, successors in interest / business, and permitted assigns, of the other party.

NOTARY Suresh Kumar Adv. & Notary ... No. 31(ob)/05 GOVT. OF U.P. IND

1. Preamble:

Whereas **CCRAS** an autonomous organization, which comes under the Ministry of AYUSH, Govt. of India is a nodal apex body in the country for the formulation and coordination of Research in Ayurvedic Sciences on Scientific lines. The Research is being executed through 30 Institutes, Units and Centers besides conducting Collaborative Research with reputed National and International Research and Academic Institutions. Regional Ayurveda Research Institute (RARI), Lucknow is one of the institutions under CCRAS which will be the executive institute for the project.

Sanjay Gandhi Postgraduate Institute of Medical Sciences was established under the State Legislature Act in 1983. It was created by the state of Uttar Pradesh as a centre of excellence for providing medical care, education and research of the highest order.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Majar ... Marg
Niwaj Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2. **OBJECTIVE OF THE MOU:**

To carry out the collaborative research project titled **"A Randomized Double Blind Placebo control clinical study to evaluate the immunomodulatory effect of Swarnprashanin moderately malnourished children "** as per the terms and conditions and guidelines of CCRAS Research Policy.

3. **PROPOSED MODES OF COLLABORATION:**

CCRAS and **SGPGIMS** propose to collaborate through:

3.1. Undertaking the research project **"A Randomized Double Blind Placebo control clinical study to evaluate the immunomodulatory effect of Swarnprashan in moderately malnourished children"** with duration of 30 months from the date of study initiation at SGPGIMS, Lucknow.

3.2. Research work (including the patient screening, enrolment and treatment) will be carried out at SGPGIMS premises wherein Dr. Vikas Agarwal, Professor, Department of Clinical Immunology and Rheumatology, SGPGIMS will be the Principal investigator and Dr.Gaurav Pandey, Additional professor, deptt of Gastroenterology, Dr.Abhaynarayan Tiwari, Director, Harsh Ayurveda Lucknow and Dr. Durga PrassannaMisra, Associate professor, Department of Clinical Immunology and Rheumatology, SGPGIMS, Dr. Madan Lal Brahma Bhatt, Professor and Head, Department of Radiotherapy, King George's Medical University, Lucknow and Dr. Siddharth Koonvar, Professor Junior Grade , In-charge of PICU, Department of Pediatrics, GM&AH, KGMU Lucknow, Dr. Shruti Khanduri, Research officer (Ay.) CCRAS, Dr. Swati Sharma Research officer (Ay.) CCRAS and Dr. Anjali Prasad, Research officer (Ay.) CCRAS will be the co-investigators.

4. Both **CCRAS** and **SGPGIMS** are interested in collaborating with each other to facilitate the execution of this project with sharing of following responsibilities:

4.1 Responsibilities of CCRAS :

4.1.1 CCRAS agrees for a collaborative research project entitled ***"A Randomized Double Blind Placebo control clinical study to evaluate the immunomodulatory effect of Swarnprashan in moderately malnourished children"*** with SGPGIMS, Lucknow.

NOTARY Suresh Kumar GOVT. OF U.P.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Maja... Marg
Niwaj Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.1.2 Standardized Ayurvedic interventions (Swarnaprashan and its matching placebo, honey, ghee) will be procured from GMP certified pharmaceuticals by CCRAS for the clinical trial and will be provided to the study site prior to the initiation of the trial.

4.1.3 Entire funding amounting to Rs. **1,21,36580/-**for the proposed project will be extended by the CCRAS and the fund will be released in the name of the Director, SGPGIMS, Lucknow, 226014.

4.1.4 The execution of the project will be done in collaboration with the RARI and SGPGIMS, Lucknow as per the guidelines of CCRAS Research Policy.

4.1.5 The final research Protocol, CRF and E-format to capture the data will be shared by the CCRAS.

4.1.6 Final statistical analysis of the same will be done by the statistical section at CCRAS Hqrs.

4.1.7 Data Safety Monitoring Board shall be constituted by RARI Lucknow after approval of the competent authority at CCRAS Hqrs.

4.1.8 CCRAS shall constitute a Monitoring Committee (consisting of 3-4 members) to monitor the study progress and fund utilization allocated in the project.

4.1.9 CCRAS reserves the right to terminate MoU at any stage after giving written notice of one month, if desired cooperation will not be provided by the second party and on any other valid cause.

4.1.10 CCRAS will get the insurance coverage of the participants for entire duration of the study.

4.1.11 Protocol of the project will be published by CCRAS with due authorship to all the investigators and project team.

4.1.12 No data of the project in any part/ whole or its outcomes will be disclosed or published by the investigators or any other authority/ faculty of CCRAS/RARI in any form and confidentiality shall be maintained at all levels from sharing of protocol to data evaluation.

4.2 Responsibilities of SGPGIMS, Lucknow :

4.2.1 SGPGIMS will conduct the aforesaid research project as approved by the CCRAS as per the study protocol and guidelines of CCRAS research policy.

4.2.2 The Ethical Clearance (from Institutional Ethics Committee)of this project will be obtained by SGPGIMS for conducting the research work.

NOTARY Suresh Kumar Advocate Notary Regd.No. 31(55) GOVT. OF U.P.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Nagar Devi Das Marg
Niwaj Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.2.3 CTRI Registration for the clinical trial would be done by the PI at SGPGIMS Lucknow

4.2.4 Dr. Vikas Agarwal, Professor, Department of Clinical Immunology and Rheumatology, SGPGIMS, Principal investigator of this study will be responsible for timely completion of the project. He shall also submit a detailed monthly, quarterly and annual progress report as per the prescribed format.

4.2.5 Fund utilization certificate along with the final report shall be submitted to the RARI Lucknow after completion of the trial and the final UC including the budget utilized at their center will be provided by the coordinating center (RARI).

4.2.6 Data and study records (including consent documents) will be stored, retained and protected in accordance with the protocol as per the CCRAS Research Policy and GCP guidelines at the SGPGIMS.

4.2.7 The Data of study participants will be shared with the CCRAS for data monitoring, verification and statistical analysis.

4.2.8 Any deviation from the currently approved protocol shall be informed to the IEC/CEC and the same shall be reported to CCRAS Hqrs.

4.2.9 Any AE/SAE shall also be reported to the IEC within 24 hours of the incident under intimation to the Council.

4.2.10 SGPGIMS shall support the monitoring committee constituted by CCRAS

4.2.11 No data of the project in any part/ whole or its outcomes will be disclosed or published by the investigators or any other authority/ faculty of SGPGIMS in any form and confidentiality shall be maintained at all levels from sharing of protocol to data evaluation.

4.2.12 In the event of premature termination of MoU, SGPGIMS shall remit the remaining/unused budget to CCRAS within the notice period of one month along with the data and the remaining trial formulation.

4.3 Joint Responsibility :

4.3.1 The timely and proper execution of the study is the joint responsibility of both the parties viz CCRAS and SGPGIMS.

4.3.2 Ensuring that the conduct of the research study adheres to Good Clinical Practice Guidelines.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Ma...
Niwaj Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

4.3.3 Reporting of any untoward outcomes or deviation from the currently approved protocol to the IEC and the Council.

4.3.4 Maintaining adequate and accurate research subject records to reflect adherence to protocol specific requirements.

4.3.5 Since it is a collaborative study, the research outcome shall be published with public acknowledgement and authorship to the contributors of each party on completion of the project and only after obtaining the approval from CCRAS.

4.3.6 All information obtained and derived either in writing or otherwise shall be treated as confidential during and after the expiry period of this MoU unless otherwise mutually agreed upon in writing by both the Parties. Both the parties will abide by the provisions of CCRAS Research Policy and other conditions enforced for transfer of technology and commercialization of research outcomes.

5. *Period of MoU and Termination Clause :*

5.1 This MoU shall be valid for a period of 3 years from the date of signing the agreement or till the completion of the project whichever is earlier, and its extension, continuation or otherwise shall be jointly decided by CCRAS and SGPGIMS two months prior to the completion of the said period.

In case of termination of the project, steps shall be taken to ensure that the termination is not prejudicial to any activity undertaken within the framework of the MoU.

5.3 This MoU may be amended, if needed, by mutual agreement of both the parties and the intention to amend any terms and/or conditions shall be communicated to the parties in writing.

NOTARY Suresh Kumar Adv. & Notary Regd. No. 31(05) GOVT. OF U.P. (INDIA)

6. Arbitration:

In the event of any dispute or differences between the parties hitherto, such differences shall be resolved amicably by mutual consultation. Where it could not be resolved so, then it shall be referred to the third arbitrator (appointed by the arbitrators of each party). The word of the said arbitrator shall be final and binding on both the parties. The place for jurisdiction for any dispute or claim before a court or an arbitration shall be Delhi.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Nawaj Gen[illegible]
Nawaj Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, both the parties have set and subscribed their respective hands to this memorandum of understanding on the date and place first mentioned above, in the presence of following witnesses:

On behalf of CCRAS	**On behalf of SGPGIMS**
(RARI Lucknow)	**(Head of the Institution/ Research Section)**
प्रभारी सहायक निदेशक क्षेत्रीय आयुर्वेद अनुसंधान संस्थान लखनऊ	Prof. R.K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014 INDIA
Signature	Signature
Name : Dr. Brij Bhushan	Name :
Date : 01/03/2023	Date :
Witness	**Witness**
1. Signature	1. Signature Mohit
Name : DR ALOK KUMAR SRIVASTAVA	Name : Mohit Kumar Rai
Address : RARI, INS-106, Sector-25 Indira Nagar, Lucknow	Address: Clinical Immunology department, SGPGIMS, Lucknow -226014, U.P.
2. Signature	2. Signature Anurag Kumar Srivastav
Name : DR. ANJALI BAIJNATH PRASAD RESEARCH OFFICER (AY.)	Name : ANURAG KUMAR SRIVAS
Address : RARI, INS-106, SECTOR-25 INDIRA NAGAR, LUCKNOW	Address : 2/255, Rajini Khand, Sharda Nagar, Lucknow U.P. -226002

NOTARY Suresh Kumar Adv. Lucknow Regd. No. 31(a-) GOVT. OF U.P. INDIA

SIGNATURE ATTESTED

SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Maja: ..arg

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

सत्यमेव जयते

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Government of Uttar Pradesh

e-Stamp

Certificate No.	:	**IN-UP157361350890085U**
Certificate Issued Date	:	13-Jun-2022 03:38 PM
Account Reference	:	NEWIMPACC (SV)/ up14238304/ MOHANLALGANJ/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14238304231475958984 34U
Purchased by	:	DR UDAY C GHOSHAL
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	
First Party	:	DR UDAY C GHOSHAL
Second Party	:	Not Applicable
Stamp Duty Paid By	:	DR UDAY C GHOSHAL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

NOTARIAL NOTARIAL

Sworn & Verified
Before Me

13/06/2022
AKHILESH KUMAR
Statutory Alertry
ADVOCATE & NOTARY
Distt. Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

Preamble:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow is a superspecialty hospital, established by Government of Uttar Pradesh, as a center of excellence for providing medical care, education and research of high order and is chartered to function as a university under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, 1983. [Hereinafter referred to as "Act"]

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day .....

AMONG

Atmo Biosciences Limited, ABN 83 626 053 183 , **a company** originally incorporated in Australia .....

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India, through its **"Director Prof. RK Dhiman** [herein referred to as "Institute"] of the Second part.

AND

Dr. Prof. Uday C Ghoshal, Department of Gastroenterology, Sanjay GandhiPostgraduate Institute of Medical Sciences [hereinafter referred to as **"Principal Investigator"**] of the Third Part.

WHEREAS The Sponsor, Institute and, Principal Investigator are willing to jointly carry out the Study Number: 2021-270-EMP-123

Entitled: "Feasibility of a new diagnostic device to assess small intestinal dysbiosis in routine clinical setting" **[Hereafter referred to as "Study"]** described in Study Protocol;

AND WHEREAS Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study through **Contract Research Organization (CRO) [if needed]**

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1.0 Statement of work

1.1 "Study" shall be deemed to be "Clinical Trial" as defined in rule-122 DAA of the Drugs and Cosmetics Rule, 1945.

1.2 Sponsor shall provide Principal Investigator with a sufficient quantity of Study Supplies to conduct the Study at investigational Site in timely manner. Institute and Principal Investigatorshall use Study Supplies only to conduct the Study in accordance with the Protocol; All Study Supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of Sponsor, unless otherwise designated. The Institute and Principal Investigator will be responsible for the return of excess, unused Study Supplies to the Sponsor.

1.3 Study Timelines: Study Timelines for the purpose of this Agreement will be as per need of Protocol.

2.0 Obligations and Responsibilities of the Principal Investigator

2.1 The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria.

2.2 The Principal Investigator will conduct the study in accordance with protocol, Schedule Y (Drug and Cosmetics Rules, 1945) and Indian Council of Medical Research (ICMR) Guidelines along with Helsinki and The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for international studies.

2.3 The Principal Investigator will make necessary arrangement for inspection of documents etc. by sponsor's monitor, official of regulatory agency or Institutional Ethics Committee (IEC) nominee.

2.4 The Principal Investigator shall report all serious and unexpected adverse events and/ or death to the Licensing Authority, Sponsor, and IEC as per Appendix XI of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

2.5 The Principal Investigator shall forward its report on Serious Adverse Event of Death after due analysis of all factors with his opinion to Chairman of IEC, Chairman of Expert Committee and Head of the Institute and the Licensing authority as per Appendix X of schedule Y (Drug and Cosmetics Rules, 1945).

2.6 The Principal Investigator shall forward its report on Serious Adverse Event (SAE) other than Death after due analysis of all factors with his opinion to Licensing Authority, Chairman of IEC and Head of the Institute as per Appendix X of schedule Y (Drug and Cosmetics Rules, 1945).

2.7 The Principal Investigator will be responsible for proper and prompt filling of Case Report Form (CRF), preservation of investigation reports and recordings.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.8 During and following a Clinical Trial Subject's participation in Study, the Principal Investigator shall ensure that adequate medical care is provided to the participant (Clinical Trial Subject) for any adverse events.

2.9 The Principal Investigator will ensure enrolment of trial participants after obtaining informed consent including audiovisual recording and also informing the provisions of adequate treatment and compensation for Serious Adverse Event (SAE) as per schedule Y (Drug and Cosmetics Rules, 1945).

2.10 Principal Investigator (PI) shall complete the Clinical Trial under his supervision as per the agreement and the Statutory provisions, but if for any reason he/she is unable to carry over the study it shall be his/her responsibility to hand over the study to his/her Co-Principal Investigator (Co-PI) or to any of the Faculty members of the Institute, to be decided by the Head of Department of the PI or Director and obtain the approval of the Ethics Committee and the Sponsor.

2.11 The Principal Investigator will be responsible for proper account of receipt, utilization and return of unused sample of trial device to sponsor and prevent its use for any other study.

2.12 The Principal Investigator will be responsible for providing non-compliance and progress report to Institutional Ethics Committee (IEC) within a week of occurrence or due date.

2.13 The Principal Investigator will be responsible for forwarding to IEC communications from sponsors within a week of receipt with comments for the need of any change in protocol or Patient Information Sheet (PIS).

2.14 The Principal Investigator shall be responsible for obtaining sponsor's permission before publication or conference presentation of any data.

3.0 Obligation and Responsibilities of the Institute:

3.1 Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirement.

3.2 Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.

3.3 Fulfillment of necessary obligations by Institutional Ethics Committee (IEC), the Principal Investigator (PI) and supporting staff.

3.4 Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.

3.5 Adequate treatment and compensation for Serious Adverse Event (SAE) to trial participants.

3.6 Necessary infrastructure support to PI.

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

3.7 Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related Study documents.

3.8 Ensuring accuracy, completeness, legibility and timelines of the Data reported to the Sponsor in the Case Report Forms (CRFs) and in all required reports.

3.9 Study shall be terminated on the recommendation of IEC, when safety and benefit of Clinical Trial Subjects is doubtful.

3.10 Safety reporting as per schedule Y (Drug and Cosmetics Rules, 1945) and/or Sponsor policy.

3.11 Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records.

3.12 The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.

3.13 If Sponsor or Contract research organization (CRO) violates the terms of this Agreement or does not provide the claimed compensation to the subject then the Institute or Principal Investigator may not conduct any other further clinical trials of this sponsor.

3.14 Approval of study within 8 weeks of receipt of Investigator's brochure, protocol including Patient Information Sheet (PIS) & Case Report Form (CRF), regulatory approvals, draft Clinical Trial Agreement (CTA), Insurance policy and IEC fee from sponsor.

3.15 Approval of midterm changes within 8 weeks of receipt of documents.

3.16 Review of progress report Data and Safety Monitoring Board (DSMB) report & Serious Adverse Event (SAE) from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

3.17 Review of SAE at Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) and necessary action within the time frame decided by regulatory agencies.

3.18 Review of final report.

3.19 Facilitate visit of sponsor's monitor or representative of regulatory agencies.

3.20 Archiving of data for 5 years (or longer if required by sponsor/regulatory agency).

3.21 Safeguarding Intellectual property rights (IPR) of sponsor and SGPGI.

3.22 Providing alternate Principal Investigator (PI) if PI unable to continue.

3.23 Audited statement of utilization of Funds.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.0 Obligation and Responsibilities of the Sponsor

4.1 To provide investigator's brochure, Protocol, Case Report Form (CRF) draft Clinical Trial Agreement (CTA).

4.2 To provide adequate supplies of trial device under proper quality control.

4.3 To provide Insurance cover for treatment and compensation of Serious Adverse Event (SAE) and an undertaking to supplement any amount not covered by the Insurance Company. Sponsor will also provide copy of Policy to the Institute.

4.4 Undertaking to provide test device free of cost to participants after termination of the trial if necessary till it become available in the country.

4.5 Provide a copy of final report at termination of the study.

4.6 Appropriate acknowledgement of contribution of SGPGI investigators in any resulting publication.

4.7 To define and follow procedure for premature termination.

4.8 To provide budget which should include cost of treatment, investigations and investigators charges, reimbursement of travel expenses to participants if necessary, Institute's overhead at the rate of 25% of the total budget and INR 25,000/- fee of IEC. Details of release of budget to be mutually settled.

5.0

5.1 Sponsor agrees that any injury or death of the Clinical Trial Subject occurring in Clinical Trial due to following reasons shall be considered as Clinical Trial related injury or death and the subject or his nominee, as the case may be, will be entitled to receive from the sponsor financial compensation for such injury or death as per the notification of the Drug Controller General of India (DCGI) & Government of India issued from time to time.

(a) Adverse effect of Investigational Product(s);

(b) Violation of the approved Protocol;

(c) Scientific misconduct or negligence by the Sponsor or his representative or Principal Investigator, Co-investigator or anymember of his/her team

(d) Failure of Investigational Product to provide intended therapeutic effect;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved Protocol;

(f) Any Clinical Trial procedures involved in the Study.

5.2 Sponsor should submit a status report on the Clinical Trial to the Licensing Authority at the prescribed Periodicity;

5.3 In case of studies permanently discontinued for any reason Sponsor shall submit a summary report to the Licensing Authority as per provisions of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

6.0 Undertaking and Representation of Principal Investigator

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format given in Appendix VII of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

7.0 Undertaking and Representation of Institute

Institute hereby represents that:-

It has constituted the Institutional Ethics Committee as per the guidelines given in the Gazette of India & it has been registered with the Drug Controller General of India (DCGI) vide letter No:……dated…..

(i) SOP is in compliance with Good Clinical Practice (GCP) guidelines and applicable regulations;

(ii) It will ensure that IEC will discharge its responsibilities as per provisions of Schedule-Y (Drug and Cosmetics Rules, 1945)

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that:-

It has furnished an undertaking along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of clinical trial related injury or death for which subjects will be entitled to compensation; as per provisions of rule 122 DAB (b) of Rules (Drug and Cosmetics Rules, 1945).

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

9.0 Administration

9.1 Overall responsibilities of the Study will rest with Principal Investigator, Institute and Sponsor to conduct the Study at Institute's premises.

9.2 The following Study plan will apply to the Study:

(a). Subject enrollment up to Institute's Enrollment Maximum (i.e.: Clinical Trial Subjects) shall be completed as stated in protocol. However, if the Institute and Principal Investigator are unable to enroll patients for the Study within 6 months of Investigation Site initiation Sponsor will be having the authority to change the Institute's Enrollment Maximum in a unilateral manner.

(b). Institute or Principal Investigator will not enroll more Study subjects than Institute's Enrollment Maximum Sponsor will not be obligated to make any payment with respect to any subject enrolled in excess of Institute's Enrollment Maximum.

(c). Subject to applicable law: Sponsor and Institute without any further obligation mutually may agree in writing to modify Institute's Enrollment Maximum.

(d). All subject visits will be conducted as proposed in the protocol. The sponsor will be informed is a visit is delayed by more than 2 weeks along with reason of delay.

(e). Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within 7 days after the subject's visit or, if applicable, receipt of the subject's test results.

(f). All Data Queries from Sponsor must be completed and returned to Sponsor within a time frame mutually negotiated.

(g). Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or Study team will not be the liability of Sponsor.

10.0 Trial device; Materials Transfer; Records Retention; Inspection

10.1 Trial device:

(i) Institute and Principal Investigator acknowledge that the trial device is owned or controlled by Sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Institute or Investigator for the Trial, shall be construed to grant to either Institute or Principal Investigator any rights in or to the Compound.

(ii) Except as otherwise agreed by the Parties, Sponsor will provide the device as part of the Trial (collectively, the **"Trial device"**) free of charge to Institute for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Trial subjects at the Trial Site in Strict compliance with the Protocol.

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(iii) Institute and Principal Investigator shall use the Trial device solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial device to any third parties. Institute and Principal Investigator shall handle, store, ship and dispose of the Trial device as directed by Sponsor or its designee and in compliance with all applicable laws, rulesand regulations.

(iv)Neither support of the Trial, nor Institute participation in the Trial, impose any obligation, express or implied, on Institute or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's products.

10.2 Records Maintenance and Retention Investigator and Institute will maintain adequate and accurate records relating to the disposition of the Trial Device and the performance of all required Protocol procedures on Trial subjects including but not limited to, written and audiovisual documents, medical records, charts pertaining to individual Trial subjects, "Case Report Forms (**"CRF"**) accounting records, notes, reports, and data. Institution will retain these documents for the longer period of at least 5 yrs. after completion or earlier termination of the Trial.

11.0 Representation and Warranties

11.1 Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the Trial in accordance with this Agreement and the Protocol.

11.2 Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

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12.0 Confidentiality

12.1 Institute will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than patient medical records), including the Trial Results, Trial Inventions and information related thereto **(Confidential Information).** Institute and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential Information will not include information that:

(i) Is or becomes publically available through no fault of Investigator or Institution.

(ii) Was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute form other source.

(iii) Is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

(iv) Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

12.2 Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

(i) To comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Institute cooperate with Sponsor efforts to limit such disclosure by appropriate legal means:

(ii) To protect any Trial subject's safety or provide appropriate medical care for any Trial subject, or to prevent a public health emergency with prompt notice to Sponsor

(iii) For purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial subject related to the procedures included in the Protocol.

13.0 Return of Confidential Information

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in

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Executive Registrar
SGPGIMS,Lucknow

writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

14.0 Trial Results and Inventions

14.1 Sponsor owns all data, Trial Results, Confidential Information, Case Report Forms (CRFs) and all other information generated as a result of or in connection with the conduct of the Trial, excluding Institution's patient medical records and Principal Investigator's personal notes and hereby grants to the Institute a nonexclusive, non–transferable, non-sub licensable right to use the Trial Results solely for its own internal, non-commercial research, patient care, and educational purposes.

14.2 All inventions, ideas, methods works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institute, Principal Investigator or Trial Personnel: (i) as a result of or in connection with the conduct of the Trial (ii) that incorporate or use Confidential Information: or (iii) that are directly related to the Compound and in each case together will all intellectual property rights relating thereto (collectively, **Trial Inventions**"), will be the sole and exclusive property of Sponsor Or its designee. Institute and Principal Investigator will promptly disclose all Trial Investigations to sponsor in writing and interest in all Trial Investigations to sponsor or its designee. At sponsor's request and expense, Institute shall take and shall cause Principal Investigator and Trial Personnel to take, all additional actions as it deems necessary to perfect the interest of sponsor or its designee in Trial Investigations or to obtain patents or otherwise protect the interest of sponsor or its designee in Trial Investigations.

15.0 Payment

15.1 In consideration for conducting the Study Sponsor shall pay Institute and Principal Investigator as described in Annexure-A. Sponsor will not make further payments, towards Study visits, procedures, or other work associated with a Study subject if Sponsor determines that the Clinical Trial Subject's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

15.2 Sponsor shall pay on a Per Subject Cost for each Satisfactorily Completed Subject (as defined below) in accordance with Annexure-A as attached to this Agreement. If a subject is discontinued for reason stipulated in the Protocol, the Institute and Principal Investigator shall be paid a prorated rate for work completed.

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(a). Per Subject Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Annexure-A. The estimated total amount per Clinical Trial Subject listed in Annexure-A is calculated for a Clinical Trial Subject that completes all the Study visits. Screening Visits are paid for consented Clinical Trial Subjects for whom all screening procedures are performed. All visit costs include Institutional overhead, staff fees and applicable taxes.

(b). The per subject costs is a fixed fee per patient which includes all costs and honoraria, including but not limited to;

- All Study related activities such as conduct of visit assessment and CRF completion
- Time and efforts of Principal Investigator/s and other Institute's Study personnel
- All diagnostic test and other investigations (ECG, Chest X-ray, Spinal X-ray etc.)
- Housing or hospital stay for patients including meals
- Patient reimbursement/ Compensation
- All overhead costs
- Usage of Instruments/ equipments which during the Study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Institute infrastructure).

(c). A completed and evaluable patient means Patient:

(i). Subjected to Study on whom all procedures have been performed and completed according to Protocol;

(ii). Who is enrolled for the Study according to inclusion and exclusion criteria;

(iii). For whom all Data documented accurately and completely;

(iv). All Data queries resolved completely in mutually agreed timely manner; and

(v). For whom all source, CRF and other Study related documents completed as per protocol standard requirements as mentioned in Annexure-A.

15.3 **Screen Failures/ Drop-outs:** For drop-outs payment will be made by Sponsor on a pro-rated basis for the number of completed visits and per screen failures (if applicable).

15.4 **Set-Up Fees:** Sponsor will pay the Institute an initial advance amount of INR 2,86,000 within 15 days after obtaining the Ethics Committee and necessary regulatory approval. This up-front advance payment would be exclusive of Institutional overhead and service charges and shall be deducted/ adjusted on pro-rata basis from further subsequent payments.

15.5 **Hospitalization costs:** Apart from Study specific the in-house, treatment of the subject in the event of any Serious Adverse Event (SAE) shall be paid by Sponsor to the Clinical Trial Subject.

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15.6 **Institutional Ethics Committee Fees:** Institutional Ethics Committee review fees will be paid by sponsor as determined.

15.7 **Payments by Sponsor to Institute shall be directed as follows:**

Principal Investigator Fee/ Clinical Trial Subject Reimbursement and Hospitalization:

Payee Name (Account name)	**Director, SGPGIMS, Research a/c**
Account Number	**10095237491**
Bank Name	**State bank of India**
Branch Name	**SGPGI Branch, Lucknow**
Swift/IFSC Code	**SBIN0007789**
PAN Number*	**AAAJS3913N**
Send to <<Cheque Delivery Address>>	**Dr. Uday C Ghoshal ,Department of Gastroenterology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014, U P, India**

15.8 Subject travel reimbursement is exclusive of Institutional overhead and will be done as mentioned in Annexure-A. However, Sponsor will release the funds to Institute and Principal Investigator for each Clinical Trial Subject, i.e., INR 33,750/- **(inclusive of 25% institutional overhead)** as per the Study schedule. The trial device will be supplied by the sponsor free of cost.

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15.9 In the event there is a refund due to Sponsor at the time of premature termination of this Agreement by any party, the Institute agrees to remit the same to Sponsor within fifteen (15) days of the effective termination date.

15.10 **Tax deduction:** All fees and amounts listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the Institute for the Study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

16.0 Use of other parties' names

The Principal Investigator and Institute shall not use Sponsor's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ CRO/Institute.

17.0 No joint venture etc.

This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18.0 Insurance and Indemnification

Insurance:

Institute shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

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19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

19.1 The Principal Investigator and Institute shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

19.2 The Principal Investigator and Institute shall notify to the Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute s facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the PrincipalInvestigator and Institute receives, obtains, or generates pursuant to any such study.

19.3 The Principal Investigator and Institute will permit the Sponsor to;

(a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.

(b) Inspect and copy all Data, documents and records related to such work and the Study

19.4 The obligations of this Section shall survive termination of this Agreement.

20.0 Term; Waiver; Severability (The trial on its time extended)

20.1 This Agreement will be in force for a period of the trial or its time extended from the date of its signing. The term of this Agreement may be extended by consent of all parties to this Agreement.

20.2 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 12 months after the Effective Date. The Date of execution of this Agreement shall be the effective Date.

20.3 This Agreement will become effective after by the last signatory it is fully executed by all the parties hereto and shall continue in effect for the full duration of the Study according to the Protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

20.4 This Agreement may be terminated by any party upon giving at least a thirty (30) days written notice to that effect to the other parties. The day following the 30th day of such notice shall be "Effective Date of Termination". A reasonable adjustment will be made between the parties to ensure the Principal Investigator and Institute is reimbursed for project costs incurred to the date of termination of this Agreement for completing the study as per protocol or already enrolled subjects.

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20.5 Sponsor may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institute subject to the discharge of their respective obligations under the terms of the agreement.

21.0 Effect of termination

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(ii). Upon notice of termination of this Agreement by Institute or Sponsor or Principal Investigator, Institute shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institute shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails to repay such funds in a timely manner, Sponsor may deduct an equivalent amount from any payment then or later due from Sponsor to Institute under this or any other arrangement between the parties.

(iii). Upon termination of this Agreement, all unused Materials and all Sponsor Confidential Information (except for such records that Institute is required by law or regulation to retain) in Institute's possession shall be promptly delivered to Sponsor at Sponsor's expense, or, at Sponsor's option, destroyed with the destruction certified in writing.

22.0 Recordkeeping

The Institute and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, Institutional Ethics Committee (IEC) requirements, and in accordance with all applicable local, state and Central laws and regulations. Institute or Principal Investigator shall cooperate with the Sponsor in making records, reports and Data developed under this Agreement.

Institute or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity.

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whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

23.0 Publication

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the Clinical Trial Study is the sole property of the Sponsor. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but his name should to be included in any publication either author or as participant in the study.

24.0 Miscellaneous

24.1 Parties to this Agreement shall comply with the current provision of Drugs and Cosmetic Act 1940, Drugs and Cosmetic Rules 1945.

For providing insurance to Clinical Trial Subjects in case of injuries or death,

24.2 The Study shall be started by Principal Investigator after this Agreement is executed by all the parties and required regulatory approvals/consent is available for the study.

24.3 The parties to this Agreement shall ensure that safety, welfare and right of the research participants (Clinical Trial Subject) are safeguard.

24.4 The Principal Investigator shall forward all Protocol deviation/non-compliance/violation/waiver reports to the IEC.

24.5 The safety completion Report shall be sent to IEC by Principal Investigator.

25.0 Governing Law

The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA as applicable in the State of Uttar Pradesh.

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SGPGIMS,Lucknow

26.0 Jurisdiction

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be Lucknow, notwithstanding any other provision to the contrary in any law in this regard.

27.0 Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed by the Chairman of the Institutional Ethics Committee of the Institute within 30 days of the receipt of a written request by the aggrieved. The Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

28.0 Amendment

This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the Study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

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Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, in triplicate, by their officers, thereunto duly authorized to sign on behalf of their party.

1. Principal Investigator, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: UCGhosal 16/6/2022

Dr. Uday C Ghoshal

(Name)

Title/Designation: Professor and Head, Department of Gastroenterology

2. Director/his nominee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: 23/09/22

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014. INDIA

Dr. RK Dhiman

(Name)

Title/Designation: Director

(Director/his nominee)

3. Sponsor

Atmo Biosciences M R Hebblewhite

Signature and date: _____

Mr. Malcolm Hebblewhite

(Name)

Title/Designation: .....

13/06/2022

AKHILESH KUMAR
ADVOCATE & NOTARY
Distt. Mohanlalganj, Lucknow

Identified by me the deponent/executant/survey who has signed/put his before me.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

सत्यमेव जयते

INDIA NON JUDICIAL

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महाराष्ट्र MAHARASHTRA ◑ 2022 ◑ जोडपत्र 2 BT 010639

जिल्हा कोषागार कार्यालय

जिल्हा कोषागार कार्यालय, ठाणे

14 NOV 2022

मुद्रांक प्रमुख किंवा लिपीक / लिपीक

14/11/2022

मुद्रांक विक्री नोंदवही अनु.क्रमांक 09050? दिनांक 23 NOV 2022

दस्ताचा प्रकार .....

दस्त नोंदणी करणार आहे का ? :- होय / नाही

मिळकतीचे थोडक्यात वर्णन .....

मुद्रांक विकत घेणा-याचे नांव..... SIRO Clinpharm Pvt. Ltd.

हस्ते असल्यास त्यांचे नाव, पत्ता.....

सही .....

दुस-या पक्षकाराचे नाव .. Dr. Kaushik Mandal

मुद्रांक शुल्क रक्कम .....

परवानाधारक मुद्रांक विक्रेत्याची सही (सौ. शिल्पा एस.नाईक) .....

तसेच मुद्रांक विक्रीचे ठिकाण/पत्ता :- नाईक कमर्शियल सेंटर, शॉप नं. 2, आनंद पॅलेस बिल्डींग, भवानी चौक, टेंबी नाका, ठाणे (प.).
(परवाना क्र.:- 1201033)

(ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून सहा महिन्यात वापरणे बंधनकारक आहे.)

Takeda

Takeda Sponsored Clinical Trial Site Agreement

A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Disease

Protocol Version 2 dated 22Feb2021

SIRO CLINPHARM PVT. LTD. THANE

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

जोडपत्र 2

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ WC 674426

मुद्रांक विक्री नोंदवही अनु.क्रमांक 90508 दिनांक 23 NOV 2022

दस्ताचा प्रकार : Agg

दस्त नोंदणी करणार आहे का ? :- होय / नाही

मिळकतीचे थोडक्यात वर्णन : NO

मुद्रांक विकत घेणा-याचे नांव : SIRO Clinpharm Pvt. Ltd.

हस्ते असल्यास त्यांचे नाव, पत्ता : Road No. 16, Wagle Industrial Estate, Thane, India.

सही : S.C. Mandal

दुस-या पक्षकाराचे नाव : Dr. Kausik Mandal

मुद्रांक शुल्क रक्कम : 100

परवानाधारक मुद्रांक विक्रेत्याची सही (सौ. शिल्पा एस.नाईक) :

तसेच मुद्रांक विक्रीचे ठिकाण/पत्ता :- नाईक कमर्शियल सेंटर, शॉप नं. २, आनंद पॅलेस बिल्डींग, भवानी चौक, टेंबी नाका, ठाणे (प)
(परवाना क्र. : 1201033)

जिल्हा कोषागार कार्यालय, ठाणे

17 NOV 2022

मुद्रांक प्रमुख लिपीक / लिपीक

(ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून सहा महिन्यात वापरणे बंधनकारक आहे.)

THIS SPONSORED CLINICAL TRIAL SITE AGREEMENT (the "Agreement") is made as of 24th November 2022, by and among **SIRO Clinpharm Private Limited**, a clinical research organization having a place of business at Kalpataru Prime, 1st Floor, Unit nos. 3 and 4, Plot no D-3, Road no 16, Wagle Industrial Estate, Thane (West) – 400 604, Maharashtra, India ("**CRO**"), **Sanjay Gandhi Postgraduate Institute of Medical Sciences**, having a place of business at Raebareli Road, Lucknow, Uttar Pradesh 226014, India ("**Institution**") and **Dr. Kausik Mandal**, (the "**Investigator**" and together with the Institution, the "**Site**")

SIRO CLINPHARM PVT. LTD. THANE 400 604

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

For purposes of this Agreement, each of CRO and the Site and the Investigator may be referred to as a "Party" and together as the "Parties."

RECITALS:

WHEREAS, Takeda Biopharmaceuticals India Pvt. Ltd ("**Sponsor**") desires to conduct a clinical trial on Sponsor's marketed drug identified as **Replagal** (the "Study Drug");

WHEREAS, Sponsor is engaged in the research and development of human pharmaceutical products;

WHEREAS, Sponsor has designated the CRO ("in the performance of services for Sponsor for the conduct of the Study as defined hereunder and to perform any or all of Sponsor's obligations under this Agreement;

WHEREAS, the CRO, on behalf of the Sponsor, is desirous to obtain the services of the Site and the Siteshall permit the CRO to perform any or all of Sponsor's obligations under this Agreement;

WHEREAS, the Investigator is an employee of Institution, experienced in the conduct of clinical research studies in humans, who shall serve as the principal investigator as contemplated in Clause 3.3 of the Indian Good Clinical Practices guidelines as amended from time to time, issued by the Director General of Health Services, India ("Indian GCP") and Rule 2(t) of the New Drugs and Clinical Trials, 2019 for the Study (defined below);

WHEREAS, the Site has reviewed sufficient information regarding the Protocol (defined below) to evaluate its interest in participating in the Study, and the Site is equipped to undertake the Study and desires to perform the Study on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein, the Parties, intending to be legally bound, have entered into this Agreement and do specifically agree as follows:

1. Study Protocol.

The Site will conduct the study entitled "**A Prospective, Open-label, Multicentre, Interventional, Single-arm, Phase IV Study to Evaluate the Safety and Efficacy of Agalsidase alfa (r-DNA origin) (Replagal™) in Indian Children and Adults With Fabry Disease**"" (the "**Study**") at Institution in accordance with the protocol, a copy of which was previously provided and incorporated herein by reference (the "**Protocol**"). The Protocol sets forth the clinical research activities and responsibilities to be undertaken by the Parties. CRO, at the direction of Sponsor, shall have the right to amend and/or supplement the Protocol from time to time on written notice to Investigator and/or Institution. If any term of this Agreement regarding the medical or scientific conduct of the Study conflicts with any term of the Protocol, the Protocol shall control. For all other matters, this Agreement shall control.

No changes to the Protocol should be implemented without prior written approval of the relevant ethics committee (the "EC") and Central Licensing Authority, that is, the Drugs Controller General of India (the "**DCGI**") and CRO to be taken by the Investigator except where the Investigator determines in his/her best medical judgment that a deviation from the Protocol is necessary to eliminate apparent immediate hazards to the trial subject or when change involves only logistic or administrative or minor aspects of the Study trial. All such exceptions including administrative or logistic changes at the Site must be immediately notified by the Investigator to CRO, Sponsor and the EC.CRO, on behalf of the Sponsor, shall notify about such exceptions and/or administrative or logistic changes to the Central Licensing Authority in accordance with the Applicable law within thirty (30) days.

Except as provided for in the previous paragraph, the Investigator shall not amend or deviate from the Protocol without the prior written approval of Sponsor. All amendments made to the Protocol with prior

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Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

iv. complete all subject case report forms (the "CRFs") using the form(s) provided by CRO, whether recorded on paper or in digital format, review the CRFs to assure their accuracy and completeness, assist the representatives and clinical monitors of CRO in promptly resolving any discrepancies or errors on CRFs, and, provided subject confidentiality is maintained, assist in performing audits of original subject records, laboratory reports, or other raw data sources for the purpose of verifying data recorded on the CRFs;

v. ensure that all data, including signatures, supplied to CRO will meet the principles of ALCOA+ (attributable, complete, legible, original, accurate, contemporaneous, permanent, readily retrievable), and further certify that appropriate controls are established to mitigate the risks related to intentional or unintentional falsification of data and signatures as required by Applicable Law;

vi. cooperate with Sponsor and the CRO, in all of their efforts to support and monitor the Study, including without limitation, allowing Sponsor on-site access to the facilities where the Study is being conducted and any and all records and other documents associated with the conduct of the Study as reasonably requested by Sponsor and/or CRO. Sponsor shall intimate and request for on-site access through CRO by giving a reasonable notice. Site shall assist in the monitoring as requested by the Sponsor (through CRO) by providing all requested documentation in a timely and organized manner, and keeping Sponsor (through CRO) fully apprised of the progress of the Study;

vii. record all adverse events on the Adverse Events ("AE") page(s) of the CRFs and promptly report all adverse events and serious adverse events to the CRO, Central Licensing Authority and EC in accordance with Applicable Law and the Protocol and cooperate with Sponsor in identifying and resolving unexpected occurrences involving the Study Drug or its use in the Study. Site acknowledges that Sponsor may, at its option, communicate directly with the Investigator or Site concerning any serious adverse event or other adverse experiences.

viii. Investigator must immediately report all serious adverse events ("SAE") (as defined in Protocol) **(within 24 hrs. of occurrence of SAE)**. which occur during the Study and up to the date of the patient's last visit, to the following addressee given below. The SAE Report form/ eCRF will be used for documentation and reporting which shall include, but shall not be limited to, the Study number, the Subject's identification number, gender and birth date, the Investigator's name, the date of the first administration of Study Drug to Subject, any concomitant medications, any confounding medical conditions of the Subject, the date of onset of the adverse event, and any actions taken to treat or mitigate the event.

a) 24 hrs. SAE Reporting

Within 24 hours of site occurrence of a SAE/Pregnancy/Partner Pregnancy, study sites will complete SAE page of the eCRF, in English, and signed by the investigator immediately or within 24 hours of first onset or notification of the event.

- Central Licensing authority: Sites will submit a SAE form and Table 5 of third schedule to regulatory authority within 24 hours. In addition, SAE also needs to report to Ethic Committee and Sponsor.

b) Sponsor: All Initial and follow up SAE reports are to be sent on the following email ID: Institutional Ethics Committee, Post Graduate Institute of Medical Sciences, Dept. of Medical Genetics, Raebareli Road, Lucknow, 226014

- Ethics Committee: All Initial and follow up SAE reports are to be sent via e-mail or fax

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xvi. familiarize themselves with the safety, efficacy and appropriate use of the Investigational New Drug as described in the Protocol, Investigator's Brochure and other information sources provided by the CRO from time to time.

D. The Site further represents and warrants to CRO that:

i. neither the Institution, nor any of the Institution's employees or agents performing the Study, (1) are under any contractual or other obligations or restrictions that are inconsistent with the Institution's obligations under this Agreement, or (2) have a financial or other interest in Sponsor or the outcome of the Study that might interfere with their independent judgment, or (3) are under investigation by any regulatory authority, for debarment or any action in relation to clinical research, or (4) are presently debarred, disqualified, or deemed ineligible to conduct clinical research or to receive investigational drugs or devices as a clinical investigator under any Applicable Law. The Institution will notify the CRO immediately (a) if Institution, the Investigator, or any of its employees or agents become debarred, disqualified, or deemed ineligible by any court or regulatory agency, or (b) upon any inquiry concerning or the commencement of any debarment or disqualification proceeding regarding any such person, the Investigator, or Institution, together with any other information known to the Site that is relevant to such proceedings or actions;

ii. The Site shall properly supervise and have full administrative control over all persons performing the Study (as its sole and exclusive responsibility) under its direction and shall ensure that such persons comply with the terms of this Agreement and they shall remain employees, agents, contractors of the Institution. The Site shall be responsible for payment of all remuneration and benefits payable to the persons performing the Study, including without limitation salary, insurance contributions, income tax or other statutory payments under Applicable Laws and will ensure compliance with all employment related laws and regulations and shall indemnify the Sponsor and the CRO against all claims in respect thereof.

iii. The Site shall ensure the persons performing the Study have the acumen, expertise, qualifications, skills and all relevant valid and subsisting permits, training, medical licenses, qualifications, approvals, certifications, immunizations, equipment and information necessary for safely and properly performing the obligations under this Agreement. The Institution shall ensure that these are always backed by documentary proof and background check and verifications are duly carried out and properly maintained throughout the term hereof.

iv. The Institution shall take all necessary steps consistent with the current state of clinical research and Indian GCP to assure that all data, reports, forms or any other records generated pursuant to the Clinical Study by Investigator and Institution or its agents, employees, authorized and approved subcontractors shall be true and accurate and shall contain no false or misleading information.

v. The Site shall ensure that all the computers, databases, and related systems that are used by them in connection with Clinical Study shall, (i) be maintained in a fully validated state, (ii) shall comply with the standards applicable to software or information systems related to the conduct of clinical trials ("System Standards") in India including but not limited to Applicable Laws and regulations, and (iii) shall be duly encrypted with restricted and password protected and controlled access to only to the persons authorized to perform the Study.

vi. The Site shall ensure that the Clinical Study documents and files shall always be complete as per the Applicable Laws and in compliance with the Protocol for the Study.

E. Conflict of Interest

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v. Comply with the directions of the relevant regulatory authorities, with prior notice to the Sponsor and the Sponsor's approval of the same, issued in respect of the Study including providing medical management and payment of direct compensation to the Study subjects.

b. Prior to providing any Sponsor Confidential Information (as defined in Article 6) to the investigator and/or Site, CRO shall obtain a signed confidentiality agreement in a template provided by Sponsor, from the investigator and/or Site protecting such confidential information.

G. Regulatory Document Collection. CRO shall monitor the Study in compliance with the Applicable Laws and Regulations and Study Protocol. The Site shall facilitate Study document review by the CRO to the extent permissible under Applicable Law.

SIRO (alone or together with representatives from SPONSOR) will perform regular on-INSTITUTION monitoring visits throughout the Clinical Study. The tasks of the monitor comprise the following:

i. to ensure Protocol adherence,
ii. to verify the data in the CRFs against source documents (SDV),
iii. to check progress of the Clinical Study and to motivate, if necessary,
iv. to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
v. to check all data for possible SAEs and AEs,
vi. to review signed informed consent forms for signatures and date of consent,
vii. to ensure accurate record of drug accountability,
viii. to ensure adequate storage of Clinical Study supplies,
ix. to collect completed CRFs,
x. to discuss and help resolve any problems,
xi. to verify adequate insurance coverage undertaken by PI,
xii. to verify the ICF(s) as per the applicable regulatory guidelines.

H. Subject Informed Consents.

It is the Investigator's responsibility to explain the Clinical Study to each potential patient (parent and/or legal guardian of the infant) and obtain written informed consent before any Study procedures are performed. This is an unconditional prerequisite for Institution for participation of a patient in the Study. The Investigator shall inform the Subject or his/her nominee(s) for their rights to contact the Sponsor or CRO (whosoever has obtained permission from the licensing authority for the conduct of clinical trial) for the purpose of lodging claims in case of any trial related injury/death. The explanation shall at least include all points listed in the International Council on Harmonisation ("ICH") Guideline for Good Clinical Practice - Section 4.8.10 including but not limited to applicable regulations, and it must be given both verbally and in writing in compliance with ICH-GCP, ethical principles based on the Declaration of Helsinki in its current version and national requirements. Patients shall be given sufficient time to consider their participation in the Study. CRO shall ensure that such signed and dated informed consents are obtained as per the approved format and the informed consent process by the relevant EC, including audio-video recording of the informed consent process, if required in case of vulnerable subjects, prior to the performance of any procedures required under the Protocol involving such Subject, and in accordance with the Applicable Law.

I. Case Report Forms.

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(xiv) The Site shall have no objection to Sponsor co-monitoring, with CRO, or visiting and/or auditing without CRO personnel present, the Study Site. Such activities may include, but not be limited to, discussions with the Investigators with respect to the Study, and auditing all records pertaining to the Study and the services provided by CRO under this Agreement.

(xv) CRO shall ensure the services required in accordance with this Agreement and otherwise, meet the demands of the Study and related services.

3. Investigator; Replacement.

A. Investigator shall provide CRO with a copy of the Investigator's current curriculum vitae.

B. If the Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Institution shall promptly notify CRO, and shall cooperate to find a replacement investigator acceptable with the prior written approval of the Sponsor (through CRO) (a "**Replacement Investigator**"); provided, however, that the Site shall continue to be responsible for fulfilling the obligations of this Agreement until a Replacement Investigator is appointed. If an acceptable Replacement Investigator is not found within thirty (30) days (or such longer period as mutually agreed upon by the Parties), CRO may terminate this Agreement in accordance with the terms herein. If a Replacement Investigator is designated, such Replacement Investigator shall be bound by all terms of this Agreement that are applicable to the Investigator herein, and the Parties shall amend this Agreement accordingly.

C. CRO reserves the right to select additional Investigator on written notice to the Site if the services are found not satisfactory (within 30 business days or as agreed in writing between parties).

D. If CRO requests, Investigator shall attend and participate in an investigator's meeting or other initiation meeting. CRO will reimburse Investigator for reasonable and necessary travel and lodging expenses incurred to attend such meeting(s). The receipts for such meeting(s) must be submitted to CRO, i.e. the CRO, within sixty (60) days of the date of the meeting. From time-to-time CRO may take photographs or create audio and/or, video recordings in connection with investigator meetings. Investigator hereby gives CRO permission to make, take or create photographs, video and/or audio recordings and transcriptions in connection with such meetings or Study related activities and to use, store, copy, display, reproduce transmit and publish such records.

4. Term; Study Initiation; Completion/Termination

A. This Agreement will become effective on which it is last signed by the Parties, whichever date is later ("**Effective Date**") and subject to compliance with all Applicable Laws. Consequently, the Institution and Investigator will not be permitted to screen patients, randomize patients, receive the Study Drugs or receive any start up payment until the validity date of this Agreement is reached. The Agreement shall continue until completion of all obligations herein, including without limitation receipt by CRO of all Study data and resolution of all corresponding queries in a form acceptable to Sponsor ("**Completion**"), unless otherwise terminated in accordance with this Agreement.

B. The Investigator shall deliver copies of the EC approval letters to CRO. If EC approval is not obtained, this Agreement shall be null and void. The Site shall promptly notify CRO if EC approval for the Study is lapsed, suspended, or withdrawn in whole or in part.

C. No subject may be enrolled in the Study without the Investigator first obtaining an approved informed consent signed by or on behalf of each subject including audio-video recording of the informed consent process, if required in case of vulnerable subjects, prior to the performance of any procedures required under the Protocol involving such Subject, and in accordance with New Drugs and Clinical Trials Rules 2019. The Site shall not request an informed consent from any subject or allow any subject to

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Information for any purpose other than the performance of the Study, and (iv) shall safeguard the Confidential Information so that there is no privacy shield break using the same degree of care, but no less than a reasonable degree of care, as the Site uses to protect its own confidential information. Such Confidential Information shall remain the exclusive confidential and proprietary property of Sponsor and shall be disclosed only on a need-to-know basis and only to the Site and the Site's employees. The Site agrees to ensure that each of the Site's employees rendering services hereunder treat the Confidential Information as confidential consistent with the terms hereof and enter in appropriate confidentiality agreements with such employees.

B. The foregoing obligations shall not apply to Confidential Information that:

i. is or becomes publicly available through no fault of the Site;

ii.is lawfully disclosed to the Site by a third party entitled to disclose such information without any obligation of confidence;

iii. is already known to the Site prior to disclosure hereunder, as shown by the Site's prior written records; or

iv. was developed by the Site without the use of any Confidential Information, as evidenced by the Site's prior written records.

C. In the event that Confidential Information is required to be disclosed by law, regulation, judicial order or under direction from appropriate regulatory authorities, the Site shall (i) timely notify Sponsor (through CRO) and provide Sponsor (through CRO) an opportunity to object to such disclosure, prior to making any such disclosure, and (ii) use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent reasonably possible.

D. Upon demand by CRO, the Site shall return all Confidential Information, including all copies thereof, to CRO; provided, however, that one (1) copy of such Confidential Information may be retained by Institution in its confidential files for compliance purposes only.

E. Injunctive Relief. The Parties acknowledge that unauthorized disclosure of Confidential Information by the Site will give rise to irreparable injury to the Sponsor as the owner of such information, which are inadequately compensable in damages. Accordingly, the CRO/Sponsor, may seek and obtain injunctive relief against the breach or threatened breach of the foregoing undertakings, in addition to any other legal remedies which may be available to it and the Sponsor, jointly or severally.

7. **Data Protection.** The Parties agree to the terms and conditions set forth in **Schedule C**.

8. **Use of Study Results.** Subject to Applicable Law, Sponsor shall have the unrestricted right to use and publish, any data and information from the Study without the consent of Investigator or Institution, provided, Sponsor maintains subjects' confidentiality. The Site will not use data generated during the Study or results of the Study for any purpose other than care of a subject, for internal research purposes, or for publication subject to Article 9, below. For the avoidance of doubt, internal research purposes mean internal, non-commercial research activities that are not funded by a third party (other than a government agency). The Site shall obtain all legally required authorizations or other documentation from Study subjects to allow for disclosures of Study subjects' data to Sponsor (through CRO) and the CRO in accordance with this Agreement and as per the Applicable Law.

9. **Ownership of Data; Publication.**

A. All data, information, and results generated during the course of conducting the Study, including without limitation, the completed CRFs and any reports prepared by the Site (collectively the "**Study Results**") shall be the sole property of Sponsor. The Site shall not publish or otherwise

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All drugs/medication supplied by CRO will be used solely in accordance with the Protocol and may not be used for any other purposes. The Site shall comply with all laws and regulations governing the storage, disposition or destruction of Study Drug(s), including but not limited to the New Drugs and Clinical Trials Rules, 2019 and the Indian GCP **Guidelines and any other drug(s)/medication provided for the Study and any instructions from CRO that are not inconsistent with such laws and regulations.**

B. Investigator shall be primarily responsible for Study Drug(s)' accountability at the Institution. Investigator should maintain records of the Study Drug to the Site, the inventory at the Site, the use by each subject, and the return to the Sponsor through CRO or any alternative disposal of the unused Study Drugs as may be agreed upon by the Parties. These records shall include dates, quantities, batch / serial numbers, expiry dates if applicable, and the unique code number assigned to the Study Drug packs and Subjects. Investigator should maintain records that describe that the Subjects were provided the dosage specified by the Protocol and reconcile all Study Drugs received from the CRO. The Investigator should ensure that the Study Drugs are stored under specified conditions and are used only in accordance with the approved Protocol and as per the Applicable Law.

C. The Site will collect, retain, use and transfer biological samples (blood, fluid and tissue samples collected from subjects enrolled in the Study, including any tangible materials derived from such samples (collectively, "**Biological Samples**"), only in accordance with the Protocol and the applicable informed consent.

D. Upon Completion or any termination of this Agreement, the Site shall deliver or dispose of Biological Samples according to CRO's instructions and any relevant provisions in the Protocol and applicable informed consent and shall immediately cease to use the Study Drug. All unused Study Drug shall be promptly returned to CRO or, at CRO's written request, destroyed by the Site and the action taken thereof shall be recorded as per the Applicable Law with a certificate of destruction provided to CRO.

13. Inspections, Audits, and Study Monitoring.

A. Regulatory Inspection. The Site shall notify CRO promptly of any inquiries, correspondence, or communications with or from the DCGI or any other governmental or regulatory authority relating to the Study. If a regulatory authority requests permission to or does inspect the Site's facilities or research records relating to the Study, the Site will cooperate with the regulatory authority's representative(s) and permit such inspection. The Site shall provide to CRO copies of all materials that the Site receives, obtains, or generates in connection with any such inspection or in connection with any communications from regulatory authorities.

B. Sponsor Inspection/Audit.

i. The Site agrees to permit representatives of Sponsor (including monitors, auditors, and inspectors) and/or CRO, upon reasonable notice and during normal business hours, to examine (i) the facilities where the Study is being conducted, (ii) raw Study Results including original Source Documents (as defined by current ICH Guidelines), regardless of media, if allowed under the terms of the informed consent, (iii) Electronic Data Capture ("**EDC**") equipment and/or EDC documentation system, and (d) any other relevant information (and to make copies) necessary for Sponsor and/or CRO to confirm that the Study is being conducted in conformance with the Protocol and the data protection requirements of Schedule B, and in compliance with Applicable Law.

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15. Patent Rights and Inventions.

A. It is expressly agreed that no Party transfers by operation of this Agreement to any of the other Parties any right in or license to any patents, copyrights, or other proprietary right owned as of the Effective Date of this Agreement or arising outside of the research conducted under this Agreement.

B. The Site acknowledges that the idea for the Study was conceived and developed by Sponsor and that CRO (on behalf of Sponsor) approached Institution and/or Investigator to perform the Study. The Site will fully and promptly disclose in writing to Sponsor (through CRO) any data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, trade secrets and other intellectual property, advancements and the like, whether patentable or not discovered by Institution or Investigator, any sub-investigator, co-investigator or any of their respective employees, agents, or contractors in the conduct of the Study or as a result of using Confidential Information (collectively "**Developments**"). Site and CRO agree and confirm that Sponsor shall have sole ownership and rights in any Developments that relate to the Study Drug(s), including without limitation, new uses, processes, derivatives, formulations, or therapeutic combinations, or markers of Study Drug(s) efficacy or safety or uses thereof or which utilize Confidential Information. The Site shall fully cooperate with Sponsor to vest rights therein in Sponsor and to obtain patents or other legal protections thereon at Sponsor's expenses.

The obligations set forth in this Clause shall continue beyond completion or any termination of this Agreement and shall be binding upon the Parties and Sponsor shall have the right to enforce the provisions of this Clause.

16. Indemnification; Insurance.

A. Principal Investigator Indemnification: Principal Investigator jointly and severally agree to indemnify, defend, and hold harmless the CRO, Sponsor and their directors, shareholders, affiliates, officers, employees, staff, and agents against any loss, liabilities, claims, actions, costs (including without limitation, interest, penalties and attorney fees) or suits for personal injury or death arising out of (i) any negligence, omission, or willful misconduct of Investigator, Institution its directors, officers, staff, trustees, employees, contractors and agents or any other third party or (ii) their failure to adhere to the terms of obligations, responsibilities and undertakings, representations and warranties under this Agreement, the Protocol, or any written instructions from the Sponsor or CRO, or to comply with any Applicable Law or governmental and judicial requirements.

B. CRO warrants that it shall indemnify, defend and hold harmless Sponsor, Institution and Investigator, including their directors, officers, agents and employees (the "Indemnitees of CRO") from any and all liabilities (including any third party liabilities and claims), claims, actions, costs (including attorney fees) or suits for personal injury or death directly arising out of negligence, omission, misconduct or wrongful acts of CRO or its directors, officers, staff, trustees, employees, contractors and agents or any other third party or their failure to adhere to the terms of this Agreement, the Protocol, or any written instructions from the Sponsor or the CRO, or to comply with any Applicable Law or governmental requirements; except to the extent that the same is caused as a result of the Study Drug provided by the Sponsor and / or adhering to the written instructions of the Sponsor or Applicable Laws while rendering the services or due to reasons attributable to the Sponsor, Institution or Investigator andtheir agents and employees.

C. Sponsor warrants that it shall defend, indemnify and hold harmless CRO, Investigator, Institution and any of their directors, officers, agents and employees ("indemnitees of Sponsor") from any and all liabilities (including any third party liabilities and claims), claims, actions , costs

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iii) Each Party will provide, upon written request, copies of documentation evidencing the existence of such insurance

iv) **Insurance details:**
Name of Insurance Company: Bajaj Allianz General Insurance Company Ltd.
Total Insurance Coverage for the Trial Subjects: Rs. 2,00,00,000.00
Duration of the Insurance along with Study Title: 11-MAY-22 To 10-MAY-23

17. Subject Injury and death.

A. Sponsor through CRO shall reimburse Site for all reasonable and customary costs incurred by the Site and associated with the diagnosis of an adverse event involving the Study Drug(s) or a Protocol procedure.

B. Sponsor through CRO shall reimburse Site all reasonable and customary costs incurred for medical management of subjects as per Applicable Law, treatment of a bodily injury to a subject injured as a result of administration of the Study Drug or undergoing a Study-related procedure in accordance with the Protocol. Sponsor shall not provide payment for costs to the extent that they are attributable to:

i. the failure of the Site, or any Site personnel, to adhere to the terms of the Protocol or any of Sponsor's written instructions related to the use of the Study Drug, or to comply with Central Licensing Authority or other governmental requirements, unless such failure is consistent with generally accepted standards of clinical research and medical practice relating to the benefit, safety, and well-being of the Study subjects or is otherwise reasonably necessary for the safety of such a subject, all as determined in good faith by the Investigator and subsequently considered to be acceptable by the Sponsor, CRO, EC & the Central Licensing Authority;

ii. any negligence or wrongful act or omission, or willful malfeasance, of the Site or any other Site personnel providing services on behalf of the Site hereunder; or

iii. the subject's primary disease or any concurrent disease not caused by the administration of the Study Drug in accordance with the Protocol which are not considered as trial related injury and where the Sponsor has no liability to compensate for under the Applicable Law.

C. The Site represents and warrants that it will notdemand and accept any money or compensation or any other benefit from the subject's personal insurer for any costs already paid by Sponsor for treatment of an injury as described above. Sponsor will not pay for any costs already covered by a third party.

D. Sponsor through CRO will be responsible for medical management or compensation to study subject(s) in case of any Adverse Events/Serious Adverse Events including death as per the New Drugs and Clinical Trial Rules, 2019.

18. Complete Agreement; Amendment; Notice. This Agreement represents the entire understanding between the Parties, and supersedes all other agreements, express or implied, between the Parties concerning the subject matter hereof. This Agreement may not be amended or modified in any manner except by a written document signed by authorized representatives of the Parties. Any notice to be given hereunder shall be given by personal delivery, by recognized express courier, or by registered or certified mail, return receipt requested. Except for matters related to Budget & Payment Schedule as set forth in **Schedule A**, such notice shall be addressed to a Party at the address set forth below. Any Party may change its address for notice by giving written notice of such change to the other Parties.

To CRO/Designee: **SIRO Clinpharm Private Limited**
Dr. Ganesh Divekar
Vice President- Clinical Operations & Biometrics
SIRO Clinpharm Pvt. Ltd

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or power failure), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference, or delay, provided that the affected Party shall use its best efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. For purposes of this article, a lack of funds shall not be considered a cause beyond the reasonable control of the Parties.

ii) The Affected Party shall forthwith endeavor to minimize the effects of such Force Majeure event and to remedy the event as soon as possible. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure event. Any timeline or time for performance which falls due during or subsequent to the occurrence of any such Force Majeure event shall be mutually extended for a period of time equal to the period of such Force Majeure event. The Parties herein shall mutually discuss the course of action and acquaint the Sponsor (through CRO) if the Force Majeure event is reported by any Party herein.

26. Arbitration. Any dispute arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, shall be referred to and finally resolved by arbitration in accordance with the Arbitration Rules of the Lucknow Centre for International Arbitration, which rules are deemed to be incorporated by reference in this clause.

The seat of the arbitration shall be Lucknow.

The Tribunal shall consist of [one/three] arbitrator(s).

The language of the arbitration shall be English.

The law governing this arbitration agreement shall be Indian laws.

The law governing the contract shall be Indian laws.

27. Waiver. Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any Party thereafter to enforce each and every provision of this Agreement.

28. Debarment. The Site certifies that neither the Site nor any person employed by the Site or any subcontractor to perform any services in connection with the Agreement has been subject to any legal or regulatory discipline, nor ever been suspended, debarred, or is under any medical license limitation or condition, or otherwise disqualified from providing medical services by any governmental, regulatory or administrative body or organization within their jurisdiction.

29. Sponsor's liability under Applicable Law. CRO is acting on behalf of Sponsor in conducting the Study as per the Protocol, New Drugs and Clinical Trials, 2019 (any amendments thereto) and Applicable Laws. The Sponsor has primary responsibilities with respect to the Study Drug's intellectual property rights and other obligations incidental to Study inception throughout its completion. Notwithstanding anything to the contrary contained in this Agreement, Sponsor shall be responsible for all its obligations, responsibilities, duties and indemnities in accordance with the applicable laws and rules thereunder.

30. List of Incorporated Schedules.

A. Chinese Walls Protection Guidelines
B. Budget and Payment Schedule
C. Data Protection Schedule

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SCHEDULE A

CHINESE WALLS PROTECTION GUIDELINES

1. The Parties understand and agree that in the course of performing the services, Site shall have access to Sponsor's proprietary information. In order to ensure compliance with the confidentiality provisions of this Agreement and to adequately protect such proprietary information, Site shall implement and enforce "Chinese Walls Protection" Guidelines as set forth in this Schedule A.
2. In the event that the Site violates any provision of this Schedule A, CRO shall have the right to terminate this Agreement immediately upon written notice to Site, without regard to any notice period set forth in this Agreement.
3. Specific Protection of Sponsor Confidential Information: In order to protect the vital confidential and proprietary interests of Sponsor, Site shall be responsible for implementing the following security measures with respect to Site's employees and assistants, as well as to any aspect relating to Site's performance of the services. Site is committed to protecting the confidentiality of all of CROs and Sponsor's Confidential Information. Site shall also implement any other security measures reasonably requested by Sponsor and shall ensure compliance of the below measures:

a) Notification: Site shall notify and distribute copies of this Schedule A to all people engaged for providing services under this Agreement and instruct such people to follow the procedures required to adhere to the requirements and procedures set forth here.

b) Assignment of code name: Site shall assign a "code name" to the services provided herein. All references to such services shall be under this code name and only those employees and assistants working on the project shall know that the services are for CRO acting on behalf of Sponsor.

c) Site Team Members: Site shall provide to CRO in writing a list of employees that are assigned to provide services under the Agreement and shall update such list in writing within three (3) business days of any change in the team. In addition to the restrictions set forth in the Agreement, no member of the Site's team shall perform services for any Sponsor's competitor which are substantially similar to services Site is performing for the CRO acting on behalf of the Sponsor.

d) No internal references to services hereunder: Site employees assigned to perform the services under this Agreement, including those who have worked or will work on any aspect relating to the said services shall not discuss, exchange documents, or communicate (including, without limitation, email, intranet, and all other means of communications) with any other non-CRO team member or Site's other employees in any manner regarding the said services.

e) Confidentiality agreements executed by all Site team members: Site shall require that the Study Personnel shall execute Site confidentiality agreement which shall include all strictest confidentiality requirements set forth in the law, a copy of which should be provided to the CRO and/or the Sponsor, upon request.

f) Restricted Access and security of paper files: Site shall implement reasonable technical and organizational measures and safeguards which are reflective of current best industry practice and technological development in order to protect the files and documents relating to the services provided under the Agreement. Site shall regularly test and monitor the effectiveness of its technical and organizational security measures. The files and documents shall not be part of any central filing system; instead, they will be maintained in separate file cabinets which will bear the following legend:

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Budget

	V1	V2	V3 to V7	V8	V9 to V14	V15	V16 to V20	V21	V22 to V27	V28		Total
Study Day/Week	Screening	Baseline	Treatment and Assessments							Safety Follow-up/ EOS/Early Termination Assessments	Unscheduled Visit	
	D -14 to -1	W1 D1	W3 D1 to W11 D1 (±7 days)	W13 D1 (±7 days)	W15 D1 to W25 D1 (±7 days)	W27 D1 (±7 days)	W29 D1 to W37 D1 (±7 days)	W39 D1 (±7 days)	W41 D1 to W51 D1 (±7 days)	W53 (+3 days)		
VISITS days	1	1	5	1	6	1	5	1	6	1		28
Principal Investigator	3500	1800	7500	1800	10800	1800	9000	1800	10800	2800	2300	53900
	1000	1000	5000	1000	6000	1000	5000	1000	6000	1000		28000
Total (A)	4500	2800	12500	2800	16800	2800	14000	2800	16800	3800	2300	81900
Institute Over Head charges (25%)	1125	700	3125	700	4200	700	3500	700	4200	950	575	20475
Total (B)	5625	3500	15625	3500	21000	3500	17500	3500	21000	4750	2875	102375
Patient Reimbursement	500	500	2500	500	3000	500	2500	500	3000	500	500	14500
Total (C)	6125	4000	18125	4000	24000	4000	20000	4000	24000	5250	3375	116875
Day Care Charges		800	4000	1500	4800	1500	4000	1500	4800	1500		24400

SIRO CLINPHARM PVT. LTD. THANE 400 604

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SGPGIMS,Lucknow

SCHEDULE C

DATA PROTECTION SCHEDULE

1. **DEFINITIONS**

   a. The terms "Controller", "Data Subject", "Personal Data", "Processor", and "Processing" shall have the same meaning as in the applicable "Data Protection Law". For avoidance of doubt, applicable Data Protection Law means all Applicable Laws in relation to data protection, privacy, interception and monitoring of communications, or requirements relating to the Processing of Personal data, including but not limited to the General Data Protection Regulation EU 2016/679, Information Technology Act, 2000 (IT Act), Information Technology (Reasonable Security Practices and Procedures and Sensitive Personal Data or Information) Rules, 2011 (2001 Rules) and the Indian GCP.

2. **IDENTIFICATION OF THE PARTIES**

   a. The Institution acts as a Processor for the Sponsor who acts as a Controller when the Institution processes coded Personal Data on behalf of the Sponsor under this Agreement and in accordance with the trial Protocol.

   b. The Institution is an independent Controller of Personal Data of patients participating in the Study for purposes other than those listed in Clause 2.a., e.g. the provision of medical care.

3. **PROCESSING OF PERSONAL DATA**

   a. The Processor shall process Personal Data only for the purposes of fulfilling an obligation under the Agreement. The Processor may not process or use coded Personal Data for any purpose other than as required by the Agreement and consistent with the Protocol and instructions provided by the Sponsor(through CRO).
   b. Site will immediately inform CRO if it cannot comply with any material term of this Schedule C regarding Personal Data. In that event, Site agrees that CRO may immediately terminate Site's processing of Personal Data.

4. **CROSS-BORDER TRANSFERS**

   a. The Processor shall not transfer Personal Data outside the country of origin unless required to do so pursuant to the Sponsor's written instructions (through CRO) and as required by Applicable Law, provided that the Processor complies with applicable Data Protection Law relevant to that transfer.

   b. The Processor shall not transfer Personal Data under this Agreement outside the India, unless the transfer is made as per one of the legally accepted mechanisms covered under the Applicable Law including Data Protection Law

5. **SECURITY**

   a. The Site shall implement appropriate technical and organizational measures in compliance with the applicable Data Protection Law.
   b. Site agrees to notify CRO no later than within twenty-four (24) hoursof discovery of a real or suspected security breach. Site shall provide to CRO sufficient information for the Sponsor to assess the security breach and determine whether to notify any Government Authority and/or data subject.

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SGPGIMS,Lucknow

b. The Processor shall limit access to Personal Data to all employees and other persons it involves in the conduct of the Study for whom access to Personal Data is necessary to fulfil the Processor's obligations. The Processor shall ensure that persons authorised to process the Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

11. PERSONAL DATA OF STUDY STAFF

a. Prior to and during the course of the Study, the Sponsor (through CRO) may request the collection of Personal Data of the Institution's Investigator and Study Staff (including principal investigator, sub-investigators, other Institution staff or personnel involved in the conduct of the Study). Institution agrees to assist Sponsor with obtaining any consents, or providing any notice, as may be necessary in accordance with Applicable Law.

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	IN-DL88[illegible]10U
Certificate Issued Date	:	11-Jul-2022 04:20 PM
Account Reference	:	IMPACC (IV)/ dl7703/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL7770[illegible]2145U
Purchased by	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Second Party	:	Not Applicable
Stamp Duty Paid By	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

CLINICAL TRIAL/RESEARCH ACTIVITY AGREEMENT

This Clinical Trial Agreement (hereinafter the "**Agreement**") is executed at New Delhi with effect from 01/08/2022 (hereinafter referred to as the "**Effective Date**") between;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(41)

GEORGE INSTITUTE FOR GLOBAL HEALTH (CIN U74900TG2007NPL055085), a company registered under section 25 the Companies Act, 1956 (India), having its office at 308, Third Floor, Elegance Tower Plot No. 8, Jasola District Centre, New Delhi 110025 (hereinafter referred to as "**GIGH**", which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the First Part;

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIECNES with PAN AAAJS3913N, having its registered office at Raibareli Road Lucknow 226014 (hereinafter referred to as the"**Institution,**" which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the Second Part;

AND

DR. NARAYAN PRASAD the principal investigator at the Institution, with office at Department of Nephrology C-Block SGPGIMS Raibareli Road Lucknow 226014 (hereinafter referred to as the "**Investigator,**" which expression shall, unless repugnant to the meaning or context thereof, be deemed to mean and include his/her heirs, representatives and assigns) of the Third Part;

(Each of GIGH, the Institution, and the Investigator may hereinafter be referred individually as a "**Party**" and collectively as the "**Parties.**")

WHEREAS GIGH, as a sponsor is conducting a study, known as the PROphylaxis for paTiEnts at risk of COVID-19 infecTion **(PROTECT)** (hereinafter referred to as the "**Study**")";

AND WHEREAS GIGH wishes the Study to be conductedin terms of the protocol (including amendments made thereto from time to time), attached hereto as Exhibit A (hereinafter referred to as the "**Protocol**");

AND WHEREAS GIGH may also conduct sub-studies from time to time (hereinafter referred to as each "**Sub-Study**") in conjunction with the Study, and upon written notification of a Sub-Study, all applicable references in this Agreement to 'Study' shall include such Sub-Study and all references in this Agreement to 'Protocol' shall include the protocol related to such Sub-Study;

AND WHEREAS Investigator and Institution possess the resources and expertise to carry out the Study at the site (s) of the Institution (hereinafter individually referred to, for the purposes of this Agreement, as the "**Study Site**"), and wish to assist GIGH in conducting the Study;

GIGH Representative Initials Institution Representative Initials PI Initials

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Executive Registrar
SGPGIMS,Lucknow

NOW THIS AGREEMENT WITNESSETH AND HEREBY RECORD THE RIGHTS AND OBLIGATIONS AGREED UPON IN CONNECTION WITH THE PERFORMANCE OF THE STUDY BY AND BETWEEN THE UNDERSIGNED PARTIES AS FOLLOWS:

1. PERFORMANCE OF THE STUDY

1.1. Institution and Investigator shall carry out and conduct the Study at the Study Site in strict conformance with:

(i) the terms of this Agreement, the Protocol and the written instructions or advice issued by GIGH;

(ii) generally accepted standards of good clinical practice, New Drus and Clinical Trials Rules, 2019 and Applicable lawsand, if applicable, international treaties and regulations, as amended from time to time.

(iii) all applicable Study documents which are duly approved by the governing Institutional Review Board/Independent Ethics Committee Board (hereinafter referred to as the "**IRB/ IEC**");

1.2. Institution and Investigator represent and agree that:

(i) they have, and at all times during the course of the Study shall have, personnel with appropriate training, information, licenses, approvals, and certifications as are necessary to safely, adequately and lawfully perform, conduct and coordinate the Study in accordance with the Applicable Laws;

(ii) Investigator has not been debarred pursuant to any Applicable Laws or by any regulatory authority; and neither the Institution nor the Investigator have been disqualified from participating in a clinical study by any regulatory authority.

(iii) Investigator is currently, and shall throughout the performance of the Study, be authorised to perform his/her duties under this Agreement; and

1.3. Investigator shall obtain written approval from the Study Site's IRB/IEC for the Protocol. Investigator shall ensure verbal and/or written consent,as per IRB/IEC approval,are obtained from each each human subject (hereinafter referred to as the "**Participant**") or their authorized legal representative(s). Consent shall be obtained in the format specified by GIGH in sample"ConsentingDocuments". Additional information may be added to the sample Consent Documents after obtaining approval from GIGH, if required by the IRB/IEC and Institution. The Institution /Investigator shall, where required, maintain each Participant's audio-visual recordings of consenting process in the Participant's permanent record in addition to the written consent. Such audio-visual recording and related documentation must be preserved adhering to the principles of confidentiality by the Investigator.

1.4. It is anticipated that up to 600 participants will be recruited from approximately 15 centres in India. The Investigator shall start recruiting Participants only after receiving written authorisation from GIGH to start recruitment, which shall be provided after

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receipt of all relevant documentation at GIGH. GIGH reserves the right to limit the recruitment of further Participants or cease the recruitment at the Study Site, on reaching the recruitment target or even otherwise. Upon written notice, the recuirtmentshall be ceased immediately.

1.5. Institution and Investigator undertake that there are not other agreements or understandings with third parties or any conflict in the performance of the Study or the acceptance by a regulatory authority of the data collected by the Study Site.

1.6. Institution and Investigator agree toprovide to GIGH, any documentation required by regulatory authorities and/or under Applicable Laws, including but not limited to any documentation or information that relates to disclosure of Institution and Investigator's interests, including any financial interests of the Institution/Investigator, in the Study.

1.7. Institution agrees that they shall promptly notify GIGH in the event of any debarment, conviction, threat, disqualification or indictment of Investigator or any person who has provided services under this Agreement, during the term of this Agreement or three (3) years following its expiration or earlier termination.

1.8. Investigator may appoint other individuals as may be deemed appropriate and approved by the Institution (**Study Team**") to assist in the conduct of the Study in accordance with the Protocol. Investigator shall be solely responsible for the Study and for leading the Study Team, which shall be bound by the same obligations as Investigator under this Agreement.

1.9. All correspondence from any regulatory authority or the IRB/IEC in relation to the study shall be shared with GIGH immediately. Institttution and/or Investigator shall take appropriate action in this regard including actions in accordance with the lawful instructions and advice of GIGH.

1.10. Institution and Investigator shall prepare and maintain complete and up to date accurate medical records, accounts, medical notes, reports, and data including all supportive documentation for each Participant (hereinafter referred to as the "**Source Documents**") in accordance with the operating procedures required by GIGH and the Applicable Laws. Such information shall be recorded into the databasevia the corresponding electronic Case Report Forms (eCRFs) found in the web-based management system for each Participant, if and as required by the Protocol. Investigator shall ensure no information that would personally identify a Participant be provided to GIGH. GIGH shall be consulted before any Source Documents are destroyed.

1.11. The Institution and Investigator shall immediately inform GIGH of any Adeverse Events and/or Serious Adverse Events ("**SAE**"), as defined in the Protocol provided by GIGH.

1.12. Investigator and/or the Institution shall submit periodic reports to GIGH regarding progress of the Study, in GIGH's agreed form and manner.

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1.13. Institution and Investigator shall cooperate and permit, upon the request of GIGH or an official of any regulatory authority, such party to examine and inspect Institution's facilities and equipment required for performance of the Study and inspect and copy all data, reports, work products and results relating to the Study.If the Institution or the Investigator is notified of an inspection by a regulatory authority, the same shall be immediately informed to GIGH. GIGH or any person designated by them shall also be authorized to participate, to the extent permitted under Applicable Laws. Information arising out of the inspections shall also be shared with GIGH as per the Applicable Law. Institution and/or the Investigator shall bear their own cost and/or expense in relation with any audits and/or inspections.

1.14. GIGH to send the DSMB report (if applicable)and its timely submission to EC.

1.15. In the event that Investigator leaves Institution or otherwise becomes unavailable during the term of this Agreement, Institution shall make reasonable efforts to find a replacement investigator of similar expertise and qualifications who is acceptable to both Institution and GIGH. Replacement Investigator shall be bound by all the terms and conditions hereunder and, where required by GIGH, a new agreement will be executed between Institution, the replacement investigator and GIGH.

1.16. From time to time, GIGH may modify the Protocol by written notice to Institution and Investigator. Except where the modification is necessary to eliminate an immediate hazard to Participants, or involves only logistical or administrative aspects of the trial, any modification may not be implemented before approval by the IRB/IEC.

1.17. Neither Institution nor Investigator shall conduct any other study, investigation or trial on the Participants recruited for the Study.

1.18. GIGH represents and warrants that:

i. It has the absolute right and authority to provide any or all material and information ("**Materials**") as per the Protocol for the purpose of the Agreement.

ii. The signatory to the present Agreement is having the right and full authority to enter into this Agreement and the Agreement so executed is binding in nature.

2. PERFORMANCE PERIOD

2.1 This Agreement commences from the Effective Date. Unless terminated early, this Agreement terminates on Study Completion.

3. DUTIES AND RESPONSIBILITIES OF THE PARTIES

3.1 In addition to applicable provisions of clause 1 of this Agreement, GIGH shall be responsible for:

(i) obtaining the necessary approvals or authorisations for the conduct of the Study in India, and coordinate the Study in India;

(ii) making timely payments to the Institution subject always to approvals mentioned in clause 3.1(i) above;

(iii) overall conduct of the study including monitoring and evaluation of study sites in India; and

(iv) Advise and provide information to the Institution and to the IRB/IEC as and when necessary and update the appropriate Regulatory Authorities of:

a) Any SAEs/adverse events/risk information; or

b) The cessation elsewhere of any relevant trial of the Study drug (or closely related products); or

c) The withdrawal of the Study drug (or closely related products) from any other market for safety reasons; or

d) Any other information available to justify any variations to the Study Protocol and the nature, scope and duration of the Study.

3.2 In addition to applicable provisions of clause 1 of this Agreement, Institution and Investigator shall be responsible for:

(i) obtaining the necessary consents, approvals or authorisations for the conduct of the Study at the Study Site;

(ii) obtaining and maintaining approvals or communications from the IRB/IEC;

(iii) ensuring the protection of the rights, safety and well-being of Participants, and the scientific integrity of the Study;

(iv) submitting the requisite documentation to the relevant regulatory authorities from time to time during and after the conclusion of the Study;

(v) providing Investigator with materials, access to personnel, facilities and information as may be reasonably required to satisfactorily perform the Study;

(vi) exercising due care and skill and work in a competent and professional manner in carrying out their obligations under this Agreement;

(vii) ensure that the equipment used for conduct of the Study are properly maintained;

(viii) monitoring to ensure that no unlawful or unethical activity arises during the conduct of the Study at the Study Site;and

(ix) any agreement concluded, or arrangement reached with the Study Team appointed by them, if any, shall be subject to the provisions of this Agreement.

(x) Institutions shall be responsible for maintaining the Master list of identifiable data which could be linked to the stored data for any future reference. Storage of hard copy is responsibility of the participating institutions.

4. OWNERSHIP OF DATA, RESULTS, INTELLECTUAL PROPERTY

4.1 The Parties acknowledge and agree that GIGH shall have all right, title and interest in and to all data and results of the Study, including without limitation all inventions, patents, tests, applications, creations, research data, intellectual property, processes, methods, software, tangible research products, formulas and techniques,

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improvements thereto, and know-how related and Confidential Information that may be developed, produced, created, furnished or disclosed by any Party made during the conduct of the Study, or arising from the performance of the Study which shall be communicated immediately to GIGH.

4.2 The ownership of any or all intellectual properties owned by the Parties before the execution date of this Agreement by the Institution (**"Background IP"**) shall remain with the such Party.

4.3 If GIGH and/or its assignee desires to file patent applications as a result of discoveries made during the Study,the Institution and Investigator shall assist in the preparation of such patent applications.

4.4 Each party will not use the other party's/ies'Background IP in any publicity, advertising or news release without the prior written consent of the other party/ies. However, the Intellectual Properties may be used for the proper performance of the services under this Agreement.

4.5 The parties will not infringe the Intellectual Property Rights of a third party or misappropriate any Know How or Intellectual Property Rights of a third party.

4.6 The Institution and Investigator shall have a right to use the Study results for non-commercial research and teaching purposes.

5. PUBLICATION

5.1 Institution and Investigator each acknowledge and agree thatunless approved by the committee (**"Steering Committee"**) appointed by GIGH to oversee the multi-centre Study,there shall be no publication, report, release, disclosure or likewise of any preliminary or final Study findings or results prior to release of the first publication of Study findings or results (**"Multi-Centre Publication"**). Attribution and authorship in the Multi-Centre Publication shall be given in accordance with academic standards and/or as per the International Committee for Medical Journal Editors (ICMJE).

5.2 The Steering Committee and GIGHmay at any time disclose or publish all information as they may reasonably decide where such disclosure or publication relates to the safety of the Participants, patients in general, or the general public.

5.3 Proposals for all publications, abstracts, and other presentations arising from the Study shall be submitted for approval to the Steering Committeethrough GIGH at least four (4) weeks prior to the date it is intended to be submitted for publication. The Steering Committee or a subcommittee thereof, may recommend changes prior to approval.

5.4 No Party shall use the name of any other Party in any advertising or promotional material without having received the prior written consent of such other Party, provided that:

(i) a Party may acknowledge, in general terms, the existence of this Agreement;

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(ii) GIGH (or its affiliates) may state on its website or in any Study material that Institution is a participating site of the Study and Investigator is the investigator of the Study at the Study Site; and

(iii) Institution may acknowledge receipt of financial support from GIGH for the Study at the Study Site.

6. PAYMENTS

6.1 The full & final amounts/fees (inclusinve of taxes) and terms of payment payable by GIGH to the Insititutionfor performance of the Study are set forth in the Payment Schedule and Payment Rule Form that is attached hereto as Exhibit C (hereinafter referred to as the "**PRF**").

6.2 Institution and Investigator each agree and undertake not to seek any payment from any third party or Participant for any services provided to a Participant in connection with such Participant's participation in the Study or the costs incurred in connection therewith.

6.3 Institution shall be responsible for the payment of any or all taxes applicable on the income received pursuant to this Agreement, including, without limitation, for paying any GST or similar tax imposed by the taxation authorities in any jurisdiction.

6.4 Institution and Investigator shall inform GIGH in writingnot later than one (1) month of any discrepancies that may exist in the payment(s) received. Institution and Investigator shall havewaived, all rights to receive further compensation in connection with the Study, if such discrepancies is not raised within the said period.

6.5 Institution warrants that the Payee as per Exhibit C, wherever different from the Institution name, is part of or an affiliate of the Institution and that the Institution shall remain responsible for all obligations under this Agreement.

7. CONFIDENTIALITY & PRIVACY

7.1 The Parties acknowledge and agree that they shall not disclose or publish Confidential Information to any third party, other than in accordance with this clause 7. For the purpose of this Agreement, "**Confidential Information**" shall mean any confidential or proprietary information, including without limitation, any derivatives thereof, which is confidential and proprietary in nature, including, but not limited to, intellectual property; internal practices and procedures; feedback relating to any results of the Participant,; deliverables information, all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere, the Protocol, and information related to the Protocol and Study materials, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, methodology, processes, sequences, structure and organisation of the Study; other information relating to

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disclosing Party's business, including, without limitation, the terms and conditions of this Agreement; and any third-party confidential information. ;

Confidential Information shall not include information:

b) which is published in accordance with the Publication Section of this Agreement,

c) which a Receiving Party can demonstrate through contemporaneous written records was in its possession prior to disclosure by the Disclosing Party,

d) which is in the public domain or which later becomes part of the public domain other than by breach of this Agreement by a Receiving Party,

e) which is lawfully disclosed to a Receiving Party by a third party not obligated to the Disclosing Party to keep the information confidential, and

f) which is required to be disclosed by law, or by order of a court of competent jurisdiction to the extent necessary.

g) which is used or disclosed for absolute performance of the Study or performance of the obligations under this Agreement to the extent necessary.

7.2 The obligations of confidentiality under this clause 7 shall be binding for the term of this Agreement and shall survive for a period of ten (10) years after expiry or termination of this Agreement.

7.3 Each Party agrees to comply with all applicable privacy laws and regulations regarding the collection, use, disclosure, holding and protection of personal and/or health information.

7.4 In the event that GIGH shall come into contact with Participants' medical records, GIGH shall hold in confidence the identity of the Participants and shall comply with Applicable Laws regarding the confidentiality of such records.

8. RELATIONSHIP OF PARTIES

8.1 This Agreement does not create, and no provision of this Agreement shall be interpreted to create, a relationship of employer and employee, principal and agent, joint venture or partnership between the parties. Neither Party (including any employee, agent or authorised representative thereof) shall have the power to bind or designate the other Party or any persons affiliated with such Party in any manner whatsoever.

8.2 No employee, agent or authorised representative of the Institution and/or Investigator or personnel of the Study Team shall be considered, an employee of GIGH. Institution shall indemnify and hold harmless GIGH (and its affiliates) against all claims and demands that may be made by any of the above mentioned parties against GIGH.

9. NOTICES

9.1 Any notice, consent, approval or other communication (each a "**notice**") under this Agreement shall be in writing and shall be delivered to the recipient Party by hand or

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by sending to the address or email specified below (or as subsequently varied by notice):

If to GIGH:	If to Institute:	If to Investigator:
Amit Khanna George Institute for Global Health 308, Elegance Tower Plot No. 8, Jasola District Centre New Delhi 110025 , India Email: akhanna@georgeinstitute.org.in	Name: Sanjay Gandhi Postgraduate Institute of Medical Sciecnes Address: Raibareli Road Lucknow 226014 Email : director@sgpgi.ac.in	Name: Dr. Narayan Prasad Address: Department of Nephrology C-Block SGPGIMS Raibareli Road Lucknow 226014 Email: narayan.nephro@gmail.com

9.2 A notice given in accordance with clause 9.1 is taken to be received: (i) if hand delivered on the day of delivery; (ii) if sent by courier upon the day of the courier's delivery (as verified by the courier's records); (iii) if sent by certified or registered mail, upon the day of the postal service's delivery (as verified by the postal service's records); or (iv) if sent by email, upon confirmed successful transmission at the sender's location; but if delivery or receipt is not on a business day or is after 5:00 P.M. on a business day, notice is taken to be received in the next business day.

10. TERMINATION

10.1 GIGH may terminate this Agreement with immediate effect by written notice(hereinafter referred to as the "**Termination Notice**") to Institution and Investigator if:

(i) any regulatory authority requires the Study to be discontinued or materially altered; Investigator or Institution is Disqualified (as defined by clause 1.8 of this Agreement);

(ii) GIGH does not approve of the proposed replacementinvestigator;

(iii) GIGH fails or ceases to receive research funding for the Study;

(iv) Institution and Investigator do not randomize at least 10 Participant within one (1) months of receiving an authorisation letter from GIGH (as provided by clause 1.4 of this Agreement);

(v) Institution or Investigator, or Study Team, fail to perform, or performs improperly, any obligation of it under this Agreement (hereinafter referred to as the "**Default**"), provided that GIGH shall first have: (i) notified Institution and Investigator of such Default; and (ii) permitted the Party in Default a period of three working days (hereinafter referred to as the "**Cure Period**"), to cure the Default, which Cure Period shall be stated in the notice from GIGH; or

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(vi) it comes to the attention of GIGH that Institution or Investigator has fabricated, falsifiedorplagiarised data pertaining to the Study or has otherwise breached or compromised the scientific integrity of the Study or caused harm to Participants.

10.2 GIGHmay terminate this Agreement for whatever reason by giving thirty (30) days' prior written notice to the other Party.

10.3 Institution and Investigator may terminate this Agreement by written notice, which shall be effective immediately if :

(i) the IRB/IEC or any regulatory authority requires that Institution and/or Investigator cease a material part or all of their activities in connection with the Study; or

(ii) GIGH fails to perform, or performs improperly, any of its material obligations under this Agreement (hereinafter referred to as "**GIGH Default**"), provided that the Institution and/or Investigator shall first have: (i) notified GIGH of such GIGH Default; and (ii) permitted GIGH a period of thirty (30)days to cure the GIGH Default, which Cure Period shall be stated in the notice from the Institution and/or Investigator.

10.4 In the event of termination, the Parties shall promptly do all that is reasonably necessary to close-out the Study and shall cooperate to ensure the continued safety of the Participants. Each Party will, upon request of a Party, return or destroy any Confidential Information of that Party.

10.5 If this Agreement is terminated under clause 10.1, GIGH shall pay Institution for any work completed up to the date of Termination and for closing-out activities in accordance with generally accepted standards of good clinical practice, including ICH-GCP. Investigator and Institution acknowledge that they shall not be entitled to any further or additional payments from GIGH (or its affiliates).

10.6 Clauses 1 (Performance of the Study), 4 (Ownership of Data, Results, Intellectual Property), 5 (Publication), 7 (Confidentiality & Privacy), 10.4 (Termination), 11 (Indemnities, Limitation of Liability & Insurance) and 13.4 (Arbitration) of this Agreement, and any other clauses or provisions giving operational effect thereto, and any other clause or provision that should by its nature, shall survive on expiry or termination of this Agreement.

11. INDEMNITIES, LIMITATION OF LIABILITY & INSURANCE

11.1 GIGH shall hold harmless the Institution and the Investigator and their respective officers, directors and employees (hereinafter individually referred to as an "**Indemnified Party**" and collectively referred to as the "**Indemnified Parties**"), as applicable, from all claims made by third parties and against any and all liabilities, losses, damages and expenses (hereinafter collectively referred to as "**Losses**") that one or more of the Indemnified Parties may sustain due to any injury, (including death), suffered by any Participant resulting only from the administration of the Study

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drug described in the Protocol, when used in accordance with the approved labelling, the Protocol and any written instructions of GIGH, provided that the Indemnified Party has (i) used reasonable medical judgment in the conduct of the Study, (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and (iii) duly complied with all Applicable Laws and regulations and all ethical and professional standards relating to the protection of Participants, including with respect to ensuring appropriate IRB approval and oversight, obtaining effective informed consent and maintaining patient privacy in accordance with the Protocol and the instructions/guidance/advice issued by GIGH, from time to time.

11.2 Each Party ("**Indemnifying Party**") agrees and undertakes to indemnify, hold harmless and defend the other Party ("**Indemnified Party**") from and against any and all **Losses** arising as a result of or arising directly out of (a) breach by the Indemnifying Party of any provision of this Agreement or (b) the Indemnifying Party's negligence or wilful default in relation to performance or non-performance of any of its obligations under this Agreement.

11.3 Each Party's obligation to indemnify the other as set forth above is conditional on the Indemnified Party: (a) providing written notice to the Indemnifying Party of any Losses for which it is seeking an indemnity hereunder within ten (10) business days from the date of knowledge of such Losses; (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend any such Losses; (c) assisting the Indemnifying Party at their own expense, in the investigation and defence of any such Losses; and (d) not compromising or settling such Losses without the Indemnifying Party's prior written approval. In turn, the Indemnifying Party will not make any settlement which adversely affects in a material manner the reputation of an Indemnified Party without such Indemnified Party's prior approval, which approval shall not be unreasonably withheld.

11.4 Notwithstanding the above or anything contained to the contrary in this Agreement:

(i) neither Party shall be liable to the other for any punitive or consequential loss, including, without limitation, any loss of business, revenue, profit, reputation or goodwill;

(ii) the Parties shall take all reasonable steps to mitigate any loss, damage, claim, action or expense (including legal expense) they may suffer in terms of this Agreement; and

(iii) GIGH's liability whether in terms of this Agreement, tort (including gross negligence), strict liability, indemnity or otherwise and for any and all claims arising out of or in connection with this Agreement shall be limited in aggregate, whether in relation to a single event or a series of events, and whether each event is related or not, to a maximum of the fees paid to the Institution and/or the Investigator under this Agreement till the date such liability arose/the per subject

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

and aggregate limit of GIGH's Clinical Trials Liability insurance cover, whichever is higher.

11.5 GIGH has made an arrangement of Clinical Trials Liability insurance cover adequate to cover the risks as specified under the aforementioned provisions of this Article. However, it is understood and agreed that the maintenance of such insurance cover will not relieve either Party of its other obligations under this Agreement.

11.6 Institution and Investigator may secure and maintain insurance coverage for medical professionals and/or medical malpractice liability, general libality and employee's compensation as per the Applicable Laws or regulations.

12. ENTIRE AGREEMENT, AMENDMENT

12.1 All exhibits, schedules attached hereto, including the Protocol referenced herein, shall be incorporated by reference and will form part of this Agreement. No part of this Agreement may be modified except where agreed to in writing by the Parties. No oral explanation or information or previous communication provided by any Party to any other Party affects the meaning or interpretation of this Agreement, or constitutes any collateral agreement, warranty or understanding between the Parties.

12.2 In the event of any inconsistency between the terms of this Agreement and the Protocol, the terms of this Agreement will prevail.

13. ASSIGNMENT& SUBCONTRACTING

13.1 The Institutionor Investigator shall not assign or transfer or sub-contract the performance any of its rights or obligationsunder this Agreement or any part thereof without the prior written consent of GIGH, such consent not to be unreasonably withheld or delayed.

14. CONCLUDING PROVISIONS

14.1 Any clause or provision of this Agreement which is prohibited or unenforceable is ineffective to the extent of the prohibition or unenforceability, but the validity or enforceability of the remaining clauses of this Agreement will not be affected.

14.2 The obligations of a Party under this Agreement shall be suspended during the period and to the extent that such Party is prevented or hindered from complying by causes or circumstances: (i) beyond its reasonable control not due to its own fault or negligence; (ii) which are not reasonably forseeable; and (iii) which the Party is by exercise of reasonable diligence, unable to prevent, including (a) act of God; (b) industrial dispute of any kind; (c) act of public enemy, war (whether declared or undeclared), blockade, revolution, riot, insurrection, malicious damage, civil commotion; (d) natural disaster/ pandemic/epidemic, medical emergency; Ć order of any court or authority, restraint, restriction, requirements, prevention, frustration or hindrance by or of any person, government or competent authority; and (f) embargo, unavailability or shortage of

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SGPGIMS,Lucknow

essential equipment, chemicals or other materials, goods, labour or services, lack of transportation or communication, breakage of facilities or machinery (each hereinafter a "**Force Majeure Event**"). A Party relying on this clause 14.2 must promptly provide notice to the other Parties of the occurrence or cessation of any Force Majeure Event as soon as practicable.Where such Majeure Event continues for more than three (3) calendar months, the other Parties have the right to promptly terminate the Agreement by written notice to the affected Party, and clauses 10.4 and 10.6 of this Agreement will apply.

14.3 This Agreement shall be construed, interpreted and applied in accordance with, and shall be governed by, the laws applicable in India within the jurisdiction of Lucknow Courts.

14.4 The Parties agree to first attempt to resolve any dispute or difference arising out of or in connection with this Agreement or in respect of any defined legal relationshipassociated therewith or derived therefrom (hereinafter referred to as the "**Dispute**"). However, if the Parties are unable to resolve the Dispute within fourteen (14) days after first commencing good faith negotiations, the Parties agree to submit such Dispute for arbitration under ICADR Arbitration Rules, 1996. The Authority to appoint arbitrator shall be with The International Centre for Alternative Dispute Resolution (ICADR). The ICADR will provide administrative services in accordance with the ICADR Arbitration Rules, 1996. There shall be one arbitrator, the language for the arbitration proceedings shall be English, and the place of arbitration proceedings shall be Lucknow, Uttar Pradesh, India. Each Party to the Dispute will be responsible for its own costs and expenses, and arbitration fees will be shared equally between the Parties to the Dispute. The decision of the arbiter shall be final and binding between the Parties. The Parties agree to continue to perform this Agreement despite the existence of a Dispute or any proceedings under this clause 14.4. Nothing in this clause prevents a Party from obtaining urgent injunctive relief from any court, including with respect to the protection of its confidential or proprietary information.

14.5 No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the Party waiving the right. Likewise, a single or partial exercise of any right, power or remedy will not preclude any other or further exercise of that or any other right, power or remedy.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

The Parties hereto have caused this Agreement to be duly executed, as of the day and year first above written.

On Behalf of GIGH:

Signature

Date: 1/8

Name: Mr. Amit Khanna
Designation: Director, Finance & Operations

Signature

Date: 1/8/22

Name: Dr. Pallab Maulik
Designation: Deputy Director and Director of Research

INSTITUTION:

Signature

Date:

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Name: Prof. R. K. Dhiman
Designation: Director

INVESTIGATOR:

Signature

Date: 8/8/22

Name:Dr. Narayan Prasad
Designation: Prof. & Head

GIGH Representative Initials Institution Representative Initials PI Initials

Lt Col Varun Bajpai (MS)
Executive Registrar
SGPGIMS,Lucknow

(27)

Exhibit A

Enclosed: PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT): A double-blind placebo-controlled trial of prophylactic niclosamide against SARS-CoV2 infection in vulnerable populations. The trial will enrol vulnerable patients with kidney or autoimmune diseases, including patients in receipt of dialysis, kidney transplant recipients, individuals with vasculitis and glomerular disease receiving immunosuppression.

STUDY PROTOCOL_ PROTECT Protocol Version _1.0 Dated_29-Jan-2021

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Executive Registrar
SGPGIMS,Lucknow

(26)

EXHIBIT B
INVESTIGATOR CONFIRMATION

Study Name:PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT-V)

A double-blind placebo-controlled trial of prophylactic niclosamide against SARS-CoV2 infection in vulnerable populations. The trial will enrol vulnerable patients with kidney or autoimmune diseases, including patients in receipt of dialysis, kidney transplant recipients, individuals with vasculitis and glomerular disease receiving immunosuppression.

Investigator: Dr. Narayan Prasad

I, the Investigator, confirm that I have received the PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT-V)I represent that I have read and fully understand the Protocol and other study related obligations. I will provide copies of the Protocol, and all information furnished by GIGH, to the Study Team and to discuss this material with them and ensure they are fully informed and understand the Protocol.

I agree and undertake to abide by the contents of the latest IRB/IEC approved Protocol and any amendments there to that are communicated to me.

Signature

Date 8/8/22

Name: **Dr. Narayan Prasad**

GIGH Representative Initials Institution Representative Initials PI Initials

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(24)

EXHIBIT C
PAYMENT SCHEDULE AND PAYMENT RULE FORM

STUDY: PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT-V)

COUNTRY: INDIA

Expected Recruitment: Upto 200 eligible participants are expected to be recruited at the Institution

Payment distribution will be as shown below, without any additional cost. All amounts mentioned below are inclusive of all taxes. All payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws and GIGH will deduct the tax at the time of making payments unless a valid certificate for Tax Exemption is made available from the tax authority in a timely manner.

Data collection will be considered complete following verification of all data entry into the eCRF and resolution of all queries.

Item	**Amount (INR)**
a) Ethics Committee Fee [a]	Nil
b) Participant Enrolment and Follow-up	**Amount (per enrolled subject in INR)**
Baseline	500
Follow up [b]	200/Follow-up (maximum of 4,500/subject)
End of treatment and final trial visit form	500
Lab investigations [c,d]	2,000
Total [e]	7,500
Institutional Overhead Charges @ 25%	1,875
Total Payment	9375

GIGH Representative Initials Institution Representative Initials PI Initials

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Executive Registrar
SGPGIMS,Lucknow

(24)

25% Institutional overheads will be paid on overall per patient budget received by site.

[a]Inclusive of the cost of adverse reactions/events review by the ethics committee.

[b] In-person/telephonic weekly follow-up for the first four weeks and once in two weeks in-person/telephonic follow-up from week eight to a maximum of week forty.

[c] Investigations and frequency: liver function test (once), COVID -19 antibody testing (up to twice), reverse transcription polymerase chain reaction (up to twice), serum pregnancy test (once).

[d] Investigations done to assess eligibility –liver function test, reverse transcription polymerase chain reaction (RT-PCR) and serum pregnancy test will be paid for should a patient meet all other eligibility criteria and be found ineligible to participate in the trial based solely on the laboratory investigations. These will be regarded as screen failures.

[e] Only on completion of all follow-ups, end of treatment, and final trial visit form. Data collection will be considered complete following verification of all data entry into the eCRF and resolution of all queries.

An advance start-up payment of Rs. 25,000 can be released upon request from the site investigator. The advance start-up will be adjusted with the total payment before the final settlement.

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Executive Registrar
SGPGIMS,Lucknow

(13)

Payments will be made to the following party:

(ALL INFORMATION BELOW MUST BE PRINTED)

Payable to: Director SGPGIMS RESEARCH ACCOUNT
PAN No. of Institution: AAAJS3913N
Account Number: 10095237491
Bank Name & Address: **State Bank of India SGPGI Campus Raibareli Road Lucknow**
IFSC Code: **SBIN0007789**
Mailing Address: **SGPGI Campus Raibareli Road Lucknow**

Signature of the authorized signatory of the Institution: _____

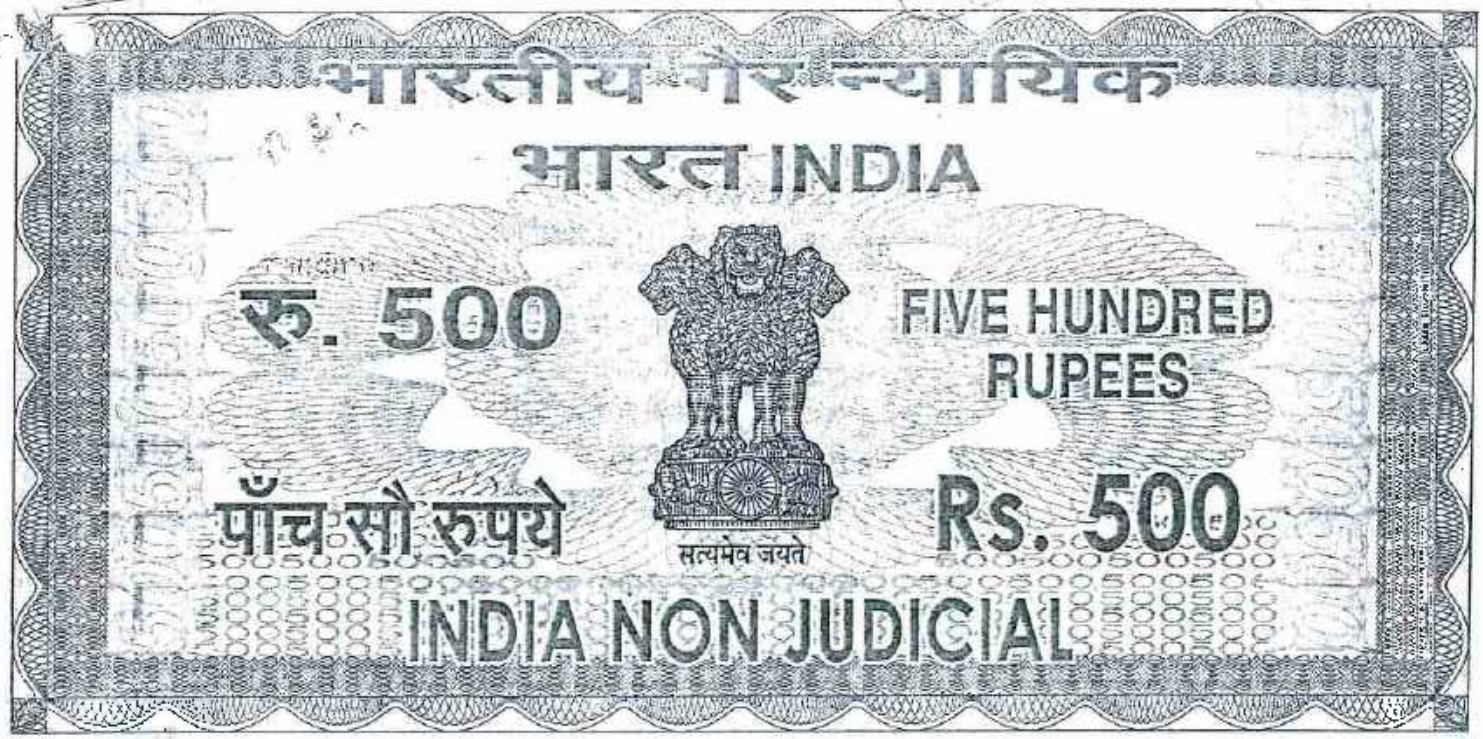
Name of authorized signatory: Prof. U.C. GHOSHAL

Phone: 0522-2494048 Email address: sro@sgpgi.ac.in

Date: 08/08/2022

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2022



महाराष्ट्र MAHARASHTRA ◐ 2021 ◐ BK 571462

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. 2000097
21 DEC 2021
सक्षम अधिकारी

डा. बी. आर. आंबेडकर

NOVARTIS HEALTHCARE PRIVATE LIMITED (First Part)

AND

Dr. Jayantee Kalita (Second Part)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Third Part)

K. Mangathai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

FIRST AMENDMENT TO CLINICAL TRIAL AGREEMENT

This First Amendment is made at Mumbai and entered into on 04 day of FEB-22, by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at 7th floor, G Block, BKC Main Road, Bandra Kurla Complex, Bandra (East), Mumbai – 400051, Maharashtra, India (hereinafter referred to as "**Novartis**", which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the First Part;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at Uttar Pradesh ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Jayantee Kalita as clinical practitioner in the field of Neurology acting in the role of principal investigator ("Principal Investigator") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

(Novartis, Investigator and Institution may hereinafter be individually referred to as '**Party**' and are collectively referred as '**Parties**').

WHEREAS

A. By a Clinical Trial Agreement dated 03-November-2021 entered into between the Parties hereto ("**Agreement**"), the Investigator and the institution have agreed to provide certain services to Novartis on the terms and conditions contained in the Agreement.

B. Now by this First Amendment, the Parties are desirous of modifying Annex-1 (Addition of CRC fees)

NOW THIS AMENDMENT WITNESSETH AND IT IS HERE BY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. This Amendment shall be effective from 7-Dec-2021 and shall be coterminous with the

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the Parties to this Amendment have caused their duly authorized representatives to enter into and execute this Amendment.

Novartis Healthcare Private Limited

By: _____ 27 Jan 2022

Name: **Murugananthan K.**

Title: Country Monitoring Head

Date:

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

Name: *Dr. Jayantee Kalita*

Title: Principal Investigator

Date: 04 Feb 2022

Dr. J. KALITA
Prof.
Department of Neurology
S.G.P.G.I.M.S., LUCKNOW

By: _____ 10/2/22

Name: _____

Title: Institute Director

Date:

Prof. R.N. DHINGRA
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ BH 135321

उप कोषागार अधिकारी
कल्याण

NOVARTIS HEALTHCARE PRIVATE LIMITED (First Part)

7 OCT 2022

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Second Part)

AND

Dr. Dharmendra Bhadauria (Third Part)

Novartis Healthcare Mumbai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

FIRST AMENDMENT TO CLINICAL TRIAL AGREEMENT

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This FIRST Amendment is made at Mumbai and entered into on 09 day of Dec 2022, by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at 7th floor, G Block, BKC Main Road, Bandra Kurla Complex, Bandra (East), Mumbai – 400051, Maharashtra, India (hereinafter referred to as "**Novartis**", which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the First Part;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at **Uttar Pradesh** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Dharmendra Bhadauria as clinical practitioner in the field of ***Nephrology*** acting in the role of principal investigator (**"Principal Investigator"**) which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

(Novartis, Investigator and Institution may hereinafter be individually referred to as '**Party**' and are collectively referred as '**Parties**').

WHEREAS

A. By a Clinical Trial Agreement dated 25-February-2022 entered into between the Parties hereto ("**Agreement**"), the Investigator and the institution have agreed to provide certain services to Novartis on the terms and conditions contained in the Agreement.

B. Now by this First Amendment, the Parties are desirous of modifying the addition of advance amount required for patient travel reimbursement in Annex-1 on the terms and conditions herein after appearing.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOW THIS AMENDMENT WITNESSETH AND IT IS HERE BY AGREED BY AND BETWEEN

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IN WITNESS WHEREOF, the Parties to this Amendment have caused their duly authorized representatives to enter into and execute this Amendment.

Novartis Healthcare Private Limited

By: _____

Name: Murugananthan K.

Title: Country Monitoring Head

Date: 09 DEC 2022

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

Name: Prof. R K Dhiman

Title: Director

Date: 22/12/22

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014 INDIA

o/c
UCGI

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Dharmendra Bhadauria

Title: Professor, Department of Nephrology

Date: 12-12-2022

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TITLE PAGE:

प्रधान मुद्रांक कार्यालय, मुंबई.
ए.सी.आर. 6000039
9 NOV 2022

ACTIVE POST-MARKETING SURVEILANCE-CLINICAL TRIAL AGREEMENT

"A Prospective, Open-Label, Multi-centered, Non-Randomized, Non-Comparative Active Post-Marketing Surveillance to test the safety and efficacy of Diperoxochloric Acid [DPOCl] topical solution in Subjects with diabetic neuropathic ulcers of skin and subcutaneous tissue."

Study No.	082-20	**Version No.**	1.0	**Date**	01-01-2020
Protocol Amendment No.			01	**Date**	14-01-2021

Investigational product	**WOXheal (Diperoxochloric Acid Topical Solution)** This pack contains two bottles: **Bottle A:** Diperoxochloric acid concentrate (each ml of solution contains: Diperoxochloric Acid Concentrate.....1.16 mg) **Bottle B:** Sterile Sodium Chloride Solution BP.....0.9% w/v (Cutaneous Solution) **Composition:** Sodium Chloride IP.....0.9% w/v In sterile neutralized aqueous vehicle .....q.s. **Reconstituted Solution (Bottle A + Bottle B) in bottle B:** Each ml of solution contains: Diperoxochloric acid ..... 0.29 mg

श्रीमती लता सांगळे

Sponsor	**Centaur Pharmaceuticals Pvt. Ltd.** (CENTAUR HOUSE, Opp. Grand Hyatt, Vakola, Santacruz - East, Mumbai - 400 055, India.) Tel. No.: +91-22-66499100 Fax: +91-22-66499108	**CRO**	LifeSan Clinical Research
		Clinical Laboratory	At individual site
		Department	Clinical Trials

Authorised personal from Sponsor	Dr. Mukund Zarapkar M. D. Vice President – Clinical Research, LifeSan Clinical Research, Division of Centaur Pharmaceuticals Pvt. Ltd., India
Investigator	**Dr. Gyan Chand** MBBS, M.S (General Surgery) Prof. Department of Endocrine Surgery Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow - 226014, Uttar-Pradesh, INDIA
Clinical Trial Site	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow - 226014, Uttar-Pradesh, INDIA

Confidentiality Statement

The information provided in this document is strictly confidential and is available for review to investigators, sponsor and appropriate Ethics Committee. No disclosure should take place without written authorization from Centaur Pharmaceuticals Pvt.

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Executive Registrar
SGPGIMS Lucknow

APPENDIX

CENTAUR PHARMACEUTICALS PVT. LTD. MUMBAI-55

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Executive Registrar
SGPGIMS,Lucknow

1. **Parties**

Sponsor:

Name: Centaur Pharmaceuticals Pvt Ltd

Authorized Personnel: Dr. Mukund Zarapkar

M. D.

Vice President – Clinical Research,

LifeSan Clinical Research,

Division of Centaur Pharmaceuticals Pvt. Ltd., India

Address: Centaur House, Near Grand Hyatt, Shanti Nagar, Vakola, Santacruz East, Mumbai, Maharashtra 400055

Investigator:

Name: Dr. Gyan Chand

MBBS, M.S (General Surgery)

Prof. Department of Endocrine Surgery

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow - 226014, Uttar-Pradesh, INDIA

Clinical trial site:

Name: Director, SGPGIMS Research

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow - 226014, Uttar-Pradesh, INDIA

2. **Definitions**

2.1 A "trial subject" means a person who is either a patient or a healthy person to whom investigational product is administered for the purposes of a clinical trial.

2.2 "clinical trial" in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,-

(i) Clinical or;

(ii) Pharmacological including pharmacodynamics, pharmacokinetics or;

(iii) Adverse effects.

2.3 "clinical trial site" means any hospital or institute or any other clinical establishment having the required facilities to conduct a clinical trial;

2.4 "adverse event" means any untoward medical occurrence (including a symptom or disease or an abnormal laboratory finding) during treatment with an investigational drug or a pharmaceutical

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Executive Registrar
SGPGIMS,Lucknow

product in a patient or a trial subject that does not necessarily have a relationship with the treatment being given;

2.5 "serious adverse event" means an untoward medical occurrence during clinical trial resulting in death or permanent disability, or hospitalisation of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalisation where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event;

2.6 "sponsor" includes a person, a company or an institution or an organisation responsible for initiation and management of a clinical trial.

2.7 "investigational product" means the pharmaceutical formulation of an active ingredient or placebo being tested or used in a clinical trial.

2.8 "medical management" means treatment and other necessary activities for providing the medical care to complement the treatment.

2.9 "Completion" of a patient's/subject's participation means a qualified patient/subject has completed the study and met the minimum attendance and compliance standards in the Protocol required to permit evaluation and that the patient's/subject's case report form has been completed by the Investigator and accepted as satisfactory by Sponsor.

2.10 A "withdrawn" participant is a qualified patient/subject who was withdrawn from the study because of treatment failure or adverse event but otherwise met the minimum attendance and compliance standards in the Protocol.

2.11 "clinical trial protocol" is a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project.

2.12 A "case report form (CRF)" is s a specialized document designed to collect the patient data in a clinical trial.

2.13 The "informed consent form" is the document that participants must sign before participating in a clinical research study.

2.14 The "Investigator's Brochure (IB)" is a comprehensive document summarizing the body of information about an investigational product ("IP" or "study drug") obtained during a drug trial.

3. SCOPE OF THE AGREEMENT

Under this agreement parties agree to conduct a clinical trial as defined in the Protocol

CENTAUR PHARMACEUTICALS PVT. LTD. MUMBAI-55

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Study title- A Prospective, Open-Label, Multi-centered, Non-Randomized, Non-Comparative Active Post-Marketing Surveillance to test the safety and efficacy of Diperoxochloric Acid [DPOCL] topical solution in subjects with diabetic neuropathic ulcers of skin and subcutaneous tissue.

Study no – 082-20

Person in charge of the research: Dr. Mayuresh Kiran and Dr. Mukund Zarapkar

4. PURPOSE OF THE AGREEMENT

This agreement is between sponsor, investigator and clinical trial site to agree on terms and conditions as well as individual roles and responsibilities by which the active post marketing surveillance study of DPOCL shall be conducted.

5. CONTACT PERSONS

Contact person from the sponsor

Name : Dr. Mukund Zarapkar

Designation: V. P. Clinical

Address : Centaur house, 2nd floor, wing- A, Pipe Line Road, Shanti Nagar, Vakola, Santacruz East, Mumbai, Maharashtra 400055

Telephone : 02266499154

Fax : 02266499112

E-mail : drzarapkar@lifesan.in

Contact details of the Investigator

Name : Dr. Gyan Chand

Address : Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar-Pradesh, INDIA

Telephone: +91-9451546353

E-mail : gyan133@sgpgi.ac.in , drgyaanchandpgi@gmail.com

Contact person from the Clinical Trial Site:

Name : Director, Prof. R K Dhiman

Address : Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar-Pradesh, INDIA

Telephone: 0522 266 8700

CENTAUR PHARMACEUTICALS PVT. LTD. MUMBAI-55

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SGPGIMS,Lucknow

6. CLINICAL TRIAL SITE

Active post marketing surveillance study shall be conducted at the below mentioned clinical trial site:

Name : Sanjay Gandhi Post Graduate Institute of Medical Sciences

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar-Pradesh, INDIA

7. BACKGROUND MATERIAL AND RIGHTS OF USE

Below mentioned documents shall be provided by the sponsor to the investigator.

1. Protocol
2. Study synopsis
3. Case report form
4. Investigator's brochure
5. Informed consent form
6. Patient information sheet
7. Updated safety information about the investigational product based on the ongoing active PMS study
8. Any additional documents if required by the CDSCO or concern ethics committee

Below mentioned documents shall be provided by the investigator to the sponsor

1. Registration of additional qualification (signed and stamped)
2. Updated CV (signed and stamped)
3. Signed and stamped undertaking by the investigator
4. Signed and stamped protocol summary by the investigator
5. Reported adverse events along with all the essential data elements required for the processing of ICSR
6. Any additional documents if required by the CDSCO or concern ethics committee

Both investigators and the sponsor shall strictly adhere to the protocol, other clinical trial documents and applicable regulatory guidelines for the conduct of clinical trial. Any deviation to the protocol during the conduct of clinical trial either from the investigator or the sponsor shall be communicated to other party as soon as it is noticed.

8. INVESTIGATIONAL PRODUCT

CENTAUR PHARMACEUTICALS PVT. LTD. MUMBAI-56

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For the active PMS study investigational products shall be provided to the investigator at no cost by the sponsor and the investigational products shall be provided to the patient at no cost by the investigator. On visits 0 and 1, one investigational product shall be provided to each patient whereas on visits 2, 3, 4 and 5, two investigational products shall be provided to each patient by the investigator at no cost. Prior to the initiation of the clinical trial, the adequate quantity of the investigational products shall be provided to the investigator by the sponsor and shall remain in the custody of the investigator until it is dispensed to the patient. Accountability of the investigational product shall be maintained at the end of investigator for the no of units received from the sponsor and the no of units dispensed to the particular patient recruited for the clinical trial. Accountability for the investigational product shall be maintained by sponsor for the no of units provided to the investigator.

9. PAYMENT SCHEDULE

Investigators shall be given the honorarium of Rs 10,000/- per completed patient i.e. any patient who has given consent and have been enrolled in the active PMS study and either completed 10 weeks study duration or have reached the outcome of complete healing of the DFU anytime within 10 weeks from enrolment in the active PMS study.

Payment schedule	
Investigator charges	Rs. 10,000/- per completed patient
Institutional overhead = 25% of the cost of the trial, which will exclude patient conveyance charges as well as charges in case of an adverse event or serious adverse event [medical management and also the compensation in c/o trial-related injury etc.]	

Payment shall be credited into the account of the Director of SGPGIMS research after successful completion of below mentioned things.

- Satisfactory study completion by the investigator with the desired number of subjects as per the protocol.
- Submission of all the required documents related to the clinical trial to Centaur Pharmaceuticals Pvt Ltd by the investigator.
- Resolution of clinical trial data related question if any
- On confirmation of the sponsor that investigator has submitted error free complete data as per the protocol and other clinical trial documents.

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10. RESPONSIBILITIES OF THE INVESTIGATOR

Responsibilities of the investigators shall be as mentioned below.

1. Recruitment of patients for the clinical trial as per the inclusion and exclusion criteria.
2. Inform patients about the investigational product, clinical trial procedures and resolve their doubts if any and take written consent from the patient for the clinical trial.
3. Keep accountability for the investigational products about the no of investigational products received from the sponsor and dispensed to the patient.
4. Inform the concern ethics committee and the sponsor about the serious and non-serious adverse event.

11. RESPONSIBILITIES OF THE SPONSOR

Responsibilities of the sponsor shall be as mentioned below.

1. Provide updated clinical trial documents to the patient
2. Provide updated safety and efficacy data to the investigator
3. Provide clinical trial liability insurance policy for all the patients involved in the study which can be used for the complete medical management in case of any patients gets adverse event or serious adverse event during the clinical trial.
4. Provide complete medical management to the trial subject in case of adverse event as long as required or till such time it is established that the injury is not related to the PMS study, whichever is earlier

12. RESPONSIBILITIES OF THE CLINICAL TRIAL SITE

Responsibilities of the clinical trial site shall be as mentioned below.

1. Provide clinical trial facility to the investigator for the conduct of clinical trial
2. Provide complete medical management to the trial subject in case of adverse event as long as required or till such time it is established that the injury is not related to the PMS study, whichever is earlier.

13. CONFIDENTIALITY

Sponsor, investigators and clinical trial site agreed on the below mentioned confidentiality terms and conditions:

13.1. Confidential Information: For purposes of this Agreement, "Confidential Information" means any information or materials related to the DPOCL active post marketing surveillance study, study no.

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082-20 disclosed by sponsor, in writing or in the form of tangible materials or orally or by virtual presentation, is marked as "confidential" at the time of such disclosure and is summarized in a writing sent by sponsor or data generated by the active post marketing surveillance study.

13.2. **Obligations and Restrictions:** The Information disclosed by sponsor to the Investigator or to the clinical trial site or any other information related to the active post marketing surveillance study or data generated by the Investigator shall be confidential and thus all agrees not to disclose the confidential information to any third party;

13.3. **Exceptions:** This Agreement imposes no obligation on the Receiving Party with respect to any portion of the Confidential Information received from the Disclosing Party which (i) is lawfully obtained by receiving party from a third party under no obligation of confidentiality, (ii) is or becomes generally known or publicly available other than by unauthorized disclosure, (iii) Information independently developed by the Investigator and not the part of active post marketing surveillance study (iv) Information disclosed by sponsor as a part of marketing or sales or published on the official website.

Nothing in this Agreement will be deemed to restrict Investigator from disclosing confidential information regarding DPOCL active post marketing surveillance study if disclosure is required by law, regulation or by any regulatory authority provided that the Investigator is required to give such information to sponsor on mail on pharmacovigilance@centaurlab.com within 24 hrs as soon as Investigator receives any notice or letter or any communication for disclosing any information related to DPOCL active post marketing surveillance study.

13.4. **Return of Confidential Information:** Within 10 days upon written request or mail from sponsor, the Investigator and the clinical trial site shall return to the sponsor all documents, files, copies, notes or any other materials containing any portion of the Confidential Information of DPOCL active post marketing surveillance study which was provided by the sponsor. The Parties shall have the right to retain one copy in a secure location for the sole purpose of determining any continuing obligations of confidentiality under this Agreement.

13.5. **No Assignment:** The rights and obligations of the Parties under this Agreement may not be sold, assigned, or otherwise transferred, without the other Party's prior written consent.

13.6. **Electronic Transmission.** Signatures to this Agreement transmitted by fax, by electronic mail in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of the Agreement, shall have the same effect as physical delivery of the paper document bearing the original signature.

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14. PERSONAL DATA PROTECTION

The sponsor, investigator and the clinical trial site are obliged to keep confidential the personal data of the trial subjects accrued in connection with the active post marketing surveillance study.

15. DATA AND RESULTS ACCRUED IN CONNECTION WITH THE TRIAL

All information, documents, reports, materials and other results accrued in connection with this active post marketing surveillance study apart from the trial subject records and other data collected by the investigator for its own use shall be the property of the sponsor. And sponsor can independently use the same without permission of the investigator or the clinical trial site.

16. PUBLICATION OF RESULTS

As this shall be the multicentric clinical trial, the data analysis shall be done by sponsor and results can be published only by the sponsor. Multicentric clinical trial data or part of it cannot be published by the investigator or the clinical trial site.

17. ENTIRE AGREEMENT

This agreement represents the entire understanding between the sponsor, investigator and clinical trial site with respect to the conduct of an active post marketing surveillance study and supersedes all prior oral or written agreements between the parties related thereto. All or any disputes arising out or touching upon or in relation to the terms and conditions of this Agreement, including the interpretation and validity of the terms thereof and the respective rights and obligations of the Parties, shall be settled amicably by mutual discussion, failing which the same shall be settled through the jurisdiction of Lucknow court.

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18. SIGNATURES

This agreement has been made in three (3) copies, one for each party.

Sponsor

Dr. Mukund Zarapkar

M. D.

Vice President – Clinical Research,

LifeSan Clinical Research,

Division of Centaur Pharmaceuticals Pvt. Ltd., India

Signature: _____

Date : 18/11/2022

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Investigator

Dr. Gyan Chand

MBBS, M.S (General Surgery)

Prof. Department of Endocrine Surgery

SGPGIMS-Lucknow

Signature: _____

Date : 02/12/2022

Clinical trial site

Director, Prof. R K Dhiman

SGPGIMS- Lucknow

Signature: _____

Date : 07/2/23

Prof. R.K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA

Undersigned is committed to work according to the Protocol and in all other ways promote the fulfilment of this agreement especially the responsibilities stated.

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Bo...

Indian-Non Judicial Stamp
Haryana Government

Date :14/06/2022

Confidential

-Certificate No. G0N2022F1059

GRN No. 91361035

Stamp Duty Paid : ₹ 101
(Rs. Only)

Penalty :₹ 0
(Rs. Zero Only)

Deponent

Name: Inventiv International pharma services Private limited

H.No/Floor : Na Sector/Ward : Na Landmark : Na

City/Village : Gurugram District : Gurugram State : Haryana

Phone : 96******93

Purpose : AGREEMENT to be submitted at Others

CLINICAL TRIAL AGREEMENT

Protocol # 417-201-00007

This Clinical Trial Agreement ("Agreement") dated as of the date of last signature and effective as of the date of last signature("**Effective Date**") between

Otsuka Pharmaceutical Development & Commercialization, Inc. a corporation incorporated in the State of New Jersey with its registered office at 2440 Research Boulevard, Rockville, Maryland 20850, United States ("**Sponsor**")
and

Sanjay Gandhi Postgraduate Institute of Medical Sciences, with a place of business at Department of Nephrology & Renal Transplantation, Sector 12, Lucknow- 226014, Uttar Pradesh, India ("**Institution**")

and

Dr. Narayan Prasad, located at Department of Nephrology & Renal Transplantation, Sector 12, Lucknow- 226014, Uttar Pradesh, India (**"Principal Investigator"**).

"Party" means Sponsor, Institution or Principal Investigator equally, and "Parties" shall mean all of them.

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BACKGROUND

By separate agreement, Sponsor has engaged George Clinical India Private Limited, a contract research organization with a principal place of business in the Plot No.5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road, Bangalore –560 001, Karnataka, India acting as an independent contractor ("CRO"), to act on behalf of Sponsor for the purposes of transferring certain obligations in connection to this Agreement, said obligations including but not limited to carrying out the Trial (as defined below) as the investigational new drug application ("IND") holder in India, execution of the Agreement and payment administration for services performed. In addition, Sponsor has engaged Syneos Health, LLC, a contract research organization with a principal place of business at 1030 Sync Street, Morrisville, North Carolina 27560 USA and its affiliates acting as an independent contractor, to assist Sponsor with negotiating clinical agreements.

Sponsor wishes to support a clinical trial with Sponsor Drug (hereinafter defined) Sibeprenlimab, encoded 417-201-00007 entitled "A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy" ("Protocol") to be conducted at Institution ("Trial") to involve patients participating in the Trial ("Trial Subjects").

The Parties agree as follows:

1. Investigators and Research Staff.

1.1 Principal Investigator. The Principal Investigator, being an employee/ of the Institution, will be responsible for the direction of the Trial in accordance with Applicable Law (hereinafter defined) and Institution policies. The Trial will be conducted under the supervision of the Principal Investigator at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Department of Nephrology & Renal Transplantation, Sector 12, Lucknow- 226014, Uttar Pradesh, India .

1.2 Sub-investigators and Research Staff. Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff (sub-investigators and research staff collectively referred to as "Research Staff") who may be employees or consultants of the Institution or contracted third parties only to the extent permitted by Applicable Law governing the Trial conduct, as described below. Per ICH E6 R2, sections 4.2.5 and 4.2.6, as the Principal Investigator is responsible for supervising the Research Staff, he/she will ensure that only individuals who are appropriately qualified and trained assist in the conduct of the Trial and the Principal Investigator will ensure the integrity of the Trial-related duties and functions performed and any Trial Data (hereinafter defined) generated by the Research Staff.The Principal Investigator shall sign an undertaking in the form prescribed in Table 4 of the Third Schedule of the Rules (defined below).

1.3 Obligations of Institution and Principal Investigator. Institution and Principal Investigator will ensure that Research Staff is informed of and agree to abide by all terms of this Agreement applicable to the activities they performand shall also abide by the terms of any permissions and approvals for the conduct of the Trial in terms of applicable laws, including permission from the Central Licensing Authority for the Trial.Institution and Principal Investigator will assume all those responsibilities assigned under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant International Council forHarmonization Good Clinical Practice ("ICH GCP") guidelines and standards and the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects" (2013), all applicable laws and guidance relating to clinical trials of medicines, the provisions of the New Drugs and Clinical Trials Rules, 2019 ("Rules") as may be amended from time to time, ethical guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Researchand other applicable law, regulations, and governmental guidance, including

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without limitation, the laws of the Republic of India, all applicable laws relating to human rights, supply of medicines legislation, legislation relating to human tissue and biological samples, and all applicable laws relating to the confidentiality, privacy and security of Trial Subject information ("Applicable Law").The Principal Investigator as a signatory/confirming party to this Agreement acknowledges the liabilities and obligations as an 'investigator' contained in Rules.

1.4 No Substitution. Institution and Principal Investigator may not reassign the conduct of the Trial to a different investigator without prior written authorization from Sponsor. Any replacement principal investigator will be required to agree to the terms and conditions of this Agreement in a separate writing. In the event Sponsor does not approve a replacement principal investigator, Sponsor may terminate this Agreement in accordance with the termination provisions below.

1.5 Delegation of Duties by Principal Investigator. Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by Applicable Law governing the Trial conduct, as described below.

1.6 Compliance with Institutional Policies. Principal Investigator will comply with the policies and procedures of the organization(s) with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Sponsor promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

1.7 Data Integrity. Data integrity is fundamental in the processing and disposition of Study data collected and further used in decisions, related to Sponsor's product quality, safety, efficacy and compliance with regulatory requirements, that are made based on data that is recorded and reported from the Study. This applies to all manual/paper-based data, electronic data, including metadata, and data in a hybrid format throughout the data lifecycle and allows for full reconstruction of GxP activities. Institution on behalf of itself and the Principal Investigator shall maintain appropriate documentation to support its compliance with these principals and furnish it promptly to Sponsor or CRO upon request. The Site shall ensure that: (1) Only qualified and delegated staff conduct Study activities at the Institution; (2) All Study staff are trained in ICH E6(R2) & ALCOA+ Data Integrity procedures to conduct the Study activities as documented in the Protocol; (3) All Study data (paper and electronic) is managed in accordance with ALCOA+ Data Integrity principles (e.g., strict adherence to data system access and zero tolerance to sharing of credentials); (4) all Study staff understand the ownership and obligations to vigorously manage data controls at the Institution to prevent data falsifications; and (5) all Study staff promptly document and escalate all potential data integrity issues to the Sponsor or the CRO within twenty-four (24) hours of knowledge of an issue.

2. Protocol. Institution and Principal Investigator will conduct the Trial in accordance with the Protocol (including any Protocol Amendments hereinafter defined), written instructions of CRO/Sponsor and Applicable Law.

2.1 Amendments. The Protocol may be modified only by a written amendment ("Protocol Amendment"), signed by Sponsor and the Principal Investigator. If applicable, the Parties acknowledge that Protocol Amendments are also subject to approval by the responsible Independent Ethics Committee ("IEC") and/or Regulatory Authority ("RA"). Sponsor may instruct a deviation from the Protocol on an emergency basis for the safety of the Trial Subjects. Institution and/or Principal Investigator will notify the responsible IECand/or RA as soon as practicable but, in any event, no later than five (5) business days after the deviation is implemented. Any emergency deviation will be followed by written Protocol Amendment.

2.2 Emergency Deviations/Urgent Safety Measures. If the Principal Investigator determines that it is necessary to deviate from the Protocol on an emergency basis for the safety of the Trial

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Subjects, Institution and/or Principal Investigator will notify Sponsor and the responsible IECand/or RA as soon as practicable but, in any event, no later than five (5) business days after the deviation is implemented

3. IEC and RA. The Parties will ensure that the Trial is initiated only after both the Trial and the informed consent form ("ICF") are approved by an IECand/or RA that complies with all Applicable Law. The Parties will further ensure that the Trial is subject to continuing oversight by the IECand/or RA throughout its conduct.

4. Sponsor Drug. Sponsor will provide Institution with sufficient quantities of the Sponsor product that is being studied ("Sponsor Drug") to conduct the Trial at no cost to the Institution and Principal Investigator. If required by the Protocol and unless otherwise agreed, Sponsor will also provide placebo or comparator drug ("Comparator Drug") at no cost to the Institution and Principal Investigator.

4.1 Custody and Dispensing. Institution and Principal Investigator will adhere to Applicable Law requiring careful custody and dispensing of Sponsor Drug or Comparator Drug, as well as appropriate documentation of such activities.

4.2 Control. Institution and Principal Investigator will maintain appropriate control of supplies of Sponsor Drug or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Research Staff.

4.3 Use. Institution and Principal Investigator will use Sponsor Drug or Comparator Drug only as specified in the Protocol. Any other use of Sponsor Drug or Comparator Drug constitutes a material breach of this Agreement.

4.4 Ownership of Sponsor Drug. Sponsor Drug is and remains the property of Sponsor. Sponsor grants Institution and Principal Investigator no express or implied intellectual property rights in the Sponsor Drug or in any methods of making or using the Sponsor Drug.

4.5 Payment for Sponsor Drug or Comparator Drug. Institution and Principal Investigator will not charge a Trial Subject or third-party payer for Sponsor Drug or Comparator Drug or for any services reimbursed by Sponsor or CRO under this Agreement.

5. Financial Arrangements. Compensation for services provided under this Agreement will be made by way of payments in accordance with Attachment A (Payment Terms) and Attachment B (Financial Arrangements Worksheet). All Parties acknowledge that amounts set forth in Attachment B represent fair market value of the services provided by Institution and Principal Investigator for conducting the Trial to the best of their knowledge. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the Parties. Neither the Institution nor the Principal Investigator will directly or indirectly seek or receive compensation from Trial Subjects or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Sponsor or its CRO, including, but not limited to, Sponsor Drug, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Sponsor Drug and/or Comparator Drug administration. Once the Payee(s) (hereinafter defined) have been paid for the performance of the Trial, neither CRO nor Sponsor shall have any further obligation or liability whatsoever to pay Principal Investigator or Institution.

6. Reporting Obligations. Principal Investigator acknowledges that various laws, statutes, regulations, directives, and/or industry requirements (collectively, "Reporting Laws") require certain companies in the pharmaceutical/healthcare industry to disclose and report information regarding payments made and agreements entered into with healthcare professionals or other individuals and entities carrying out activities in certain countries. Accordingly, where such Reporting Laws are applicable, Principal

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Investigator acknowledges and agrees that information, including but not limited to: (i) name, address, qualifications and medical specialties, registration number; (ii) information regarding the Agreement; and (iii) information concerning all payments or benefits (in cash or in kind) made to Principal Investigator under the Agreement may be disclosed by CRO to Sponsor and/or to the relevant responsible authority for publication of such information publicly in accordance with the relevant Reporting Laws. The right of Principal Investigator to object to data collection and data processing pursuant to applicable privacy laws may not apply where the disclosure obligation results from a statutory requirement. Execution of this Agreement serves as Principal Investigator's consent to the data collection, processing and disclosure of the information set forth herein for the purposes stated.

7. Trial Subject Enrollment. Institution and Principal Investigator have agreed to enroll Trial Subjects in the Trial in accordance with the Protocol and in accordance with IECand/or RA approval. Sponsor may discontinue Trial Subject enrollment if the total enrollment needed for a multi-center Trial has been achieved, if applicable.

8. Informed Consent. Principal Investigator shall ensure that the ICF approved by Sponsor, IECand/or RA is signed on behalf of each Trial Subject before the first Trial related procedure starts for the Trial Subject.

9. Reporting Adverse Events and ICH GCP Breaches. Institution and Principal Investigator will report ICH GCP breaches as well as adverse events experienced by Trial Subjects at any time in accordance with instructions in the Protocol and Applicable Law.

10. Personal Data Protection and Privacy. The parties shall comply with all applicable privacy and data security laws and regulations, as provided under this Agreement, including for the avoidance of doubt, all local laws and regulations applicable to data protection, including but not limited to GDPR, and their related ordinances, regulations, directives, guidance and guidelines ("Information Protection Laws"), as applicable. "GDPR" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation). In addition, Institution and Principal Investigator shall comply with the following provisions:

10.1 Authorization to Use and Disclose Health Information. Institution and Principal Investigator shall provide an appropriate privacy notice to and will obtain a written privacy authorization, complying with Information Protection Law, for each Trial Subject which will enable Institution and Principal Investigator to provide Sponsor and other persons and entities designated by Sponsor access to completed case report forms (CRFs), source documents and all other information required by the Protocol.

10.2 Use of Trial Subject Personal Data. Use of Personal Data. Institution and Principal Investigator will collect and use personal information obtained from Trial Subjects collected by Institution and Principal Investigator for the sole purpose outlined in the Protocol ("Personal Data") and shall manage such Personal Data in accordance with Information Protection Law and this Agreement.

10.3 Disclosure of Personal Data. Institution and Principal Investigator shall not disclose personal data to CRO or the Sponsor except as is required to satisfy the requirements of the Protocol, for the purpose of monitoring or adverse event reporting, in relation to a claim or proceeding brought by a Trial Subject in connection with the Trial, or as required by law. In all such cases of disclosure, Institution and Principal Investigator shall respect the "data minimization" principle of privacy, including but not limited to the following example: implementing appropriate technical and organizational measures, de-identification of Personal Data prior to sharing it with Sponsor, CRO or other parties, actual Trial Subject names shall not be included on any invoices for payment submitted by Institution and Principal Investigator.

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10.4 Right of Trial Subject.

a. The parties will respond to Trial Subjects' requests for access, amendment, transfer, blocking, or deletion of Personal Data in accordance with Information Protection Law and this Agreement. The parties acknowledge that in order to maintain the integrity of Trial results, the ability to amend, block, or delete Personal Data may be limited, in accordance with Information Protection Law. Institution and Principal Investigator and/or CRO will notify Sponsor within five (5) calendar days of receipt of any communication relating to a Trial Subject's right to access, modify or correct his or her Personal Data and will comply with all reasonable instructions of Sponsor before responding to such communication.

b. Institution and Principal Investigator and/or CRO will provide to Sponsor, and as otherwise required by Information Protection Law, written notice within twenty-four (24) hours of any security incident that involves, or which CRO and/or Institution and Principal Investigator reasonably believes involves, the unauthorized access, use, disclosure or other unauthorized processing of Personal Data; provided, further, CRO and/or Institution and Principal Investigator shall (i) provide updates to Sponsor as further information becomes available as to the breach, and (ii) at the earliest possible time, summarize in reasonable detail the impact on Sponsor of the breach or unauthorized use or disclosure of, or access to, Personal Data and the corrective action taken or to be taken by CRO and/or Institution and Principal Investigator; provided, further, CRO and/or Institution and Principal Investigator shall promptly take all necessary and appropriate corrective action including, without limitation, at the request of Sponsor and at CRO's and/or Institution and Principal Investigator 's expense, to provide notices to Trial Subjects whose Personal Data may have been affected, whether or not such notice is required by law; each party shall reasonably cooperate with the other party to facilitate compliance with Information Protection Laws, including but not limited to notification of affected individuals and regulatory authorities.

11. Confidential Information. During the course of the Trial, Institution and Principal Investigator may receive or generate information that is confidential to Sponsor or a Sponsor affiliate.

11.1 Definition. Except as specified below, confidential information ("Confidential Information") includes all information provided by Sponsor or CRO, or developed for Sponsor or CRO, Inventions (hereinafter defined) and all data collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with the Sponsor or CRO, commercialization and Trial strategies, trade secrets and know-how disclosed by Sponsor to Institution and/or Principal Investigator directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

11.2 Exclusions. Confidential Information does not include information that is in the public domain prior to disclosure by Sponsor or CRO; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Institution or Principal Investigator; is already known to Institution or Principal Investigator at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Institution or Principal

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Investigator, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

11.3 Obligations of Confidentiality. Unless Sponsor provides prior written consent, Institution and Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Institution or Principal Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by Applicable Law. Required disclosure of Confidential Information to the IECand/or RA is specifically authorized.The Institution and Principal Investigator agrees not to reveal Confidential Information to third parties, other than those Research Staff, agents, local service providers and/or contractors with a need to know directly involved in conducting the Trial or services in support of the Trial. Institution and Principal Investigator shall ensure that prior to any disclosure of Confidential Information to any such recipients are subject to similar confidentiality obligations no less onerous than those in this Agreement.

11.4 Disclosure Required by Applicable Law. If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Institution and Principal Investigator: (i) notify Sponsor in writing as far as possible in advance of the disclosure so as to allow Sponsor to take legal action to protect its Confidential Information; (ii) discloses only that Confidential Information required to comply with the legal requirement; and (iii) continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

11.5 Survival of Obligations. For Confidential Information other than Trial Data and Biological Samples (hereinafter defined) analysis data, these obligations of nonuse and nondisclosure survive termination of this Agreement and continue for a period of ten (10) years after termination. Permitted uses and disclosures of Trial Data are described in Section 16 (Publications) of this Agreement.

11.6 Return of Confidential Information. If requested by Sponsor or CRO in writing, Institution and Principal Investigator will return all Confidential Information, at Sponsor's expense, except that required to be retained at the Institution by Applicable Law. However, Institution and Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

12. Personal information of the parties. Prior to and during the course of the Trial, the Principal Investigator and other employees/contractors of Institution may be called upon to provide personal information to the Sponsor and other third parties involved in the conduct of the Trial, including the CRO. Personal information may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and/or information relating to payments made pursuant to this Agreement ("Personal Information").

12.1 To the extent permitted by Information Protection Law, the Personal Information may be stored electronically by Sponsor and/or CRO and/or transferred to third parties (situated throughout the world) for the following purposes:

i. the conduct of clinical trials;

ii. verification by government or regulatory agencies, the Sponsor, CRO, and their agents and affiliates;

iii. compliance with legal and regulatory requirements;

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iv. publication on www.clinicaltrials.gov and other websites and/or databases that serve a comparable purpose;

v. storage in databases to facilitate the selection of investigators for future clinical trials; and

vi. anti-corruption compliance.

Institution confirms that the Principal Investigator and its employees/contractors consent to provide the Personal Information to Sponsor and/or CRO to be electronically stored by Sponsor and/or CRO and for Sponsor and/or CRO to transfer to third parties as stated above.

12.2 Institution and Principal Investigator shall provide the information reasonably requested by Sponsor and/or CRO and shall authorize the processing and storage of certain Personal Information about the Principal Investigator, Institution personnel, research staff and other individuals involved in the Trial for the purpose of fulfilling legitimate business requirements relating to clinical trials and meeting regulatory requirements as well as for the purpose of evaluating Institution or Principal Investigator for inclusion in future clinical trials. Institution or Principal Investigator shall give an appropriate privacy notice and obtain consent as required from the Institution personnel, research staff and other individuals for the processing of their personal data under applicable Information Protection Law.

12.3 Institution shall process Personal Information relating to CRO employees/contractors only to the extent, and in such a manner as is necessary for the purposes of this Agreementand in compliance with the Information Protection Law. Institution shall not transfer such Personal Information relating to CRO's employees/contractors to a third party without the prior written consent of CRO.

12.4 During the term of this Agreement, the Institution and CRO will maintain a comprehensive privacy and security program designed to ensure that Personal Information will only be processed in accordance with this Agreement and pursuant to privacy and security regulations, including appointment of a data protection officer as required by applicable Information Protection Law. Institution and CRO agree to implement administrative, technical, and physical security measures to protect Personal Information and ensure a level of security appropriate to the risk as required by applicable Information Protection Law. Institution and CRO agrees to regularly test, assess and evaluate the effectiveness of the measures for ensuring the security of processing.

12.5 The Institution agree to allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Institution's compliance with the obligations described by the Information Protection Law, on reasonable notice subject to the Sponsor and/or to provide the Sponsor with evidence of its compliance with the obligations set out in the Information Protection Law.

12.6 Sponsor agrees: (a) to process Personal Information only for the limited and specified purposes under this Agreement and in compliance with the Information Protection Law; (b) to provide the same level of privacy protection as is required by the Information Protection Law; (c) upon reasonable notice, to permit its designees

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and/or CRO to perform an audit at Sponsor's own expense or to take other reasonable and appropriate steps to ensure that Institution and Principal Investigator effectively process the Personal Information transferred under this Agreement in a manner consistent with Sponsor's obligations under the Information Protection Law; (d) upon notice, to take reasonable and appropriate steps to stop and remediate any unauthorized processing hereunder; (e) to permit its designees and/or CRO to provide a summary or a representative copy of the relevant privacy provisions of this Agreement to supervisory authorities' request; and (f) to notify any competent supervisory or regulatory authorities and CRO, where required, if Institution and Principal Investigator determine it can no longer meet the obligations under this Section or if it otherwise breaches any obligations imposed under this Section.

12.7 Sponsor acknowledges and warrants that the sub processors or other third parties, engaged by Sponsor will be bound by obligations regarding the processing of Personal Data no less restrictive than those set forth herein.

12.8 Sponsor shall implement appropriate technical and organizational measures to meet the requirements of the Information Protection Law.

12.9 Each Party shall be responsible for its own processing of Personal Data in accordance with all Information Protection Law and with the Informed Consent Forms obtained from Trial Subjects and to the extent applicable, the Protocol.

12.10 If any Party becomes aware of a Personal Data breach in connection with the performance of this Agreement, that Party shall promptly notify the other Party/-ies. In such case, Parties will fully cooperate with each other in order to fulfil the (statutory) notification obligations timely.

13. Trial Data, Biological Samples, and Records.

13.1 Trial Data. During the course of the Trial, Institution and Principal Investigator will collect and submit certain data to Sponsor or its agent, as specified in the Protocol. This includes CRFs (or their equivalent) or electronic data records, as well as any other documents or materials created for the Trial and required to be submitted to Sponsor or its agent, such as X-ray, magnetic resonance imaging ("MRI"), or other types of medical images, electrocardiogram ("ECG"), electroencephalography ("EEG"), or other types of tracings or printouts, or data summaries (collectively, "Trial Data"). Institution and Principal Investigator will ensure accurate and timely collection, recording, and submission of Trial Data.

a. Ownership of Background Intellectual Property. All intellectual property rights and know how owned by or licensed to any of the Parties prior to and after the date of this Agreement, other than any intellectual property rights and know how arising from the Trial, are the exclusive property of the that Party and shall not be affected by this Agreement.

b. Ownership of Trial Data. Subject to Institution's and/or Principal Investigator's right to publish any Trial Data and the non-exclusive license that permits certain uses, Sponsor is the exclusive owner of all Trial Data.

c. Non-Exclusive License. Sponsor grants Institution and Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal non-commercial research or educational purposes.

d. Medical Records. Medical records relating to Trial Subjects that are not submitted to

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Sponsor may include some of the same information as is included in Trial Data; however, Sponsor makes no claim of ownership to those documents or the information they contain.

13.2 Biological Samples. If so specified in the Protocol, Institution and Principal Investigator may collect and provide to Sponsor or its designee Biological Samples ("Biological Samples").

a. Use. Institution and Principal Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Sample Data. Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, Sponsor will not provide the results of such tests ("Sample Data") to the Institution or Principal Investigator or Trial Subject. Sample Data will be treated as Trial Data; therefore, if Sponsor provides Sample Data to the Institution or Principal Investigator, that data will be subject to the permitted use of Trial Data as outlined in this Agreement.

13.3 Records. Institution and Principal Investigator will retain all records and documents pertaining to the Trial under storage conditions conducive to their stability and protection, for the longest of: (i) fifteen (15) years after termination of the Trial unless Sponsor authorizes, in writing, earlier destruction; or (ii) as otherwise required by Applicable Law. Institution and Principal Investigator further agree to permit Sponsor to ensure that the records are retained for a longer period if necessary, at Sponsor's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

14. Inspections and Audits.

14.1 Access. Upon reasonable request, Sponsor, authorized representatives of Sponsor, and/or authorized representatives of the RA may, during and after the Trial, during regular business hours: (i) examine and copy: all CRFs and other Trial records (including Trial Subject records and medical charts, Trial Subject ICF documents, and Sponsor Drug and Comparator Drug receipt and disposition logs); (ii) examine and inspect the facilities and other activities relating to the Trial or the IEC; and (iii) observe the conduct of the Trial.

14.2 Notice. Institution and/or Principal Investigator shall: (i) inform Sponsor and CRO as soon as practicable of any effort or request by the government, the RA or other persons to inspect or contact the Institution, Principal Investigator or Research Staff with regard to the Trial; (ii) provide Sponsor and CRO with a copy of any communications sent by such persons; and (iii) provide Sponsor the opportunity to participate in any proposed or actual responses by Principal Investigator or Institution to such communications and to make reasonable efforts to ensure that Sponsor may be present or represented during any such visit.

14.3 Cooperation. Institution and Principal Investigator will ensure the full cooperation of the Research Staff and IECmembers with any such inspection and will ensure timely access to applicable records and data. Institution and/or Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records.

15. Inventions. If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Institution and Principal Investigator will promptly inform Sponsor . Institution and Principal Investigator will assign all interest in any such Invention to Sponsor, free of any obligation or consideration beyond that provided for in this Agreement. Institution and Principal Investigator will provide reasonable assistance to Sponsor in filing and prosecuting any patent applications relating to Invention, at Sponsor's expense. Sponsor grants Institution and Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Inventions for internal research or educational purposes.

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16. Publications. Sponsor does not object to publication by Institution or Principal Investigator of the results of the Trial based on information collected or generated by Institution and Principal Investigator, whether or not the results are favorable to the Sponsor Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, Institution and Principal Investigator will provide Sponsor an opportunity to review at least sixty (60) days prior any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. If in the Sponsor's judgment, publication or presentation at a given time would hinder the Sponsor's development of the Sponsor Drug, the Principal Investigator shall consider modifying the publication or presentation schedules accordingly. The Institution and/or Principal Investigator further agrees to delete information identified by CRO or the Sponsor as Confidential Information, prior to submitting such manuscript and/or abstract for publication or presentation, or defer publication or presentation of such manuscript and/or abstract at the request of the Sponsor, to permit the filing of any desired patent applications by the Sponsor. If part of a multi-center Trial, Institution and Principal Investigator agree that the first publication is to be a joint publication involving all Trial sites. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of the Trial at all participating Trial sites, Institution and/or Principal Investigator are free to publish separately, subject to the other requirements of this Agreement.

17. Publicity. No Party will use the name of another Party or any of its employees for promotional or advertising purposes without written permission from the other Party. However, Sponsor reserves the right to identify the Principal Investigator and Institution in association with a listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

18. Advertising.

18.1 If applicable and in accordance with the Food and Drug Administration Amendments Act of 2007, Public Law 110-85, Sponsor agrees to fully register this Study with the public registry at clinicaltrials.gov before enrollment of the first Study Subject at Center, if applicable. Sponsor may use, refer to, and disseminate reprints of scientific, medical, and other published articles relating to the Study which disclose the name of Site consistent with U.S. copyright laws. Site shall not publicly disclose the existence or the contents of this Agreement and any amendments. For example, Center shall not post this Agreement on a public website. For purposes of internal reporting or internal advertising, Center is specifically authorized to disclose a description of the Study based on, and not exceeding, the information posted by Sponsor on clinicaltrials.gov. No party to this Agreement shall use the name of any other party hereto in connection with any advertising or promotion of product or service without the prior written permission of such party.
18.2 Use of Social Media for Study Recruitment. Due to the highly regulated industry in which OPDC operates, and the serious health concerns related to improper use of any OPDC or its affiliates products, Site shall not participate in any social media postings/activities related to OPDC or its affiliates' products, investigational drugs, compounds or services, or this Study unless expressly permitted in writing by Sponsor. This restriction shall not be construed as prohibiting any conduct protected or required by Applicable Laws. Notwithstanding the foregoing, Site may use social media content to recruit potential Study Subjects to the Study. Accordingly, Site shall:

i. submit for review and approval all Site Study recruitment initiatives and content in accordance with OPDC's social media requirements.

ii. identify a Community Manager (as defined herein) if Site's social media recruitment content: (i) will enable user generated commenting ("UGC"); or (ii) will not or cannot turn off UGC as required by specific social media platforms. For purposes of this Agreement, the "Community Manager" may be either an individual employed by the Center or a third-party vendor ("Monitoring Vendor") that will be responsible for monitoring and managing the social media platform and/or social media content used for potential Study Subject

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recruitment when UGC is enabled. Site shall be responsible for all actions of its Community Manager.

iii. ensure that the Community Manager posts only OPDC pre-approved content, monitors social media comments once each weekday (excluding public holidays except when the holiday is a Monday), and completes all required AE and Product Quality Complaint ("PQC") training prior to posting any Study related social media content advertisement, and ensure all Site staff given access to the social media platform, undergo training on how to compliantly manage and moderate the social media content for recruitment purposes.

iv. report all AEs immediately in accordance with Article 18 Adverse Events and all PQCs in compliance with this Agreement and OPDC pharmacovigilance guidelines and training provided.

v. Any violations of this Section 17.2 shall be considered a material breach of this Agreement and cause for immediate termination by Sponsor. If Site is unable to comply with 17.2 i-iv, Site agrees it will not use social media that enables UGC to recruit potential Study Subjects.

19. Indemnification. Sponsor agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the Trial investigators; any institution at which the Trial is conducted, its officers, agents, and employees; and the IEC and/or RA that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities and/or expenses arising out of a Trial Subject Injury (hereinafter defined), the design of the Trial, or the specifications of the Protocol. Trial Subject Injury means a physical injury or drug-related psychiatric event caused by administration or use of the Sponsor Drug required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial ("Trial Subject Injury"). Sponsor further agrees to reimburse Institution and/or Principal Investigator for the actual cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject Injury and where required under any Applicable Law, any necessary compensation to Trial Subject for Trial Injury in accordance with Applicable Law and rules determining the quantum of any such compensation which is commensurate with the nature of the injury. Institution and Principal Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any Trial Subject Injury. Institution and Principal Investigator further agree to promptly notify Sponsor of any Trial Subject Injury.

19.1 Exclusions. Excluded from this Agreement to Indemnify are any claims for damages resulting from: (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Sponsor; (b) failure of an Indemnified Party to comply with Applicable Law; or (c) negligence or willful misconduct by an Indemnified Party.

19.2 Notice and Cooperation. Institution and Principal Investigator agree to provide Sponsor with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by Sponsor, Institution and Principal Investigator agree to authorize Sponsor to carry out the sole management of defense of an indemnified claim.

19.3 Settlement or Compromise. No settlement or compromise of a claim subject to this indemnification provision will be binding on Sponsor without Sponsor's prior written consent. Sponsor will not unreasonably withhold such consent of a settlement or compromise. Neither Party will admit fault on behalf of the other Party without the written approval of that Party.

19.4 Limit of Liability of CRO. The Parties agree that CRO expressly disclaims any and all liability whatsoever in connection with the Sponsor Drug or the Protocol and any claims or injuries arising therefrom, except to the extent that such liability arises from CRO's negligent act, omission or willful misconduct.

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19.5 In no event will a Party's liability towards the other Party include any indirect damages (indirect damages meaning: loss of profit, loss of revenue, loss of reputation, loss of contracts, or anticipated savings and loss of business opportunities).

20. Termination.

20.1 Termination Conditions. This Agreement terminates upon the earlier of any of the following events:

a. IECand/or RA Rejection. If, through no fault of Institution or Principal Investigator, the Trial is never initiated because of IECand/or RA disapproval, this Agreement can be terminated by any Party immediately.

b. Trial Completion. For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subjects; receipt by Sponsor or CRO of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either Party.

c. Early Termination of Trial. If the Trial is terminated early as described below, the Agreement will terminate after receipt by Sponsor or CRO of all relevant Protocol-required data, Trial documents and Biological Samples and receipt of all payments due to either Party.

(1) Termination of Trial upon Notice. Sponsor reserves the right to terminate the Trial for any reason upon thirty (30) calendar days written notice to Institution and Principal Investigator. Upon receipt of such notice, Institution and Principal Investigator agree to promptly terminate conduct of the Trial, to the extent medically permissible, for all Trial Subjects.

(2) Immediate Termination of Trial by Sponsor. Sponsor further reserves the right to terminate the Trial immediately upon written notification to Institution and Principal Investigator for causes that include failure to enroll Trial Subjects at a rate sufficient to achieve Trial performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in Sponsor's opinion pose risks to the health or wellbeing of Trial Subjects; or regulatory agency actions relating to the Trial or the Sponsor Drug or Comparator Drug.

(3) Immediate Termination of Trial by Institution and/or Principal Investigator. Institution and/or Principal Investigator reserve the right to terminate the Trial immediately upon notification to Sponsor if requested to do so by the responsible IECand/or RA or if such termination is required to protect the health of Trial Subjects.

20.2 Payment upon Termination. If the Trial is terminated early in accordance with this Agreement, Sponsor or CRO will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with Attachment A, less payments already made. The termination payment will include any non-cancelable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by Sponsor, and, only to the extent such costs cannot reasonably be mitigated. If the Trial was never initiated because of disapproval by the IECand/or RA, Sponsor or CRO/its designee will reimburse Payee for IEC fees and for any other expenses that were prospectively approved, in writing, by Sponsor.

20.3 Return of Materials. Unless Sponsor and/orCRO instructs otherwise in writing, Institution and Principal Investigator will promptly return all materials supplied by Sponsor and/orCRO, at Sponsor's expense, for Trial conduct, including CRFs and any Sponsor and/orCRO-supplied

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Equipment (hereinafter defined). Institution will return any unused Sponsor Drug or Comparator Drug, as applicable, at Sponsor's expense.

21. Insurance.

21.1 Institution and Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with Applicable Law for all medical professionals conducting the Trial.

21.2 Sponsor will secure and maintain in full force and effect insurance coverage to fulfill its indemnification obligations expressed in this Agreement herein in accordance with Applicable Law.

22. Debarment, Exclusion, Licensure and Response. Institution and Principal Investigator represent that to the best of their knowledge that neither they nor any Research Staff are restricted or prevented under any healthcare or medicines law from taking part in clinical research activities and the Institution and Principal Investigator will not knowingly use in any capacity the services of any person who is so restricted or prevented under any such laws with respect to the service being performed under this Agreement. During the term of this Agreement and for one (1) year thereafter, the Institution and Principal Investigator will immediately notify the Sponsor and CROif they become aware of any such restriction or prevention being applied to the Principal Investigator or any Research Staff. Institution and Principal Investigator represent that they and, to the best of their knowledge, the Research Staffare not the subject of any past or pending governmental or regulatory investigation, inquiry, warning or enforcement action, including a government-mandated corporate integrity agreement and that they have not violated any applicable anti-kickback or false claims laws or regulations related to their conduct of research that has not been disclosed to the Sponsorand CRO. Institution and Principal Investigator will promptly notify Sponsorand CRO if they become aware of any such action regarding compliance with ethical, scientific or regulatory standards for the conduct of research if such action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

23. Assignment and Delegation. The Parties agree that Sponsor may at any time and upon written notice to Institution and Principal Investigator assume the obligations and rights of CRO or substitute CRO with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Institution or Principal Investigator to another without the prior written consent of Sponsor, and the express agreement of Institution, Principal Investigator, CRO, and the requisite new assignee or subcontractor. Principal Investigator and/or Institution must notify Sponsor, and/or CRO in advance, prior to moving to another location. This Agreement will bind and inure to the benefit of the successors and permitted assigns of the Sponsor.

24. Equipment. Sponsor may provide, or arrange for a vendor ("Vendor") to provide, certain equipment for use by Institution and Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C (Equipment Use, Ownership & Disposition).

25. Anti-Bribery and Anti-Corruption Laws. Institution and Principal Investigator acknowledge that Sponsor and CRO are bound by anti-bribery and anti-corruption laws. As such, Sponsor and CRO employees, agents, contractors and/or representatives are prohibited from making or offering payment (or anything of value), directly or indirectly, to employees or officials of any foreign government, public international organization, political party, or candidates for political office in order to retain any business or secure any improper advantage. Institution and Principal Investigator shall ensure that neither they nor any of their officers, employees, collaborators, directors, consultants, agents, representatives or sub-contractors take any action which could render Sponsor or CRO liable under the anti-bribery and anti-corruption laws.

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26. Survival of Obligations. Obligations relating to Financial Arrangements, Reporting Obligations, Personal Data Protection and Privacy, Confidential Information, Records, Inspections and Audits, Inventions, Publications, Publicity, Debarment, Exclusion, Licensure and Response, and Indemnification survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

27. Entire Agreement. This Agreement contains the complete understanding of the Parties and will, as of the Effective Date, supersede all other agreements between the Parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the mutual consent of the Parties,except for certain mutually agreeable changes in the Trial budget as identified in Attachment A. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

28. Conflict with Attachments. To the extent that terms or provisions of this Agreement conflict with the terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in writing between the Parties.

29. Severance.In case any one or more of the provisions of this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained in this Agreement shall not in any way be affected or impaired.

30. Relationship of the Parties. The relationship of Institution and Principal Investigator to Sponsor is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

31. Force Majeure. Neither Party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) and are promptly notified to the other Party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) calendar days, then the Parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

32. Governing Law. Subject to the terms of the Trial conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions.

33. Notices. All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

Sponsor:
Otsuka Pharmaceutical Development & Commercialization, Inc.
2440 Research Boulevard
Rockville, Maryland 20850 USA

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With a copy to:
George Clinical India Private Limited
Plot No.5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road,
Bangalore --560 001, Karnataka, India
Attention: CEO
Email: contracts@georgeclinical.com

Institution:
Insert Institution's name Sanjay Gandhi Post Graduate Institute of Medical Sciences
Insert Institution's address Raebareli Road
Insert City, State zip code, Country Lucknow U.P 226014
Attention: DR R K Dhiman
Telephone: (0522) 2668004-008
Email: director@sgpgi.ac.in

Principal Investigator:
Insert Principal Investigator's name Dr Narayan Prasad
Insert Principal Investigator's address Dept of Nephrology C Block
Insert City, State zip code, Country Lucknow U.P India 226014
Telephone: 05222495187
Email: narayan.nephro@gmail.com

In case of any changes in the address, name, subordination, or other identifying information, the Party to the Agreement shall notify the other Party on the fact in writing, no further amendments to this Agreement are required.

34. Financial Disclosure. The Institution and/or Principal Investigator shall complete and return to CRO or the Sponsor in a timely manner, financial certification or disclosure forms, as applicable, provided to the Institution and/or Principal Investigator by CRO or the Sponsor. The Institution and/or Principal Investigator shall also complete and return to CRO or the Sponsor, all disclosure updates, as so instructed by CRO or the Sponsor, for the duration of the Trial, and for one year thereafter. The Institution and/or Principal Investigator shall ensure that all sub investigators, performing a Trial-related function shall complete and return all financial certification/disclosure forms as described in this Section.

35. Counterparts and Signatures. In the eventthat the Parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the Parties agree that, upon being signed by all Parties, this Agreement will become effective from Effective Date and binding and that facsimile copies and/or electronic signatures will constitute evidence of a binding agreement with the expectation that original documents may later be exchanged in good faith. Where this Agreement is executed by Institution and/or Principal Investigator through the use of an electronic or digital signature, Institution and/or Principal Investigator agree that: (i) their electronic or digital signature has same effect as a handwritten signature; (ii) signature by electronic or digital means is permitted under Applicable Law for the execution of the Agreement; (iii) the electronic or digital signature platform used to generate such signature meets the requirements under Applicable Law for creating a valid advanced electronic or digital signature; and (iv) Institution and/or Principal Investigator shall provide to CRO and/or to Sponsor any further necessary certification or supporting documentation around their electronically generated signatures in compliance with this Section.

[SIGNATURE PAGE FOLLOWS]

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Agreed to and accepted:

OTSUKA PHARMACEUTICAL DEVELOPMENT & COMMERCIALIZATION, INC. BY SYNEOS HEALTH, LLC AS ITS ATTORNEY-IN-FACT:

Signature

JOHN MICHAEL DOMINIC CD
Printed Name

ASSOCIATE DIRECTOR, CSH
Title

13 JAN 2023
Date

INSTITUTION

13/02/2023
Signature

Dr R K Dhiman
Printed Name

Director
Title

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date

PRINCIPAL INVESTIGATOR

Signature

Dr. Narayan Prasad
Printed Name

Principal Investigator
Title

Date 20.1.23

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA47294385281600V
Certificate Issued Date	:	11-Jan-2023 01:23 PM
Account Reference	:	NONACC (FI)/ kagcsl08/ YELAHANKA4/ KA-GN
Unique Doc. Reference	:	SUBIN-KAKAGCSL08889672927748 53V
Purchased by	:	HEALTHIUM MEDTECH LIMITED
Description of Document	:	Article 5(J) Agreement (In any other cases)
Property Description	:	CLINICAL INVESTIGATION AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	HEALTHIUM MEDTECH LIMITED
Second Party	:	APEX TRAUMA CENTRE SGPGIMS DR PULAK SHARMA
Stamp Duty Paid By	:	HEALTHIUM MEDTECH LIMITED
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

SEVA KENDRA YELAHANKA BRANCH Authorized Signatory

Please write or type below this line

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SGPGIMS,Lucknow

Statutory Alert.
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile app of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.

CLINICAL TRIAL AGREEMENT

Preamble:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow is a super specialty hospital, established by Government of Uttar Pradesh, as a center of excellence for providing medical care, education and research of high order and is chartered to function as a university under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, 1983. [Hereinafter referred to as "Act"]

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day 14th Feb 2023 **AMONG**

Healthium Medtech Limited (Formerly known as Healthium Medtech Private Limited), located at 472D, 13th cross, 4th phase, Peenya Industrial Area, Bangalore-560058 ("**Sponsor**") of the First part.

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India, through its **"Director/Director's Nominee**.....[herein referred to as "**Institute**"] of the Second part.

AND

Dr. Pulak Sharma, Associate professor, Department of Orthopedics, Sanjay Gandhi Post Graduate institute of Medical Sciences [hereinafter referred to as "**Principal Investigator**"] of the Third Part.

WHEREAS The Sponsor, Institute and, Principal Investigator are willing to jointly carry out the Study Number: HML-ACL-002-22 Entitled "A Randomized, Multi Center, Parallel, Open Label Study Assessing Clinical and Functional Outcomes After Anterior Cruciate Ligament (ACL) Reconstruction Procedure Using Suspensory Tibial Fixation with Open and Closed Peek Button" **[Hereafter referred to as "Study"]** described in Study Protocol;

AND WHEREAS Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study through **Contract Research Organization (CRO)** [iDD Research Solutions Pvt Ltd, located at 12/A, First floor, 3rd Sector, HSR Layout, Bengaluru, Karnataka-560102]

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

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1.0 Statement of work

1.1 "Study" shall be deemed to be "Clinical Trial" as defined in rule-122 DAA of the Drugs and Cosmetics Rule, 1945 and Indian Medical Devices Rules-2017.

1.2 Sponsor shall provide Principal Investigator with a sufficient quantity of Study Supplies to conduct the Study at investigational Site in timely manner. Institute and Principal Investigator shall use Study Supplies only to conduct the Study in accordance with the Protocol; All Study Supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of Sponsor, unless otherwise designated. The Institute and Principal Investigator will be responsible for the return of excess, unused Study Supplies to the Sponsor.

1.3 Study Timelines: Study Timelines for the purpose of this Agreement will be as per need of Protocol.

2.0 Obligations and Responsibilities of the Principal Investigator

2.1 The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria.

2.2 The Principal Investigator will conduct the study in accordance with protocol, Schedule Y (Drug and Cosmetics Rules, 1945), Indian Medical Devices Rules-2017 and Indian Council of Medical Research (ICMR) Guidelines along with Helsinki and The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for international studies.

2.3 The Principal Investigator will make necessary arrangement for inspection of documents etc. by sponsor's monitor, official of regulatory agency or Institutional Ethics Committee (IEC) nominee.

2.4 The Principal Investigator shall report all serious and unexpected adverse events and/ or death to the Licensing Authority, Sponsor, and IEC as per Appendix XI of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945) and Indian Medical Devices Rules-2017.

2.5 The Principal Investigator shall forward its report on Serious Adverse Event of Death after due analysis of all factors with his opinion to Chairman of IEC, Chairman of Expert Committee and Head of the Institute and the Licensing authority as per Appendix X of schedule Y(Drug and Cosmetics Rules, 1945) and Indian Medical Devices Rules-2017.

2.6 The Principal Investigator shall forward its report on Serious Adverse Event (SAE) other than Death after due analysis of all factors with his opinion to Licensing Authority, Chairman of IEC and Head of the Institute as per Appendix X of schedule Y (Drug and Cosmetics Rules, 1945) and Indian Medical Devices Rules-2017.

2.7 The Principal Investigator will be responsible for proper and prompt filling of Case Report Form (CRF), preservation of investigation reports and recordings.

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2.8 During and following a Clinical Trial Subject's participation in Study, the Principal Investigator shall ensure that adequate medical care is provided to the participant (Clinical Trial Subject) for any adverse events.

2.9 The Principal Investigator will ensure enrolment of trial participants after obtaining written informed consent and also informing the provisions of adequate treatment and compensation for Serious Adverse Event (SAE) as per schedule Y (Drug and Cosmetics Rules, 1945) and Indian Medical Devices Rules-2017.

2.10 Principal Investigator (PI) shall complete the Clinical Trial under his supervision as per the agreement and the Statutory provisions, but if for any reason he/she is unable to carry over the study it shall be his/her responsibility to hand over the study to his/her Co-Principal Investigator (Co-PI) or to any of the Faculty members of the Institute, to be decided by the Head of Department of the PI or Director and obtain the approval of the Ethics Committee and the Sponsor.

2.11 The Principal Investigator will be responsible for proper account of receipt, utilization and return of unused sample of trial device to sponsor and prevent its use for any other study.

2.12 The Principal Investigator will be responsible for providing non-compliance and progress report to Institutional Ethics Committee (IEC) within a week of occurrence or due date.

2.13 The Principal Investigator will be responsible for forwarding to IEC communications from sponsors within a week of receipt with comments for the need of any change in protocol or Patient Information Sheet (PIS).

2.14 The Principal Investigator will be responsible for obtaining IEC and sponsors permission for storage of blood or tissue samples for future use.

2.15 The Principal Investigator shall be responsible for obtaining sponsor's permission before publication or conference presentation of any data.

3.0 Obligation and Responsibilities of the Institute:

3.1 Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirement.

3.2 Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.

3.3 Fulfillment of necessary obligations by Institutional Ethics Committee (IEC), The Principal Investigator (PI) and supporting staff.

3.4 Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.

3.5 Adequate treatment and compensation for Serious Adverse Event (SAE) to trial participants.

3.6 Necessary infrastructure support to PI.

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3.7 Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related Study documents.

3.8 Ensuring accuracy, completeness, legibility and timelines of the Data reported to the Sponsor in the Case Report Forms (CRFs) and in all required reports.

3.9 Study shall be terminated on the recommendation of IEC, when safety and benefit of Clinical Trial Subjects is doubtful.

3.10 Safety reporting as per schedule Y (Drug and Cosmetics Rules, 1945), Indian Medical Devices Rules-2017 and/or Sponsor policy.

3.11 Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records.

3.12 The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.

3.13 If Sponsor or Contract research organization (CRO) violates the terms of this Agreement or does not provide the claimed compensation to the subject then the Institute or Principal Investigator may not conduct any other further clinical trials of this sponsor.

3.14 Approval of study within 8 weeks of receipt of Investigator's brochure, protocol including Patient Information Sheet (PIS) & Case Report Form (CRF), regulatory approvals, draft Clinical Trial Agreement (CTA), Insurance policy and IEC fee from sponsor.

3.15 Approval of midterm changes within 8 weeks of receipt of documents.

3.16 Review of progress report Data and Safety Monitoring Board (DSMB) report & Serious Adverse Event (SAE) from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

3.17 Review of SAE at Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) and necessary action within the time frame decided by regulatory agencies.

3.18 Review of final report.

3.19 Approval of storage of blood or tissues for use in future studies.

3.20 Facilitate visit of sponsor's monitor or representative of regulatory agencies.

3.21 Institutional clearance for sample to be sent abroad for non-pharmacokinetic studies.

3.22 Archiving of data for 15 years (or longer if required by sponsor/regulatory agency).

3.23 Safeguarding Intellectual property rights (IPR) of sponsor and SGPGI.

3.24 Providing alternate Principal Investigator (PI) if PI unable to continue.

3.25 Audited statement of utilization of Funds.

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4.0 Obligation and Responsibilities of the Sponsor

4.1 To provide investigator's brochure, Protocol, Case Report Form (CRF) draft Clinical Trial Agreement (CTA), Insurance policy from an Indian Insurance company and regulatory approvals.

4.2 To provide adequate supplies of trial device, comparator and /or placebo prepared under proper quality control.

4.3 To provide Insurance cover for treatment and compensation of Serious Adverse Event (SAE) and an undertaking to supplement any amount not covered by the Insurance Company. Sponsor will also provide copy of Policy to the Institute. Sponsor will also annually renew the policy and keep it active until the last patient last visit.

4.4 Undertaking to provide test drug free of cost to participants after termination of the trial if necessary till it become available in the country.

4.5 Not to send samples for Pharmacogenetic study abroad.

4.6 To permit the storage of samples for future study if requested by Principle Investigator.

4.7 Provide a copy of final report at termination of the study.

4.8 Appropriate acknowledgement of contribution of SGPGI investigators in any resulting publication.

4.9 To define and follow procedure for premature termination.

4.10 To provide budget which should include cost of treatment, investigations and investigators charges, reimbursement of travel expenses to participants if necessary, Institute's overhead at the rate of 25% of the total budget and INR 25,000/- fee of IEC. Details of release of budget to be mutually settle.

5.0

5.1 Sponsor agrees that any injury or death of the Clinical Trial Subject occurring in Clinical Trial due to following reasons shall be considered as Clinical Trial related injury or death and the subject or his nominee, as the case may be, will be entitled to receive from the sponsor financial compensation for such injury or death as per the notification of the Drug Controller General of India (DCGI) & Government of India issued from time to time.

(a) Adverse effect of Investigational Product(s);

(b) Violation of the approved Protocol;

(c) Scientific misconduct or negligence by the Sponsor or his representative or Contract research organization (CRO) or Principal Investigator, Co-investigator or any member of his/her team

(d) Failure of Investigational Product to provide intended therapeutic effect;

(e) Use of placebo in a placebo-controlled Clinical Trial;

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(f) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved Protocol;

(g) For injury to a child in utero because of the participation of parent in Clinical Trial;

(h) Any Clinical Trial procedures involved in the Study.

5.2 Sponsor should submit a status report on the Clinical Trial to the Licensing Authority at the prescribed Periodicity;

5.3 In case of studies permanently discontinued for any reason Sponsor shall submit a summary report to the Licensing Authority as per provisions of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945) and Indian Medical Devices Rules-2017.

6.0 Undertaking and Representation of Principal Investigator

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format given in Appendix VII of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945) and Indian Medical Devices Rules-2017.

7.0 Undertaking and Representation of Institute

Institute hereby represents that:-

It has constituted the Institutional Ethics Committee as per the guidelines given in the Gazette of India & it has been registered with the Drug Controller General of India (DCGI) vide letter No: ECR/16/Inst/UP/2013/RR-20

(i) SOP is in compliance with Good Clinical Practice (GCP) guidelines and applicable regulations;

(ii) It will ensure that IEC will discharge its responsibilities as per provisions of Schedule-Y (Drug and Cosmetics Rules, 1945)

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that:-

It has furnished an undertaking along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of clinical trial related injury or death for which subjects will be entitled to compensation; as per provisions of rule 122 DAB (b) of Rules (Drug and Cosmetics Rules, 1945).

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9.0 Administration

9.1 Overall responsibilities of the Study will rest with Principal Investigator, Institute and Sponsor to conduct the Study at Institute's premises.

9.2 The following Study plan will apply to the Study:

(a). Subject enrollment up to Institute's Enrollment Maximum (i.e.: Clinical Trial Subjects) shall be completed as stated in protocol. However, if the Institute and Principal Investigator are unable to enroll patients for the Study within 6 months of Investigation Site initiation Sponsor will be having the authority to change the Institute's Enrollment Maximum in a unilateral manner.

(b). Institute or Principal Investigator will not enroll more Study subjects than Institute's Enrollment Maximum Sponsor will not be obligated to make any payment with respect to any subject enrolled in excess of Institute's Enrollment Maximum.

(c). Subject to applicable law: Sponsor and Institute without any further obligation mutually may agree in writing to modify Institute's Enrollment Maximum.

(d). All subject visits will be conducted as proposed in the protocol. The sponsor will be informed is a visit is delayed by more than 2 weeks along with reason of delay.

(e). Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within 7 days after the subject's visit or, if applicable, receipt of the subject's test results.

(f). All Data Queries from Sponsor must be completed and returned to Sponsor within a time frame mutually negotiated.

(g). Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or Study team will not be the liability of Sponsor.

10.0 Trial Device; Materials Transfer; Records Retention; Inspection

10.1 Trial Device:

(i) Institute and Principal Investigator acknowledge that the trial device is owned or controlled by Sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Institute or Investigator for the Trial, shall be construed to grant to either Institute or Principal Investigator any rights in or to the Compound.

(ii) Except as otherwise agreed by the Parties, Sponsor will provide the Compound and any control/placebo material to be administered to Trial subjects as part of the Trial (collectively, the **"Trial Device"**) free of charge to Institute for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Trial subjects at the Trial Site in Strict compliance with the Protocol.

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(iii) Institute and Principal Investigator shall use the Trial Device solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial device to any third parties. Institute and Principal Investigator shall handle, store, ship and dispose of the Trial device as directed by Sponsor or its designee and in compliance with all applicable laws, rules and regulations.

(iv) Institute and Principal Investigator will ensure that empty and partially used Trial Device container and any Trial Device remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

(v) Neither support of the Trial, nor Institute participation in the Trial, impose any obligation, express or implied, on Institute or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's products.

(vi) Unless required by the Protocol, Institute will not modify the Trial Device or its container. If the Institute policy requires any modification to the Trial Device container, such modification must be approved in advance in writing by Sponsor. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Institute for use in a future study to be approved by Institutional Ethics Committee (IEC).

10.2 Records Maintenance and Retention Investigator and Institute will maintain adequate and accurate records relating to the disposition of the Trial Device and the performance of all required Protocol procedures on Trial subjects including but not limited to, written and audiovisual documents, medical records, charts pertaining to individual Trial subjects, "Case Report Forms ("**CRF**") accounting records, notes, reports, and data. Institution will retain these documents for the longer period of at least 5 yrs. after completion or earlier termination of the Trial.

11.0 Representation and Warranties

11.1 Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the Trial in accordance with this Agreement and the Protocol.

11.2 Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

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12.0 Confidentiality

12.1 Institute will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than patient medical records), including the Trial Results, Trial Inventions and information related thereto (**Confidential Information**). Institute and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential information will not include information that:

(i) Is or becomes publically available through no fault of Investigator or Institution.

(ii) Was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute form other source.

(iii) Is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

(iv) Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

12.2 Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

(i) To comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Institute cooperate with Sponsor efforts to limit such disclosure by appropriate legal means:

(ii) To protect any Trial subject's safety or provide appropriate medical care for any Trial subject, or to prevent a public health emergency with prompt notice to Sponsor

(iii) For purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial subject related to the procedures included in the Protocol.

13.0 Return of Confidential Information

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in

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writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

14.0 Trial Results and Inventions

14.1 Sponsor owns all data, Trial Results, Confidential Information, Case Report Forms (CRFs) and all other information generated as a result of or in connection with the conduct of the Trial, excluding Institution's patient medical records and Principal Investigator's personal notes and hereby grants to the Institute a nonexclusive, non–transferable, non-sub licensable right to use the Trial Results solely for its own internal, non-commercial research, patient care, and educational purposes.

14.2 All inventions, ideas, methods works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institute, Principal Investigator or Trial Personnel: (i) as a result of or in connection with the conduct of the Trial (ii) that incorporate or use Confidential Information: or (iii) that are directly related to the Compound and in each case together will all intellectual property rights relating thereto (collectively, **Trial Inventions**"), will be the sole and exclusive property of Sponsor Or its designee. Institute and Principal Investigator will promptly disclose all Trial Investigations to sponsor in writing and interest in all Trial Investigations to sponsor or its designee. At sponsor's request and expense, Institute shall take and shall cause Principal Investigator and Trial Personnel to take, all additional actions as it deems necessary to perfect the interest of sponsor or its designee in Trial Investigations or to obtain patents or otherwise protect the interest of sponsor or its designee in Trial Investigations.

15.0 Payment

15.1 In consideration for conducting the Study Sponsor shall pay Institute and Principal Investigator as described in Annexure-A. Sponsor will not make further payments, towards Study visits, procedures, or other work associated with a Study subject if Sponsor determines that the Clinical Trial Subject's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

15.2 Sponsor shall pay on a Per Subject Cost for each Satisfactorily Completed Subject (as defined below) in accordance with Annexure-A as attached to this Agreement. If a subject is discontinued for reason stipulated in the Protocol, the Institute and Principal Investigator shall be paid a prorated rate for work completed.

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(a). Per Subject Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Annexure-A. The estimated total amount per Clinical Trial Subject listed in Annexure-A is calculated for a Clinical Trial Subject that completes all the Study visits. Screening Visits are paid for consented Clinical Trial Subjects for whom all screening procedures are performed. All visit costs include Institutional overhead, staff fees and applicable taxes.

(b). The per subject costs is a fixed fee per patient which includes all costs and honoraria, including but not limited to;

- All Study related activities such as conduct of visit assessment and CRF completion
- Time and efforts of Principal Investigator/s and other Institute's Study personnel
- All manpower cost involved in the Study conduct
- All diagnostic test and other investigations (ECG, Chest X-ray, Spinal X-ray etc.)
- Housing or hospital stay for patients including meals
- Patient reimbursement/ Compensation
- All overhead costs
- Usage of Instruments/ equipments which during the Study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Institute infrastructure).

(c). A completed and evaluable patient means Patient:

(i). Subjected to Study on whom all procedures have been performed and completed according to Protocol;

(ii). Who is enrolled for the Study according to inclusion and exclusion criteria;

(iii). For whom all Data documented accurately and completely;

(iv). All Data queries resolved completely in mutually agreed timely manner; and

(v). For whom all source, CRF and other Study related documents completed as per protocol standard requirements as mentioned in Annexure-A.

15.3 **Screen Failures/ Drop-outs:** For drop-outs payment will be made by Sponsor on a pro-rated basis for the number of completed visits and per screen failures (if applicable).

15.4 **Set-Up Fees:** Sponsor will pay the Institute an initial advance amount of INR 50,000 within 15 days after obtaining the Ethics Committee and necessary regulatory approval. This up-front advance payment would be exclusive of Institutional overhead and service charges and shall be deducted/ adjusted on pro-rata basis from further subsequent payments.

15.5 **Hospitalization costs:** Apart from Study specific cost, treatment of the subject in the event of any Serious Adverse Event (SAE) shall be paid by Sponsor to the Clinical Trial Subject.

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15.6 **Institutional Ethics Committee Fees:** Institutional Ethics Committee review fees will be paid by sponsor as determined.

15.7 **Payments by Sponsor to Institute shall be directed as follows:**

Principal Investigator Fee/ Clinical Trial Subject Reimbursement and Hospitalization:

Payee Name (Account name)	**Director, SGPGIMS, Research a/c**
Account Number	**10095237491**
Bank Name	**State bank of India**
Branch Name	**SGPGI Branch, Lucknow**
Swift/IFSC Code	**SBIN0007789**
PAN Number*	**AAAJS3913N**
Send to <<Cheque Delivery Address>>	**Dr. Pulak Sharma, Department of Orthopedics, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014,U P, India**

15.8 Payments will be made **on monthly** basis according to actual work performed (CRF completion, source Data verification and CRF retrieval for completed visits). Advance payment will be adjusted against the 1st payment. Final payment will be made at the time of Investigation Site close-out visit or immediately after Investigation site close-out visit and payment will not be made until all queries are resolved.

15.9 Subject travel reimbursement is exclusive of Institutional overhead and will be done as mentioned in Annexure-A. However, Sponsor will release the funds to Institute and Principal Investigator for each Clinical Trial Subject, i.e., **Rs.**1000 per physical visit as per the Study schedule.

15.10 Sponsor will provide a Clinical Research coordinator for the Study from the Investigation Site initiation visit to Investigation Site close out visit (until all the Data queries are resolved at the Institute's premises).

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15.11 In the event there is a refund due to Sponsor at the time of premature termination of this Agreement by any party, the Institute agrees to remit the same to Sponsor within fifteen (15) days of the effective termination date.

15.12 **Tax deduction:** All fees and amounts listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the Institute for the Study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

16.0 Use of other parties' names

The Principal Investigator and Institute shall not use Sponsor's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ CRO/Institute.

17.0 No joint venture etc.

This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18.0 Insurance and Indemnification

Insurance:

Institute shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

Indemnification:

Sponsor shall, at all times to come, indemnify the Principal Investigator and Institute without demure for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institute arising directly or indirectly out of the performance of the Study pursuant to the Protocol and SOP.

The Sponsor will indemnify the subject suffering in any manner as a result of trial for any reason whatsoever including negligence or violation of the protocol by the Principal Investigator or any member of his team as per order of the Licensing authority or the Institutional Ethics Committee.

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19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

19.1 The Principal Investigator and Institute shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

19.2 The Principal Investigator and Institute shall notify to the Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute s facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the Principal Investigator and Institute receives, obtains, or generates pursuant to any such study.

19.3 The Principal Investigator and Institute will permit the Sponsor to;

(a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.

(b) Inspect and copy all Data, documents and records related to such work and the Study

19.4 The obligations of this Section shall survive termination of this Agreement.

20.0 Term; Waiver; Severability (The trial on its time extended)

20.1 This Agreement will be in force for a period of the trial or its time extended from the date of its signing. The term of this Agreement may be extended by consent of all parties to this Agreement.

20.2 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 36 months after the Effective Date. The Date of execution of this Agreement shall be the effective Date.

20.3 This Agreement will become effective after by the last signatory it is fully executed by all the parties hereto and shall continue in effect for the full duration of the Study according to the Protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

20.4 This Agreement may be terminated by any party upon giving at least a thirty (30) days written notice to that effect to the other parties. The day following the 30th day of such notice shall be "Effective Date of Termination". A reasonable adjustment will be made between the parties to ensure the Principal Investigator and Institute is reimbursed for project costs incurred to the date of termination of this Agreement for completing the study as per protocol or already enrolled subjects.

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20.5 Sponsor may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institute subject to the discharge of their respective obligations under the terms of the agreement.

21.0 Effect of termination

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(ii). Upon notice of termination of this Agreement by Institute or Sponsor or Principal Investigator, Institute shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institute shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails to repay such funds in a timely manner, Sponsor may deduct an equivalent amount from any payment then or later due from Sponsor to Institute under this or any other arrangement between the parties.

(iii). Upon termination of this Agreement, all unused Materials and all Sponsor Confidential Information (except for such records that Institute is required by law or regulation to retain) in Institute's possession shall be promptly delivered to Sponsor at Sponsor's expense, or, at Sponsor's option, destroyed with the destruction certified in writing.

22.0 Recordkeeping

The Institute and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, Institutional Ethics Committee (IEC) requirements, and in accordance with all applicable local, state and Central laws and regulations. Institute or Principal Investigator shall cooperate with the Sponsor in making records, reports and Data developed under this Agreement.

Institute or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 15 years after completion of all regulatory activity,

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whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

23.0 Publication

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the Clinical Trial Study is the sole property of the Sponsor. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but his name should to be included in any publication either author or as participant in the study.

24.0 Miscellaneous

24.1 Parties to this Agreement shall comply with the current provision of Drugs and Cosmetic Act 1940, Drugs and Cosmetic Rules 1945.

For providing insurance to Clinical Trial Subjects in case of injuries or death,

The parties to this Agreement have tied up with the company IFFCO Tokio General Insurance Co. Ltd. which covers per patient amount (INR 80 Lacs per Insured Person per patient limit). This insurance is valid from the period from (1-DEC-2022) to (30-NOV-2023). This insurance shall be extended from time to time till the expiry of Agreement.

24.2 The Study shall be started by Principal Investigator after this Agreement is executed by all the parties and required regulatory approvals/consent is available for the study.

24.3 The parties to this Agreement shall ensure that safety, welfare and right of the research participants (Clinical Trial Subject) are safeguard.

24.4 The Principal Investigator shall forward all Protocol deviation/non-compliance/violation/waiver reports to the IEC.

24.5 The safety completion Report shall be sent to IEC by Principal Investigator.

25.0 Governing Law

The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA as applicable in the State of Uttar Pradesh.

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26.0 Jurisdiction

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be Lucknow, notwithstanding any other provision to the contrary in any law in this regard.

27.0 Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed by the Chairman of the Institutional Ethics Committee of the Institute within 30 days of the receipt of a written request by the aggrieved. The Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

28.0 Amendment

This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the Study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, in triplicate, by their officers, thereunto duly authorized to sign on behalf of their party.

1. Principal Investigator, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: _____ 1/5/23

Name: Dr. Pulak Sharma

Title/Designation: Associate Professor, Department of Orthopedics

2. Director/his nominee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: _____

Dr. .....Prof. R.K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA.....

(Name)

Title/Designation: .....

(Director/his nominee)

3. Sponsor

Signature and date: Ashok Kumar Moharana 26-04-2023

Name: Dr. Ashok Kumar Moharana

Title/Designation: Chief Medical Officer, Healthium Medtech Limited

Dr. Ashok Kumar Moharana
Chief Medical Officer
Healthium Medtech Limited

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IN-GJ11389953597585V

INDIA NON JUDICIAL

Government of Gujarat

Certificate of Stamp Duty

सत्यमेव जयते

Certificate No.	:	IN-GJ11389953597585V
Certificate Issued Date	:	20-Feb-2023 01:50 PM
Account Reference	:	IMPACC (AC)/ gj13265911/ GULBAI TEKRA/ GJ-AH
Unique Doc. Reference	:	SUBIN-GJGJ13265911502138779821 70V
Purchased by	:	ZYDUS LIFESCIENCES LIMITED
Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	ZYDUS LIFESCIENCES LIMITED
Second Party	:	Not Applicable
Stamp Duty Paid By	:	ZYDUS LIFESCIENCES LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

ACC * DEVENDRA K. PRAJAPATI * CHANDLODIA AHMEDABAD

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SGPGIMS,Lucknow

Scrutiny Alert
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("Agreement") is made and entered into on this 25th day of April 2023 ("Effective Date") by and between:

1. **Zydus Lifesciences Limited (Formerly known as Cadila Healthcare Limited)**, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad – 382481, Gujarat, India (hereinafter referred to as **"the Sponsor"**) and

2. **Dr. Amit Goel**, Department of Hepatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow- 226014, Uttar Pradesh, India (hereinafter referred to as **"Principal Investigator"**) and

3. **Sanjay Gandhi Postgraduate Institute of Medical Sciences** (SGPGIMS), Raebareli Road, Lucknow- 226014, Uttar Pradesh, India (hereinafter referred to as **"the Institution"**) and

This Agreement is executed for the study entitled "A prospective, randomized, two-arm, parallel, placebo-controlled, multicentre, superiority, phase II clinical trial to evaluate the immunogenicity and safety of Recombinant Hepatitis E Vaccine (Adsorbed) of M/s. Zydus Lifesciences Limited in healthy subjects. (Project No.: 22-06)" (hereinafter referred to as "Study").

This Agreement also covers any companion protocol(s) later developed and approved by all the Parties that are conducted concurrently with the protocol identified herein (collectively "Protocol") and that involve some or all the same subjects. The Sponsor and the Institution hereby declare that all the necessary permissions and licences required under the provisions of various acts and rules thereunder have been obtained for the performance of their respective obligations under this Agreement.

THE PARTIES AGREE AS FOLLOWS

The Sponsor would like to evaluate the immunogenicity and safety of Recombinant Hepatitis E Vaccine (Adsorbed) of M/s. Zydus Lifesciences Limited in healthy subjects.

The Sponsor hereby declares that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely Drugs & Cosmetics Act, 1940 and Drug & Cosmetic Rules 1945 and their subsequent amendments (including New Drugs and Clinical Trials Rules, 2019 - CDSCO) will be obtained before the start of the Study.

1 The Sponsors have approached the Principal Investigator, as they desire to perform the Study in regards to the said drug in accordance with the Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices and Local Regulations and have accordingly finalized the Protocol.

2 The Principal Investigator hereby confirms that he has read and understood all conditions, requirements, and written directions specified by Sponsor, the Protocol, and Protocol amendments and/or addenda thereof. The Principal Investigator agrees to the Protocol and will perform the Study in accordance with the Protocol, Declaration of Helsinki, the Indian Guidelines on Good Clinical Practices, and applicable laws, rules and regulations. The Principal Investigator and Institution shall ensure that all sub investigators, associates, colleagues, and

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employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

3 Principal Investigators and Research Staff

3.1 Principal Investigator: The Study will be conducted by the Principal Investigator. He hereby confirms that he is a competent person to sign this Agreement on behalf of his sub-investigators and research staff. The terms "Principal Investigator" or "Principal Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub-investigators and research staff and the Institution.

3.2 Sub-investigators and Research Staff: Principal Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub-investigators or research staff.

3.3 Obligations: Principal Investigator will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement. The Principal Investigator shall be responsible for performing the Study in strict compliance with specifications and timelines provided by Sponsor. The Principal Investigator agree to be responsible for any breach of this Agreement, the Protocol, and Protocol amendments and/or addenda thereof by its sub investigators, associates, colleagues, and employees.

3.4 No Substitution: The Principal Investigator shall not reassign the conduct of the Study to a different investigator without prior written authorization from the Sponsor.

3.5 Delegation of Duties by Principal Investigator: The Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical trials in India.

3.6 Compliance with Institutional Policies: The Principal Investigator will comply with the policies and procedures of the organization/institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify the Sponsor promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the Parties will attempt to reach an appropriate accommodation.

4 Funding: The conduct of the Study will not impose any financial burden on the Principal Investigator or the Institution. The Sponsor declares to bear all the expenses pertaining to the conduct of the Study.

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Financial Support for Clinical Trial:

Sr. No.	Budgetary Provision	Amount (in rupees) per completed visit	Amount (in rupees) per completed subject
1.	Investigator Fees	2,600	20,800
2.	Institutional overhead charges (25% of total Budget [1]	650	5,200
3.	Reimbursement (travel allowance) to subjects	500	4000
	TOTAL	**3,750 /-**	**30,000 /-**

- Payments will be calculated as per the completed visits of subjects (reserving 20% payment for end of study)
- Not more than 10% of enrolled subjects at the site will be compensated for as screen failures
- GST as applicable will be paid as per the invoice(s) raised

Other expenses to be borne directly by the Sponsor are as per the following:

Sr. No.	Budgetary provision for *other expenses*	Amount (in rupees)
1.	Ethics Committee charges	As per actuals
2.	Charges for laboratory investigations (if any)	As per actuals
3.	Study vaccines	Supplied by Sponsor
4.	CRF and other study material(s)	Supplied by Sponsor
5.	Charges for immunogenicity assessment (Anti-HEV IgG analysis by ELISA)	Borne by Sponsor
6.	Charges for exploratory immunogenicity assessment	Borne by Study Sites
7.	Archival charges	As per actuals

Payee Details:

Payee / Account Name	DIRECTOR SGPGIMS RESEARCH ACCOUNT
Account No.	10095237491
Bank Name	State Bank of India
Branch Name	PGI Branch
IFSC / Swift Code	SBIN0007789
PAN No.	AAAJS3913N
GST No. (if applicable)	09AAAJS3913N2ZN

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5 Protocol: Principal Investigator will conduct the Study in accordance with the Protocol, Indian GCP guidelines and applicable rules and regulations in India.

5.1 Amendments: The Protocol may be modified only by a written Amendment, signed by the Sponsor, Institution and the Principal Investigator.

5.2 Emergency Amendments: If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Principal Investigator will notify the Sponsor and the IRB (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment.

6. No Additional Research: No additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.

7 Subject Enrolment: Principal Investigator agrees to enrol the subjects in the study as may be defined and decided by the Sponsor from time to time. A qualified subject is one who meets all Protocol criteria such as inclusion & exclusion criteria and agrees to participate in the Study through informed consent in writing.

7.1 Excess Enrolment: If Principal Investigator enrols the maximum number of qualified subjects, the Sponsor may or may not invite Principal Investigator to enrol additional subjects. However, the Principal Investigator shall not enroll more than maximum number without prior approval by the Sponsor.

7.2 Failure to Enrol: If Principal Investigator fails to enroll subjects at a rate adequate to meet the enrollment requirement, the SPONSOR shall be free to terminate the Study as per Clause 24.

8 Study Conduct: The Principal Investigator will conduct Study in accordance with the Protocol, the Sponsor's written instructions, Indian Good Clinical Practices (Indian GCP) guidelines and all applicable governmental laws, rules, and regulations.

8.1 No Charge for Investigational Drug or Reimbursed Services: Principal Investigator will not charge a Study subject or third-party payer for Investigational Drug (see Section 13, Investigational Drug) or for any services reimbursed by the Sponsor under this Agreement.

9 Independent Ethics Committee/Institutional Review Board: Before the Study is initiated, Investigator will ensure that both the Study and the informed consent form are approved by an Independent Ethics Committee or Institutional Review Board (as applicable) (both referred to as a "IRB") that complies with all applicable laws and regulations. Principal Investigator will further ensure that the Study is subject to continuing oversight by the IRB throughout its conduct.

10 Study Disapproval: If, through no fault of Principal Investigator, the Study is disapproved by the IRB, this Agreement will immediately terminate with no penalty to the Principal Investigator, as provided in clause 24.1.a, Disapproval by IRB, below.

11 Data Protection: Data collected in Study may include personal data and sensitive information which is subject to specific legislation relating to the processing, storage, transfer and use of such data or information. The Principal Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Principal

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Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Principal Investigator in connection with the Study. Personal data relating to the Principal Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Principal Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Sponsor or the Sponsor's group of companies, to representatives and contractors working on behalf of the Sponsor group and to regulatory authorities across the world. The Principal Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause 11.

12 Informed Consent and Authorization to Use and Disclose Health Information

12.1 Informed Consent: Investigator will obtain a written informed consent from each Study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow the Sponsor to inspect signed informed consent forms or photocopies thereof during monitoring visits or audits (see Monitoring and Audits, Section 16).

12.2 Adverse Events: Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone, e-mail or facsimile. the Sponsor and the Investigator shall, so far as is lawful, have full responsibility for the reporting of all serious adverse events or deaths to local regulatory authorities as per prevailing regulations. The Sponsor has and will maintain during the Study, an insurance policy adequate to cover adverse events or injury to Study Subject(s) as a direct result of participation in the Study.

12.3 Hospitalization costs: Apart from Study specific the in-house, treatment of the subject in the event of any Serious Adverse Event (SAE) shall be paid by Sponsor to the Clinical Trial Subject.

13. Investigational Drug: The Sponsor will provide Principal Investigator with sufficient quantities of the Investigational drug(s) needed to conduct the Study ("Investigational Drug").

13.1. Custody and Dispensing: The Principal Investigator will maintain appropriate control of supplies of Investigational Drug and will not provide it to anyone else except sub-investigators or research staff. The Principal Investigator shall maintain the records of inventory of the Investigational Drug.

13.2. Use: The Principal Investigator will use Investigational Drug only as specified in the Protocol. Any other use of Investigational Drug constitutes a material breach of this Agreement.

13.3. Ownership of Investigational drug: Investigational drug remains the property of the Sponsor except for, and limited to, the use specified in the Protocol, the Sponsor grants the Principal Investigator no express or implied intellectual property rights in Investigational Drug or in any methods of making or using the Investigational Drug.

14. Confidential Information: During the course of the Study, the Principal Investigator may receive or generate information that is confidential to the Sponsor. Any information marked by the Sponsor as confidential and provided to the Principal investigator 1 year before the execution of this Agreement will also be treated as confidential information.

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14.1. Definition: Except as specified in Section 14.2, Exclusions, below, "Confidential Information" includes

a. the Protocol,
b. the Investigator Brochure,
c. Study Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), subject to Investigator's right to publish the results of the Study (as described in Section 18, Publications, below),
d. Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), and
e. Any other information related to the Study, the Sponsor's DRUG, or The Sponsor technology, research, or business plans that THE SPONSOR provides to Investigator in writing or other tangible form and marks as CONFIDENTIAL or initially discloses orally and then summarizes and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure.

14.2. Exclusions: Confidential Information does not include information that

a. is known or open to the public or otherwise in the public domain at the time of disclosure,
b. becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by the Principal Investigator,
c. is already known to the Principal Investigator at the time of disclosure and is free of any obligations of confidentiality, or
d. Is obtained by the Principal Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

14.3 Obligations of Confidentiality: Unless the Sponsor provides prior written consent, the Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may the Principal Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the IRB or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by the Principal Investigator is specifically authorized, subject to the provisions of Section 18, Publications, of this Agreement.

14.4 Disclosure Required by Law: If disclosure of Confidential Information to any party other than the IRB relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator

a. Notifies the Sponsor in writing in 15 working days advance of the disclosure so as to allow the Sponsor to take legal action to protect its Confidential Information,
b. Discloses only that Confidential Information required to comply with the legal requirement, and
c. Continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 Individually Identifiable Health Information: If, in connection with this Study or performance of this Agreement, the Sponsor comes into contact with individuality identifiable health information relating to subjects who are not Study subjects, the Sponsor

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agrees to maintain the confidentiality of such information and not to use it for any purpose.

14.6 Survival of Obligations: These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the Study and marketing of the drug.

14.7 Return of Confidential Information: If requested by the Sponsor in writing, the Principal Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, the Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Study Data, Biological Samples and Study Records:

15.1 Study Data: During the course of the Study, the Principal Investigator will collect and submit certain data to the Sponsor or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical images, ECG, or other types of tracings or printouts, data summaries, or any combination of these (collectively, "Study Data"). The Principal Investigator will ensure accurate and timely collection, recording, and submission of Study Data. The Principal Investigator will deliver Study Data to the Sponsor or its agent within the reasonable time period.

a. Ownership of Study Data: Subject to the Principal Investigator's right to publish the results of the Study (see Section 18, Publications), the Sponsor is the exclusive owner of all Study Data.
b. Non-exclusive License: The Sponsor grants the Principal Investigator right to use study data for any purpose including internal research and/or education purpose.

c. Data Management and statistical Analysis: The Sponsor or its representative shall carry out the data management and statistical analysis. The Sponsor may consult and / or provide the Principal Investigator for interpretation during report writing.

d. THE SPONSOR is the exclusive owner of Study Data.

15.2 Biological Samples: If so specified in the Protocol, the Principal Investigator may collect and provide to the Sponsor or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Study subjects for testing that is directly related to subject care or safety monitoring, including pharmacokinetic, pharmacogenomic, or biomarker testing ("Biological Samples").

a. Use: The Principal Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Analysis samples: The Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, the Sponsor will provide the results of these tests ("Biological Sample Analysis Data") to the Principal Investigator or Study subject.

c. Ownership: The Sponsor is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

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15.3 Study Records: The Principal Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a. Retention: The Principal Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of 5 years after termination of the Study unless the Sponsor authorizes, in writing, earlier destruction. The Principal Investigator agrees to notify the Sponsor before destroying any Study Records after the required retention period. The Principal Investigator further agrees to permit the Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16. Monitoring, Inspections and Audits

16.1 Monitoring: The Sponsor shall be entitled at its absolute discretion (and in such form as the Sponsor sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, the Principal Investigator will permit the Sponsor representatives access to the premises, facilities, procedures and records relating to the Study, sub- investigators, and research staff as required to accomplish this. The Principal Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by the Sponsor will relieve the Principal Investigator of any of its obligations hereunder.

16.2 Inspections and Audits: The Study is subject to 'inspection' by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. The Sponsor may also choose to audit Study Records as part of its monitoring of Study conduct.

a. Notification: The Principal Investigator will notify the Sponsor as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.

b. Cooperation: The Principal Investigator will cooperate with regulatory agency or the Sponsor representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

c. Resolution of Discrepancies: The Principal Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

d. Inspection Findings and Responses: The Principal Investigator will promptly forward to the Sponsor copies of any inspection findings that the Principal Investigator receives from a regulatory, agency. Whenever feasible, the Principal Investigator will also provide. The Sponsor with an opportunity to prospectively review and comment on any the Principal Investigator responses to regulatory agency inspections.

e. Data Clarification Form: The Sponsor may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the Principal Investigator or his nominee shall clarify within 7 working days.

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f. Study Conduct Evaluations: The Sponsor or its external service providers may document and evaluate the performance of the Principal Investigator in the conduct of the Study. The Sponsor will use these evaluations solely for internal purposes.

17. Inventions

17.1 Notification: If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), the Principal Investigator will promptly inform the SPONSOR

17.2 Assignment: The Principal Investigator will assign all interest in any such Invention to the Sponsor, free of any obligation or consideration beyond that provided for in this Agreement.

17.3 Assistance: The Principal Investigator will provide reasonable assistance to the SPONSOR in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

18. Publications

18.1 Prepublication Review: The Sponsor has no objection to publication by the Principal Investigator of any information collected or generated by the Principal Investigator, whether or not the results are favourable to the Investigational Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, the Principal Investigator will provide the Sponsor, an opportunity to review any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. The timing of such publication shall be mutually agreed upon.

a. Submission to the Sponsor: The Principal Investigator will provide manuscripts, abstracts, or the full text of any other intended disclosure (poster presentation, invited speaker or guest lecturer presentation, etc.) to the Sponsor at least 90 days before they are submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Investigator agrees to delay the disclosure for a period not to exceed an additional 360 days.

b. Redaction of Confidential Information: The Principal Investigator will, on request, remove any previously undisclosed Confidential Information (other than the Study results themselves) before disclosure.

19. Debarment and Exclusion: The Principal Investigator certify that it/s/he / she is not debarred and that it/s/he/she is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Principal Investigator will notify the SPONSOR promptly if either of these certifications needs to be amended in light of new information.

20. Use of Name: Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify the Principal Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

21. Assignment and Delegation

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21.1 The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the Sponsor. Any attempt to so assign, delegate, or subcontract is invalid. If the Sponsor authorizes delegation or subcontracting, Institution remains responsible to the Sponsor for the performance of all delegated duties.

21.2 The Sponsor may not assign its rights or delegate its duties under this Agreement without written permission from the Principal Investigator. Any attempt to so assign or delegate is invalid. However, the SPONSOR may freely subcontract Study-related duties to an external provider upon advance notice to the Principal Investigator, and also may freely assign its rights or delegate its duties to any of the Sponsor affiliate. If the SPONSOR delegates or subcontracts any duties, the Sponsor remains responsible to the Principal Investigator for the performance of those duties.

21.3 Affiliates: As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with the Sponsor

21.4 Successors and Assigns: This Agreement will bind and inure to the benefit of the successors arid permitted assigns of each party.

22. Conflict with Attachments: If there is any conflict between this Agreement and any attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

23. Indemnity: Each Party upon receipt of prompt notice and opportunity to defend, shall indemnify and hold the other party harmless, and hereby forever releases and discharges the other Party from and against claims, demands, liabilities, damages and expenses including attorney fees arising out of the negligence of the indemnifying Party in connection with the work performed under this Agreement, provided, however, each party shall not be obligated to indemnify, defend or hold harmless the indemnified party to the extent the claim is caused by gross negligence or wilful misconduct of that party.

24. Term and Termination

24.1 Termination Conditions: This Agreement shall commence on the Effective Date and expire or terminate upon earlier occurrence of any of the following events:

a. Disapproval by IRB: If, through no fault of the Principal Investigator, the Study is never initiated because of IRB disapproval, this Agreement will terminate immediately.

b. Study Completion: For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by the Sponsor of all Protocol-required data and Biological Samples; and receipt of all payments due to either party.

c. Termination Upon Notice: The SPONSOR reserves the right to terminate the Study for any reason upon 30 days written notice to the Principal Investigator.

d. Immediate Termination by the Sponsor: The Sponsor further reserves the right to terminate the Study immediately upon written notification to the Principal Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the

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Sponsor 's opinion pose risks to the health or well-being of Study subjects; or regulatory agency actions relating to the Study or the Investigational Drug.

e. Termination Upon Notice by Investigator: The Principal Investigator may terminate the study, if the Sponsor does not comply with the agreement related to finance, supply of medication for the study and supply of related material. Written notice of any such termination by the Principal Investigator including the reasons therefore shall be provided by registered mail to the SPONSOR fifteen days prior to termination and the Sponsor shall have fifteen days to cure its default.

f. Immediate Termination by Investigator: The Principal Investigator reserves the right to terminate the Study immediately upon notification to the SPONSOR if requested to do so by the responsible IRB or if such termination is required to protect the health of Study subjects.

24.2 Payment upon Termination: If the Study is terminated early in accordance with Section 24.2 Termination Conditions, above, the Sponsor will provide a termination payment equal to the amount owed for work already performed, less' payments already made. If the Study was never initiated because of disapproval by the IRB (see Section 24.2.a, Disapproval by IRB, above), the Sponsor will reimburse the Principal Investigator for IRB fees and for any other expenses that were prospectively approved, in writing, by the Sponsor

24.3 Return of Materials: Unless the Sponsor instructs otherwise in writing, the Principal Investigator will promptly return all materials supplied by the Sponsor for Study conduct, including unused Investigational Drug, unused Case Report Forms, other study related material and any the Sponsor -supplied Equipment.
24.3.1 Electronics Items: On completion of the clinical study, the Principal Investigator will return all the electronic items & their accessories in the working condition (if any) as provided by the Sponsor during the study.

24.4 Treatment Code (Blinded Studies Only): Upon request, the Sponsor will provide the Principal Investigator with a treatment assignment list that identifies, by subject number, the treatment that each Study subject received. Unless otherwise specified in the Protocol, the Sponsor will provide such treatment assignment information only after the Study is completed (or has been terminated and all data submitted) at all participating sites.

24.5 Survival of Obligations: Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, and Debarment and Exclusion survive termination of this Agreement as does any other provision in this Agreement or its attachments that by its nature and intent remains valid after the term of the Agreement.

25 Modification: Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.

26 Entire Agreement: This Agreement and any Exhibits and attachments and the Indemnity at Exhibit represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

27 This agreement shall be interpreted and enforced under the laws of India and the Courts of Lucknow shall have exclusive jurisdiction to resolve any dispute under this Agreement.

(Signature page follows)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Executed by the parties:

SPONSOR:

Name : Mukund Thakkar

Dhaval Soni

Designation : SVP- Legal

Company Secretary

PRINCIPAL INVESTIGATOR:

Dr. Amit Goel, Department of Hepatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow- 226014, Uttar Pradesh, India.

Sign: _____ Date: 8/5/23

Dr. AMIT GOEL
Professor
Department of Hepatology
SGPGI; LUCKNOW

INSTITUTION:

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, Uttar Pradesh, India.

Sign: _____ Date: 30/5/23

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub-investigators and research staff are informed of their obligations under this Agreement.

Sign: _____ Date: 8/5/23

Dr. Amit Goel, Department of Hepatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow- 226014, Uttar Pradesh, India.

Dr. AMIT GOEL
Professor

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Certificate No.	:	IN-UP38860504821601V
Certificate Issued Date	:	20-Feb-2023 11:37 AM
Account Reference	:	NEWIMPACC (SV)/ up14756204/ BAKSHI KA TALAB/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14756204716488692522O4V
Purchased by	:	CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Second Party	:	SGPGIMS LUCKNOW
Stamp Duty Paid By	:	CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

NOTARY Suresh Kumar Adv. & Notary Distt. Lucknow Reg. No. 31/89/09 GOVT. OF U.P. INDIA

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

"A Randomized Double Blind Placebo Control Clinical Study to Evaluate the Immunomodulatory Effect of Swarnprashan in Moderately Malnourished Children"

SIGNATURE ATTESTED

SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Malai Devi ... Colony
Shrivastava Alert, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Between

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES (CCRAS)

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS), LUCKNOW

This memorandum of understanding (MoU) entered into and executed on date..... between **Central Council for Research in Ayurvedic Sciences** (hereinafter referred to as "CCRAS"), a society registered under the Societies Registration Act 1860, having its office at 61-65, Opp. 'D" Block, Institutional Area, Janakpuri, New Delhi which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include its nominees, istrators, legal representatives, executors. successors in interest / business, and permitted assigns, of the of the First part

And

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow (hereinafter referred to as SGPGIMS) which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include its nominees, istrators, legal representatives, executors, successors in interest / business, and permitted assigns, of the other party.

NOTARY Suresh Kumar Adv. & Notary No. 31(65)/09 GOVT. OF U.P. IND.

1. Preamble:

Whereas **CCRAS** an autonomous organization, which comes under the Ministry of AYUSH, Govt. of India is a nodal apex body in the country for the formulation and coordination of Research in Ayurvedic Sciences on Scientific lines. The Research is being executed through 30 Institutes, Units and Centers besides conducting Collaborative Research with reputed National and International Research and Academic Institutions. Regional Ayurveda Research Institute (RARI), Lucknow is one of the institutions under CCRAS which will be the executive institute for the project.

Sanjay Gandhi Postgraduate Institute of Medical Sciences was established under the State Legislature Act in 1983. It was created by the state of Uttar Pradesh as a centre of excellence for providing medical care, education and research of the highest order.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Katra, Near Main ... Marg

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

2. **OBJECTIVE OF THE MOU:**

To carry out the collaborative research project titled **"A Randomized Double Blind Placebo control clinical study to evaluate the immunomodulatory effect of Swarnprashanin moderately malnourished children "** as per the terms and conditions and guidelines of CCRAS Research Policy.

3. **PROPOSED MODES OF COLLABORATION:**

CCRAS and **SGPGIMS** propose to collaborate through:

3.1. Undertaking the research project **"A Randomized Double Blind Placebo control clinical study to evaluate the immunomodulatory effect of Swarnprashan in moderately malnourished children"**with duration of 30 months from the date of study initiation at SGPGIMS, Lucknow

3.2. Research work (including the patient screening, enrolment and treatment) will be carried out at SGPGIMS premises wherein Dr. Vikas Agarwal, Professor, Department of Clinical Immunology and Rheumatology, SGPGIMS will be the Principal investigator and Dr.Gaurav Pandey, Additional professor, deptt of Gastroenterology, Dr.Abhaynarayan Tiwari, Director, Harsh Ayurveda Lucknow and Dr. Durga PrassannaMisra, Associate professor, Department of Clinical Immunology and Rheumatology, SGPGIMS, Dr. Madan Lal Brahma Bhatt, Professor and Head, Department of Radiotherapy, King George's Medical University, Lucknow and Dr.Siddharth Koonvar, Professor Junior Grade , In-charge of PICU, Department of Pediatrics, GM&AH, KGMU Lucknow, Dr. Shruti Khanduri, Research officer (Ay.) CCRAS, Dr. Swati Sharma Research officer (Ay.) CCRAS and Dr. Anjali Prasad, Research officer (Ay.) CCRAS will be the co-investigators.

4. Both **CCRAS** and **SGPGIMS** are interested in collaborating with each other to facilitate the execution of this project with sharing of following responsibilities:

4.1 **Responsibilities of CCRAS :**

4.1.1 CCRAS agrees for a collaborative research project entitled "***A Randomized Double Blind Placebo control clinical study to evaluate the immunomodulatory effect of Swarnprashan in moderately malnourished children***" with SGPGIMS, Lucknow.

NOTARY Suresh Kumar Govt. of U.P.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Maja...

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

4.1.2 Standardized Ayurvedic interventions (Swarnaprashan and its matching placebo, honey, ghee) will be procured from GMP certified pharmaceuticals by CCRAS for the clinical trial and will be provided to the study site prior to the initiation of the trial.

4.1.3 Entire funding amounting to Rs. 1,21,36580/-for the proposed project will be extended by the CCRAS and the fund will be released in the name of the Director, SGPGIMS, Lucknow, 226014.

4.1.4 The execution of the project will be done in collaboration with the RARI and SGPGIMS, Lucknow as per the guidelines of CCRAS Research Policy.

4.1.5 The final research Protocol, CRF and E-format to capture the data will be shared by the CCRAS.

4.1.6 Final statistical analysis of the same will be done by the statistical section at CCRAS Hqrs.

4.1.7 Data Safety Monitoring Board shall be constituted by RARI Lucknow after approval of the competent authority at CCRAS Hqrs.

4.1.8 CCRAS shall constitute a Monitoring Committee (consisting of 3-4 members) to monitor the study progress and fund utilization allocated in the project.

4.1.9 CCRAS reserves the right to terminate MoU at any stage after giving written notice of one month, if desired cooperation will not be provided by the second party and on any other valid cause.

4.1.10 CCRAS will get the insurance coverage of the participants for entire duration of the study.

4.1.11 Protocol of the project will be published by CCRAS with due authorship to all the investigators and project team.

4.1.12 No data of the project in any part/ whole or its outcomes will be disclosed or published by the investigators or any other authority/ faculty of CCRAS/RARI in any form and confidentiality shall be maintained at all levels from sharing of protocol to data evaluation.

4.2 **Responsibilities of SGPGIMS, Lucknow :**

4.2.1 SGPGIMS will conduct the aforesaid research project as approved by the CCRAS as per the study protocol and guidelines of CCRAS research policy.

4.2.2 The Ethical Clearance (from Institutional Ethics Committee) of this project will be obtained by SGPGIMS for conducting the research work.

NOTARY Suresh Kumar Adv. & Notary Govt. of U.P. Reg.No. 31(35)

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Major Devi Das Marg
Niwaj Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

4.2.3 CTRI Registration for the clinical trial would be done by the PI at SGPGIMS Lucknow

4.2.4 Dr. Vikas Agarwal, Professor, Department of Clinical Immunology and Rheumatology, SGPGIMS, Principal investigator of this study will be responsible for timely completion of the project. He shall also submit a detailed monthly, quarterly and annual progress report as per the prescribed format.

4.2.5 Fund utilization certificate along with the final report shall be submitted to the RARI Lucknow after completion of the trial and the final UC including the budget utilized at their center will be provided by the coordinating center (RARI).

4.2.6 Data and study records (including consent documents) will be stored, retained and protected in accordance with the protocol as per the CCRAS Research Policy and GCP guidelines at the SGPGIMS.

4.2.7 The Data of study participants will be shared with the CCRAS for data monitoring, verification and statistical analysis.

4.2.8 Any deviation from the currently approved protocol shall be informed to the IEC/CEC and the same shall be reported to CCRAS Hqrs.

4.2.9 Any AE/SAE shall also be reported to the IEC within 24 hours of the incident under intimation to the Council.

4.2.10 SGPGIMS shall support the monitoring committee constituted by CCRAS

4.2.11 No data of the project in any part/ whole or its outcomes will be disclosed or published by the investigators or any other authority/ faculty of SGPGIMS in any form and confidentiality shall be maintained at all levels from sharing of protocol to data evaluation.

4.2.12 In the event of premature termination of MoU, SGPGIMS shall remit the remaining/unused budget to CCRAS within the notice period of one month along with the data and the remaining trial formulation.

4.3 Joint Responsibility :

4.3.1 The timely and proper execution of the study is the joint responsibility of both the parties viz CCRAS and SGPGIMS.

4.3.2 Ensuring that the conduct of the research study adheres to Good Clinical Practice Guidelines.

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SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

4.3.3 Reporting of any untoward outcomes or deviation from the currently approve protocol to the IEC and the Council.

4.3.4 Maintaining adequate and accurate research subject records to reflect adherence t protocol specific requirements.

4.3.5 Since it is a collaborative study, the research outcome shall be published with publi acknowledgement and authorship to the contributors of each party on completion o the project and only after obtaining the approval from CCRAS.

4.3.6 All information obtained and derived either in writing or otherwise shall be treated as confidential during and after the expiry period of this MoU unless otherwise mutually agreed upon in writing by both the Parties. Both the parties will abide by the provisions of CCRAS Research Policy and other conditions enforced for transfer of technology and commercialization of research outcomes.

5. **Period of MoU and Termination Clause :**

5.1 This MoU shall be valid for a period of 3 years from the date of signing the agreement or till the completion of the project whichever is earlier, and its extension, continuation or otherwise shall be jointly decided by CCRAS and SGPGIMS two months prior to the completion of the said period.

In case of termination of the project, steps shall be taken to ensure that the termination is not prejudicial to any activity undertaken within the framework of the MoU.

5.3 This MoU may be amended, if needed, by mutual agreement of both the parties and the intention to amend any terms and/or conditions shall be communicated to the parties in writing.

NOTARY Suresh K... Adv. & Notary Reg. No. 31(00)... GOVT. OF U.P.

6. Arbitration:

In the event of any dispute or differences between the parties hitherto, such differences shall be resolved amicably by mutual consultation. Where it could not be resolved so, then it shall be referred to the third arbitrator (appointed by the arbitrators of each party). The word of the said arbitrator shall be final and binding on both the parties. The place for jurisdiction for any dispute or claim before a court or an arbitration shall be Delhi.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Major ... Marg
Niwaj Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, both the parties have set and subscribed their respective hands to this memorandum of understanding on the date and place first mentioned above, in the presence of following witnesses:

On behalf of CCRAS

(RARI Lucknow)

प्रभारी सहायक निदेशक
क्षेत्रीय आयुर्वेद अनुसंधान संस्थान लखनऊ

Signature

Name : DR. OM PRAKASH

Date : 01/03/2023

On behalf of SGPGIMS

(Head of the Institution/ Research Section)

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014 INDIA

Signature

Name :

Date :

Witness

1. Signature

Name : DR ALOK KUMAR SRIVASTAVA

Address : RARI, INS-106, Sector-25
Indira Nagar, Lucknow

2. Signature

Name : DR. ANJALI BAIJNATH PRASAD
RESEARCH OFFICER (AY.)

Address : RARI, INS-106, SECTOR-25
INDIRA NAGAR, LUCKNOW

Witness

1. Signature

Name : Mohit Kumar Rai

Address: Clinical Immunology department, SGPGIMS, Lucknow -226014, U.P.

2. Signature

Name : ANURAG KUMAR SRIVAST

Address : 2/255, Rajini Khand, Sharda Nagar, Lucknow 226002

NOTARY
Suresh K...
Adv...
Regd. No. 51...
GOVT. OF U.P. INDIA

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Maja... ...arg
Niwai Ganj, Chowk, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

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उत्तर प्रदेश UTTAR PRADESH

GH 142854

04 AUG 2023

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this 9th May of Two thousand and Nineteen (09.05.2019) BY AND BETWEEN President of India, acting through Dr. Onkar N. Tiwari, Scientist-E, **Department of Biotechnology, Ministry of Science and Technology**, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

I identify the deponent who has signed before me

AND

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow-226014 (INDIA) a society under the Societies Registration Act – 1860, having its registered office in/at **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow-226014** (INDIA) hereinafter referred to as SGPGIMS, (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

ATTESTED

24/9/19

WHEREAS DBT being desirous of Clinical Research Project decided to support a project submitted by Dr. Shubha R. Phadke, HOD & P.I. Department of Medical. **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow-226014 (INDIA)** Dr. Shubha R Phadke, HOD & P.I.

Avadhesh Kumar Maurya
Adv. & Notary
Mohanlalganj, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SGPGIMS, Lucknow for the attainment of the objectives. here in after described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **"Training of in-service Clinicians from Government Hospitals and Outreach Program for Aspirational Districts"** funded by **Department of Biotechnology (Medical Biotechnology)** New Delhi, under Dr. Shubha R. Phadke, HOD & P.I. Department of Medical Genetics.

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of Total costs **Rs. 4,21,12000/-** (INR Four crore twenty one lac and twelve thousand only) Total cost of the project to be provided by DBT over a period (Sanction letter No: **BT/Med/NIDAN-Trag/02/2019 dt. 9th May, 2019) of 03 years** from the date of sanction of the project. to **Dr. Shubha R. Phadke, HOD & P.I. Department of Medical Genetics, SGPGIMS Raebareli Road, Lucknow-2260**. for undertaking activities as detailed in Annexure I. Details of the funds to be provided are given in Annexure II.

2.0.ROLE OF SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow-226014 (INDIA) (Institute/NGO)

2.1. To provide their contribution of ___(NIL)___ for 3 years from date of sanction of the project as detailed in Annexure – II.

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

NOTARY Awadhesh Kumar Maurya Adv. & Notary Lucknow GOVT. OF U P INDIA

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

To prepare and submit all periodical reports and other documents that would be required by DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.6. To maintain a separate audit head of account for the grants received from DBT for the project.

2.7. To submit an annual audited statement of expenditure incurred under the project.

2.8. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be 3 years (**Sanction letter No. BT/Med/NIDAN-Trag/02/2019 dt. 9th May, 2019**) from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by SGPGIMS Lucknow, will be the joint property of SGPGIMS, Lucknow and DBT, Government of India. It shall be the responsibility of DIRECTOR, SGPGIMS, Lucknow to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of SGPGIMS, LUCKNOW under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of the project investigator (s) SGPGIMS, LUCKNOW to ensure that support of DBT is suitably acknowledged in the in scientific publication/ patents/ technology transfer documents etc. arising out of the PROJECT. It shall also be the responsibility of the project investigators and institute to ensure the inclusion of reference/

NOTARY GOVT OF INDIA Awadhesh Kumar Maurya Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

grant number and duration of the financial support while making the acknowledgement of the financial support received from DBT.

5.0 SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6.0 MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of SGPGIMS, LUCKNOW for the grants received from DBT for this project.

NOTARY GOVT. OF INDIA Avadhesh Kumar Maurya Adv. & Notary Lucknow

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant SGPGIMS, shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain in force for the duration of the project and until all claims are settled between DBT and SGPGIMS, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

NOTARY
Avadhesh Kumar Maurya
Adv. & Notary
Lucknow
GOVT. OF INDIA

Signed by ----------

(Designation)

For and on behalf of The President of India

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Signatures of two witnesses (from DBT):

Dr. Shubha R. Phadke
Professor & Head
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014 INDIA

i.

ii.

Signed and stamped by:
(Dr. Shubha R Phadke)
Head of Department & Principal Investigator
SGPGIMS, Lucknow, UP (INDIA)

Signed and stamped by:
DEAN / DIRECTOR
For and on behalf of **SGPGIMS, Lucknow**

Lucknow (U.P.) India
Director
S.G.P.G.I.M.S.

Name, Signature and stamp of Two Witnesses (from *Institute/ University/ Organization*):

i. Dr. Somya Srivastava
Assistant Professor
Department of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226014 (U.P.) INDIA

ii.

Dr. Meirangthem Amita
Associate Professor
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
Lucknow-226014, INDIA

NOTARY
Avadhesh Kumar Maurya
Adv. & Notary
Lucknow
GOVT. OF U.P. INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – I of MoA

Detailed Project Activities

Details of the activities to be undertaken by Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow under the project entitled *"Training of in-service Clinicians from Governemnt Hospitals and Outreach Program for Aspirational Districts"*

Objectives:

1. Training of clinicians in clinical and laboratory aspects of medical genetics

2. To establish preventive services for genetic disorders at district hospital

3. To train the medical officers for the preventive program for genetic disorders.

4. To train the nursing staff and other paramedical workers in the process, to increase the awareness about genetic disorders

NOTARY
Avadhesh Kumar Maurya
Adv. & Notary
Lucknow
GOVT. OF U P INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – II of MoA

Details of Funds

Dr. Shubha R Phadke, PI, Department of Medical Genetics, SGPIGMS, Lucknow

A. Component I : Training of in-service clinicians

Budget Head	Year I	Year II	Year III	Total (Rs.)
Equipment	2500000.00	0.00	0.00	2500000.00
Consumables	1200000.00	1200000.00	1200000.00	3600000.00
Travel	25000.00	25000.00	25000.00	75000.00
Contingency	50000.00	50000.00	50000.00	150000.00
Displacement allowance	720000.00	720000.00	720000.00	2160000.00
Overhead	100000.00	100000.00	100000.00	300000.00
Total	4595000.00	2095000.00	2095000.00	**8785000.00**

B. Component II : Outreach Program for Aspirational Districts

Budget Head	Year 1	Year II	Year III	Total (Rs.)
Manpower	1680000.00	1680000.00	1680000.00	5040000.00
Consumables	7750000.00	7750000.00	7750000.00	23250000.00
Travel	200000.00	200000.00	200000.00	600000.00
Contingency	150000.00	150000.00	150000.00	450000.00
Overhead	489000.00	489000.00	489000.00	1467000.00
Total (in Rs.)	10269000.00	10269000.00	10269000.00	**30807000.00**

Total: A+B+Additional Budget (Approval let. No. BT/Med/NIDAN-Trg/02/2018 dated 07.06.2021)

→Rs. 8785000.00+Rs. 30807000+Rs. 252000/-

=Rs. 421,12,000.00

NOTARY
Avadhesh Kumar Maurya
Adv. & Notary
Lucknow
GOVT OF U P INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with MoA)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

NOTARY Avadhesh Kumar Maurya Adv. & Notary Lucknow GOVT. OF U.P. INDIA

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure **(Copy enclosed at Appendix - 'C')** duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

NOTARY Avadhesh Kumar Maurya Adv. & Notary Lucknow GOVT. OF U.P. IND.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Signature of Executive Authority of Institute/ University With seal:

Director

S.G.P.G.I.M.S. Lucknow (U.P.) India

Date:

Signature and seal of Project Coordinator (If applicable) Not Applicable

Date:

NOTARY
Avadhesh Kumar Maurya
Adv. & Notary
Lucknow
GOVT. OF U.P. INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Signature and seal of all Principal Investigator(s)/ Co- PI (s):

Date :

Dr. Shubha R Phadke
Professor & Head
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, INDIA

Signature and seal of all Co-Investigator (s)

Date :

Co-PI: Dr. Kausik Mandal, Dr. Deepti Saxena and

Dr. Amita Moirangthem

ATTESTED
24/5/23

Avdhesh Kumar Maurya
Adv. & Notary
Mohanlalganj, Lucknow
Reg No. 21/03/20

NOTARY
Avadhesh Kumar Maurya
Adv. & Notary
Lucknow
GOVT. OF U P INDIA

Dr. Moirangthem Amita
Associate Professor
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, INDIA

Dr. Deepti Saxena
Associate Professor
Dept. of Medical Genetics
S G P G I M S.
Lucknow-226014

Dr. Kausik Mandal
Additional Professor
Department of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226014 (U.P.) INDIA

Dr. Shubha R. Phadke
Professor & Head
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH ET 290874

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this **9th May** day of Two thousand and Nineteen (*for eg. Ten*) **9.5.2019** BY AND BETWEEN President of India, acting through ~~-------(to be left blank)----------~~ Dr. Gautam Pal Tiwari Sc. 'E', **Department of Biotechnology, Ministry of Science and Technology,** Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

AND

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow -226014 (INDIA) a society under the Societies Registration Act – 1860, having its registered office in/at **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow -226014 (INDIA)** *Address of the organization*)....., hereinafter referred to as **SGPGIMS, LUCKNOW** (*Short name of the organization*)..... (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of Clinical Research Project (*area of research to be given*) _____decided to support a project submitted by Dr. Shubha R. Phadke, HOD & P.I. Department of Medical Genetics, **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow -226014 (INDIA)** (*Name of the PI & organization*) **Dr. Shubha R. Phadke, HOD & P.I.**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

क्रय संख्या 3829

स्टाम्प लिखत की तिथि 22/05/2019

स्टाम्प क्रय करने का प्रयोजन Office work

स्टाम्प लिए जाने वाले व्यक्ति का नाम Director SGPGI Lucknow
C/o Shubha R. Phadke

मूल्य की धनराशि 100

(167)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Department of Medical Genetics, SGPGIMS, Lucknow for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the extramural project entitled "Training of in-service Clinicians from Government Hospitals and Outreach Program for Aspirational Districts" funded by Department of Biotechnology (Medical Biotechnology) New Delhi under Dr. Shubha R. Phadke, HOD & P.I. Department of Medical Genetics.

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0. ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Total cost 359.92** *Total cost of the project to be provided by DBT)* over a period of **First Years (Sanction letter No: BT/Med/NIDAN-Trag/ 02/2019 dt. 9th May, 2019)** (*duration in years*) **3 years** from the date of sanction of the project, to **Dr. Shubha R. Phadke, HOD & P.I. Department of Medical Genetics, DIRECTOR, SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow -226014 - (*Name of the PI & short name of the organization*)** SGPGIMS, Lucknow for undertaking activities as detailed in Annexure I. Details of the funds to be provided are given in Annexure II.

2.0.ROLE OF SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow -226014 (Institute/NGO)

2.1. To provide their contribution of **(NIL)** for ---(*duration in years)* -- -- years from date of sanction of the project as detailed in Annexure – II. *(provide the cost in place of NIL if a jointly supported project).*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be **3 years** (***duration of the project in years***. (**Sanction letter No: BT/Med/NIDAN-Trag/ 02/2019 dt. 9th May, 2019) 3 years** from the date the Project has been sanctioned by DBT (Rs. 395.92)

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by **SGPGIMS, Lucknow** (***Short Name of the organization***).....will be the joint property of SGPGIMS, Lucknow (***Short Name of the organization***) **SGPGIMS, Lucknow** and DBT, Government of India. It shall be the responsibility of **DIRECTOR, SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road, Lucknow -226014** (***Name of the organization***) SGPGIMS to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **SGPGIMS, Lucknow (*Short Name of the organization*)**..... under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of the project investigator (s) and **SGPGIMS, Lucknow (*Short Name of the organization*)**____ SGPGIMS, Lucknow to ensure that support of DBT is suitably acknowledged in the in scientific publication/ patents/ technology transfer documents etc. arising out of the PROJECT. It shall also be the responsibility of the project investigators and institute to ensure the inclusion of reference/ grant number and duration of the financial support while making the acknowledgement of the financial support received from DBT.

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of **SGPGIMS, Lucknow (*Short Name of the organization*)**..... for the grants received from DBT for this project.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, **SGPGIMS, Lucknow** (***Short Name of the organization***)..... shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and **SGPGIMS, Lucknow** (***Short Name of the organization***)..

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Gmail

Shubha Phadke <shubharaophadke@gmail.com>

UMMID- BT/MED/NIDAN-Trg/02/2018-reg

Karthikeya K <ummid-support@dbt.nic.in>
To: shubharaophadke@gmail.com
Cc: Karthikeya K <karthikeya.k.dbt@nic.in>

Thu, Aug 18, 2022 at 12:28 PM

Dear Dr. Phadke,

This has reference to your ongoing Project "Training of in-service Clinicians' from Government Hospitals and Outreach Programme for Aspirational Districts". The documents submitted have been examined and the following documents are required for further release of grant:

1. UC, SoE, for FY 2021-22 (from 01.04.2021 to 31.03.2022). Asset certificate (Financial year wise) for FY2019-20 and FY2021-22.

2. Justification regarding Non expenditure under NR head.

3. Manpower details (mentioning complete qualification details including NET/GATE and Experience) along with certificates and Resume

4. Please submit the following MoA annexures:

a. Terms and conditions signed and stamped on each page by PI and on last page by Head of Institute

b. Copy of sanction order signed and stamped on each page by PI.

5. As per recommendations of the UMMID Expert Committee regarding ethics approval, please submit one of the following:

a. Certificate of approval from IEC

OR

b. Certificate/letter of non-requirement/exemption from IEC approval

6. Registration of Ethics Committee with National Ethics Committee Registry for Biomedical and Health Research (NECRBHR), DHR registration.

7. DSIR Scientific and Industrial Research Organization (SIRO) Certificate is to be mandatorily provided by agencies seeking grants from the Department. Kindly submit ONE of the following as applicable:

a) Copy of valid DSIR SIRO certificate

OR

b) Undertaking for exemption from DSIR-SIRO certification citing appropriate reference (e.g. for Hospitals).

8. Manpower statement for FY2021-22 and details (mentioning complete qualification details including NET/GATE and Experience) along with certificates

9. Refund the following to consolidated fund of india through online portal www.bharatkosh.gov.in.

a. unspent balance under NR head

b. interest earned for FY2021-22

Kindly address the above observations and submit the required documents.

With regards

Support @ DBT UMMID Initiative / सहायता @ DBT उम्मीद

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with MoA)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I. the Head of the Institute and the

Received

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

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TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with MoA)

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The Memorandum Agreement, to be sent to Department of Biotechnology should be on Non- Judicial stamp paper of Rs. 100/-.

23. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

12/9/22

Signature of Executive Authority of Institute/ University With seal:

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date :

Signature and seal of Project Coordinator (If applicable) Not applicable

Date:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Signature and seal of all Principal Investigator(s)/ Co- PI (s):
Date :

Dr. Shubha R Phadke

Dr. Shubha R. Phadke
Professor & Head
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, INDIA

Signature and seal of all Co-Investigator (s)
Date :

Co-P.I: Dr. Kausik Mandal, Dr. Deepti Saxena and
Dr. Amita Moirangthem.

Dr. Kausik Mandal
Additional Professor
Department of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226014 (U.P.) INDIA

Dr. Deepti Saxena
Associate Professor
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, INDIA

Dr. Moirangthem Amita
Associate Professor
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(ii) making timely payments to the Institution subject always to approvals mentioned in clause 3.1(i) above;

(iii) overall conduct of the study including monitoring and evaluation of study sites in India; and

(iv) Advise and provide information to the Institution and to the IRB/IEC as and when necessary and update the appropriate Regulatory Authorities of:

a) Any SAEs/adverse events/risk information; or

b) The cessation elsewhere of any relevant trial of the Study drug (or closely related products); or

c) The withdrawal of the Study drug (or closely related products) from any other market for safety reasons; or

d) Any other information available to justify any variations to the Study Protocol and the nature, scope and duration of the Study.

3.2 In addition to applicable provisions of clause 1 of this Agreement, Institution and Investigator shall be responsible for:

(i) obtaining the necessary consents, approvals or authorisations for the conduct of the Study at the Study Site;

(ii) obtaining and maintaining approvals or communications from the IRB/IEC;

(iii) ensuring the protection of the rights, safety and well-being of Participants, and the scientific integrity of the Study;

(iv) submitting the requisite documentation to the relevant regulatory authorities from time to time during and after the conclusion of the Study;

(v) providing Investigator with materials, access to personnel, facilities and information as may be reasonably required to satisfactorily perform the Study;

(vi) exercising due care and skill and work in a competent and professional manner in carrying out their obligations under this Agreement;

(vii) ensure that the equipment used for conduct of the Study are properly maintained;

(viii) monitoring to ensure that no unlawful or unethical activity arises during the conduct of the Study at the Study Site;and

(ix) any agreement concluded, or arrangement reached with the Study Team appointed by them, if any, shall be subject to the provisions of this Agreement.

(x) Institutions shall be responsible for maintaining the Master list of identifiable data which could be linked to the stored data for any future reference. Storage of hard copy is responsibility of the participating institutions.

4. OWNERSHIP OF DATA, RESULTS, INTELLECTUAL PROPERTY

4.1 The Parties acknowledge and agree that GIGH shall have all right, title and interest in and to all data and results of the Study, including without limitation all inventions, patents, tests, applications, creations, research data, intellectual property, processes, methods, software, tangible research products, formulas and techniques,

improvements thereto, and know-how related and Confidential Information that may be developed, produced, created, furnished or disclosed by any Party made during the conduct of the Study, or arising from the performance of the Study which shall be communicated immediately to GIGH.

4.2 The ownership of any or all intellectual properties owned by the Parties before the execution date of this Agreement by the Institution (**"Background IP"**) shall remain with the such Party.

4.3 If GIGH and/or its assignee desires to file patent applications as a result of discoveries made during the Study,the Institution and Investigator shall assist in the preparation of such patent applications.

4.4 Each party will not use the other party's/ies'Background IP in any publicity, advertising or news release without the prior written consent of the other party/ies. However, the Intellectual Properties may be used for the proper performance of the services under this Agreement.

4.5 The parties will not infringe the Intellectual Property Rights of a third party or misappropriate any Know How or Intellectual Property Rights of a third party.

4.6 The Institution and Investigator shall have a right to use the Study results for non-commercial research and teaching purposes.

5. PUBLICATION

5.1 Institution and Investigator each acknowledge and agree thatunless approved by the committee (**"Steering Committee"**) appointed by GIGH to oversee the multi-centre Study,there shall be no publication, report, release, disclosure or likewise of any preliminary or final Study findings or results prior to release of the first publication of Study findings or results (**"Multi-Centre Publication"**). Attribution and authorship in the Multi-Centre Publication shall be given in accordance with academic standards and/or as per the International Committee for Medical Journal Editors (ICMJE).

5.2 The Steering Committee and GIGHmay at any time disclose or publish all information as they may reasonably decide where such disclosure or publication relates to the safety of the Participants, patients in general, or the general public.

5.3 Proposals for all publications, abstracts, and other presentations arising from the Study shall be submitted for approval to the Steering Committeethrough GIGH at least four (4) weeks prior to the date it is intended to be submitted for publication. The Steering Committee or a subcommittee thereof, may recommend changes prior to approval.

5.4 No Party shall use the name of any other Party in any advertising or promotional material without having received the prior written consent of such other Party, provided that:

(i) a Party may acknowledge, in general terms, the existence of this Agreement;

Lt Col Varun Bajpai VSM
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(ii) GIGH (or its affiliates) may state on its website or in any Study material that Institution is a participating site of the Study and Investigator is the investigator of the Study at the Study Site; and

(iii) Institution may acknowledge receipt of financial support from GIGH for the Study at the Study Site.

6. PAYMENTS

6.1 The full & final amounts/fees (inclusinve of taxes) and terms of payment payable by GIGH to the Insititutionfor performance of the Study are set forth in the Payment Schedule and Payment Rule Form that is attached hereto as Exhibit C (hereinafter referred to as the "**PRF**").

6.2 Institution and Investigator each agree and undertake not to seek any payment from any third party or Participant for any services provided to a Participant in connection with such Participant's participation in the Study or the costs incurred in connection therewith.

6.3 Institution shall be responsible for the payment of any or all taxes applicable on the income received pursuant to this Agreement, including, without limitation, for paying any GST or similar tax imposed by the taxation authorities in any jurisdiction.

6.4 Institution and Investigator shall inform GIGH in writingnot later than one (1) month of any discrepancies that may exist in the payment(s) received. Institution and Investigator shall havewaived, all rights to receive further compensation in connection with the Study, if such discrepancies is not raised within the said period.

6.5 Institution warrants that the Payee as per Exhibit C, wherever different from the Institution name, is part of or an affiliate of the Institution and that the Institution shall remain responsible for all obligations under this Agreement.

7. CONFIDENTIALITY & PRIVACY

7.1 The Parties acknowledge and agree that they shall not disclose or publish Confidential Information to any third party, other than in accordance with this clause 7. For the purpose of this Agreement, "**Confidential Information**" shall mean any confidential or proprietary information, including without limitation, any derivatives thereof, which is confidential and proprietary in nature, including, but not limited to, intellectual property; internal practices and procedures; feedback relating to any results of the Participant,; deliverables information, all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere, the Protocol, and information related to the Protocol and Study materials, know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques, methodology, processes, sequences, structure and organisation of the Study; other information relating to

disclosing Party's business, including, without limitation, the terms and conditions of this Agreement; and any third-party confidential information. ;

Confidential Information shall not include information:

b) which is published in accordance with the Publication Section of this Agreement,

c) which a Receiving Party can demonstrate through contemporaneous written records was in its possession prior to disclosure by the Disclosing Party,

d) which is in the public domain or which later becomes part of the public domain other than by breach of this Agreement by a Receiving Party,

e) which is lawfully disclosed to a Receiving Party by a third party not obligated to the Disclosing Party to keep the information confidential, and

f) which is required to be disclosed by law, or by order of a court of competent jurisdiction to the extent necessary.

g) which is used or disclosed for absolute performance of the Study or performance of the obligations under this Agreement to the extent necessary.

7.2 The obligations of confidentiality under this clause 7 shall be binding for the term of this Agreement and shall survive for a period of ten (10) years after expiry or termination of this Agreement.

7.3 Each Party agrees to comply with all applicable privacy laws and regulations regarding the collection, use, disclosure, holding and protection of personal and/or health information.

7.4 In the event that GIGH shall come into contact with Participants' medical records, GIGH shall hold in confidence the identity of the Participants and shall comply with Applicable Laws regarding the confidentiality of such records.

8. RELATIONSHIP OF PARTIES

8.1 This Agreement does not create, and no provision of this Agreement shall be interpreted to create, a relationship of employer and employee, principal and agent, joint venture or partnership between the parties. Neither Party (including any employee, agent or authorised representative thereof) shall have the power to bind or designate the other Party or any persons affiliated with such Party in any manner whatsoever.

8.2 No employee, agent or authorised representative of the Institution and/or Investigator or personnel of the Study Team shall be considered, an employee of GIGH. Institution shall indemnify and hold harmless GIGH (and its affiliates) against all claims and demands that may be made by any of the above mentioned parties against GIGH.

9. NOTICES

9.1 Any notice, consent, approval or other communication (each a "**notice**") under this Agreement shall be in writing and shall be delivered to the recipient Party by hand or

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by sending to the address or email specified below (or as subsequently varied by notice):

If to GIGH:	If to Institute:	If to Investigator:
Amit Khanna George Institute for Global Health 308, Elegance Tower Plot No. 8, Jasola District Centre New Delhi 110025 , India Email: akhanna@georgeinstitute.org.in	Name: Sanjay Gandhi Postgraduate Institute of Medical Sciecnes Address: Raibareli Road Lucknow 226014 Email : director@sgpgi.ac.in	Name: Dr. Narayan Prasad Address: Department of Nephrology C-Block SGPGIMS Raibareli Road Lucknow 226014 Email: narayan.nephro@gmail.com

9.2 A notice given in accordance with clause 9.1 is taken to be received: (i) if hand delivered on the day of delivery; (ii) if sent by courier upon the day of the courier's delivery (as verified by the courier's records); (iii) if sent by certified or registered mail, upon the day of the postal service's delivery (as verified by the postal service's records); or (iv) if sent by email, upon confirmed successful transmission at the sender's location; but if delivery or receipt is not on a business day or is after 5:00 P.M. on a business day, notice is taken to be received in the next business day.

10. TERMINATION

10.1 GIGH may terminate this Agreement with immediate effect by written notice(hereinafter referred to as the "**Termination Notice**") to Institution and Investigator if:

(i) any regulatory authority requires the Study to be discontinued or materially altered; Investigator or Institution is Disqualified (as defined by clause 1.8 of this Agreement);

(ii) GIGH does not approve of the proposed replacementinvestigator;

(iii) GIGH fails or ceases to receive research funding for the Study;

(iv) Institution and Investigator do not randomize at least 10 Participant within one (1) months of receiving an authorisation letter from GIGH (as provided by clause 1.4 of this Agreement);

(v) Institution or Investigator, or Study Team, fail to perform, or performs improperly, any obligation of it under this Agreement (hereinafter referred to as the "**Default**"), provided that GIGH shall first have: (i) notified Institution and Investigator of such Default; and (ii) permitted the Party in Default a period of three working days (hereinafter referred to as the "**Cure Period**"), to cure the Default, which Cure Period shall be stated in the notice from GIGH; or

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(vi) it comes to the attention of GIGH that Institution or Investigator has fabricated, falsifiedorplagiarised data pertaining to the Study or has otherwise breached or compromised the scientific integrity of the Study or caused harm to Participants.

10.2 GIGHmay terminate this Agreement for whatever reason by giving thirty (30) days' prior written notice to the other Party.

10.3 Institution and Investigator may terminate this Agreement by written notice, which shall be effective immediately if :

(i) the IRB/IEC or any regulatory authority requires that Institution and/or Investigator cease a material part or all of their activities in connection with the Study; or

(ii) GIGH fails to perform, or performs improperly, any of its material obligations under this Agreement (hereinafter referred to as "**GIGH Default**"), provided that the Institution and/or Investigator shall first have: (i) notified GIGH of such GIGH Default; and (ii) permitted GIGH a period of thirty (30)days to cure the GIGH Default, which Cure Period shall be stated in the notice from the Institution and/or Investigator.

10.4 In the event of termination, the Parties shall promptly do all that is reasonably necessary to close-out the Study and shall cooperate to ensure the continued safety of the Participants. Each Party will, upon request of a Party, return or destroy any Confidential Information of that Party.

10.5 If this Agreement is terminated under clause 10.1, GIGH shall pay Institution for any work completed up to the date of Termination and for closing-out activities in accordance with generally accepted standards of good clinical practice, including ICH-GCP. Investigator and Institution acknowledge that they shall not be entitled to any further or additional payments from GIGH (or its affiliates).

10.6 Clauses 1 (Performance of the Study), 4 (Ownership of Data, Results, Intellectual Property), 5 (Publication), 7 (Confidentiality & Privacy), 10.4 (Termination), 11 (Indemnities, Limitation of Liability & Insurance) and 13.4 (Arbitration) of this Agreement, and any other clauses or provisions giving operational effect thereto, and any other clause or provision that should by its nature, shall survive on expiry or termination of this Agreement.

11. INDEMNITIES, LIMITATION OF LIABILITY & INSURANCE

11.1 GIGH shall hold harmless the Institution and the Investigator and their respective officers, directors and employees (hereinafter individually referred to as an "**Indemnified Party**" and collectively referred to as the "**Indemnified Parties**"), as applicable, from all claims made by third parties and against any and all liabilities, losses, damages and expenses (hereinafter collectively referred to as "**Losses**") that one or more of the Indemnified Parties may sustain due to any injury, (including death), suffered by any Participant resulting only from the administration of the Study

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drug described in the Protocol, when used in accordance with the approved labelling, the Protocol and any written instructions of GIGH, provided that the Indemnified Party has (i) used reasonable medical judgment in the conduct of the Study, (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and (iii) duly complied with all Applicable Laws and regulations and all ethical and professional standards relating to the protection of Participants, including with respect to ensuring appropriate IRB approval and oversight, obtaining effective informed consent and maintaining patient privacy in accordance with the Protocol and the instructions/guidance/advice issued by GIGH, from time to time.

11.2 Each Party ("**Indemnifying Party**") agrees and undertakes to indemnify, hold harmless and defend the other Party ("**Indemnified Party**") from and against any and all **Losses** arising as a result of or arising directly out of (a) breach by the Indemnifying Party of any provision of this Agreement or (b) the Indemnifying Party's negligence or wilful default in relation to performance or non-performance of any of its obligations under this Agreement.

11.3 Each Party's obligation to indemnify the other as set forth above is conditional on the Indemnified Party: (a) providing written notice to the Indemnifying Party of any Losses for which it is seeking an indemnity hereunder within ten (10) business days from the date of knowledge of such Losses; (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend any such Losses; (c) assisting the Indemnifying Party at their own expense, in the investigation and defence of any such Losses; and (d) not compromising or settling such Losses without the Indemnifying Party's prior written approval. In turn, the Indemnifying Party will not make any settlement which adversely affects in a material manner the reputation of an Indemnified Party without such Indemnified Party's prior approval, which approval shall not be unreasonably withheld.

11.4 Notwithstanding the above or anything contained to the contrary in this Agreement:

(i) neither Party shall be liable to the other for any punitive or consequential loss, including, without limitation, any loss of business, revenue, profit, reputation or goodwill;

(ii) the Parties shall take all reasonable steps to mitigate any loss, damage, claim, action or expense (including legal expense) they may suffer in terms of this Agreement; and

(iii) GIGH's liability whether in terms of this Agreement, tort (including gross negligence), strict liability, indemnity or otherwise and for any and all claims arising out of or in connection with this Agreement shall be limited in aggregate, whether in relation to a single event or a series of events, and whether each event is related or not, to a maximum of the fees paid to the Institution and/or the Investigator under this Agreement till the date such liability arose/the per subject

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and aggregate limit of GIGH's Clinical Trials Liability insurance cover, whichever is higher.

11.5 GIGH has made an arrangement of Clinical Trials Liability insurance cover adequate to cover the risks as specified under the aforementioned provisions of this Article. However, it is understood and agreed that the maintenance of such insurance cover will not relieve either Party of its other obligations under this Agreement.

11.6 Institution and Investigator may secure and maintain insurance coverage for medical professionals and/or medical malpractice liability, general libality and employee's compensation as per the Applicable Laws or regulations.

12. ENTIRE AGREEMENT, AMENDMENT

12.1 All exhibits, schedules attached hereto, including the Protocol referenced herein, shall be incorporated by reference and will form part of this Agreement. No part of this Agreement may be modified except where agreed to in writing by the Parties. No oral explanation or information or previous communication provided by any Party to any other Party affects the meaning or interpretation of this Agreement, or constitutes any collateral agreement, warranty or understanding between the Parties.

12.2 In the event of any inconsistency between the terms of this Agreement and the Protocol, the terms of this Agreement will prevail.

13. ASSIGNMENT& SUBCONTRACTING

13.1 The Institutionor Investigator shall not assign or transfer or sub-contract the performance any of its rights or obligationsunder this Agreement or any part thereof without the prior written consent of GIGH, such consent not to be unreasonably withheld or delayed.

14. CONCLUDING PROVISIONS

14.1 Any clause or provision of this Agreement which is prohibited or unenforceable is ineffective to the extent of the prohibition or unenforceability, but the validity or enforceability of the remaining clauses of this Agreement will not be affected.

14.2 The obligations of a Party under this Agreement shall be suspended during the period and to the extent that such Party is prevented or hindered from complying by causes or circumstances: (i) beyond its reasonable control not due to its own fault or negligence; (ii) which are not reasonably forseeable; and (iii) which the Party is by exercise of reasonable diligence, unable to prevent, including (a) act of God; (b) industrial dispute of any kind; (c) act of public enemy, war (whether declared or undeclared), blockade, revolution, riot, insurrection, malicious damage, civil commotion; (d) natural disaster/ pandemic/epidemic, medical emergency; € order of any court or authority, restraint, restriction, requirements, prevention, frustration or hindrance by or of any person, government or competent authority; and (f) embargo, unavailability or shortage of

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essential equipment, chemicals or other materials, goods, labour or services, lack of transportation or communication, breakage of facilities or machinery (each hereinafter a "**Force Majeure Event**"). A Party relying on this clause 14.2 must promptly provide notice to the other Parties of the occurrence or cessation of any Force Majeure Event as soon as practicable.Where such Majeure Event continues for more than three (3) calendar months, the other Partics have the right to promptly terminate the Agreement by written notice to the affected Party, and clauses 10.4 and 10.6 of this Agreement will apply.

14.3 This Agreement shall be construed, interpreted and applied in accordance with, and shall be governed by, the laws applicable in India within the jurisdiction of Lucknow Courts.

14.4 The Parties agree to first attempt to resolve any dispute or difference arising out of or in connection with this Agreement or in respect of any defined legal relationshipassociated therewith or derived therefrom (hereinafter referred to as the "**Dispute**"). However, if the Parties are unable to resolve the Dispute within fourteen (14) days after first commencing good faith negotiations, the Parties agree to submit such Dispute for arbitration under ICADR Arbitration Rules, 1996. The Authority to appoint arbitrator shall be with The International Centre for Alternative Dispute Resolution (ICADR). The ICADR will provide administrative services in accordance with the ICADR Arbitration Rules, 1996. There shall be one arbitrator, the language for the arbitration proceedings shall be English, and the place of arbitration proceedings shall be Lucknow, Uttar Pradesh, India. Each Party to the Dispute will be responsible for its own costs and expenses, and arbitration fees will be shared equally between the Parties to the Dispute. The decision of the arbiter shall be final and binding between the Parties. The Parties agree to continue to perform this Agreement despite the existence of a Dispute or any proceedings under this clause 14.4. Nothing in this clause prevents a Party from obtaining urgent injunctive relief from any court, including with respect to the protection of its confidential or proprietary information.

14.5 No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the Party waiving the right. Likewise, a single or partial exercise of any right, power or remedy will not preclude any other or further exercise of that or any other right, power or remedy.

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The Parties hereto have caused this Agreement to be duly executed, as of the day and year first above written.

On Behalf of GIGH:

Signature

Date: 1/8

Name: Mr. Amit Khanna
Designation: Director, Finance & Operations

Signature

Date: 17/8/22

Name: Dr. Pallab Maulik
Designation: Deputy Director and Director of Research

INSTITUTION:

Signature

Date:

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Name: Prof. R. K. Dhiman
Designation: Director

INVESTIGATOR:

Signature

Date: 8/8/22

Name:Dr. Narayan Prasad
Designation: Prof. & Head

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Exhibit A

Enclosed: PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT): A double-blind placebo-controlled trial of prophylactic niclosamide against SARS-CoV2 infection in vulnerable populations. The trial will enrol vulnerable patients with kidney or autoimmune diseases, including patients in receipt of dialysis, kidney transplant recipients, individuals with vasculitis and glomerular disease receiving immunosuppression.

STUDY PROTOCOL_ PROTECT Protocol Version _1.0 Dated_29-Jan-2021

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EXHIBIT B
INVESTIGATOR CONFIRMATION

Study Name:PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT-V)

A double-blind placebo-controlled trial of prophylactic niclosamide against SARS-CoV2 infection in vulnerable populations. The trial will enrol vulnerable patients with kidney or autoimmune diseases, including patients in receipt of dialysis, kidney transplant recipients, individuals with vasculitis and glomerular disease receiving immunosuppression.

Investigator: Dr. Narayan Prasad

I, the Investigator, confirm that I have received the PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT-V)I represent that I have read and fully understand the Protocol and other study related obligations. I will provide copies of the Protocol, and all information furnished by GIGH, to the Study Team and to discuss this material with them and ensure they are fully informed and understand the Protocol.

I agree and undertake to abide by the contents of the latest IRB/IEC approved Protocol and any amendments there to that are communicated to me.

Signature

8/8/22
Date

Name: **Dr. Narayan Prasad**

GIGH Representative Initials Institution Representative Initials PI Initials

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EXHIBIT C
PAYMENT SCHEDULE AND PAYMENT RULE FORM

STUDY: PROphylaxis for paTiEnts at risk of COVID-19 infecTion (PROTECT-V)

COUNTRY: INDIA

Expected Recruitment: Upto 200 eligible participants are expected to be recruited at the Institution

Payment distribution will be as shown below, without any additional cost. All amounts mentioned below are inclusive of all taxes. All payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws and GIGH will deduct the tax at the time of making payments unless a valid certificate for Tax Exemption is made available from the tax authority in a timely manner.

Data collection will be considered complete following verification of all data entry into the eCRF and resolution of all queries.

Item	**Amount (INR)**
a) Ethics Committee Fee [a]	Nil
b) Participant Enrolment and Follow-up	**Amount (per enrolled subject in INR)**
Baseline	500
Follow up [b]	200/Follow-up (maximum of 4,500/subject)
End of treatment and final trial visit form	500
Lab investigations [c,d]	2,000
Total [e]	7,500
Institutional Overhead Charges @ 25%	1,875
Total Payment	9375

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25% Institutional overheads will be paid on overall per patient budget received by site.

[a]Inclusive of the cost of adverse reactions/events review by the ethics committee.

[b] In-person/telephonic weekly follow-up for the first four weeks and once in two weeks in-person/telephonic follow-up from week eight to a maximum of week forty.

[c] Investigations and frequency: liver function test (once), COVID -19 antibody testing (up to twice), reverse transcription polymerase chain reaction (up to twice), serum pregnancy test (once).

[d] Investigations done to assess eligibility –liver function test, reverse transcription polymerase chain reaction (RT-PCR) and serum pregnancy test will be paid for should a patient meet all other eligibility criteria and be found incligible to participate in the trial based solely on the laboratory investigations. These will be regarded as screen failures.

[e] Only on completion of all follow-ups, end of treatment, and final trial visit form. Data collection will be considered complete following verification of all data entry into the eCRF and resolution of all queries.

An advance start-up payment of Rs. 25,000 can be released upon request from the site investigator. The advance start-up will be adjusted with the total payment before the final settlement.

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Payments will be made to the following party:

(ALL INFORMATION BELOW MUST BE PRINTED)

Payable to: Director SGPGIMS RESEARCH ACCOUNT
PAN No. of Institution: AAAJS3913N
Account Number: 10095237491
Bank Name & Address: **State Bank of India SGPGI Campus Raibareli Road Lucknow**
IFSC Code: **SBIN0007789**
Mailing Address: **SGPGI Campus Raibareli Road Lucknow**

Signature of the authorized signatory of the Institution: _____

Name of authorized signatory: Prof. U.C. GHOSHAL

Phone: 0522-2494048 Email address: sro@sgpgi.ac.in

Date: 08/08/2022

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA81134179471857U
Certificate Issued Date	:	11-Nov-2022 04:00 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ KORAMAGALA9/ KA-JY
Unique Doc. Reference	:	SUBIN-KAKACRSFL08681208529304931U
Purchased by	:	CBCI SOCIETY FOR MEDICAL EDUCATION
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CBCI SOCIETY FOR MEDICAL EDUCATION
Second Party	:	CHRISTIAN MEDICAL COLLEGE VELLORE AND OTHERS
Stamp Duty Paid By	:	CBCI SOCIETY FOR MEDICAL EDUCATION
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

RESEARCH STUDY AGREEMENT

This Research Study Agreement (referred to as the "**Research Study Agreement**") is made effective as of the 15th November 2022 (the "**Effective Date**").

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Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), having its registered office at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttarpradesh-226014, India, represented by its Director (which expression shall, where the context so permits include his successors in office and assigns).

AND

Dr. Mohan Gurjar (Principal Investigator of **SGPGIMS**), from the Department of Critical Care Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttarpradesh-226014, India hereinafter referred to as "**Participant 3**".

AND

Rajendra institute of medical sciences (RIMS), having its registered office at Rajendra Institute of Medical Sciences, RIMS circle, Bariatu, Ranchi-834009,Jharkhand, India, represented by its Dean (which expression shall, where the context so permits include his successors in office and assigns).

AND

Dr. Mohd Saif Khan (Principal Investigator of **RIMS**), from the Department of Critical Care, Trauma and Central Emergency, Rajendra Institute of Medical Sciences, RIMS circle, Bariatu, Ranchi-834009, Jharkhand, India, hereinafter referred to as "**Participant 4**".

AND

All India Institute of Medical Sciences, Jodhpur (AIIMS-J), having its registered office at Marudhar Industrial Area, 2nd Phase, M.I.A. 1st Phase, Basni, Basni, Jodhpur, Rajasthan 342005, India, represented by its Director (which expression shall, where the context so permits include his successors in office and assigns).

AND

Dr. Ankur Sharma (Principal Investigator of AIIMS-J), from the Department of Anaesthesiology & Critical Care, All India Institute of Medical Sciences, Marudhar Industrial Area, 2nd Phase, M.I.A. 1st Phase, Basni, Basni, Jodhpur, Rajasthan 342005 Jodhpur, Rajasthan, India, hereinafter referred to as "**Participant 5**".

AND

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AND

Dr. Jagadish Chandran. (Principal Investigator of PSGIMR), from the Department of Critical care medicine, PSG Institute of Medical Science and Research, Off Avinashi Road, Peelamedu, Coimbatore – 641004, herein after referred to as "Participant 9"

AND

Bharati Hospital and Research centre (BHRC), having its registered office at 9th floor Super speciality building, Bharati Hospital and Research centre, Satara road, Pune, Maharashtra 411043, india, represented by its Director (which expression shall, where the context so permits include his successors in office and assigns)

AND

Dr. Jignesh N Shaw (Principal Investigator of BHRC), from the Department of Critical Care Medicine, Bharati Hospital and Research centre Satara road, Pune, Maharashtra 411043, India hereinafter referred to as "**Participant 10**".

1. **Purpose:**
   The purpose of this Research Study Agreement is to have a research collaboration to conduct a research study titled " **Laryngotracheal and Upper airway symptoms due to mechanical ventilation after orotracheal intubation in critically ill patients – A prospective multicentre cohort study**" on laryngotracheal and upper airway symptoms after intubation in critically ill patients. This would entail data collection from participating ICUs to understand the laryngotracheal and upper airway symptoms after intubation in critically ill patients.

2. **Objectives, Scope, Background and Major Activities**
   The study aims at estimating the prevalence of laryngotracheal and upper airway symptoms after intubation in critically ill patients and the factors affecting it. The study also aims to know about the resolution of those symptoms, the treatment needed, and their impact on quality of life by following up with the patients. You, as the Participant, represent the health facility at which critically ill patients are treated. The patient screening, recruitment, data collection, and follow-up are per the study protocol. The entire study-related activities will be the responsibility of the participant and his/her team. Participation in the study is strictly voluntary and without remuneration. The study-related details will be collected in the case record form and subsequently transferred to the electronic database (Microsoft accessdesed). The database may be entirely or partly offline. The platform will enable entry, review, and submission of the data. You will have access to your unit's information. After submission of your data, the data will be de-identified for the institution and no other institute intensive care unit will be able to view your site's data. The PI will make all efforts to maintain the confidentiality of data by deidentifying and modifying a part of the data. The PI will provide access to a limited set of data it receives from all participating centers.

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from 11/11/2022 (effective date) to 10/11/2023 (starting from the time of data collection or patient recruitment for the study to the end of the study and analysis of data). This entire process from patient recruitment to data analysis may approximately take 12 months from the date of the first patient recruitment.

6. **Termination:**
A Party may terminate this RESEARCH STUDY AGREEMENT with immediate effect for any reason upon written notice period of 30 days.

7. **Notices:**
   i. All notices, requests and other communications which shall be or may be issued pursuant to this Research Study Agreement shall be sent by registered mail and/or personal delivery and/or courier and shall be addressed to the parties hereto at their respective offices set forth in the premises of this Research Study Agreement.
   ii. Such notices, requests and other communications shall be deemed to be received and made effective when duly arrived at the other party's address.
   iii. Any alteration or change in the addresses of each of the parties hereto shall be notified in writing to the other Party hereto without undue delay.
   iv. No alterations to this research study agreement shall be made by the parties unless there occurs a mutual agreement, in writing, by the authorized representatives of the parties.
   The parties shall not transfer or assign all or any of their rights, obligations or benefits hereunder to any other party.

8. **Amendment:**
This Research Study Agreement and the Appendices hereto constitute the entire Research Study Agreement among the Parties with respect to the subject matter of this Research Study Agreement and supersede all prior agreements, whether written or oral, with respect to the subject matter of this Research Study Agreement. Any amendment or modification to this Research Study Agreement must be in writing and signed by authorized representatives of each Party.

9. **Financing /Payment /Funds /Budget:**
This is a collaborative study and each investigator will meet his/her own costs.

10. **Governing Law**
This Research Study Agreement shall be governed and construed in accordance with the laws of India.

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v. In the event the research performed under the RSA enables or facilitates creation of any kind of legally enforceable intellectual property ("IP"), all Parties agree and endorse that ownership rights for such IP will be considered and determined on a case-to-case basis as determined through efforts and inputs.

15. Data Sharing and Publications.

All data that is captured during this study will be de-identified of any identifier's, anonymized, encoded, and handled in a secure and confidential manner. All parties will ensure the confidentiality of the data received by them from the other party, and this confidentiality clause shall survive beyond the expiry or termination of this Research Study Agreement.

All parties intend to publish research findings obtained from work under this Research Study Agreement in the scientific media. All parties would have to be adequately represented in such publications following participation, discussion and prior approval.

The authorship is based on the extent of contribution. The PI who contributed during the concept, design stage of the study, and protocol development will be the lead authors followed by all primary investigators (Site PIs) based on the extent of contribution/ alphabetical order (first name) as these are commonly practiced. This will be on common understanding. The credits will be given to other investigators from all participating centres in the supplementary authors' list based on the journal norms sequencing based on the extent of contribution by the participating centres/alphabetical order (first name).

The Parties agree that all scientific publications and use of research data generated through research activities with respective Principal Investigators from all parties pursuant to this Research Study Agreement will have to be approved by each party's authorized representatives within a reasonable span of time. A party shall not make any announcement, issue press note, without the permission of the other Party.

16. Nature of Relationship

The parties are independent contractors, and this RESEARCH STUDY AGREEMENT will not establish any relationship of partnership, joint venture, employment, franchise or agency between the parties.

17. Force Majeure.

Neither Party shall be liable for any failure to perform or for any delay in performing their obligations under this Research Study Agreement caused by a force majeure event (hereinafter defined) and the time for performance shall, if the Party affected so requires, be extended by a period corresponding with the duration of such an event causing such failure or delay. For the purpose of this paragraph "**Force Majeure**" means requisition or

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18. Signatures.

IN WITNESS THEREOF, the parties hereto have caused this RESEARCH STUDY AGREEMENT to be executed by their duly authorized officers or representatives. The signed and scanned copies of this document will be considered original.

For SJRI

Name: Dr. Tony D. S. Raj
Title: Dean, St. John's Research Institute
Date: 18/11/2022

DEAN
St. John's Research Institute
St. John's National Academy of Health Sciences
Bangalore - 560 034

For CBCI Society for Medical Education

Name: Rev. Dr. Paul Parathazham
Title: Secretary, CBCI - Society for Medical Education
Date:

SECRETARY
CBCI SOCIETY FOR MEDICAL EDUCATION
ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
BANGALORE - 560 034

For Principal Investigator

Name: Dr. Natesh Prabu R
Title: Associate Professor, Department of Critical Care Medicine, St John's Medical College Hospital
Date: 14/11/2022

Dr. NATESH PRABU R, MD, DNB, DM
Associate Professor
Department of Critical Care Medicine
KMC No.TMN20090000767KTK, T2031
SJMCH, Bengaluru - 560 034

Dr. NATESH PRABU R, MD, DNB, DM
Associate Professor
Department of Critical Care Medicine
KMC No.TMN20090000767KTK, T2031
SJMCH, Bengaluru - 560 034

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SGPGIMS,Lucknow

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For Participant's centre 3 Principal investigator

Mohan 24/01/2023

Name: Dr. Mohan Gurjar

Title: Professor,
Department of Critical Care Medicine,
Sanjay Gandhi Postgraduate Institute
of Medical Sciences

Date:

For the Dean/Director/Head of the participating centre 3

Name: Dr Professor R K Dhiman

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Title: The Director,
Sanjay Gandhi Postgraduate Institute
of Medical Sciences
Raebareli Road, Lucknow,
Uttarpradesh-226014

Date:

Dr. NATESH PRABU R, MD. DNB, DM
Associate Professor
Department of Critical Care Medicine
KMC No.:MN20090000767KTK, T2031
SJMCH, Bengaluru - 560 034

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SGPGIMS,Lucknow

INDIA NON JUDICIAL (24)

सत्यमेव जयते

Government of National Capital Territory of Delhi

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e-Stamp

Certificate No.	:	IN-DL70441998339931V
Certificate Issued Date	:	01-Mar-2023 05:14 PM
Account Reference	:	IMPACC (IV)/ dl947603/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL94760313103923893577V
Purchased by	:	CLICEBO SOLUTIONS PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CLICEBO SOLUTIONS PVT LTD
Second Party	:	SGPGIMS LUCKNOW AND DR SUDEEP KUMAR
Stamp Duty Paid By	:	CLICEBO SOLUTIONS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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Please write or type below this line IN-DL70441998339931V

ACADEMIC STUDY AGREEMENT

CLICEBO SOLUTIONS PVT. LTD. CIN: U73100DL2020PTC374136

Academic Study Agreement __ "TRANSEVER REGISTRY STUDY"

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Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy [illegible]

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ACADEMIC STUDY AGREEMENT

This Agreement ("the Agreement") is made on this _____2023.

By and between

M/s CLICEBO SOLUTIONS PRIVATE LIMITED, a Private Limited Company incorporated under the provisions of the Companies Act, 1956 and having registered office located at E-961, Lower Ground Floor, C.R. Park, New Delhi-110019, hereinafter referred to as the **"CRO" – (Contract Research Organisation, appointed by Dr. Praveen Chandra, hereinafter referred to as the Principal Investigator for this Study)** represented through its **Director – Mr. Asim Roy,** (which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

AND

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, having address at **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, RAIBARELI ROAD, LUCKNOW, Uttar Pradesh-226014** (hereinafter referred to as **"Site"**) (which expression shall mean and include unless repugnant to the context, its successors and permitted assigns)

AND

Dr. Sudeep Kumar with his working address at **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, RAIBARELI ROAD, LUCKNOW, Uttar Pradesh-226014** (hereinafter referred to as **Investigator)** (which expression shall mean and include unless repugnant to the context, its successors and permitted assigns)

The CRO, Investigator and the Institution are henceforth referred to individually as **"Party"** and collectively as **"Parties".**

1. BACKGROUND

WHEREAS, the CRO acting on behalf of the Principal Investigator for this study, has requested Institution and **Dr. Sudeep Kumar (Investigator),** to conduct A prospective, open-labelled, multicenter, observational registry of ISAR SUMMIT in CAD patients undergoing PCI in real world Indian population (TRANSEVER REGISTRY)", hereinafter referred to as the **"Academic Study".**

AND WHEREAS, the Site is equipped to undertake the Study and Site has the experience and expertise to perform clinical studies of medical devices and Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

Now, therefore, in consideration of the premises and the mutual promises and covenants expressed herein, the CRO, Site and/or the Investigator hereby agree to conduct the Study on the following terms and conditions and as described from time to time in the relevant Study Protocol.

2. RULES FOR INTERPRETING THIS AGREEMENT

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Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this Agreement, except where the context makes it clear that a rule is not intended to apply.

(a) reference to any statute, regulation, proclamation, ordinance, by-law or guideline includes all statutes, regulations, proclamations, ordinances, by-laws or guidelines varying, consolidating or replacing them and a reference to a statute includes all regulations, proclamations, ordinances, by-laws or guidelines issued under that statute;

(b) Words importing the singular include the plural and vice versa and reference to one gender includes all genders;

(c) a reference to a document or agreement including this Agreement includes a reference to that document or agreement as amended, supplemented, varied or replaced from time to time;

(d) Where a word or phrase is given particular meaning, other parts of the speech or grammatical forms of that word or phrase have corresponding meanings;

(e) The whole and/or part of a recital or annexure forms part of this Agreement; and

(f) A reference to an individual or person includes a corporation, partnership, joint venture, association, authority, state or government and vice versa.

3. CONDUCT OF THE STUDY

3.1 The Investigator shall conduct the Study at the Site according to the Study Protocol, the Regulations, this agreement, written instructions of CRO and terms of approval of the IRB/IEC.

3.2 The Protocol will be considered final following approval by the IRB/IEC. Any amendments in the Protocol may be carried out by the Investigator only with written consent of the CRO/Principal Investigator and as otherwise required by the IRB/IEC.

3.3 Investigator may deviate from the Protocol in the event only, if the Investigator considers it necessary to deal with a Subject medical emergency and such emergency deviation must be notified by the Investigator to CRO/Principal Investigator and the IRB/IEC as per the timelines agreed in the Protocol.

3.4 Investigator shall fully comply with the SAE reporting provisions of the Protocol and all applicable Regulations and shall keep the IRB/IEC notified of the same.

3.5 The Investigator/Site will ensure that Eligible Subjects sign the written informed consent addendum using the Consent Form as provided by or on behalf of the CRO and approved and cleared by the IRB/IEC. The Investigator/Site will maintain a signed original of the Consent Form in the Subject's records.

3.6 The Investigator shall maintain a Site Trial Master File which shall include all details about the conduct of the Study including without limitation approvals of the IRB/IEC, final approved Protocol, Consent Forms, amendments to the above, correspondence, log of all site visits. Such Site Trial Master File will be maintained and retained as per ICH GCP requirements and all applicable Regulations. Investigator will retain the Site Trial Master and all Study records in appropriate storage conditions for the length of (i) the record retention period mandated by Regulations and (ii) such period of time specified by CRO. Investigator will contact CRO at least thirty (30) days before the planned destruction of any or all of the Site Trial Master File, at which time CRO may request that Investigator deliver such records to CRO or its designee. Investigator will notify CRO (if during the term of

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this Agreement) immediately in writing of any accidental loss or destruction of Study records.

4. COVENANTS OF THE PARTIES

4.1 The Site and the Investigator undertake this Study in furtherance of their goal of seeking new knowledge and furthering their tasks and objectives as a research site and medical interventional center.

4.2 Each Party warrants that it has power and authority to enter into and perform this Agreement and the Study and services contemplated by this Agreement and its entry into and performance of this Agreement and the acts contemplated by it, do not constitute a breach of any obligation or default of any other agreement/arrangement by which it is bound or of any applicable law, regulation or policy.

4.3 Each Party warrants that the person executing this Agreement on its behalf is duly authorized to do so and that nothing contained herein conflicts with any of the provisions of the Memorandum and Articles of Association or similar or other documents relating to the incorporation or of the rules and regulations governing the party.

4.4 None of the services provided by CRO, under or in connection with this Agreement can or shall be construed as an undertaking that the Study under or pursuant to this Agreement will lead to any particular results or that CRO has any interest, right or liability in the results of the Study. CRO confirms that it provides only management services for the Study under agreement with **Dr. Sudeep Kumar** (Investigator) and all liabilities, responsibilities of the Study, and its results or impact, is solely of the Principal Investigator and CRO shall have no liability of any manner whatsoever in this regard. CRO has performed no independent research or analysis regarding the safety or efficacy of the Investigational Product, the Protocol, or any other Study Materials or treatment procedures involved in this Study and therefore CRO does not make any warranties, express or implied concerning the same.

4.5 The Site/Investigator warrant that they have obtained all consents and approvals to carry out the Study as per the Study Protocol.

4.6 The Site/Investigator ensure that in the event of a temporary absence of the Investigator, a nominated and authorized substitute Sub-Investigator shall perform the functions of the Investigator, though the Investigator will remain responsible for all his/her obligations under this Agreement. Such nomination/authorization will be done with prior written approval of CRO. If, however a permanent substitution is required it will be notified to CRO/Principal Investigator who shall send a written approval only after consulting with the CRO/Principal Investigator, otherwise the Study will be suspended, till a resolution is found.

4.7 No Party hereto shall use the name of another Party hereto or the CRO/Principal Investigator either expressly or by implication in any news or publicity release, policy recommendation or commercial purpose without the express written approval of that Party or the CRO/Principal Investigator, as the case may be. Nothing herein shall be construed as prohibiting the CRO/Principal Investigator from reporting on this Study to other investigators conducting the Study, or of exercising its publication rights.

5. MONITORING AND REPORTING

5.1 As per the Protocol, Site/Investigator shall report any SAE suffered by a Patient during the Study, whether or not causally related to the study or Subject's participation in the Study, immediately (and in any event within 24 hours) to CRO describing the circumstances under which the SAE occurred and the remedies applied. Site/Investigator shall follow-up such

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immediate report by sending a written report to CRO, IRB/IEC within 24 Hours and complete analysis report to be send within 14 days of the occurrence of the SAE/ Site comes to know.

5.2 If in the medical judgment of the Investigator alternatives on or deviations from the Protocol are required due to a medical emergency, the alternatives and / or deviations and reasons for their use, will be documented and be forwarded to CRO at the earliest possible occasion following the occurrence of any such event, within five (05) days.

5.3 The Site/Investigator shall notify CRO promptly if any Regulatory Authority requests permission to inspect the Site/Investigator facilities, records regarding the Study and shall permit such Regulatory Authority to conduct such inspection. If the inspection occurs then the Site/Investigator shall provide CRO with all materials, correspondence, statements, forms and records. received from or exchanged with the Regulatory Authorities.

5.4 Qualified personnel from the CRO (or their representatives) may call on Site periodically at any time during any working day convenient to all parties concerned to monitor and/or audit the Study and ask procedural questions, inspect records and documents, which the Site/Investigator will provide access to. Institution will make Study records available for the CRO, only as far as permitted under the Protocol and in accordance with the requirements made by the IRB/IEC. Furthermore, such records can only be made available as far as permitted and/or required by applicable Regulations including but not limited to the legislation regarding the privacy of persons and the protection of personal anonymized data.

5.5 If in accordance with Regulations, the facilities at the Site are determined as being inadequate for the purposes of the Study or not as per the Protocol, and the Site/Investigator do not remedy such inadequacies upon notice to them from the CRO, then CRO may in its discretion terminate this Agreement immediately without further obligation to the Site/Investigator or refuse to commence or continue the Study.

6. RECORDING AND PUBLICATION OF RESULTS

6.1 It is understood by all the Parties that the final report of the Study is a scientific report. The report and analysis required to be submitted as per Regulations will be drafted by and under the full responsibility of CRO/Principal Investigator.

6.2 Site/Investigator will report the findings of the Study to CRO in the form of Study reports, to be submitted to CRO/Principal Investigator at such stages or intervals as set out in the Protocol (including for instance the progress and the number of included patients) and/or as further agreed between the Parties.

6.3 The Parties acknowledge that Principal Investigator shall have the exclusive right to publish and present the results of the Study. Principal Investigator shall take into account that these results represent a joint effort among Principal Investigator, the Site and Investigator. Publications or presentations by Principal Investigator shall contain no matter of the Parties agreed by the Parties and Principal Investigator to be kept confidential. Principal Investigator shall mention the Investigator of the Site in a footnote in the manuscript as a member of the Study.

6.4 The Investigator/Site shall have no right to publish and present the results of the Study unless the prior written consent of CRO/Principal Investigator has been obtained. CRO/Principal Investigator recognizes the wishes of Site/Investigator to publish details of academic research in scientific journals. CRO/Principal Investigator shall however have the full right to withhold such consent.

6.5 CRO on behalf of the Principal Investigator shall retain ownership of all original CRFs, data, analyses and reports that result from the Study.

7. INTELLECTUAL PROPERTY RIGHTS

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7.1 All rights, title and interest including, but not limited to, all Intellectual Property Rights of any nature whatsoever in the Investigational Product and the Study, and all materials, data, reports and information connected thereto shall remain the sole and exclusive property of Principal Investigator and Site/Investigator shall take all actions as CRO may require to protect such rights and intellectual property.

7.2 Any information, inventions or discoveries (whether patentable, copyrightable or not), innovations, communications and reports (collectively, "Inventions") conceived, reduced to practice, made or developed by Site/Investigator as a result of conducting the Study shall be promptly disclosed to CRO/Principal Investigator and shall be the sole property of Principal Investigator.

7.3 All data supplied by CRO to the Site and Investigator, and all data generated in the performance of the Study, (collectively, "Data") shall be and remain the absolute and exclusive property of Principal Investigator. All copy rights and other rights of intellectual and industrial property with regard to the Data shall be vested in Principal Investigator.

7.4 Site/Investigator hereby assign to Principal Investigator all of their rights, title and interest in and to the Inventions and Data and further agree, upon request by CRO/Principal Investigator and at CRO/Principal Investigator's expense, to execute such documents and to take such other actions as CRO/Principal Investigator deems necessary or appropriate to affect such assignment and to obtain patent or other proprietary protection in Principal Investigator's name covering any of the foregoing.

8. FEE AND COMPENSATION

8.1 In consideration for the Study, the Investigator will be paid fee/compensation in accordance with the approved payment rates detailed in the budget proposal attached hereto as **Exhibit B** and in accordance with the payment milestones mentioned therein (the "Payment Schedule"). The consideration mentioned under Exhibit B is the total consideration for the Investigator, Site and any Institutional Overheads. The Payment Schedule may be modified only upon the prior written consent of CRO.

8.2 In the event of Investigator recruiting more or less than minimum number of eligible subjects, the consideration for the services will be pro-rated according to the actual number of Eligible Subjects enrolled as per the agreed per Subject fee.

8.3 Upon completion or termination of the study, the Site/Investigator agrees to provide written acknowledgement to the CRO/Principal Investigator that all work requested under this Agreement has been completed and all monies due have been received. In any event, acceptance of payments as "final" constitutes such acknowledgement.

9. TERM AND TERMINATION

9.1 The Study shall be completed within the time period of 24 months from the last patient enrolment.

9.2 The Parties have agreed that all reasonable efforts will be made to complete the Study within the above-mentioned period, unless agreed otherwise explicitly between Parties. The Study will be completed on the day on which Site has completed the final report of the Study and has sent the same to CRO.

9.3 The Study and this Agreement may be terminated by written notice from CRO to Site/Investigator, with immediate effect, for any of following reasons:

a. Notification by CRO to terminate the Study.
b. Notification by a IRB/IEC to terminate the Study with relevant report. .
c. Determination by CRO that Investigator is not performing the Study as required in the Protocol.

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d. Failure of the Investigator/ Site to provide access to any and all original medical records necessary to verify entries on Study CRF's
e. Failure of Investigator/Site to comply with all Regulations
f. Unauthorized replacement of Investigator.
g. CRFs/eCRF provided to Investigator for use in the study, are not completed and forwarded to CRO, within the timelines prescribed in the Protocol.

9.4 The Study may be suspended by written notice from Site/Investigator to CRO, with immediate effect, if in the Investigator's reasonable medical opinion such suspension is necessary to protect patient safety. Promptly after CRO's receipt of such notice, representatives of the Parties and CRO shall meet (in person or via teleconference) to discuss in good faith Investigator's concerns and an appropriate resolution to such concerns, which may include mutual termination of the Study and this Agreement.

9.5 The Study and this Agreement may be terminated by written notice from the Site/Investigator to CRO, if CRO commits any material breach of this Agreement which it does not remedy within 30 days of receipt of written notice from the Site/Investigator specifying the breach and requiring remedy; provided that Site/Investigator shall not be entitled to serve such notice of termination until (i) Site/Investigator has notified CRO in writing that CRO has failed to remedy the specified breach within such 30 day period and (ii) either the breach has been remedied or this Agreement has been assigned to CRO within 30 days of CRO's receipt of such notice from Site/Investigator.

9.6 Immediately upon termination, the Site/Investigator agrees to stop enrolling subjects. In the event of termination, the payments under this Agreement shall be prorated basis on actual work performed in accordance with the Protocol. Any funds not due under this calculation but already paid shall be returned to CRO by the Site/Investigator.

9.7 Upon completion or termination of the study, "**DIRECTOR SGPGI RESEARCH ACCOUNT**" (Payee name) agrees to provide written acknowledgement to CRO that all work requested under this Agreement has been completed and all monies due have been received. In any event, acceptance of the payments as "final" constitutes such acknowledgement.

10. INDEMNITY

CRO/Principal Investigator on behalf of the Principal Investigator, shall indemnify and hold harmless the Investigator, institution, Directors, Co-investigator, Coordinators & Ethics committee, in respect of matters including third party arising out of or in connection with (i) an injury to a Subject arising from the use of the Study Material in the Study (ii) any breach of this Agreement by CRO/Principal Investigator or its employees or agents, or (iii) any breach by CRO/Principal Investigator of any representation, warranties or covenants set forth herein, except to the extent the same is caused by the gross negligence or willful misconduct of Investigator; however, that any such liability, loss, or damage resulting from (1) a failure to adhere to the terms of the protocol, or this Agreement or CRO's written instructions relative to use of the Device; (2) failure to obtain the Subjects' informed consent (3) failure to comply with any applicable governmental requirements; or (4) negligence or willful malfeasance by the Site, its trustees, the Investigator or associated staff is excluded from this agreement to indemnify and hold harmless.

The Site and the Investigator agree to notify CRO/Principal Investigator as soon as they become aware of a claim or action as to which CRO CRO/Principal Investigator has indemnification obligations under this agreement and to cooperate with and to authorize CRO/Principal Investigator to carry out the sole management and defense of such claim or action.

Neither CRO/Principal Investigator nor its representatives shall assume any liability for any direct or indirect damage incurred by any of the subjects in the course of normal patient care and/or treatment by the Site/Investigator.

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11. CONFIDENTIALITY

11.1 In handling a Subject's medical records, the Site/Investigator and associated staff shall hold in strict confidence the identity of the patient, and shall comply fully with any and all Regulations regarding the confidentiality of such records and anonymized data protection.

11.2 The Site/Investigator shall be responsible for effecting and maintaining all registrations for the processing of personal anonymized data that are required by Regulations, including under the Drugs and Cosmetics Rules 1945. Investigator hereby consents for CRO and CRO's affiliates to collect and/or otherwise process personal anonymized data provided by or relating to Investigator for purposes of sharing such personal data with Regulatory Authorities and for any use by CRO and its affiliates. Investigator agrees that CRO and CRO's affiliates may transfer such personal anonymized data to CRO's facilities and to Regulatory Authorities.

11.3 The Site/Investigator acknowledge and agree that all information disclosed to them by or on behalf of CRO/Principal Investigator or developed by the Site or Investigator in connection with the Study is the proprietary information of CRO/Principal Investigator and shall be deemed to be CRO/Principal Investigator's Confidential Information and each undertakes to CRO/Principal Investigator, for its own benefit and for the benefit of CRO/Principal Investigator, that it will ensure that such information is kept confidential, without limitation for ever even after expiry or termination of this Agreement and is nor disclosed to any third party without prior written consent of CRO/Principal Investigator. The Site/Investigator will hold in strictest confidence and will not directly or indirectly, disclose, reveal, report, use, lecture, broadcast, transfer, disseminate in any form, upon or publish any Confidential Information of CRO/Principal Investigator.

11.4 The Site/Investigator shall limit access to the Confidential Information of CRO/Principal Investigator to their officers, directors and employees (collectively "Representatives") who require access to such Confidential Information in order to effectuate the purposes of this Agreement. The Site/Investigator agrees and shall obligate their Representatives to agree, that they will use the same degree of care and discretion as they use to protect their own Confidential Information.

11.5 The Site/Investigator shall use the Confidential Information of CRO/Principal Investigator only for the purpose of fulfilling their obligations under this Agreement. The Site/Investigator shall not be entitled to use any of the results or anonymized data, or any other information, resulting from or related to the Study for own research or other purposes, nor shall the Investigator be involved in such research, without having obtained the prior written consent of CRO/Principal Investigator.

11.6 Excluded from the above confidentiality obligations shall be information which, may be demonstrated by the Site/Investigator to the reasonable satisfaction of CRO/Principal Investigator, as the case may be:

(i) was already in its possession of the Site/Investigator at the time of disclosure or acquisition in connection with the Study;

(ii) was at the time of such disclosure or acquisition already in the public domain or subsequently enters the public domain without default on the part of the Site/Investigator; or

(iii) was received from a third party, who did not acquire it unlawfully.

11.7 Consent shall be deemed to have been given by CRO/Principal Investigator to the following disclosures of their respective Confidential Information:

(i) Disclosure of such Confidential Information to employees or consultants of the Site/Investigator provided that the Site/Investigator ensures that, by means of a

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statement in writing, such employees or consultants are bound by obligations of confidentiality no less strict than those set out herein and that they require the information disclosed for the purposes of the Study;

(ii) Disclosure of such information to the extent required by law or by any Regulatory Authority, provided that CRO/Principal Investigator, as the case may be, is informed of such requirements and in so far as practicable, the Site/Investigator arranges for the disclosure to be made in confidence.

12. SERVICES

In this undertaking the Investigator agrees to perform the work required by this Agreement (more specifically as defined under **Exhibit A** attached herewith) and the Investigator has fully understood the service deliverables under this agreement. Investigator representing that he is duly authorized by the Ethics Committee of the Institution to do so, agrees to enroll min **60 Patients** or such higher numbers as agreed upon with CRO/Principal Investigator from time to time to meet the subject selection criteria described in the Protocol. Investigator acknowledges that enrollment for the Study is competitive and that the enrollment period may be terminated at any time. The **estimated study duration is 24 months from the date of the last enrolled patient.**

13. GENERAL PROVISIONS

13.1 **Notices**: Unless otherwise provided herein, any notice required or permitted to be given hereunder shall be in writing and emailed, mailed by courier/registered mail, or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder at the addresses set out above (or such other address as a party may designate by notice in writing). If delivered by registered mail, any such correspondence shall be deemed to have been delivered after three business days from dispatch, and if delivered by hand, any such correspondence shall be deemed to have been delivered on receipt.

13.2 **Governing law**: This Agreement, and any disputes arising hereunder, shall be governed by and interpreted in accordance with the **laws of India** and the PARTIES submit to the exclusive jurisdiction of the courts of **LUCKNOW.**

13.4 **Entire Agreement**: This Agreement sets forth the entire Agreement and understanding of the Parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, between the Parties.

13.5 **Severability**: If any provision of this Agreement shall be held invalid, illegal or unenforceable, such provision shall be enforced to the maximum extent permitted by law and in compliance with the Parties' intent, and the remaining provisions shall not be affected or impaired.

13.6 **Amendments, Waivers**: This Agreement may be amended, modified, superseded, cancelled, renewed or extended, and the terms or covenants hereof may be waived, only by a written instrument (which identifies this Agreement and states the plan or intent to modify) executed by all Parties hereto, or in the case of a waiver, by the Party waiving compliance.

13.7 **Assignment**: Site/Investigator may not assign this Agreement to any party and may not subcontract any of their obligations under this Agreement, unless CRO/Principal Investigator have given prior written consent for the same.

13.8 **Survival**: Notwithstanding the termination of this Agreement, obligations which have accrued or have application beyond the term including without limitation those relating to

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confidentiality, intellectual property, publications, indemnification and enforcement of Parties' rights, shall survive the expiration or earlier termination of this Agreement

13.9 **Relationship of the Parties**: The Parties agree that Site/Investigator shall perform services hereunder as an independent contractor, and not as an agent, retaining control over and responsibility for its own operations and personnel. Site/Investigator shall not, and will ensure that its Representatives shall not, represent themselves to be the agents, employees, partners or joint-ventures of CRO/Principal Investigator and shall not otherwise cause CRO/Principal Investigator to be liable under any contract or otherwise.

13.10 **Attachments**: Exhibits A & B form an integral and substantial part of this Agreement.

13.11 **Force Majeure**: No Party hereto shall be liable in damages or have the right to cancel this Agreement for any delay or default in performing its obligations hereunder if such delay or default is caused by conditions beyond its control, including but not limited to natural disasters, acts of God, government restrictions/policy, laws, wars, terrorist acts, or insurrections, pandemics, lockdown restrictions, curfew. Whichever of Site/Investigator and CRO/Principal Investigator is affected by such circumstances (the "Affected Party") shall promptly notify the other (the "Non-Affected Party") in writing when such circumstances cause a delay or failure in performance ("a Delay"). In the event of a Delay lasting for four (4) weeks or more the Non-Affected Party shall have the right to terminate this Agreement immediately by notice in writing to the Affected Party.

13.12 **Arbitration:** Any dispute or difference whatsoever arising between the parties out of or relating to the construction, meaning, scope operation or effect of this contract or the validity or the breach thereof shall be settled by arbitration in accordance with the Rules of Arbitration of the Indian Council of Arbitration, as per the Arbitration and Conciliation (Amendment) Act, 2015 and the award made in pursuance thereof shall be binding on the parties. The Seat of Arbitration shall be Lucknow.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(14)

IN WITNESS WHEREOF the parties hereto have accepted and executed this Agreement as of the day and year first set above. This Agreement has been executed in triplicate; each party having received one original.

ACCEPTED AND AGREED:

INSTITUTE/CENTRE/HOSPITAL:

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW 226 014 INDIA

Name:

Title:

Date:

INVESTIGATOR:

Dr. Sudeep Kumar
Professor
Department of Cardiology
Sanjay Gandhi PGIMS, Lucknow

Name: Dr. Sudeep Kumar

Title: Investigator

Date: 02/March/2023

CRO:

CLIGEO SOLUTIONS PVT. LTD. * CIN: U73100DL2020PTC373136 *

Name: Asim Roy

Title: Director

Date: 01-03-2023

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(13)

EXHIBIT – A

LIST OF SERVICES

1. *IDENTIFICATION OF PROTOCOL ELIGIBLE PATIENTS FOR THE STUDY*
2. *ADMINISTRATION OF INFORMED CONSENT PROCESS*
3. *RECRUITING PATIENTS AS PER PROTOCOL INCLUSION EXCLUSION CRITERIA*
4. *TREAT STUDY PARTICIPANTS AS PER ENROLMENT & ADEQUATE FOLLOW UP*
5. *TAKING COMPLETE MEDICAL HISTORY OF THE PATIENTS*
6. *PHYSICAL EXAMINATION -- SIGNS AND SYMPTOMS OF ALL THE PATIENTS*
7. *RESPONSIBILITY FOR ADVERSE EVENTS REPORTING*
8. *WRITING THE PATIENT STUDY SUMMARY-COMPLETION OF SOURCE DOCUMENTATION*

CLICEBO SOLUTIONS PVT. LTD.

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SGPGIMS,Lucknow

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EXHIBIT – B

BUDGET AND PAYMENT SUMMARY:

BUDGET AND PAYMENT SCHEDULE:

1) The CRO shall compensate the Site for each enrolled Subject that completes the Study, as per the table below.

2) Grant Per Patient:

Milestone	Grant Per patient (INR)
Screening, enrolment and discharge (baseline)	2000/-
First Follow-Up (1 Month Telephonic)	1000/-
Second Follow-up (6 Month Telephonic)	1000/-
Third and Final Follow Up (1 year Telephonic)	1000/-
Total per patient grant	**5000/-**

*The above fees are all inclusive (PI Fees, CRC Fees and Institutional Overheads)

3) PAYMENT TERMS:

All payments will be paid based on submission of the data in compliance with the terms and condition of this agreement.

All grant payments are subject to deduction of tax at source as per applicable laws.

GST/IGST will be applicable for all payments as per Government norms.

4) DISCONTINUED OR EARLY TERMINATION PAYMENTS:

No payment will be made in the event of a failure to follow the study procedure as defined by the protocol, except where such failures are beyond the reasonable control of the Site. Reimbursement will not be provided for patients who enter the study but fail to meet all the inclusion and exclusion criteria. Reimbursement for discontinued or early termination patients will be prorated based on the number of confirmed completed visits.

5) IRB/EC PAYMENT:

IRB/EC costs will be reimbursed as per SOP. Any subsequent IRB/EC re-submissions or renewals, upon approval by "CRO", will be reimbursed upon receipt of appropriate documentation.

6) PAYEE INFORMATION

The parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee (the "Payee").

Payments will be issued **Quarterly** by the CRO according to visits completed, as verified by the study monitor in the electronic data captured tool E-CRF records. Tax Invoice will be raised by the Site to the CRO. Payments will be made by cheque or NEFT/RTGS in favor of this agreement payee details.

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SGPGIMS,Lucknow

PAYEE NAME: Please note: This should be a business name and must match the business name used to file for PAN	**DIRECTOR SGPGI RESEARCH ACCOUNT**
PAYEE ADDRESS:	**SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, RAIBARELI ROAD, LUCKNOW, Uttar Pradesh-226014**
PAYEE ACCOUNT NUMBER	**10095237491**
BRANCH ADDRESS	**State Bank of India SGPGI Lucknow**
IFSC CODE	**SBIN0007789**
TYPE OF ACCOUNT	**CURRENT**
PERMANENT ACCOUNT (PAN) OF PAYEE	**AAAJS3913N**
GSTIN OF PAYEE	**09AAAJS3913N2ZN**

-:End:-

CLICEBO SOLUTIONS PVT. LTD. * CIN: U73100DL2020PTC374138 *

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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	IN-DL42251295460244V
Certificate Issued Date	:	28-Jul-2023 11:45 AM
Account Reference	:	IMPACC (IV)/ dl889803/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL88980353157990346442V
Purchased by	:	DATT MEDIPRODUCTS PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DATT MEDIPRODUCTS PVT LTD
Second Party	:	DR GYAN CHAND P I AND HEAD INSTITUTE SGPGI LUCKNOW
Stamp Duty Paid By	:	DATT MEDIPRODUCTS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

This non judicial stamp paper from an integral part of the Clinical Trial Agreement (CTA) executed between, **Datt Mediproducts Pvt. Ltd.** and **Dr. Gyan Chand** (Principal Investigator in the trial) & the **Head of the Institution**, Both, SGPGIMS, Lucknow

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

Clinical Investigation Plan/Protocol Title:	A prospective, randomized, assessor-blind, active controlled, multi-center study to demonstrate the safety and efficacy of VELGRAFT, an allogenic cell-based wound dressing, in comparison to standard moist wound dressing in management of chronic diabetic foot ulcers that have attained granulation tissue
Clinical Investigation Plan/Protocol Number:	**Protocol No.: CBCC/2020/019** **Version No.: 4.0, 12/Apr/2022**
Date of Agreement:	**28-Jul-2023**
SPONSOR	
Name:	**Datt Mediproducts Pvt. Ltd.**
Address:	**Registered office:** Gazraj Chambers, 2B, Second Floor, 86 B/2, Topsia Road (South), Kolkata, 700046. **Corporate office:** 56, Community Center, East of Kailash, D Block, New Delhi, Delhi 110065.
PRINCIPAL INVESTIGATOR	
Name:	**Prof. Dr. Gyan Chand**
Address:	Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli road, Lucknow,226014,Uttar Pradesh.
INSTITUTION	
Name:	**Prof. Dr. R K Dhiman**
Address:	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India.

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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Executive Registrar
SGPGIMS,Lucknow

This Clinical Trial Agreement, "Agreement" is made between;

DATT MEDIPRODUCTS PRIVATE LIMITED, (hereinafter referred to as **"SPONSOR"**) a company incorporated under the COMPANIES ACT 1956, having registered office at **Gajraj Chambers, 2B, second floor, 86 B/2, Topsia Road (South), Kolkata 700046** and corporate office at **56, Community Center, East of Kailash, New Delhi – 110065**, on the First Party.

AND

Director, SGPGIMS (hereinafter referred to as "Investigation Site"), which is located at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India., on the Second Party.

AND

Prof. Gyan Chand, whose designation is **"Professor"** at **Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences,**(herein after referred to as "Principal Investigator" (PI), which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executers, administrators and successors) of the Third Party;

Sponsor, Principal Investigator (PI) and Institution shall individually be referred as **"Party"** and collectively as "Parties".

RECITALS:

WHEREAS,

A. **SPONSOR,**is inter-alia, engaged in the business of manufacturing and marketing of medical device along with research, product development & clinical research,
B. The **INVESTIGATOR**is engaged in the treatment of subjects with potential exposure to the indication intended for treatment, at an Institution/hospital;
C. The **INSTITUTION** is the facility where the clinical trials and study will be conducted ethically and as per the approved Clinical Investigation Plan/protocol;
D. **SPONSOR** is willing to engage the **Principal Investigator** and **Institution** to conduct the clinical trial and the study on non-exclusive basis and Institution and **Principal INVESTIGATOR** are willing to carry out the study on the terms set out in this Agreement.
E. The purpose of this **AGREEMENT**is to agree on terms and conditions, as well as procedures, according to which the clinical trials and the study will be conducted, and on the division of duties and responsibilities between the parties conducting the said trials/study.
F. The **SPONSOR**is desirous of conducting the study as per **IEC** approved protocol.
G. The clinical trials/study will be initiated at the site only after an approval from the registered ethics committee of the institute.

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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H. On the faith and strength of the aforesaid representations and warranties, the **SPONSOR** has agreed to appoint the institution and Investigator for the conduct and supervision of the clinical trial/study in accordance with the approved **Clinical Investigation Plan/protocol,** subject to the terms and conditions hereinafter appearing.

NOW TIIEREFORE, the Partics agree as follows:

1. DEFINITIONS:

1.1 "Adverse Event (AE)" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH-GCP Guidance page-2 section-1.2) for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.2 "Affiliate" means with respect to an entity, any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such entity. "Control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean (a) the power to direct the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (b) to own 50% or more of the outstanding voting securities or other ownership interest of such entity. "Entity" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.3 "Applicable law" means the Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945 with its amendments and any other law or rules for the time being in force in India.

1.4 "Case Report form" means a printed, optical or electronic document or database designed to record subject information.

1.5 "Confidential information" means any or all data or information whether oral, written or in electronic form disclosed by sponsor and its affiliates to Principal Investigator and/or to the Institution, including – i. all information collected in the

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course of, resulting from, or arising directly from the study; **ii.** Clinical Investigation Plan/protocol, Investigator's Brochure, study materials and Investigational Product, business plans, sales or marketing methods; **iii.** Information, ideas, concepts, IPR, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the sponsor and its affiliates; **iv.** Know-how, methodology, trade secrets, sequences and structure of the study; and v. Information concerning the business affairs or clients and its affiliates.

1.6 **"Fees"** shall mean the milestone payments agreed by the parties of the study.

1.7 **"Force Majeure Event"** shall mean circumstances beyond reasonable control of a party, including but not limited to, change in government policy, fire, flood, epidemic, act of God, war and riot;

1.8 **"GCP"** means good clinical practices guidelines issued by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. of India and under applicable Laws;

1.9 **"GLP"** shall mean good laboratory practices guidelines issued by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. of India and under applicable Laws;

1.10 "ICH-GCP" shall mean International Conference of Harmonization of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice Guidelines, is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of Human subjects;

1.11 "IEC" shall mean Institutional Ethics Committee of the Institution;

1.12 "Investigational Product" shall mean an allogenic cell based wound dressing (VELGRAFT), which will use, as how it will be used.

1.13 "IPR" shall mean patent, copyright, trademark, service mark, service name, trade name, interned domain name, brand name, trade dress, label, logo, know-how, technical and non-technical information, trade secret, formulae, technique, sketch drawing, model, invention, design, specifications, processes, apparatus, equipment, database, research, experimental work, development, study materials and Investigational Product and all the confidential or proprietary information obtained by the Principal Investigator and Institution from the Sponsor or generated or created by Principal Investigator and Institution as a direct or sole result of performing clinical trial/study under this agreement, including, without limitation results of the clinical trial/study, data generated, confidential proprietary, commercial, scientific, medical or technical information.

1.14 **"Party"** shall individually mean sponsor or Principal Investigator or Institution.

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(Principal& Co-Investigator) (Institute/Hospital)

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1.15 **"Parties"** shall collectively mean Sponsor, Principal Investigator and Institution.

1.16 **"Clinical Investigation Plan/protocol"** shall mean a document that states the background, objectives, rationale, design, methodology and statistical considerations of the study.

1.17 **"Regulatory Authorities"** means the Drugs Controller General (India), Directorate General of Health Services, Ministry of Health and family Welfare, Drug Advisory Committee and relevant government authority having jurisdiction under applicable Laws.

1.18 **"Representative"** shall mean the employees, directors and officers of a party.

1.19 **"Serious Adverse Event"** means an untoward medical occurrence that leads to,— (i) a death; or (ii) a serious deterioration in the health of the subject that either- (A) resulted in a life-threatening illness or injury; or (B) resulted in a permanent impairment of a body structure or a body function; or (C) required in-patient hospitalization or prolongation of existing hospitalization; or (D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or (iii) foetal distress, foetal death or a congenital abnormality or birth defect;

1.20 **"Study site"** shall mean the Institution facility(Department of Endocrine Surgery), Located at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow– Uttar Pradesh, India.

"Clinical trial/Study" means the clinical trial/study(A prospective, randomized, assessor-blind, active controlled, multi-center study to demonstrate the safety and efficacy of VELGRAFT, an allogenic cell-based wound dressing, in comparison to standard moist wound dressing in management of chronic diabetic foot ulcers that have attained granulation tissue.) to be conducted on eligible subjects by the Principal Investigator and Institution to test the Safety and Efficacy of the study device.

1.21 Study completion occurs when the final **Clinical Study Report (CSR)** is signed by the Principal Investigator and Institution and Sponsor. Data generated in the clinical trial/study has been locked and provide to Sponsor, including a copy of approval letter of IEC acknowledgment of final report.

1.22 Study Material means Medical Device (VELGRAFT).

1.23 Subject means patient enrolled in said study.

2. SCOPE AND CONDUCT OF THE STUDY:

2.1 Sponsor hereby engages the Principal Investigator and Institution to conduct the Clinical trial/study on non-exclusive basis.

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(Principal& Co-Investigator) (Institute/Hospital)

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2.2 Institution agrees to provide all the facilities to the Principal Investigator and confirms that the study shall be conducted at the study site under the direction of Principal Investigator.

2.3 Principal Investigator shall conduct the study in accordance with the Clinical Investigation Plan/protocol, GCP, Regulatory Authority requirements including ICH-GCP, institution standard Operating procedures and other applicable laws.

2.4 Institution shall perform the Clinical Trial/Study under the direct supervision and control of Principal Investigator. If Principal Investigator is unwilling or unable to perform the study, Institution shall refer alternative Investigator to Sponsor as replacement of Principal Investigator and based on Sponsor's written approval, such Investigator shall be engaged as Principal Investigator for the clinical trial/study. If a mutually acceptable Principal Investigator is not referred by the Institution, then the study may be continued with the study Co-Investigator (Dr Subhash B Yadav) until/unless the Sponsor suspends or terminates the study or till completion of the study.

2.5 Sponsor will not accept the study until relevant milestones are achieved as identified in the Clinical Investigation Plan/protocol. In the event of any actual or anticipated failure by Site to perform the Clinical Trial/Study in strict compliance with the standards specified in the Clinical Investigation Plan/protocol or otherwise described in this Agreement for any reason other than Sponsor's acts or omissions, Sponsor shall be entitled to, at its sole option, require the Principal Investigator and Institution to re-perform the relevant milestone in the study without any additional cost to the Sponsor within timelines specified by the Sponsor

3. SUBJECT RECRUITMENT:

3.1 Principal Investigator shall enroll the Subjects in the study after IEC approval.

3.2 Principal Investigator shall ensure that all Subjects comply with Clinical Investigation Plan/protocol.

3.3 It shall be the responsibility of the Institution and Principal Investigator to notify Sponsor and IEC of any significant deviation from Clinical Investigation Plan/protocol and/or Applicable and Regulatory Authority guidelines including without limitation to Serious Adverse Events within Forty-eight (48) Hours.

3.4 Principal Investigator and Institution shall enroll **UP to 24 (in Phase-1) patients at site. If additional subjects are enrolled or less subjects are enrolled then, it should be communicated with sponsor.**, additional Subjects may be recruited only upon Sponsor's prior written consent.

3.5 Principal Investigator and Institution agrees that Sponsor can limit or stop Subject inclusion in the Study at any time for any reasons. If Sponsor limits Subject inclusion in the Study, milestone Fees under the payment schedule shall be paid by

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Sponsor based on the milestones achieved by the Principal Investigator and Institution as defined in Annexure - I. Should there be no Subject enrollment or there is no Study kick-off by Principal Investigator and Institution inaccordance with the Agreement, entire milestone Fees paid by Sponsor shall be refunded immediately.

3.6 If a Subject suffers with any Study related injury, Principal Investigator and Institution shall notify Sponsor within 24hours, however, Principal Investigator and Institution shall be responsible to provide complete medical treatment to the Subject. Sponsor will bear actual medical expenses incurred by the Principal Investigator and Institution forthe Subject as a result of any studyrelated injury. In case of death ofSubject due to Study related injury, PrincipalInvestigator and Institutionshall immediatelynotify theSponsor and Sponsor will pay the financial compensation as a result of Study related death as provided under Regulatory Authority guidelines and Applicable Law.

4. RESPOSNIBILITIES OF PARTIES:

4.1 PRINCIPAL INVESTIGATOR & INSTITUTION:

4.1.1 Principal Investigator and Institution shall be responsible to conduct the said Study at the Study Site.

4.1.2 Principal Investigator and Institution shall not subcontract the Study to any third party, except with prior written consent of Sponsor.

4.1.3 Principal Investigator and Institution shall provide preliminary and final detailed reports to Sponsor as per the timelines specified in the Protocol.

4.1.4 Principal Investigator and Institution shall be responsible to provide daily updates in respect of Serious Adverse Events, milestones pending, completed and safety issues.

4.1.5 Principal Investigator and Institution agrees that the Investigational Product and Study Materials are owned by Sponsor and all unused Investigational Product and Study Materials shall be returned to Sponsor on Study Completion. However, Institution is responsible to maintain full and accurate records for the use of Investigational Product and Study Materials in the Study.

4.1.6 Principal Investigator and Institution shall be responsible to notify Sponsor and IEC if there is a requirement for change in Clinical Investigation Plan/Protocol. Principal Investigator shall carry out the modifications and/or amendments in the Clinical Investigation Plan/Protocol based on the approval of IEC and Sponsor.

4.1.7 Principal Investigator and Institution agrees that Sponsor can monitor the Clinical Trial/Study and advise Principal Investigator and Institution on

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cessation of the Clinical Trial/Study or withdrawal of Investigational Product and Study Materials for safety reasons.

4.1.8 Principal Investigator and Institution shall maintain all Study Materials, including copies of signed consent forms, Case Report Forms, Protocol and information relating to Investigational Product and Study Materials in safe custody always locked.

4.2 PRINCIPAL INVESTIGATOR:

4.2.1 Principal Investigator thoroughly familiarizes him/herself with the appropriate use study materials/Investigational Product **(VELGRAFT)** and described in Clinical Investigation Plan/Protocol, Informed Consent Documents and Case Report Form.

4.2.2 Principal Investigator shall be responsible to coordinate with the research staff and Institution and deliver all reports, data, statement and deliverables of the Clinical Trial/Study to the Sponsor.

4.3 INSTITUTION:

4.3.1 Institution is responsible to ensure that Principal Investigator is conducting the study under this agreement is not debarred by the Regulatory Authority or under applicable laws.

4.3.2 If Principal Investigator leaves the Institution or otherwise ceases to be available, then the Institution must consult with the Sponsor and use reasonable endeavors to nominate as soon as possible, a replacement reasonably accepted to both parties; and the Sponsor many require recruitment into the study by the Institution to cease, or move the study to a different study site.

4.3.3 The Institution shall be responsible for ensuring sufficient, appropriate and necessary facilities, equipment and resources for the conduct of the trials/Study, and all other resources reasonably required to complete the Study and that no other than legal obligations or commitments of the Institution cause unreasonable damage to or delay in conducting the said trial/Study as set forth in this agreement.

4.3.4 Institution will ensure that the Study is subject to the continuing oversight of the Principal Investigator and IEC throughout the Study Completion.

4.3.5 Institution shall be responsible to retain archival records of the Study including the original or a copy of al Subject consent forms in conformance with applicable regulations for a minimum free storage period of **fifteen (15) years.**

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4.3.6 Institution shall notify Sponsor before destroying any Study Materials and retain the Study Materials for such longer period as reasonably required by the Sponsor at the mutually agreed costs after completion of free storage period of **fifteen (15) years.**

4.4 SPONSOR:

4.4.1 Sponsor will provide study materials to the Principal Investigator and Institution for the purpose of conducting the Clinical Trial/Study.

4.4.2 Sponsor will share relevant information of study materials and Investigational Product with Principal Investigator and Institution.

5. REGULATORY AUTHORITY:

5.1 Principal Investigator and Institution shall obtain IEC approval and Sponsor will obtain regulatory authority clearance under applicable law as specified in Clinical Investigation Plan/Protocol.

5.2 If Principal Investigator and Institution fails to obtain the IEC approval within the agreed timelines stated in the Clinical Investigation Plan/Protocol, Sponsor shall at its sole option, immediately suspend or terminate the Clinical Trial/Study and terminate this Agreement as per Section 13 Principal Investigator and Institution shall notify sponsor within twenty-four (24) hours upon receipt of written communication from Regulatory Authority inspection or inquiry related to the Clinical Trial/Study.

5.3 Principal Investigator and Institution shall cooperate with Sponsor from time to time in inquiry, investigation, audit or proceedings of Regulatory Authority without additional cost to Sponsor.

6. REPRESENTATION & WARRANTIES:

6.1 Parties represent and warrant that they are authorized to execute this agreement and that the terms of this agreement are not in violation of any contract to which they are a party.

6.2 Principal Investigator and Institution represents and warrants that they have relevant skill, experience, expertise, regulatory approvals/licenses and facilities to conduct the Clinical Trials/Study as required by Sponsor from time to time.

6.3 Institution represents and warrants that the processes and clinical tools used by Principal Investigator to perform the Study herein does not infringe any Intellectual Property Rights including patent, copyright, trade secret, industrial rights or other proprietary right of any third party.

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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6.4 Institution warrants that Principal Investigator, and all Representatives deputed for performing the Study shall possess relevant skills and qualifications and the Clinical Trial/Study shall be rendered in a professional and workmanlike manner.

6.5 Principal Investigator and Institution shall diligently and timely respond to all queries and requests of Sponsor.

6.6 Principal Investigator and Institution shall comply with all Applicable laws including data privacy, confidentiality and data security policies from time-to-time.

7. INTELLECTUAL PROPERTY:

7.1 All rights, title and interests resulting from the said Clinical Trials/Study, Study Materials and Investigational Product including IPR whether created, developed, generated, modified or improved by Principal Investigator and/or Institution shall be the exclusive property of Sponsor. Principal Investigator and Institution agrees that Sponsor owns the right, title and interest in any inventions, designs, discoveries, improvements, developments, innovations and works of authorship produced as a result of the Study. Principal Investigator and Institution shall irrevocably transfer and assign all rights, title and interest in IPR in favor of Sponsor.

7.2 Principal Investigator and Institution shall not use the Confidential Information and IPR and/or data generated from the study directly or indirectly for any purpose other than the Clinical Trial/Study.

7.3 Principal Investigator and Institution agrees that all inventions, data, works, discoveries, technology and innovations or improvements in relation to the study and IPR, whether or not subject to any protection by statute which are conceived of, made, reduced to practice, created, written, designed or developed, authored or made by Principal Investigator and/or Institution either alone or in combination, in the course of the performance of study under this Agreement including modifications or improvements to any proprietary technology, information or materials provided by Sponsor to Principal Investigator and Institution shall be the exclusive property of Sponsor. The Inventions are to be promptly reported to Sponsor. Sponsor is free to use the results of the Clinical Trial/Study without any further communication to Principal Investigator and Institution.

7.4 Principal Investigator and Institution agrees to cooperate with Sponsor and its nominees to obtain patents or register copyrights in any and all countries for the inventions and IPR and to execute all documents for use in applying for and obtaining such protection thereon as Sponsor may desire, together with assignments thereof to confirm Sponsor's ownership. In the event that any improvements, innovations or developments do not qualify to be work for hire, Principal Investigator and Institution herby irrevocably transfers, assigns and

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conveys, all rights, title and interest in such improvements or developments to Sponsor free from all encumbrances and agrees to execute and shall cause it's representative to execute, all necessary documents in favor of Sponsor.

8. FEES:

8.1 Principal Investigator and Institution shall submit any invoice to the Sponsor for conducting the said Clinical Trial/Study. Principal Investigator and Institution agrees that the payment made by Sponsor for conducting the Clinical Trial/Study is fair as mutually agreed by the parties as per **Annexure I.**

8.2 Principal Investigator consideration of the Clinical Trial/Study, Sponsor will pay the Fees/ charges to the Institute on completion of relevant milestones as specified in **Annexure I**.

8.3 Institute shall submit to Sponsor the invoices for Clinical Trial/Study completed till the relevant milestones. All invoices shall be approved by the Sponsor representative. Principal Investigator shall give supportive documents upon successful completion of deliverables within the agreed timelines. Sponsor will make payments against undisputed invoices within thirty (30) business days from the date of receipt of invoice. If there is any discrepancy in the invoice submitted by the Institute, Sponsor will notify Institute within fifteen (15) business days from the date of receipt of such invoice and withhold disputed invoice amounts until resolved by the Parties. However, pending resolution of any dispute under this Agreement, Principal Investigator and Institution shall proceed diligently with its performance of Clinical Trial/Study and complete the Clinical Trial/Study during dispute proceeding, unless otherwise instructed by the Sponsor.

8.4 All payments made by Sponsor to Institute shall be subject to tax deduction at source, service tax and payments, other applicable taxes as per their applicable rates, shall be paid extra by Sponsor.

8.5 Institute has provided NEFT/RTGS/wire transfer details to the Sponsor for processing the payments and subject to undisputed invoices, payment will be processed by the Sponsor.

All invoices to be sent to:

SPONSOR:	Datt Mediproducts Private Limited
BILLING ADDRESS:	Datt Mediproducts Private Limited, 56, Community Center, East of Kailash, New Delhi – 110065, India
ATTENTION OF:	Dr. Pankaj Bablani
TELEPHONE:	+91 –9999059412

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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EMAIL:	clinical@dattmedi.com

All invoices will be sent to the Sponsor via email and the electronic version of the invoices will be considered as the original and hard copies of the invoices will be shared by Institute on above address.

9. PUBLICATION:

9.1 Principal Investigator and Institution shall not, without prior written consent of the Sponsor, report or publish or make available the data, results or any report of the Clinical Trial/Study conducted under this Agreement to any third party or in any journal, book, magazine etc.

9.2 Accordingly, Study results may be published in medical journals or presented at a public forum such as conferences only after Sponsor's written consent and Sponsor has determined that such publication will not compromise IPR issues and/or confidentiality issues associated with the Clinical Trial/Study and approved or consented in writing that the Principal Investigator and Institution may publish or report the data, results or any report of the Clinical Trial/Study.

The Principal Investigator and Institution shall declare that Sponsor has provided her/him with funding for the Study whenever she/he writes or speaks in public about a matter that is the subject of this Agreement or about any other issue relating to Sponsor.

9.3 In all publications, the Sponsor's support of the Study shall be acknowledged. The Study will be clinically and statistically evaluated collaboratively by the Sponsor, Principal Investigator and on behalf of Institution and manuscript shall be prepared for submission to a peer-reviewed journal, subject to written approval of Sponsor.

9.4 Authorship credits shall, upon mutual consent between the Institution and the Sponsor, shall be decided considering all those participating in the Study program. The Sponsor may freely use, copy and disseminate any manuscript following its publication in a journal without further obligation to the Principal Investigator & Institution or disclosure. All communications in relation to the Clinical Trial/Study such as press release or responses to inquiries from media should receive prior written approval from the Sponsor.

10. CONFIDENTIALITY:

10.1 Principal Investigator and Institution agrees that CONFIDENTIAL information shall be used only for rendering the services. Principal Investigator and Institution shall keep CONFIDENTIAL information strictly confidential, protect from unauthorized use, reproduction, access and damage or destruction and employ the same degree of care as it would employ to protect its own confidential Information.

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10.2 Principal Investigator and Institution shall limit disclosure of Confidential Informationonly to its Representatives who necessarily require access to render the Services, provided that –

(a) Principal Investigator and Institution first require each of them to agree in writing, either as a condition of their service to Principal Investigator and Institution or in order to obtain Confidential Information, to be bound by terms and conditions substantially similar to those terms and conditions applicable to Principal Investigator and Institution under this Agreement, and

(b) Principal Investigator and Institution shall maintain a record of Confidential Information disclosed to the Representatives and such record shall contain the name, designation of the Representatives and details of Confidential Information disclosed, which shall be made available to Sponsor upon request. However, Principal Investigator and Institution shall, under all circumstances, continue to be liable as a principal party.

10.3 In the event Principal Investigator and Institution becomes legally compelled by government or judicial process to disclose any Confidential Information, Principal Investigator and Institution will provide prior written notice thereof to Sponsor before making any disclosures, to enable Sponsor to seek protective order or other appropriate remedy to minimize disclosure and Principal Investigator and Institution shall disclose only such portion of Confidential Information absolutely necessary in the opinion of its legal counsel to comply with the process.

10.4 All Confidential Information is provided "as is", without any warranty, express, implied or otherwise, regarding its accuracy or performance and in no event shall Sponsor be liable to Principal Investigator and Institution for disclosure of Confidential Information under this Agreement.

10.5 Upon the first written request of Sponsor at any time during the term or immediately upon expiry or earlier termination of the Agreement, Principal Investigator and Institution shall return **within fifteen (15) days** all Confidential Information to Sponsor, by registered mail/courier of international repute, and/or destroy such Confidential Information as per the directions and instructions of Sponsor and provide written certification to Sponsor. Principal Investigator and Institution may, however, retain one copy of such Confidential Information in its legal archives solely for legal compliance purposes, under strict obligations of confidentiality as stated in this Agreement.

10.6 All obligations contained in the Agreement shall however survive the expiry or early termination of this Agreement and the Parties shall always remain bound by the same.

11. INDEMNITY:

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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11.1 Principal Investigator and Institution shall indemnify and hold Sponsor, its Affiliates and/or their respective representatives and assigns harmless against all notices, claims, demands, actions, suits or proceedings given, made or initiated against Sponsor on account of or arising out of any and all liabilities, damages, injuries, cause of action and expenses including attorney's fees suffered or incurred by Sponsor for –

(a) Breach of responsibility of Parties;

(b) Loss or damage caused to Investigational Product and Study Materials;

(c) Willful negligence, misconduct and misrepresentation

(d) Breach of representation and warranties and confidentiality obligations under this Agreement;

(e) Any third-party claims for infringement of IPR and injury and/or death of Subjects.

The Institution and Principal Investigator agrees to indemnify and hold harmless the Sponsor from any and all liability of trial subjects, loss, or damage it may suffer as a result of either the institution's negligence or breach of contract of the Principal Investigator during the Study.

11.2 In context to the section 11.1 the sponsor ensures and indemnifies that in any such event the sponsor's liability towards resolving the issue would be restricted only monetarily and as per the decision of the Ethics Committee and or as per the decision of the regulatory body, if applicable.

11.3 Sponsor's only liability to Principal Investigator and Institution for conducting the Study shall be the payment of Fees not exceeding relevant milestone mentioned in **Annexure I,** provided Principal Investigator and Institution have satisfactorily achieved the relevant milestone and/or completed the Study.

12. TERM:

This agreement shall commence from the effective date and shall be valid for a period of **Two (02) Years** or on Clinical Trial/Study completion or unless sooner terminated by Sponsor in accordance with **section 13,** whichever is applicable. Parties may renew this Agreement upon mutually agreed terms & conditions.

13. TERMINATION:

13.1 Sponsor shall be entitled to terminate this Agreement in the following circumstances:

13.1.1 Without cause at any time by **giving seven (7) days'** prior written notice to the Principal Investigator and/or Institution.

13.1.2 In the event of breach by Principal Investigator and Institution that is not cured within **thirty (30) days** from the date of written notice by Sponsor.

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13.1.3 Immediately, if Principal Investigator and Institution fails to obtain ethics committee clearance.

13.1.4 Immediately, if Institution becomes insolvent or files for bankruptcy.

13.1.5 In the event of change of control of Institution, unless Sponsor decides otherwise, in which case, the acquiring entity undertakes in writing to assume all liabilities and responsibilities of Institution under this Agreement.

13.2 If this Agreement is terminated by Sponsor and/or Principal Investigator, Institution:

13.2.1 If Sponsor terminates the study: Fees for successful completion of Study till the date of termination as per the relevant milestone shall be paid by Sponsor.

13.2.2 If Principal Investigator/Institution terminate the study: Principal Investigator and Institution shall be liable to reimburse the Fees and expenses to Sponsor as a result of Sponsor retaining third party contractor to complete the Study.

13.2.3 Should Sponsor retain a third party for completion of the Study, then Principal Investigator and Institution shall provide transition services to such third party within the timelines specified by Sponsor without any costs thereon.

14. INSURANCE:

14.1 Sponsor shall secure and maintain in full force and effect throughout the performance of the Study, insurance coverage from a reputed insurance company to cover its obligations including the Principal Investigator and Representatives and all the claims arising out of Subjects injury and/or death.

15. NOTICE:

15.1 Any notice given under this Agreement shall be in writing and signed by or on behalf of party giving it and may be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or by email or fax to the address and for the attention of the relevant **Party.** Any changes in address shall be notified by a **Party** to the other.

15.2 Any such notices be deemed to have been received;
-If delivered personally at the time of delivery;
-In the case of registered airmail, pre-paid recorded delivery or registered post-upon receipt;
-In the case of fax, at the time of transmission

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The addresses, Email IDs and fax number of **Parties** for the purpose of any written notice is as follows:

FOR SPONSOR	FOR PRINCIPAL INVESTIGATOR
DATT MEDIPRODUCTS PRIVATE LIMITED 56, COMMUNITY CENTER, EAST OF KAILASH, NEW DELHI – 110065, INDIA TELEPHONE: +91 (11) 47191777 EMAIL: clinical@dattmedi.com	**Dr. GYAN CHAND.** DEPARTMENT OF ENDOCRINE SURGERY, SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW. EMAIL: drgyanchandpgi@gmail.com

15.3 This agreement and the Parties rights and obligations hereunder shall be governed by and interpreted in accordance with the laws of India.

15.4 All disputes arising under this Agreement shall be mutually settled by the Parties within **thirty (30) days**, failing which, shall be finally resolved by arbitration under the Rules of Lucknow Arbitration Centre situated at the Lucknow High Court, Lucknow by one/sole arbitrator appointed in accordance with its Rules. The language of the arbitration proceedings shall be English. The place of arbitration shall be the Lucknow Arbitration Centre at Luck now. Award passed by the arbitrator shall be final and binding on the Partics.

16. GENERAL PROVISION:

16.1 The relationship between Sponsors is Institute is of independent contractor.

16.2 A Party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by a Force Majeure Event provided that the affected **Party** promptly notifies the other of the occurrence of Force **Majeure Event.**

16.3 Principal Investigator and Institution shall not assign this Agreement to any person without prior written consent of Sponsor.

16.4 Any waiver by a **Party** of any provisions of this Agreement shall not operate or De construed as a waiver of any subsequent breach of such provision or any other provision hereof by such Party.

16.5 The invalidity or unenforceability of any provision of this Agreement shall not in any way affect, impair or render unenforceable this Agreement or any other provision contained herein, which shall remain in full force and effect.

16.6 No amendment to this agreement shall be valid unless mutually agreed in writing and executed by the parties.

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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16.7 This Agreement represents the entire engagement between parties and supersedes all prior negotiations, understanding the agreements, written or oral, relating to the subject matter herein.

In Witness, whereof, the Parties herby sign and execute this Agreement as of **Effective** Date.

FOR SPONSOR:

DATT MEDIPRODUCTS PVT. LTD. New Delhi

Signature: _____

Name: Ms. Shefali Kapur

Title: Director

Address: Datt Mediproducts Pvt. Ltd., 56, Community Center, East of Kailash, New Delhi – 110065, India

FOR SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES:

Signature: _____

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014. INDIA

Name: Prof. Dr. R K Dhiman

Title: Director

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, (SGPGIMS) Raibareli Road, Lucknow- 226014, Uttar Pradesh, India.

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FOR PRINCIPAL INVESTIGATOR:

Signature: _____

Name: Dr. Gyan Chand

Title: Professor

Address: Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS) Raibareli Road, Lucknow- 226014, Uttar Pradesh, India.

ANNEXURE I

Study Title:

A prospective, randomized, assessor-blind, active controlled, multi-center study to demonstrate the safety and efficacy of VELGRAFT, an allogenic cell-based wound dressing, in comparison to standard moist wound dressing in management of chronic diabetic foot ulcers that have attained granulation tissue

Fixed cost as investigators includes both investigators Principal and Co-Investigator fee: Datt Mediproducts Pvt. Ltd. will pay maximum up to INR 700/ per visit upon achieving the milestones listed below.

Clinical research coordinator shall be provided by the sponsor and cost of the same shall be borne by the sponsor.

1. **Payment Milestones**

As per monthly invoice generated by site. Invoice will be clear by sponsor within 30 days of receipt of invoice.

2. **Allocated study budget (₹)**

Particulars	Per visit *(15 visits in total)*	Cost Per subject
Investigators Fee	INR 700/ visit	**INR 10,500/-**
Dressing including standard dressing	Under discussion with site	
Institutional charges @ 25% of total Budget	-	*25%Institutionaloverhead*
Grand Total	-	

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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3. **Bank details for payment transfer:**

Beneficiary Name	Director SGPGI Research Account
Bank Name	State Bank of India
Bank Address	Sanjay Gandhi PGIMS, Rae Bareli Road, Lucknow, Uttar Pradesh, India 226014
Account No.	10095237491
Account Type	Current
NEFT/ IFC / RTGS code	IFSC code. SBIN0007789

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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Executive Registrar
SGPGIMS,Lucknow

THIS CLINICAL TRIAL SERVICE AGREEMENT ("Agreement") is made on this **21st Day of Oct, 2023**

BETWEEN:

Lambda Therapeutic Research Ltd.
Plot No. 38, Survey no 388, Near Silver Oak Club, S G Highway,
Gota, Ahmedabad - 382481, Gujarat, India.
(Hereinafter referred to as "LAMBDA" or "CRO")

AND

Intas Pharmaceuticals Limited,
Corporate House, Nr. Sola Bridge,
S.G. Highway, Thaltej,
Ahmedabad – 380054 Gujarat, India.
(Hereinafter referred to as the "Sponsor")

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences,
New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014

(Hereinafter referred to as the "Institution" or "Site")

AND

Dr. Amita Aggarwal,
Head of Department of Clinical Immunology and Rheumatology,
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014

(Hereinafter referred to as the "Investigator")

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THIS AGREEMENT shall come into effect on the date on which the last Party sign.

WHEREAS:

LAMBDA is acting as a Contract Research Organization (CRO) under a Service Agreement with Sponsor and has been authorized as such by the sponsor to handle, negotiate and conclude various Sites under an Agreement on its behalf;

LAMBDA for and on behalf of Sponsor wishes the Investigator and Institute to involve and participate in a clinical trial titled **A Prospective, Nonrandomized, Open label, Single Arm, Multicentric, Phase III Clinical Study To Evaluate Efficacy, Pharmacokinetics And Safety of Human Normal Immunoglobulin For Intravenous Administration In Patients With Primary Immunodeficiency Diseases.**

and,

The Investigator has adequate authority, qualifications and experience in conducting clinical trials, having reviewed the necessary information including the Protocol for the Clinical Trial, the Investigator Brochure and/or Prescribing Information, the Investigational Product has determined his interest to conduct and participate in the Clinical Trial. The Investigator also agree that all aspects of the Study will be conducted in conformity with all applicable laws and regulations, including the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice: consolidated Guideline and other generally accepted standards of good clinical practice.

The Institution certifies that, to its best knowledge, its facilities and patient population are adequate to perform the Clinical Trial contemplated by this Agreement and the Protocol.
The Institution has necessary personnel with the requisite skills, experience, and knowledge required to support the performance of the Clinical Trial by the Investigator; and the Institute is willing to participate in the Clinical Trial; and,

The Investigator has represented that it is authorized by Institution to conduct the clinical trial at the Institution and has agreed to monitor, review and supervise The Clinical Trial for patient safety, scientific validity, and utilization of hospital resources in accordance with the protocol and applicable regulatory requirements.

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IN CONSIDERATION of the mutual promises and covenants herein, the parties agree as follows:

1. Definitions

1.1 In this Agreement, the following terms shall have the following meanings:

Term	Meaning
"Compound"	**Test Product (T):** Human normal immunoglobulin intravenous 5% and 10% solution
"Auditor"	means a person/s authorized to certify and carry out independent review and examination of clinical trial related activities and documents to determine whether the clinical trial related activities were conducted and accurately recorded and analysed in accordance with the Protocol, the Standard Operating Procedures of Sponsor and/or CRO, ICH GCP and the other applicable regulatory requirements.
"Central Licensing Authority"	means the Drugs Controller, India as referred to in rule 3;
"Clinical Trial"	in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,- (i) clinical or; (ii) pharmacological including pharmacodynamics, pharmacokinetics or; (iii) adverse effects, with the objective of determining the safety, efficacy or tolerance of such new drug or investigational new drug;
"Clinical Trial Site"	means any hospital or institute or any other clinical establishment having the required facilities to conduct a clinical trial;
"Clinical Trial Subject"	means individual (s) enrolled to participate in the Clinical Trial in accordance with the applicable regulatory requirements.
"Confidential Information"	means information provided by a Party (the Disclosing Party) to the other Party (the Receiving Party) or to any other of such Receiving Party's employees or agents, and means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of the Disclosing Party or the Disclosing Party's Affiliates that are provided in connection with this Agreement or the Clinical Trial. Sponsor's Confidential Information shall include Clinical Trial

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	data, results, or reports created by Institution, Investigator, or Research Staff in connection with the Clinical Trial (except for a Clinical Trial Subject's medical records); and cumulative Clinical Trial data, results, and reports from all sites conducting the Clinical Trial
"CRF"	means the case report form in a format prepared by Sponsor and documenting the administration of the Investigational Product to Clinical Trial Subjects as well as all tests and observations related to the Clinical Trial;
"CRO"	Contract/Clinical Research Organization
"DCGI"	Drug Controller General of India.
"Declaration Of Helsinki"	The 2013 version of the Helsinki Declaration of the World Medical Association and amendments.
"Ethics Committee"	means, for the purpose of, - (i) clinical trial, Ethics Committee, constituted under rule 7 and registered under rule 8; (ii) biomedical and health research, Ethics Committee, constituted under rule 16 and registered under rule 17;
"ICH GCP"	ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) as may be amended from time to time.
"Intellectual Property Rights"	means patents, trademarks, trade names, service marks, domain names, copyrights, rights in and to databases (including rights to prevent the extraction or reutilization of information from a database), design rights, topography rights and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them;
"Investigational Product"	the Study Drug identified above and the control material, as further detailed in the Protocol;
"Investigator"	means a person who is responsible for conducting clinical trial at the clinical trial site;
"Investigator Site File"	The file maintained by the Investigator containing the documentation specified in section 8 of ICH GCP.

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"New Drug"	(i) a drug, including active pharmaceutical ingredient or phytopharmaceutical drug, which has not been used in the country to any significant extent, except in accordance with the provisions of the Act and the rules made thereunder, as per conditions specified in the labelling thereof and has not been approved as safe and efficacious by the Central Licensing Authority with respect to its claims; or (ii) a drug approved by the Central Licensing Authority for certain claims and proposed to be marketed with modified or new claims including indication, route of administration, dosage and dosage form; or (iii) a fixed dose combination of two or more drugs, approved separately for certain claims and proposed to be combined for the first time in a fixed ratio, or where the ratio of ingredients in an approved combination is proposed to be changed with certain claims including indication, route of administration, dosage and dosage form; or (iv) a modified or sustained release form of a drug or novel drug delivery system of any drug approved by the Central Licensing Authority; or (v) a vaccine, recombinant Deoxyribonucleic Acid (r-DNA) derived product, living modified organism, monoclonal anti-body, stem cell derived product, gene therapeutic product or xenografts, intended to be used as drug; *Explanation.*— The drugs, other than drugs referred to in sub-clauses (iv) and (v), shall continue to be new drugs for a period of four years from the date of their permission granted by the Central Licensing Authority
"Payment Agreement"	The payment agreement set out in Schedule "B".
"Protocol"	The protocol as agreed between the parties under (Schedule "A") as may be amended from time to time.
"Schedule"	means the Schedule annexed to Protocol & Budget Break-up;
"Serious Adverse Event (SAE) "	an untoward medical occurrence during clinical trial resulting in death or permanent disability, hospitalization of the trial subject where the trial subject is an outdoor patient or a healthy person, prolongation of hospitalization where the trial subject is an indoor-patient, persistent or significant disability or incapacity, congenital anomaly, birth defect or life threatening event;
"Sponsor"	includes a person, a company or an institution or an organization responsible for initiation and management of a clinical trial;
"Study"	The study titled **Prospective, Nonrandomized, Open label, Single Arm, Multicentric, Phase III Clinical Study To Evaluate Efficacy, Pharmacokinetics And Safety of Human Normal Immunoglobulin For Intravenous Administration In Patients With Primary**

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	Immunodeficiency Diseases to be undertaken by the Investigator and the Institution in accordance with the Protocol, ICH-GCP and applicable regulatory requirements.
"Trial Subject"	A person who is either a patient or a healthy person to whom investigational product is administered for the purposes of a clinical trial.
"Controller"	For the purpose of the Data Protection Laws and Guidance, the CRO or LAMBDA is the Controller
"Processer"	For the purpose of the Data Protection Laws and Guidance, the Investigator, Institute & SMO, if applicable is the Processor
"Data Protection Laws and Guidance"	means the General Data Protection Regulation (EU) 2016/679 ("GDPR")
"Serious Breach"	means a breach likely to affect to a significant degree the safety and rights of a subject or the reliability and robustness of the data generated in the clinical trial.

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2. Investigator/Institution responsibilities

2.1 The Investigator in his personal capacity and as an authorized representative of the Institution and also the Institution undertakes to adhere to the Protocol and general acceptable clinical practices for the conduct of the Clinical Trial.

2.2 The Investigator and the Institution will adhere to ICH GCP E6 R2 & all the processes mentioned in the guideline should be followed which needs to be demonstrated by SOPs, trained and qualified staff, QC procedure, good document practices, Declaration of Helsinki, New Drugs and Clinical Trials Rules, 2019 of CDSCO, USFDA, ANVISA, EMA regulations and all applicable laws and regulations for the conduct of the Clinical Trial.

2.3 The Investigator and Institute are jointly and severally responsible for supporting Sponsor and Lambda in addressing any situation and resolving any technical issues that may arise during the performance of the Clinical Trial. The Investigator and the Institute will reply, respond and address queries from national / international authorities in close consultation and coordination with Lambda in a timely manner. The provisions of this article shall remain in force for a period of 25 years even after expiry or termination of this Agreement.

2.4 The Investigator and Institute are responsible for submitting (i.e. Ethics Committee dossier & study related applicable documents) to the Ethics Committee; the conduct of the Clinical Trial in accordance with the terms of the Protocol and for obtaining written approval from the Ethics Committee prior to the commencement of the Clinical Trial. The Investigator will deliver a copy of such approval to LAMBDA. Trial materials (i.e. IP, Laboratory Kits etc.) to the Investigator or the Institution will be supplied only after LAMBDA has received a copy of such approval. The said approval must indicate the date of approval bearing the name and signature of the Chairperson/member secretary of the Ethics Committee. In case there is any additional requirement under the applicable protocol / approval, Investigator / Institution shall obtain the same.

2.5 The Investigator is responsible for training and supervision of sub-investigators if any and other site study team members on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any change or a replacement in any of the study team member, the Investigator shall promptly notify such change to LAMBDA.

2.6 The Investigator shall communicate all relevant information and matters concerning the Clinical Trial to the Subjects who intend to participate in the trial and/or their legally

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acceptable representatives and shall obtain voluntary signed written informed consent from all prospective patients and their legally acceptable representatives prior to start of any study related procedures.

2.7 An investigator shall maintain the data integrity of the data generated during the clinical trial.

- Investigator shall maintain and assure the accuracy and consistency of data over its entire lifecycle.
- Investigator shall ensure that the accuracy, completeness, consistency, trustworthiness, and reliability of records and data are maintained and retained throughout their entire lifecycle. Data integrity principles shall apply to all forms of data storage—non-electronic (paper) and electronic , to the study records as well as routine medical records encompassing the study requirements and total period. Data shall be collected and maintained in a secure manner, so that they are attributable, legible, contemporaneously recorded, original (or a true copy) and accurate. Data integrity shall be ensured by the use of appropriate quality and risk management systems, including adherence to sound scientific principles and good documentation practice

2.8 During the performance of the Clinical Trial and for a period of 25 years after expiry/termination of the agreement, the Investigator and/or Institute is responsible for followings:

a) Keeping and maintaining required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s) , confirmation of adequate site facilities, etc.);

b) Submission of progress report accurately (including recruitment figures) to ethics committee and LAMBDA on a regular basis;

c) ensuring direct access of all authorized monitors, auditors and regulatory authority to original study documents, medical records (electronic/paper copy), study materials, etc and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection respectively;

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d) to facilitate any regulatory audit by DCGI or any applicable regulatory authority within 25 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; all correspondences, documentation and submissions to the regulatory authority concerning the Trial shall be submitted only after written consent of CRO.

e) safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial as per applicable country specific guideline;

f) Inform the Ethics Committee on conclusion of the study and provide the notification documentation duly supported by data and records to Lambda.

g) Maintenance of drug accountability records, study documents including study drug acknowledgement receipts, study drug supply receipts, payment receipts, EC approvals etc. in Investigator Site File (ISF);

h) Handling and storage of IMP/Non IMP according to protocol, IMP and non-IMP manuals or any such related documents.

i) In case if any study team member disengage from the study on account of separation, discontinuation from the employment or otherwise of the Institution / Investigator, the Investigator/ Institution shall inform CRO of the same and shall make necessary alternate arrangement in shortest possible time so to ensure smooth conduct of the trial without any delay or interruption.

j) The records (study documents including source data/patient medical documents, site master file) of the Clinical Trial as required by the Protocol and applicable laws created during the course of the study at the site will be archived at third party archival agency as recommended by Sponsor for a minimum of twenty five (25) years from date of database closure, [As per Article 58 of the Regulation new EMA Requirement: 25 years "unless other Union law requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical TMF for at least 25 years after the end of the clinical trial.]

k) In case the Investigator / Institution sub-contracts or outsource any services or activities covered under the trial including the diagnostic test or clinical procedure required by the protocol are being outsourced by Investigator /Institution at other facilities/ institutions then the same shall be done through the execution of proper documentation such as agreement / MOU, the copies where of shall be provided to LAMBDA.

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2.9 Investigator shall promptly report all SAEs to LAMBDA, Sponsor and Ethics Committee. The Investigator shall be responsible for reporting all such findings in the manner and in time frame as set out in the applicable provisions of ICH GCP and the applicable legislation i.e. within 24 hours of occurrence to LAMBDA, IEC and Institution by Investigator; and further follow up reporting will be done as per the regulatory guidelines prescribed in New Drug Rules, 2019 to ethics committee and Regulatory Authority (DCGI) via first draft report. LAMBDA and/or Sponsor confirms an effective system for centralized tracking and notification to investigators and to applicable regulatory authorities of all findings that could adversely affect the safety of Clinical Trial subject, including, without limitation, all unexpected serious adverse drug reactions experienced by any subject taking part in the Clinical Trial at any site has been established. Notwithstanding anything in this Agreement to the contrary, the Investigator and the Institution shall always be free to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deemed necessary to protect the health of study participants, provided that Sponsor is copied on such reports.

2.10 The Investigator and the Institution shall indemnify, defend and hold harmless Lambda and the Sponsor against any and all claims arising out of or in connection with the performance of this agreement, Investigator's and / or his team's negligence or reckless or intentional misconduct, breach or failure to perform its duties, obligations and responsibilities under this agreement. Lambda will provide timely written notice for indemnity upon any third party claim being served upon Lambda / Sponsor. The Investigator shall while indemnifying and keeping harmless Lambda and Sponsor, have the right to defend the action, proceedings or claim at his own expenses including selection of counsel, control of the proceedings and settlement of the claim. Lambda shall cooperate and aid in such defense. In the event that the claim, proceeding, actions is asserted or initiated against Lambda. Lambda shall have the right to select and to obtain representation by separate counsel, at its own expense. Investigator may not settle or compromise a claim or suit without the express prior written approval of Lambda.

2.11 The Investigator/Institute shall ensure that all procedures defined in the Protocol are complied with, so that all data generated at the Trial Site are reliable and have been processed correctly and will ensure that the content of the e-CRFs will accurately reflect source documents.

2.12 The Investigator/Institute should follow the Good Document Practices for all the source documents generated at site by the investigator, research staff or any other associated member of the study team including local laboratory/any other sub-contracted vendor

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appointed by the site. The team needs to ensure all the essential documents either paper or electronic should have all the attributes like Accurate, Legible, Contemporaneous, Original, Attributable Complete, Consistent, Enduring and Available. It is essential that source data capture methods/system are identified prior to study initiation and followed diligently during the study.

2.13 The Investigator/Institute shall take appropriate measures for the quality of the data generated at site and by any other sub-contracted vendor appointed by the site. Data should be reviewed & authenticated by investigator periodically. Also, Investigator/Institute shall take corrective actions without delay for all issues reported by the Monitors, Auditors, or representatives of the Ethics Committee or any regulatory authority.

2.14 The Investigator is responsible for supporting LAMBDA in development of the Clinical Trial Report.

2.15 The Investigator & Institute should ensure to report & escalate any potential serious breaches to LAMBDA & Sponsor immediately within 24 hrs. from becoming aware of the serious breach.

2.16 The Investigator should ensure that all the data generated at the sites and by any other sub-contracted vendor appointed by the site are under his/her control & ownership.

- Investigator shall provide inspection history along with redacted inspection report and closure status, where applicable, for atleast 05 Years inspections occurred before study initiation. And in case an inspection occurs during the study or within 02 years of site close out then the investigator should provide this information in a real-time manner.

3. SPONSOR/CRO responsibilities

3.1 LAMBDA will and cause the Sponsor to adhere to ICH GCP, the Declaration of Helsinki, requirements New Drug & Clinical Trial Rules, 2019 of DCGI, and all applicable guidelines, laws and regulations for the conduct of the Clinical Trial.

3.2 LAMBDA confirms that the Sponsor has agreed to provide Lambda with the Compound and with guidelines and descriptions for the safe and proper handling, use, storage and disposal of the Compound for the use in the trial. Sponsor/Lambda will be responsible for shipment of drug supplies and investigational products to the PI or Site. The Compound is the property of Sponsor and is being provided only for the purposes of the performance of the Clinical Trial by the PI or by individuals working under his direct

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supervision at the Institution. The Compound shall not be used for any other research or study activities other than outlined in this Agreement.

3.3 LAMBDA and/or Sponsor is responsible for obtaining and maintaining all applicable government or regulatory approvals for the Clinical Trial in India before the Clinical Trial begins at the Institution. Development and improvement of the Protocol is the responsibility of LAMBDA and Sponsor.

3.4 LAMBDA on behalf of the Sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

3.5 LAMBDA on behalf of the Sponsor will provide the Investigator with documentation, which describes the Compound being tested in the Clinical Trial and its known effects and safety information (e.g. Prescribing Information / Summary of Product Characteristics, an Investigator Brochure equivalent document). LAMBDA on behalf of Sponsor will, to the best of its knowledge; answer any questions the Investigator or the Institution may have regarding the Protocol or the Compound being tested, whether such questions are asked before the commencement of the Clinical Trial or during its conduct. Sponsor is responsible for reporting of relevant new information regarding the investigational Compound.

3.6 LAMBDA will transfer on behalf of Sponsor the financial support to the Institution or Investigator according to the budget agreed by Sponsor, Investigator and the Institution as set out in Schedule B subject to the terms of this Agreement. No deviation will be made in the agreed budget without prior concurrence of the Lambda/Sponsor.

3.7 At the end of the study, LAMBDA shall ensure an independent investigator copy of the data (i.e. eCRF) provided to the investigator and should revoke investigator's further access to data eCRF system.

4. Performance standards of the work to be conducted by the Investigator

4.1 The Investigator and/or the Institution shall use all reasonable endeavors to enroll at least **09-10 Eligible Patients within 20 of months;** minimum expected recruitment rate from the site is **01 patient per 02 month**. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of **20 months**; however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more than specified.

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4.2 Conditions of Non recruitment: In the event of zero patients screened and/or enrolled within 03 months of Site Initiation, then Lambda would initiate site closure discussions with the Investigator and Site.

"Eligible Patients" is defined as those who fulfill inclusion and exclusion criteria specified in the Protocol which is verifiable from source documents.

4.3 In the event that the study is part of a multi-center trial, Sponsor may amend the number of Eligible Patients to be recruited as follows:

a) if in the reasonable opinion of LAMBDA or Sponsor recruitment of Eligible Patients is proceeding at a rate below that required for the relevant timelines to be met, LAMBDA may by notice to the Investigator or the Institution require recruitment at the Site to cease and the terms of this Agreement shall relate to the number of patients that have been accepted for entry into the Study at the date of such notice; or

b) If recruitment of Eligible Patients is proceeding at a rate above that required meeting the relevant timelines, LAMBDA may, with the agreement of the Investigator or the Institution increase the number of patient to be recruited.

4.4 The Investigator or the Institution shall use all reasonable endeavors to comply with the time frames as agreed with LAMBDA.

4.5 The Investigator/ designee shall enter the visit data into the eCRF within 3 working days after completion of each subject visit.

4.6 The investigator/designee will resolve all data queries within 2 working days from the query generation.

4.7 The Investigator/ designee will address all the follow up/action items generated during site visits and resolve them within the specified timelines.

4.8 The Investigator shall participate in teleconference and meeting as required by LAMBDA or Sponsor to update the Compound information and to resolve issues, if any.

4.9 The Investigator shall strictly adhere to the SAE reporting timelines in accordance with requirement of Site SOPs, Ethics Committee SOPs, Indian GCP, ICH GCP, New Drugs and Clinical Trials Rules, 2019 and standard operating procedure ("SOP") of LAMBDA, whichever is most stringent.

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4.10 In the event of change in the Principal Investigator after site initiation and before site closeout, the outgoing Principal Investigator and the Institute will ensure the following are facilitated up to 15 working days from the appointment of new PI;

4.10.1 Notification to Lambda / Sponsor
4.10.2 Notification to Ethics Committee and approval from Ethics Committee of the incoming Principal Investigator for the referenced study

4.10.3 Provide Lambda with the following documents:-
- 4.10.3.1 CDA signed by the incoming PI
- 4.10.3.2 Signed and dated and updated CV/MRC of the incoming PI
- 4.10.3.3 Protocol Investigator Signature Page signed by the incoming PI
- 4.10.3.4 Investigators' Undertaking by the incoming PI
- 4.10.3.5 Form 1572 & Form 3455 signed by the incoming PI, where applicable
- 4.10.3.6 Signed/ dated training log containing the Training on the Study Protocol of the incoming PI by the outgoing PI
- 4.10.3.7 Once the training is complete, Updated Delegation log with addition of the incoming PI
- 4.10.3.8 Signed and dated Clinical Trial Agreement with incoming PI
- 4.10.3.9 Any other documents, as requested

5. Payment

5.1 In consideration of providing the service under this Agreement, LAMBDA / Sponsor agrees to pay in accordance with the provisions of this Agreement and the Payment Agreement as set out in Schedule B.

6. Period of the Agreement

6.1 This Agreement shall be effective as of the date executed by all the parties and shall continue in effect until the site is closed upon conclusion of the Clinical Trial and Clinical Trial Report are completed unless otherwise extended, renewed, or amended by mutual written consent or unless terminated earlier in accordance with Section 14 of this Agreement. The terms of this Agreement shall not be longer than twenty five (25) years from the date of commencement, [As per Article 58 of the Regulation new EMA Requirement: 25 years "unless other Union law requires archiving for a longer period, the sponsor and the investigator shall archive the content of the clinical TMF for at least 25 years after the end of the clinical trial.]

6.2 However following matters shall survive even after expiry/termination of the agreement:
- a) Archival of study documents including source data as referred to in para 2.8 "J" and 15

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b) Reasonable access by monitors, auditors and regulatory authority to original study documents and source data and providing appropriate working conditions for monitors, auditors and regulatory authority to perform study-related monitoring, audit and inspection;
c) Confidentiality obligations as per para 11

6.3 In case of early termination of trial at site, due to any clause, data and documents are to be archived at Site (PI's /Institution /third party). This shall be discussed during the execution of CTA and should be clearly documented in the CTA. The said data must be archived for at least twenty five (**25**) years or for the period required by applicable regulatory authority following termination or conclusion of the study at the Site or such other facilities as agreed between Sponsor and the Investigator. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements. In case of early close out/termination the validity of the agreement would remain for 5 years.

7. Data ownership / Intellectual property rights

7.1 LAMBDA, the Institution and the Investigator undertake to be bound by applicable privacy laws and regulations in relation to preservation, handling and the protection of personal data in the course of conduct of the trial and thereafter.

7.2 The Investigator undertakes to transfer all data, particulars, records, findings and reports concerning the Clinical Trial to Sponsor, LAMBDA, Ethics Committee, and the regulatory authority. In the event of any audit/inspection conducted by LAMBDA, the Sponsor, Ethics Committee and regulatory authority, the Investigator and/or Institute shall assists and facilitates such audit and will provide all information including information related to patient identification.

7.3 All data, results, findings, analysis, derived from the Study, all research, developments, creations, inventions or discoveries in all form whether tangible or intangible and howsoever recorded or memorized made in the course of result of the Clinical Trial will be the exclusive property of Sponsor only. Any disclosure, dissemination, transfer or providing an access thereto to LAMBDA, Ethics Committee, or regulatory authority shall not vest any right, title, interest of whatsoever nature and same shall belong and vest on Sponsor only for all purposes. LAMBDA, Ethics committee, Investigator and Institution shall do all acts, things and deeds as may be required to vest into or perfect the title thereto in favor of Sponsor.

7.4 The intellectual property rights whether owned or licensed to the Investigator / Institute prior to and after the date of this Agreement, other than intellectual property rights

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arising from the Clinical Trial is and shall remain the property of the Investigator / Institution.

7.5 For the sake of brevity, the intellectual property rights in all forms whether owned possessed or licensed to Sponsor prior to and after the date of this Agreement, including intellectual property rights arising from the Clinical Trial is and shall remain the property of Sponsor.

7.6 All intellectual property rights in the data and results derived from the Clinical Trial shall be the property of Sponsor and shall automatically stand assigned to Sponsor.

7.7 The Investigator/Institute is obliged to report any inventions or discoveries promptly to Sponsor and/or LAMBDA.

7.8 Investigator and Institute agree that Sponsor may utilize the data at its own discretion in compliance with the applicable data protection rules, including but not be limited to, submission to government regulatory authorities.

7.9 The Investigator and the Institution shall assist Sponsor in making any application for patent and shall execute, complete, deliver and perform any and all instruments necessary to make and obtain such registrations of patent in favor of Sponsor.

7.10 It would be the primary responsibility of the institution to maintain custody of study records and all other applicable study items in purview of the study protocol and this agreement, irrespective of the PI presence in the institution. Institution will allow regulatory authorities, sponsor and CRO to perform inspections of study data. In case the PI has to leave the institution, the PI should handover charge of the study to any other designee in form of document and forward all future communications received to institute pertaining to trial. PI is responsible to update CRO and / or sponsor for this change and all applicable communications, henceforth. Designee will execute all PI responsibilities, henceforth. In case of change in institution management, the institute will inform CRO and / or sponsor

8. Publication

8.1 Study results are Sponsor's property and shall have all rights including Copyright thereto and no publication in any form can be made by Lambda, Institute and Investigator without the written approval of the sponsor.

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9. Indemnity / Liability

9.1 In no event, shall LAMBDA, Sponsor, Investigator or Institution/Site be liable for any indirect, incidental, special, or consequential damages or lost profits arising under or as a result of this agreement (or the termination hereof).

9.2 In the event of a material error by Investigator/Institute in the performance of the Services, which renders the Services invalid or incomplete or not in conformity with agreed Protocol, Investigator/Institute agree to repeat and redo the functions, operations and Services contemplated under this Agreement at no additional expense to LAMBDA. If Lambda requests or Investigator/ Institute should reimburse the payment already made by Lambda. Lambda has the right to terminate the services of Investigator due to any breach of this agreement.

9.3 LAMBDA (on behalf of Sponsor) will indemnify the Investigator and/or Institution from any claims due to acts of omission or breach by Sponsor.

9.4 LAMBDA (on behalf of Sponsor) will indemnify liability arising from design or manufacture of the Compound, sale and use of the Compound following the Clinical Trial and injury to study subject directly attributable to Compound, which is jointly identified by a medical monitor/ Sponsor's medical expert and the Investigator.

9.5 The Investigator and/or the Institution will indemnify LAMBDA and Sponsor from any claims due to acts of negligence, omission or wrong by the Investigator or Institution.

9.6 The Investigator and/or the Institution are responsible and liable for conduct of the Clinical Trial at the Institution according to the Protocol and the Agreement.

9.7 Each party will notify other parties of any claim related to the Clinical Trial.

9.8 Sponsor (on behalf of LAMBDA) will cover medical expenses for the treatment of any SAE as identified by the Investigator, as long as required as per the opinion of investigator or till such time it is established that the injury is not related to, whichever is earlier, which arise from using the Compound and study procedures in accordance with the Protocol, to the extent not covered by any other insurance by patient and provided the patient did nothing to cause or contribute to the injury.

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10. Compensation / Insurance

10.1 Sponsor, LAMBDA and Investigator and / or the Institution shall maintain their respective insurance coverage for the Study / clinical trial in accordance with New Drugs and Clinical Trials Rules, 2019 and other applicable local laws.

11. Confidentiality

11.1 For a period of 25 years from the effective date of this Agreement, Recipient shall not disclose the Discloser's Confidential Information to any third party. Recipient shall use the Confidential Information solely for purpose of the terms of the agreement, unless otherwise mutually agreed in writing. Upon request, Recipient shall return or destroy, at the Discloser's option, all Confidential Information, including any copies and extracts thereof, will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.2 Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this article shall remain in force for a period of 5 years from the date of execution of this Agreement but shall, thereafter, cease to apply provided that the expiry of such period shall not entitle Investigator or Institution to sell or otherwise dispose of, or otherwise turn to use for its own or another's advantage, any confidential information received during the conduct of projects covered by this Agreement.

11.3 The Investigator may only to the extent is, as far as necessary for the performance of its obligations under this Agreement, but not further or otherwise, disclose confidential information to study staff or to any relevant committee, that need to know the same to undertake and/or participate in this study. Investigator shall ensure that all persons shall be made aware of the relevant terms and conditions of this Agreement and shall agree to be bound by them.

11.4 The Investigator/institution shall not disclose or use any confidential information, which is provided by Sponsor or LAMBDA or generated by Investigator as a result of the Study, for any purpose other than the conduct of the Clinical Trial as outlined in the Protocol and this Agreement.

11.5 Confidential information shall remain the confidential and proprietary property of Sponsor, and shall only be disclosed to those who have a need to know the same. Where it is necessary to disclose any confidential information to any third party for the

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performance of this Agreement, a confidentiality agreement with the same terms and conditions as this Agreement shall be entered into with such third party.

11.6 Each party will keep an updated list of all individuals who have received the other parties' confidential information, together with their contact information and job title, and will provide the list if it is legally requested. All confidential information must be identified as confidential at the time of disclosure, preferably provided in writing. If the disclosure is verbally, visually, or otherwise (e.g. an X-ray, a visit to a site or lab), then the information must be summarized in writing within thirty (30) days after the disclosure and provided to the receiving party.

11.7 Confidential information shall not include any information which:

a) is already in the public domain at the time of disclosure

b) becomes part of the public domain after receipt of the information through no fault of the Institution or the Investigator

c) was previously known to the Institution or the Investigator as evidenced by written documents

d) Is disclosed to the Institution/Investigator by a third party who has the right to disclose and who is not under a direct or indirect obligation of confidentiality to Sponsor.

e) Has been permitted to be disclosed by Sponsor.

11.8 All Confidential Information disclosed to a party under this Agreement will remain the property of the disclosing party (or the Sponsor, if such information was disclosed through LAMBDA) and may be re-called and withdrawn by the disclosing party at any time. Upon receipt of a written request from the disclosing party for return or destroy of such Confidential Information, the receiving party will immediately cease using such Confidential Information and shall deliver to the disclosing party all such Confidential Information including all copies, reproduction, facsimiles and any other tangible records of such information.

11.9 Any previous Confidentiality Agreement between Sponsor and/or LAMBDA and the Investigator or the Institution shall be superseded by the confidentiality obligations in this Agreement.

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12. Privacy

12.1 Sponsor, LAMBDA, the Investigator and the Institution will adhere to applicable privacy laws, regulations, and other standards.

12.2 The Investigator and Institute/Institution consents to LAMBDA and Sponsor and its affiliates collecting and/or otherwise processing personal data provided by or relating to the Investigator for purposes of any necessary sharing with regulatory authorities and for any use by Sponsor and its affiliates and their agents.

12.3 The Investigator and Institute consents to Sponsor or LAMBDA transferring such personal data to Sponsor's facilities, Sponsor's affiliated companies, regulatory authorities, and third party vendors that may be utilized in other countries. For such purposes, the Investigator and Institute acknowledge that such other countries may not provide the same level of data protection as the laws in India.

12.4 The Investigator and Institution will inform each study subject of the potential for disclosure of their personal or health information to Sponsor, Sponsor's affiliated companies, LAMBDA, the Ethics Committee, and the regulatory authorities and the measures being taken to ensure their privacy.

13. Independent Contractor

13.1 Investigator is an independent contractor engaged by LAMBDA to perform the Services in accordance with the provisions of this Agreement, and the relationship hereby created is specifically governed by, limited to, and subject to all of the terms and conditions contained in this Agreement. The parties further agree that LAMBDA does not have the authority to hire or fire employees of the Investigator / Institution, nor does LAMBDA determine the rate or method of pay of such employees. Additionally, nothing contained in this Agreement shall entitle Investigator/Institute to the right or authority to make any representation on behalf of LAMBDA or the Sponsor, bind LAMBDA or Sponsor to others in any manner, or use LAMBDA's / Sponsor's name or trademarks in any public disclosure, without LAMBDA's / Sponsor's prior written permission.

14. Termination

LAMBDA on behalf of Sponsor retains the right to terminate this Agreement on Institution or Investigator's involvement in the Study for any reason with or without cause including but not limited to the following;

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a) Investigator or Institution fails to recruit desired patients within 60 days of site initiation visit.
b) The incidence and/or severity of adverse drug reactions in this or other studies with the Compound which in the opinion of Sponsor or Lambda indicate a potential health issue or hazard.
c) Adherence to the Protocol is poor and/or data recording is inaccurate or incomplete.
d) LAMBDA, the Principal Investigator and/or the Institution mutually agree to terminate this Agreement.
e) The total number of patients required to be randomised is reached before the end of the recruitment period.
f) The Sponsor of the Study mandates the termination of the Study for any reason, with or without cause.
g) The appropriate Regulatory Agency mandates the termination of the Study.

In case of termination of the agreement without any fault on the part of Investigator or Institution, except in the event of non-recruitment of patients by the Institution or Principal Investigator, LAMBDA shall reimburse the Institution or Principal Investigator on a pro rata basis of the number of visits completed by patients. Should the Institution or the Principal Investigator have already received payments in excess of the actual pro rated amounts due then that overpayment will be promptly remitted to LAMBDA by the Institution or Principal Investigator. Payments should be payable to LAMBDA. On termination / completion of trial or expiration of this Agreement all unused Investigational Product shall, either be returned to the Lambda Pharmacy / Sponsor or disposed of in accordance with the Protocol or the Sponsor's written Instructions.

14.1 Consequences of Completion or Early Termination of the Trial:

a) Upon completion of the Clinical Trial (whether prematurely or otherwise) the Principal Investigator and Sponsor shall co-operate in producing a report of the Clinical Trial detailing the methodology, results and containing an analysis of the data generated at site and drawing appropriate conclusions.

b) The Investigator/ Institute shall permit authorized representatives of the Ethics Committee and Competent Authorities to have access to, copy and verify information relating to the Clinical Trial, as required by and in accordance with applicable Law. Furthermore Sponsor and/or CRO acknowledges and agrees that the Institution executive management (or a local review board appointed by such management) will have the right to audit the performance of the Clinical Trial at the Trial Site. Institution acknowledges that the Clinical Trial is subject to

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inspection by regulatory authorities worldwide and that such inspections may occur after the completion of the Clinical Trial. In case at the time of inspection if the Investigator/appointed study staff is unavailable, the Institute will appoint reasonably qualified personnel to manage the inspection.

c) On completion, termination of the Trial, following termination or expiration of this Agreement Investigator/ Institution shall immediately deliver to the LAMBDA/Sponsor all Confidential Information, except for copies to be retained in order to comply with Institution's archiving obligations or for evidential purposes. Furthermore the Site Parties shall immediately return and deliver to the Sponsor any equipment provided to them for the conduct of the trial at the site.

- Below listed equipment will be provided by LAMBDA/Sponsor to Principal Investigator/Institute at the time of SIV if required to effectively conduct of the study at site & same will be returned by Principal Investigator/Institute to LAMBDA on the day of Close out Visit.

1. Deep freezer (-80^{0}C)
2. Normal Centrifuge
3. Data logger
4. Thermohygrometer
5. Infusion pump
6. Digital clock
7. Refrigerator

d) Upon notice of termination of trial or this Agreement, Investigator/Institution will not recruit and/or enroll additional Clinical Trial subjects, and will cooperate with the Sponsor in the orderly discontinuation of the Clinical Trial, including, without limitation, discontinuing Investigational Product as soon as medically appropriate, allowing Sponsor and/or CRO access to records and facilities as required for Clinical Trial close-out procedures at mutually agreed times, and requiring Principal Investigator to complete any actions required in compliance to ICH GCP and Local regulations by the role Principal Investigator.

e) In all circumstances causing the early termination of trial and, LAMBDA shall confer with the Principal Investigator/ Institution and use their best endeavors to minimize any inconvenience or harm to Clinical Trial Subjects caused by the premature termination of the Clinical Trial. Parties (LAMBDA, Investigator and Institution) agree that in case of early termination of this Agreement, they will in good faith make arrangements concerning the continuation of the treatment of the enrolled patients if such is in their medical best interest. Furthermore the

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Investigator and Institution shall ensure that the rights, safety and well-being of the trial subjects are protected in all circumstances.

14.2 Termination of Trial/ Trial Agreement by Investigator or Institution:

a) The Institution and/or the Principal Investigator shall notify the Sponsor and/or CRO if the Principal Investigator ceases to be associated with the Institution where the Clinical Trial will be conducted or if he/she is otherwise unavailable to continue as Principal Investigator, and Institution and/or Principal Investigator shall use all reasonable endeavors to find a qualified successor acceptable to the LAMBDA, subject to the Principal Investigator's overriding obligations in relation to Clinical Trial Subjects and individual patient care. In the event Principal Investigator is for whatever reason unable or unwilling to appoint a successor personally, the Institution will have the right to recommend a suitable successor and the Institution will make all possible efforts to appoint the successor/ PI to conduct the study.

b) In case if the Institution is unable to carry out the ongoing trial for any reasons the Institution will make all the necessary arrangement to ensure that the enrolled trial patient can receive the best medical care, In case if the patients still want to continue in the study, they can be referred to the other Institution/ Investigator. In all such cases Institute/investigator will be responsible for the safety follow up and further medical care of the patients for the period as appropriate as per the study drug and the nature of the study. In case if the trial subject do not wish to continue with the trial at referred site and the site has to be closed data retention, patient safety and maintenance of study data for the required period as required by the applicable regulatory authority would be the responsibility of the Institution.

15. Record retention

15.1 The Investigator and/or the Institution shall provide Sponsor through LAMBDA any and all records and data in relation to the Clinical Trial in time and in full according to requirements of ICH GCP, Drugs and Clinical Trials Rules, 2019 and the Declaration of Helsinki, and all applicable guideline, laws and regulations.

15.2 The Investigator and/or the Institution, LAMBDA/CRO and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records. The Investigator and /or the Institution shall inform Sponsor in the event of relocation of trial site.

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15.3 The Investigator Site File containing the essential documents, case report forms, informed consent forms and any other source data/document (like patient medical records) must be archived for at least twenty five (25) years following completion of the study at third party location recommended by sponsor. Sponsor shall also keep all clinical trial data and documents according to the relevant regulatory requirements.

15.4 In the event that Sponsor removes the Clinical Trial records, Institution and/or Investigator may nevertheless retain a copy of Clinical Trial records (1) as required by law, regulation, regulatory guidelines or ICH GCP and (2) in order to ascertain and fulfill their obligations of confidentiality under this Agreement.

15.5 In the event that the Investigator/Institute is to destroy the Site Investigator File or source data, the Investigator/Institute should inform LAMBDA prior to destruction to confirm it is acceptable for them to be destroyed.

16. Representation and Warranty

16.1 The Investigator and Institution represent and warrant that they have and will keep throughout the Clinical Trial study all such qualifications, approvals, permits, licenses and conditions as necessary for performance of the Clinical Trial hereunder as required by laws and regulations of India.

17. Laws and Jurisdiction

17.1 This Agreement shall be governed by and interpreted in accordance with the laws of India and the parties submit to exclusive jurisdiction of the courts at Lucknow.

18. Notice

18.1 All notices shall be delivered to the following addresses:

CRO	:	Lambda Therapeutic Research Ltd
Address	:	Plot No. 38, Survey no 388, Near Silver Oak Club, S.G. Highway, Gota, Ahmedabad 382481, Gujarat, India.
Telephone	:	+91-79 4020 2020
Fax	:	+91-79 4020 2021
Contact Person	:	**Mr. Naresh Khemani**
Email	:	nareshkhemani@lambda-cro.com

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Institution	:	**Sanjay Gandhi Post Graduate Institute of Medical Sciences,**
Address	:	New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
Contact Person	:	Prof RK Dhiman, Director SGPGI
Telephone	:	0522-2494001
Email	:	director@sgpgi.ac.in

Investigator	:	**Dr. Amita Aggarwal**
Address	:	Department of Clinical Immunology and Rheumatology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
Telephone	:	aa.amita@gmail.com
Email	:	8004904387

Institute/Investigator Finance /Accountant Name	:	**Dr. Amita Aggarwal**
Address	:	Department of Clinical Immunology and Rheumatology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
Telephone	:	aa.amita@gmail.com
Email	:	8004904387

18.2 Either party should inform the other party of any change of the said addresses in writing within forty-eight (48) hours of the change.

18.3 Any notice shall be deemed to be given: a) If sent by courier - on the day when the recipient signs for the notice; b) If sent by registered letter - at 9:00 am on the five (5) working day of dispatch; or c) If sent by telefacsimile - at 9:00 am on the second day of delivery.

18.4 Any notice one party delivered to other parties, which concerns important issues such as claims or amendments under this Agreement should be signed by the legal representative or the authorized representative of the delivering party.

19. Miscellaneous

19.1 Any unsettled issues of this Agreement shall be negotiated and agreed upon in separate supplementary agreement signed by all parties. The supplementary agreement and Schedules of this Agreement which form an integral part of this Agreement and have the same legal effect as this Agreement.

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19.2 No party shall assign to any third party its rights and obligations hereunder without the prior written consent of the other parties except when Sponsor takes over some of the activities from Lambda. The Investigator and the Institution acknowledge that Lambda is acting as the agent of the Sponsor and hence in such case Sponsor will get into the shoes of Lambda for all rights and obligations contemplated under this agreement as between Lambda on one side and Investigator and the Institution on the other side.

19.3 This Agreement constitutes the entire agreement among the parties and supersedes all previous negotiations, discussions, understandings or agreements among the parties whether written oral.

19.4 No amendment or modification to this Agreement shall be effective unless made in writing and signed by all the parties or their duly authorized representatives.

19.5 All infrastructures provided by Lambda on behalf of Sponsor for the conduct of this clinical trial to the Institute/Investigator will be retrieved from the Institute/Investigator upon completion or termination of the trial.

19.6 An inflationary price review can be addressed at a minimum of five years (60 consecutive months) from the date of Clinical Trial contract signature. The rate of inflation to be applied will be agreed by the Sponsor and the Institute at the time of the inflationary review and will be applied to all remaining Clinical Trial costs, excluding previously invoiced costs, for the duration of the Clinical Trial. The agreed inflation rate applied and resultant cost changes will be documented in a Clinical Trial Agreement amendment which all Parties of the original Clinical Trial Agreement will sign and subsequent invoices will reflect the agreed change(s).

19.7 If SMO is involved in any study related activities, PI / Institution needs to provide the copy of valid and binding /Agreement specifying the role and responsibilities and indemnity etc. of each party to CRO prior to the execution of CTA. The agreement provided should have the clarity on the responsibilities of Investigator /Institute and SMO.

20. Data Protection Laws and Guidance

The Parties agree to comply with all Data Protection Laws and Guidance in Processing the Personal Data of Clinical Trial Subjects. AND when the Parties are acting as independent Controllers, to promptly and without undue delay, notify and inform the other Parties in the event of any Personal Data Breach that relates to Personal Data Processed for the purpose of the Clinical Trial

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20.1 Protection of Personal Data

A. In the performance of the Services under this Agreement, all parties shall comply with all applicable laws and regulations, relating to data privacy, including but not limited to, Directive 95/46/EC and when applicable, Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data.

B. "Personal Data" means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

C. Parties shall collect, use and disclose any Personal Data obtained in the course of performing this Agreement solely for the purposes of complying with the regulatory obligations. Parties shall use electronic, physical, and other safeguards appropriate to the nature of the information to prevent any use or disclosure of Personal Data other than as provided for by this Agreement. The Parties shall also take reasonable precautions to protect the Personal Data from alteration or destruction.

D. Processer shall notify Lambda within twenty four (24) hours of any accidental, unauthorized, or unlawful destruction, loss, alteration, or disclosure of, or access to, the Personal Data ("Security Breach"), and take immediate steps to rectify any Security Breach.

E. Processer shall indemnify Client for the loss, damages, compensations reasonable attorney fees, court costs resulting or arising from any third party claims due to failure to comply with applicable law or regulation by Service Provider.

20.2 Processing of Clinical Trial Subject Personal Data

A. For the purpose of the Data Protection Laws and Guidance, the Sponsor/CRO is the Controller and the Investigator & Institute are Processors of Personal Data Processed for the purpose of the Clinical Trial.

B. The Investigator/Institute's Processing of Personal Data, as a Processor of the Sponsor/CRO, shall be governed by this Agreement, including the Protocol, which sets out the subject matter, duration, nature and purpose of the Processing, the type of Personal Data and the categories of Data Subjects, and obligations and rights of the Sponsor/CRO as Controller.

C. The Investigator/Institute is the Controller of Personal Data Processed for purposes other than the Clinical Trial, e.g. the provision of medical care.

D. The Investigator/Institute, in its role as Processor of the Personal Data agrees to only Process Personal Data for and on behalf of the Sponsor/CRO in accordance with the documented instructions of the Sponsor/CRO, including with regard to transfers of personal data to a third country or an international organisation. If the

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Investigator/Institute is required by law to otherwise Process the Personal Data, the Investigator/Institute shall notify the Sponsor/CRO before undertaking the Processing, or as soon as possible thereafter, unless such notification is prohibited on important grounds of public interest in accordance with GDPR

E. The Investigator/Institute agrees to comply with the obligations applicable to Processors as per the GDPR, as well as those additional obligations required by the Sponsor/CRO pursuant to this Agreement, including but not limited to the following:

i. implementing and maintaining appropriate technical and organisational security measures for Personal Data Processed in its systems,

ii. ensuring that Personnel authorised to Process Personal Data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality

iii. taking all measures required by GDPR in relation to the security of Processing

iv. subject to complying with the conditions described in GDPR for engaging another Processor

v. taking into account the nature of the Processing, assist the Sponsor/CRO, by appropriate technical and organisational measures, insofar as this is possible, to respond to requests for exercising Data Subjects' rights

vi. assisting the Controller, to ensure compliance with the obligations pursuant to GDPR taking into account the nature of the Processing and the information available to the Investigator/Institute

vii. maintaining a record to demonstrate compliance with this Clause and Data Protection Laws and Guidance, including the records required pursuant to GDPR

viii. in the event of any Personal Data Breach by the Investigator/Institute as a Processor of the Sponsor/CRO, the Investigator/Institute shall: (i) promptly and without undue delay following discovery of such Personal Data Breach, send written notice of the incident via e-mail to [CRO Mail ID]; (ii) not make any statements or notifications about the Personal Data Breach, as it relates to the Processing for the purpose of the Clinical Trial, to any individual affected by the incident, the public or any third party without (Sponsor/CRO's) prior written approval; and (iii) immediately take steps to investigate and mitigate the Personal Data Breach and reasonably cooperate with the Sponsor/CRO

ix. Personal data must be deleted or returned to the data controller after processing services have been completed

x. All information needed to demonstrate the data processor's compliance with these requirements must be made available to the data controller

F. The data processor must permit and contribute to audits conducted by the data controller

G. In furtherance of its obligations, the Investigator/Institute agrees that it will not engage another Processor for the purpose of the Clinical Trial without prior written authorisation from or on behalf of the Sponsor/CRO,

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H. At the expiry or lapse of this Agreement, the Investigator/Institute shall, return all Personal Data to the Sponsor/CRO unless there is a legal requirement for retention and storage and/or where that Personal Data is held by the Investigator/Institute as Controller for its own purpose(s).

I. The Investigator/Institute will:

i. ensure that its Personnel and the Principal Investigator, do not Process Personal Data except in accordance with the Protocol and this Agreement;

ii. take all reasonable steps to ensure the reliability and integrity of the Principal Investigator and any of its Personnel who have access to the Personal Data and will ensure that the Principal Investigator and the Personnel:

iii. are aware and comply with the Investigator/Institute's duties under this Clause (Data Protection);

iv. are subject to mandatory training in their information governance responsibilities and have appropriate contracts, including sanctions, including for breach of confidence or misuse of Personal Data; and

v. are informed of the confidential nature of the Personal Data and understand their responsibilities for information governance, including their obligation to Process Personal Data securely and to only disseminate or disclose it for lawful and appropriate purposes.

J. The Investigator/Institute agrees to Provide the Sponsor/CRO with evidence of its compliance with the obligations set out in this Agreement, and at the Sponsor/CRO discretion and on reasonable notice, to allow the Sponsor/CRO or a third party appointed by the Sponsor/CRO, to audit the Investigator/Institute's compliance with the obligations described in this Agreement, complying with all relevant health and safety and security policies of the Investigator/Institute.

K. The Investigator/Institute, acting as the Sponsor's Processor, Processes Personal Data outside of the European Economic Area, the Investigator/Institute warrants that it does so in compliance with the Data Protection Legislation and Guidance.

20.3 Sharing of Personal Data and/or Clinical Trial Subject Pseudonymised Data

A. The Investigator/Institute agree not to pass & disclose Personal Data or Pseudonymised Data of Clinical Trial Subjects provided under this Agreement to any person except its required or permitted by law or applicable guidance, or to any third party unless that third party is bound by contractual obligations at least as stringent as in this clause.

B. The Investigator/Institute agree to ensure persons Processing Personal Data and/or Pseudonymised Data of Clinical Trial Subjects under this Agreement are equipped to do so respectfully and safely. In particular:

i. to ensure any such persons (excluding employees, honorary employees, researchers, consultants and sub-contractors of the Institute) who have appropriate contracts providing for personal accountability and sanctions for breach of confidence or misuse of data including deliberate or avoidable Personal Data Breaches &

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understand the responsibilities for information governance, including their obligation to Process Personal Data and/or Pseudonymised Data of Clinical Trial Subjects securely and to only disseminate or disclose for lawful and appropriate purposes;

C. The Investigator/Institute agree to proactively prevent Personal Data Breaches, and equivalent breaches relating to Pseudonymised Data of Clinical Trial Subjects, and to respond appropriately to incidents or near misses. In particular:

i. to ensure that Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are only accessible to persons who need it for the purposes of the Clinical Trial and to remove access as soon as reasonably possible once it is no longer needed;

ii. to ensure all access to Personal Data and/or Pseudonymised Data of Clinical Trial Subjects on IT systems Processed for Clinical Trial purposes can be attributed to individuals;

iii. to review processes to identify and improve processes which have caused Personal Data Breaches or near misses, or which force persons Processing Personal Data and/or Pseudonymised Data of Clinical Trial Subjects to use workarounds which compromise data security;

iv. to adopt measures to identify and resist cyber-attacks against services and to respond to relevant external security advice;

v. to take action immediately following a Personal Data Breach or near miss.

D. The Investigator/Institute agree to ensure Personal Data and/or Pseudonymised Data of Clinical Trial Subjects are Processed using secure and up-to-date technology.

In particular:

i. to ensure no unsupported operating systems, software or internet browsers are used to support the Processing of Personal Data and/or Pseudonymised Data of Clinical Trial Subjects for the purposes of the Clinical Trial;

ii. to put in place a strategy for protecting relevant IT systems from cyber threats which is based on a proven cyber security framework;

iii. to ensure IT suppliers are held accountable via contracts for protecting Personal Data and/or Pseudonymised Data of Clinical Trial Subjects they Process and for meetings all relevant information governance requirements.IN WITNESS hereof, the parties hereto have caused this Agreement to be executed by their respective duly authorized representatives and the Agreement shall come into effect on the latest date of signature.

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LAMBDA:

Sign: _____ **Date:** 23-Oct-2023

Name: Dr. Tarak Parikh

Designation: VP-CTM

Lambda Therapeutic Research Ltd.

Witness:

Sign: _____ **Date:** 23-OCT-2023

Witness Name : **Mr. Harmil Shah, Deputy General Manager, Finance & Purchase Lambda Therapeutic Research Ltd.**

Sponsor:

Sign: _____ **Date:** 23.10.23.

Name: AKSHAYA NATH SHARMA.

Designation: E-VP

Intas Pharmaceuticals Limited.

WITNESS:

Sign: _____ **Date:** 25.10.23

Witness Name: Hiralal N. Sonawane

Witness Address: Intas Pharmaceuticals LTD Ahmedabad

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Payees for this agreement:

Payee	1st Payee
Role of Payee	Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow.
Name of Payee:	Director SGPGI
Percentage of Total Payment	100%

INSTITUTE:

Sign: _____ 23/11/23 **Date:** 23/11/23

Prof RK Dhiman,
Director,
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Lucknow.

PRINCIPAL INVESTIGATOR:

ACKNOWLEDGMENT: In signing below, I, the Investigator, acknowledge that there is no real or perceived conflict-of-interest in the execution of this clinical trial project (e.g. stock or equity in companies which manufacture products being tested in the clinical trial, or obligations or restrictions which will conflict with the performance of this Agreement). I hereby agree to act in accordance with all the terms and conditions of this Agreement and further agree to ensure that all participants in the clinical trial are informed of their obligations under such terms and conditions.

Sign: _____ **Date:** 27/10/23.

Dr. Amita Aggarwal,
Head of Department of Clinical Immunology and Rheumatology,
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Lucknow.

WITNESS:

Sign: _____ **Date:** 27/10/23.

Witness Name: Dr Anu Balakrishnan
Witness Address: SGPGI, Lucknow

Signatory authority can be but not limited to HOD, Board of directors/designee/Financial head of the institute, as per site SOP.

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Schedule A

Study Protocol

Protocol No: 0121-22

A Prospective, Nonrandomized, Open label, Single Arm, Multicentric, Phase III Clinical Study To Evaluate Efficacy, Pharmacokinetics And Safety of Human Normal Immunoglobulin For Intravenous Administration In Patients With Primary Immunodeficiency Diseases

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Schedule B: Budget and Payment Agreement

A. 21 Days Infusion Schedule

For participants receiving 3-weekly regimen

Phase	Screening	Intervention Period																	EOS/ E/D	Total for Activity
Visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	
Infusion Number		1		2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17		
Day	-21 to -1	1	8	22	43	64	85	106	127	148	169	190	211	232	253	274	295	316	337	358	
Window period (Day)			±1	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±5	
PI Grant	4500	4000	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	4000	55000
Sub I Grant	3500	3000	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	3500	35500
CRC Grant	1500	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1500	15000
QC Cordinator Grant	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	10000
Study Nurse		1000		1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000	1000		17000
Phlebotmist Grant	500	500					500				3000				500					500	5500
Pregnancy test (WOCBP only)	Central Lab	Kit by central		Kit by central	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central	Kit by central	Kit by central	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central	Kit by central lab	Kit by central	Kit by central	Kit by central	Kit by central	Central Lab	0
Hematology	Local lab						Local lab				Local lab				Local lab					Local lab	0
Hospitalisation for series PK as per PI discretion (If required)											14000										14000
Serum Trough Ig level	Local lab	Local lab		Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	0
Direct Coombs Test and Test for hemolysis	Local lab																			Local lab	0
12-lead ECG	560																			560	1120
Chest X-ray (PA view)	990																				990
Day Care Charges		3000		3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000		51000
Patient Travel	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	10500	1500	1500	1500	1500	1500	1500	1500	1500	1500	39000
Institute Overheads (20%)	2710	2900	1400	2200	2200	2200	2300	2200	2200	2200	7400	2200	2200	2200	2300	2200	2200	2200	2200	2412	50024
Bio Chemistry	Central Lab						Central Lab				Central Lab				Central Lab					Central Lab	0
Urinanalysis	Central Lab						Central Lab				Central Lab				Central Lab					Central Lab	0
TFT evaluation	Central Lab																			Central Lab	0
Serial PK sampling for Total Ig											Central Lab										0
Serum IgG subclass (IgG1, IgG2, IgG3, IgG4)	Central Lab	Central Lab									Central Lab									Central Lab	0
IgA, IgM	Central Lab																			Central Lab	0
Serum Free Hemoglobin	Central Lab																			Central Lab	0
Retention Sample		Central Lab																		Central Lab	0
Total for Visit	16260	17400	8400	13200	13200	13200	13800	13200	13200	13200	44400	13200	13200	13200	13800	13200	13200	13200	13200	14472	300132
																				Total grant per patient	300132

Footnotes: EOS: End of Study visit; E/D = Early Discontinuation Visit
1. TTI assessment will include testing for HIV, HBV, HCV, HAV, parvovirus B19, and syphilis.
2. Blood draws for PK assessment (ONLY 20 Adults if Enrolled) will be taken at the following time points after Infusion 9 for subjects on a 21-day schedule: -5 minutes before start of infusion; within 0.5 hour of the start of infusion; immediately at the completion of the infusion; 1 hour after completion of infusion, 1 day ± 2 hours post infusion; 2 days ± 2 hours post infusion; 3 days ± 4 hours post infusion; 5 days ± 4 hours post infusion; 7 days ± 1 day post infusion; 14 days ± 1 day post infusion; 21 days ± 1 day post infusion. Last sample will be collected within 0.5 hour prior to the next scheduled infusion.
3. IgG subclasses (IgG1, IgG2, IgG3, IgG4) will be measured before infusion.
4. Testing of IgA and IgM will be done only in participant who does not have any results available for previous 12 months.
5. Phlebotomist Grant & Patient Travel at Visit 11: The visit 11 charges covers 7 days Trough PK sample blood collection Phlebotomist grant & Patient travel on respective day after dosing 9.
6. Direct Coombs Test & Haemolysis: Haemolysis assessment may be done additionally during study as per the investigator's discretion or for AE management only in case Direct Coombs Test is positive.
7. Hospitalization Cost for series PK sampling: As the patient need to visit to site on Day 1,2,3,5 & 7 after Dosing 9 and to avoid frequent travel to site considering patient health condition the Patient hospitalization can be allowed in this study. But the hospitalization cost will be reimbursed only for the adult patient who will participate in PK arm.

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B. 28 Days Infusion Schedule

For participants receiving 4-weekly regimen																	
Phase	Screening	Intervention Period														EOS/ E/D	Total for Activity
Visit number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
Infusion Number		1		2	3	4	5	6	7	8	9	10	11	12	13		
Day	-21 to -1	1	8	29	57	85	113	141	169	197	225	253	281	309	337	365	
Window period (Day)			±1	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±4	±5	
PI Grant	5000	4500	3500	4000	4000	4000	4000	4000	4000	4000	4000	4000	4000	4000	4000	5000	66000
Sub I Grant	4000	2500	2000	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	4000	42500
CRC Grant	2500	2000	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	2000	26000
QC Cordinator Grant	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	500	8000
Study Nurse		1000		1000	1000	1000	1000	1000	2000	1000	1000	1000	1000	1000	1000		14000
Phlebotmist Grant	500	500				500			3000			500				500	5000
Pregnancy test (WOCBP only)	Central Lab	Kit by central lab		Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Kit by central lab	Central Lab	0
Hematology	Local lab					Local lab			Local lab			Local lab				Local lab	0
Hospitalisation for series PK as per PI discretion (If required)									14000								14000
Serum Trough Ig level	Local lab	Local lab		Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	Local lab	0
Direct Coombs Test and Test for hemolysis[6]	Local lab															Local lab	0
12-lead ECG	560															560	1120
Chest X-ray (PA view)	990																990
Day Care Charges		3000		3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000		39000
Patient Travel	1500	1500	1500	1500	1500	1500	1500	1500	10500	1500	1500	1500	1500	1500	1500	1500	33100
Institute Overheads (20%)	3110	3100	1820	2800	2800	2900	2800	2800	8200	2800	2800	2900	2800	2800	2800	2812	50022
Bio Chemistry	Central Lab					Central Lab			Central Lab			Central Lab				Central Lab	0
Urinanalysis	Central Lab					Central Lab			Central Lab			Central Lab				Central Lab	0
TTI evaluation	Central Lab															Central Lab	0
Serial PK sampling for Total Ig									Central Lab								0
Serum IgG subclass (pre-dose)	Central Lab	Central Lab							Central Lab							Central Lab	0
IgA, IgM	Central Lab															Central Lab	0
Serum Free Hemoglobin	Central Lab															Central Lab	0
Retention Sample		Central Lab														Central Lab	0
Total for Visit	18660	18600	10820	16800	16800	17400	16800	16800	49200	16800	16800	17400	16800	16800	16800	16872	300132
																Total grant per patient	300132

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Footnotes: EOS: End of Study visit; E/D = Early Discontinuation Visit
1. TTI assessment will include testing for HIV, HBV, HCV, HAV, parvovirus B19, and syphilis.
2. Blood draws for PK assessment (ONLY 20 Adults if Enrolled) will be taken at the following time points after Infusion 7 for subjects on a 28-day schedule: -5 minutes before start of infusion; within 0.5 hour of the start of infusion; immediately at the completion of the infusion; 1 hour after completion of infusion, 1 day ± 2 hours post infusion; 2 days ± 2 hours post infusion; 3 days ± 4 hours post infusion; 5 days ± 4 hours post infusion; 7 days ± 1 day post infusion; 14 days ± 1 day post infusion; 21 days ± 1 day post infusion; and 28 days ± 1 day post infusion. Last sample will be collected within 0.5 hour prior to the next scheduled infusion.
3. IgG subclasses (IgG1, IgG2, IgG3, IgG4) will be measured before infusion.
4. Testing of IgA and IgM will be done only in participant who does not have any results available for previous 12 months.
5. Phlebotomist Grant & Patient Travel at Visit 9: The visit 9 charges covers 7 days Trough PK sample blood collection Phlebotomist grant & Patient travel on respective day after dosing 7.
6. Direct Coombs Test & Hemolysis: Hemolysis assessment may be done additionally during study as per the investigator's discretion or for AE management only in case Direct Coombs Test is positive.
7. Hospitalization Cost for series PK sampling: As the patient need to visit to site on Day 1,2,3,5 & 7 after Dosing 9 and to avoid frequent travel to site considering patient health condition the Patient hospitalization can be allowed in this study. But the hospitalization cost will be reimbursed only for the adult patient who will participate in PK arm.

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(I) Payment Schedule

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) LAMBDA will pay a sum
A. **INR. 300132 (Three lakh one hundred thirty-two rupees only)** for every complete and evaluable patient participating in 21 Days Infusion Schedule &
B. **INR. 300132 (Three lakh one hundred thirty-two rupees only)** for every complete and evaluable patient participating in 28 Days Infusion Schedule in accordance with the above payment or budget schedule after 30 days of receipt of original, correct/valid invoice. Whereas the TDS would be deducted on above payment, where applicable.

b) A complete and evaluable patient is defined as follows:
- all procedures must be performed according to the protocol
- a patient who meets the inclusion/exclusion criteria
- all data are documented completely and accurately as per timelines mentioned in agreement sections above

c) All payments will be on a *pro rata* basis as mentioned in budget above. For patients who do not complete the study period (early termination, drop-out, etc), the budget will be evaluated according to the number of visits completed as per protocol. If any investigation is not performed during a visit then an equivalent amount mentioned in the above budget will not be considered for payment. All payments will be made to the site after source data verification and CRFs review for completed visits

d) Invoice will be generated/requested for payment on monthly basis according to the actual work performed. Invoice will be generated / requested according to days completed by patient as specified above.

e) Any other parties designated by you (including Radiology, Local Laboratory & Cardiology, etc) will be managed and paid by you. Site need to provide invoices on the letterhead of payee with payee's PAN & GST only to whom payment to be made

f) The **Ethics Committee fees** are separate from per patient grant as mentioned in budget.

g) Central Laboratory costs will be paid by the CRO/Sponsor.

h) For Screen failure patients, the payment will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG, radiological investigation or in case patient withdrew consent. Payment for patients withdrawn before dosing on Day 1 will be paid for screening visit. Reimbursement for screen failures will be at the amount indicated

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on the screening visit of the schedule-B budget, not to exceed One (1) screen failure(s) paid to four (4) subject(s) randomized. Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits. Whereas the patient travel etc. will be reimbursed for all screen failure patients.

i) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

j) **Patient conveyance** is to be paid on actual basis by CRO/Sponsor as mentioned in the EC approved ICF. Sites to provide original conveyance bills following which payments will be released. Site also needs to maintain a conveyance payout log at the site for the CRA to verify. GST would be applicable extra as per prevailing rate. GST of Investigator Site detail is as follows (copy of the GST shall be attached).

k) This includes payment of meals provided to patient and patient's relative (if applicable) during the study.

l) The last amount payable will be considered as Final Payment. Final Payment will be paid after site close out visit. CRO/Sponsor will release payment in 30 days from the receipt of original and accurate invoice.

m) Payment reconciliation will be made before the final payment to sites

n) Above budget schedule include all the payment toward the clinical trial and no additional payment towards set-up, infrastructure, deep freezer, centrifuge, printer, laptop etc shall be made to SMO, Site or PI.

o) Advance payment i.e. Start-up cost, etc. will not be paid to the Institute, Investigator, SMO.

p) Below listed instruments will be purchased by Principal Investigator/Institute before Site Initiation Visit (SIV), if required. Whereas the cost of instrument & calibration process nearing expiry of the calibration will be reimbursed by LAMBDA on actual bills provided by Principal Investigator/Institute within 30 days receipt of original and correct invoice. The cost, including GST, of these instrument & calibration should not exceed the following.

Instrument Name	Make & Model Details	Instrument Cost	Calibration Cost (Nearing expiry)
Thermo Hygrometer	**Eurolab** (288ATH)/ **Mextech** (IT-202)	800/-	475/-
Data Logger with Cable	**Escort** (MP-OE-D-8-L)	8500/-	425/-
Digital Clock	**Ajanta** (ODC)	850/-	325/-

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Digital Weighing Balance	30.0 -150.0 kg	1500/-	1000/-

For calibration, **prior written approval** to be taken from Lambda before incurring expenses and in absence of prior approval expenses will not be reimbursed by Lambda.
Also, it would be Principal Investigator/Institute responsibility to return all the instruments to Lambda as and when required/informed by Lambda. Instruments will be of Lambda ownership and site will be responsible for any damages. Damages if any will be deducted in Final payment to site.

Method of payment

Lambda on behalf of Sponsor shall pay the relevant cost and fees as set out in this Payment Agreement to following payee through NEFT/RTGS. Details of Payee are:

Payee 1 details :	
Name of Payee:	Director SGPGI
Address of Payee:	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
PAN / TAN Number:	AAAJS3913N
GST Number:	09AAAJS3913N2ZN
Name of Beneficiary Account:	Director SGPGI
Beneficiary's Account Number:	10095237491
Bank Name:	State Bank of India
Bank Address:	SANJAY GANDHI PGIMS, LUCKNOW, RAE BARELI ROAD, LUCKNOW, UP, PIN - 226014
IFSC:	SBIN0007789

Payee 1 (Director SGPGI) hereby confirms to pay all the liabilities including Interest and penalty if any arises to Lambda Therapeutic Research Limited due to non-Issuance of GST "E-Invoices"

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. LAMBDA will deduct the tax at the time of making payments unless a valid Certificate from tax authority is made available. No payments by cheque will be done.

(III) Per Patient Fee, Payment Schedule and Terms

1. As consideration for performance under the terms of this Agreement, the Sponsor will provide financial support for the trial that will be transferred by the LAMBDA on behalf of the Sponsor to the Investigator / Institute at the rate specified above per patient grant, for each Subject completing all Protocol specified treatments.

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The "Per patient grant" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and CRF completion
- time and effort of investigators and other site staff
- study coordinator salary
- electricity expenses for use of equipment for study conduct
- procurement of any study related material
- site set-up and infrastructure
- all diagnostic tests and other investigations (e.g. ECG, X-ray, Slit lamp examination etc)
- housing/hospital stay (if applicable) and meals during housing for patient and patient's relative
- Phlebotomy expenses
- usage of internet while filling of eCRF
- miscellaneous (telephone, fax, courier, etc)
- all overhead or any incidental costs.

Not included are (which are separate and in addition to per patient payment):

- EC submission fee "All Ethics committee Payment will be made as per the Ethics committee SOP. In case, Ethics committee has not added payment details in SOP site need to provide detail of payment raised by Ethics committee throughout the study. Any revision or addition of Ethics committee payment must be approved by CRO/Sponsor"
- AE related medical management
- SAE related medical management and compensation as per DCGI's order

2. In the event that the LAMBDA/Sponsor requests that additional Subjects be enrolled in the Trial, the Trial Cost will be equal to the Per patient grant multiplied by the number of complete and evaluable Subjects.

3. All payments to be made by the Sponsor under this Agreement will be done within 30 days following receipt of the corresponding original and accurate invoice (complete in all respects) from the Investigator to Sponsor through LAMBDA. All such payments will be made by wire transfer/NEFT/RTGS to the Institution/Investigator.

4. As regards tasks that are not specifically itemized in this Agreement, payments will not be made without prior written approval of the activity by LAMBDA/Sponsor. These additional tasks will be submitted to LAMBDA/Sponsor in writing, with estimated completion dates and costs, if any. Any expenses not specified in this Agreement or any changes to the amounts mentioned in this agreement, will be communicated to LAMBDA/Sponsor and are subject to prior written approval by LAMBDA/Sponsor, which, in its turn, must obtain prior written approval from Sponsor.

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5. In the event that a randomized Subject is determined to be ineligible for the Trial, LAMBDA will decide, together with the Sponsor, if required, whether or not to pay to the Institution/Investigator the Per Subject Fee for such Trial Subjects. In the event that a Trial Subject withdraws voluntarily or is withdrawn from the Trial (a) by LAMBDA or (b) by the Investigator for any reason other than the Trial Subject failing to meet eligibility requirements for the Trial, then LAMBDA/Sponsor will pay the Institution/Investigator a prorated amount of the per patient grant through the date of such withdrawal. Further, if, at the completion of the Trial, Sponsor has advanced sums under the terms of this Agreement that exceed the adjusted Trial Cost, the Investigator/Institute will reimburse to Sponsor any amount by which amounts advanced by the Sponsor exceed the adjusted Trial Cost.

6. The CRO/Sponsor may withhold all or part of any amounts in the event of:
   (1) failure of the Investigator/Institute to complete the services according to the Protocol;
   (2) failure to provide LAMBDA with requested documentation within specified timeframe:
   (3) Failure of the Investigator/Institute to comply with the terms of this Agreement.
   (4) Failure of the Investigator/Institute to comply with the applicable regulatory requirements

Schedule C: Rate List

Kindly attached "Rate List (Price List)" of all tests/procedure as would be performed at site per Protocol:

Sr. No.	Tests	Please tick (✔) Applicable for study
1.	Local Laboratory Charges	NA
2.	ECG	✔
3.	CT Scan, MRI & Bone Scan Charges	NA
4.	Hospitalization/Day Care Charges	✔ (Only Hospitalization)
5.	Institutional Overhead	✔
6.	Other if any special Investigation performed at site	NA

Note: Please provide Rate list on Institute/Laboratory/Imaging Centre/Diagnostic Centre Letter Head only with Authorized personal date, signed & stamp

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SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Name of the Acc. HIMANSHU TIWARI
Code UP14090604
Licence No. 116-Ghaziabad
Nyay Khand-2, Indirapuram
Tehsil & District - Ghaziabad
Mob 9971246261

Certificate No.	:	IN-UP09705844078061V
Certificate Issued Date	:	16-May-2023 09:02 PM
Account Reference	:	NEWIMPACC (SV)/ up14090604/ GHAZIABAD SADAR/ UP-GZB
Unique Doc Reference	:	SUBIN-UPUP14090604139444289608 20V
Purchased by	:	HCL TECHNOLOGIES LIMITED
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	AGREEMENT
Consideration Price (Rs.)	:	
First Party	:	HCL TECHNOLOGIES LIMITED
Second Party	:	AS PER AGREEMENT WITH HCL TECHNOLOGIES LIMITED
Stamp Duty Paid By	:	HCL TECHNOLOGIES LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please verify at egrashi.com

This Stamp Paper forms part of the Agreement For Agreement for Exchange of Confidential Information dated 1st August 2023 executed between M/s HCL Technologies Limited. and M/s Dr. Amit Keshri.

CONTRACT :: CW2342663 LEGAL SPOC ::AMITA JANAKRAJ SHARMA-51738357

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(11)

AGREEMENT FOR EXCHANGE OF CONFIDENTIAL INFORMATION

This Agreement for Exchange of Confidential Information (the "Agreement") is entered into as of 1st August 2023 (the "Effective Date") by and between HCL Technologies Limited, (HCLTech) a company incorporated under the laws of India with Registration No. 55-46369 having its registered office at 806, Siddharth, 96, Nehru Place, New Delhi, 110019, India and Dr. Amit Keshri, Additional Professor and the Head of the Department of Neurotology at SGPGI, Lucknow ("Vendor").

Hereinafter, referred to individually as a "Party" and collectively as the "Parties".

1. Term: This Agreement shall have a term of two (2) year from the Effective Date. Either Party may request for an extension of the Term by giving a renewal notice to the other Party. The Parties may agree to extend the Term of Agreement by an instrument in writing.

2. Purpose: The Parties intend to share Confidential Information related to the HCLTech Suno CI Program ("Purpose").

3. Discloser & Recipient: Either Party, including its Affiliates, may disclose Confidential Information under this Agreement for the Purpose and shall be referred to as "Discloser" hereunder. The other Party, including its Affiliates, receiving Confidential Information hereunder shall be referred to as "Recipient". For the purpose of this Agreement, "Affiliates" shall mean any legal entity which, is directly or indirectly controlling, controlled by or under the common control of the Party.

4. Confidential Information: The information disclosed by Discloser to Recipient hereunder relating to Discloser's business, including, without limitation, computer programs, technical drawings, algorithms, know-how, processes, designs, reports, specifications, device specifications, ideas, trade secrets, inventions, schematics, pricing information, and other technical, business, financial, customer and product development plans, strategies or any other information which is reasonably understood to be confidential or proprietary based on the circumstances of disclosure or the nature of the information itself, such information is hereinafter referred to as "Confidential Information" of the Discloser.

Information which is orally or visually disclosed, or is disclosed in writing without being marked as confidential, shall constitute Confidential Information, if Discloser within seven (7) days after such disclosure, delivers to Recipient, a written document(s) describing such information and referencing the place and date of such oral or visual disclosure and the names of the employees or officers of the Recipient to whom such disclosure was made.

Confidential Information shall not include any information that is **a)** lawfully known by the Recipient at the time of disclosure without any obligation to keep the same confidential; **b)** or becomes, through no fault of the Recipient, known or available to the public; **c)** independently developed by the Recipient without use or reference to such Confidential Information; or **d)** rightfully disclosed to Recipient by a third party without any restrictions on disclosure.

5. Confidentiality Obligation: Discloser shall observe the duty of reasonable care while disclosing any Confidential Information to the Recipient. Recipient agrees that it shall **a)** not use any such Confidential Information except for the Purpose of this Agreement; **b)** hold the Confidential Information in confidence and shall take all reasonable precautions to protect such Confidential Information from unauthorized disclosure including all precautions that Recipient employs to protect its own confidential material; **c)** not divulge any such Confidential Information to any third party without prior approval of Discloser; and **d)** not copy or reverse engineer any such Confidential Information. Recipient may permit access to Confidential Information to its employees, consultants, vendors and agents, on a need to know basis and to the extent required to meet the Purpose, and shall ensure that they are bound to maintain confidentiality of such Confidential Information to the same extent as provided under this Agreement.

6. Survival, Exception & Return: Confidentiality obligations under this Agreement shall survive for a period of ten (10) years following the expiry of this Agreement, provided that the obligations shall be perpetual with regard to any source code or trade secret that may be disclosed hereunder.

Recipient may make disclosures to the extent required by law or by order of any court or regulatory body, provided the Recipient promptly notifies the Discloser in writing about such requirement to disclose.

Recipient will return to Discloser, upon request, any Confidential Information under its possession or control and/or destroy all documents or media containing any such Confidential Information provided that Recipient may retain a copy of Confidential Information to the extent necessary to meet any statutory requirements.

7. Disclaimer: Parties acknowledges that providing or receiving Confidential Information under this Agreement shall not constitute an offer, acceptance, or promise to enter into or amend any other contract.

To the extent permitted by law, Confidential Information is disclosed on "as is" basis, without any express or implied warranties and in particular, without any limitation, as to fitness for the intended Purpose.

8. The ownership of all intellectual property rights (IPRs) in Confidential Information disclosed hereunder shall remain with its original owner and no grant of license or conveyance of any IPRs in such Confidential Information is to be implied from exchange or sharing of any such information under this Agreement.

9. Anti-Bribery: Vendor confirms that it will comply with HCLTech's ethics, anti-bribery and anti-corruption policies; it shall, at all time, comply with all applicable laws, statutes, regulation, and codes relating to HCLTech's code of Business Ethics and Conduct ("COBEC") and Anti-Bribery and Anti-Corruption policy ("ABAC Policy"), as available at https://www.hcltech.com/investors/governance-policies

10. Injunctive Relief: Recipient acknowledges that due to the unique nature of the Discloser's Confidential Information, any breach of its obligations hereunder will result in irreparable harm to the Discloser, and therefore, upon any such breach or threat thereof, the Discloser shall be entitled to appropriate equitable relief including the relief of injunction and/or specific performance, in addition to any other remedies available at law.

11. General: The Parties agree to be bound by any applicable export control regulations while sharing Confidential Information hereunder.

This Agreement shall be governed by the laws of India and shall be subject to the exclusive jurisdiction of courts in Delhi.

Neither party may assign or transfer any rights or obligations arising out of this Agreement without the prior written consent of the other party.

No failure or delay in enforcing any right will be deemed a waiver unless made in writing and signed by a duly authorized representative of such Party.

Any notice under this Agreement shall be in writing and shall be sent at the registered addresses of the Parties specified in this Agreement.

This Agreement may be modified only by an amendment executed in writing by a duly authorized representative of both Parties.

This Agreement constitutes the entire agreement between the Parties and supersedes all prior discussions or agreements relating to subject matter hereof.

For HCL TECHNOLOGIES LIMITED	DocuSigned by: Amita Sharma 6A37C08CE12B4AD...
Signature:	Amita Sharma
Name:	AGM-Legal
Designation:	18-Aug-23 | 10:59 AM IST
Date:	
For Dr. Amit Keshri	DocuSigned by: Dr. Amit Keshri 3A11BE6A19DC448...
Signature:	
Name:	Dr. Amit Keshri
Designation:	Additional Professor, neuro-otology
Date:	17-Aug-23 | 10:11 PM IST

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Executive Registrar
SGPGIMS,Lucknow

(10)

If to the Sponsor:

Name:	HCL Technologies Limited
For the attention of:	Kalirajan Bose
Address:	HCL Technologies Ltd, AMB6, 8th main road, Ambattur Industrial Estate, Chennai - 600058
E-mail address:	kalirajanb@hcl.com

If to the Institution:

Name:	Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI)
For the attention of:	_____
Address:	Raibareli Rd, Haibat Mau Mawaiya, Lucknow, Uttar Pradesh 226014
E-mail address:	_____

If to the Investigator:

Name:	Prof. Dr. Amit Keshri
For the attention of:	Prof. Dr. Amit Keshri
Address:	SGPGI, Raibareli Rd, Haibat Mau Mawaiya, Lucknow, Uttar Pradesh 226014
E-mail address:	amitkeshri2000@yahoo.com

12.2 Any notice served in accordance with Section 12 shall be deemed to have been received:

i. If delivered by hand, at the time of delivery.

ii. If sent by airmail, at 9:30 a.m. on the seventh (7th) day after (and excluding) the date of posting; or

iii. If sent by e-mail, at the time of transmission by the sender, provided that receipt shall not occur if the sender receives an automated message that the e-mail has not been delivered to the recipient, provided that if a notice would otherwise be deemed to have been received outside Normal Business Hours (as defined below), it shall instead be deemed to have been received at the recommencement of such Normal Business Hours.

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Executive Registrar
SGPGIMS,Lucknow

12.3 For the purposes of this Agreement, "**Normal Business Hours**" means 9.00 a.m. to 6.00 p.m. local time in the place of receipt on any day which is not a Saturday, Sunday, or public holiday in that location. In the case of service on any Party by e-mail, the place of receipt shall be deemed to be the address specified for service on that Party by post.

12.4 In proving receipt of any notice served in accordance with this Section 12, it shall be sufficient to show that the envelope containing the notice was properly addressed and either delivered to the relevant address by hand or posted as an airmail letter, or that the e-mail was sent to the correct e-mail address.

13.0 Anti-Bribery: The Parties further agree to:

13.1 Comply with all applicable and other relevant laws, regulations and sanctions relating to anti-bribery and anti-corruption.

13.2 Observe prohibiting bribery as per sub-section (13.1) and in doing so provide nothing of value to anyone including any government official.

13.3 Not offer to give or receive or agree to give to or receive from any person any gift or consideration of any kind as an inducement or reward for doing or forbearing to do or for having done or forborne to do any act or for showing or forbearing to show favour or disfavour to any person.

13.4 Maintain an effective ethical compliance regime including relevant policies to detect violations of and ensure compliance with each of the above matters.

14.0 Independent Contractor: The Investigator acts in the capacity of independent contractor hereunder and not as an agent or employee of the Sponsor. The Investigator will make no claim against the Sponsor for compensation, vacation pay, sick leave, retirement benefits, social security benefits, workers compensation, disability or unemployment benefits or employee benefits of any kind, including right/status as an employee of the Sponsor.

15.0 Publicity: None of the Parties shall use the name of any other Party for promotional, advertising or any publicity purposes without the prior written consent of the Party whose name is proposed to be used nor shall either Party disclose the existence or substance of this Agreement except as required by law.

16.0 Agreement Modifications: This Agreement or any of its Annexures shall not be altered, amended or modified except by written document signed by all Parties.

17.0 Assignment: The Sponsor shall have the right to assign this Agreement to an affiliate the Sponsor upon prior written notice to the Investigator. In all other instances, neither Party shall assign its rights or duties under this Agreement to another without prior written consent of the other Party. Subject to the foregoing, this Agreement shall bind and inure to the respective Parties and their successors and assigns.

18.0 Conflict with Protocol: If any of the provisions of this Agreement conflict with any provision of the Protocol, this Agreement shall take precedence.

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SGPGIMS,Lucknow

19.0 Severability: If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected.

20.0 Force Majeure: If any Party is delayed in performing an obligation under this Agreement by an exceptional event or circumstance: (a) which is beyond a Party's reasonable control; (b) whether or not such Party could reasonably have provided against before entering into this Agreement; (c) which, having arisen, such Party could not reasonably have avoided or overcome, including but not be limited to strike, or industrial disputes by labour not employed by the affected Party and which affects a substantial or essential portion of the execution of the Clinical Trial or the Study; or restrictive governmental or judicial order not directly related to this Agreement; or riots, insurrection, war, inclement weather, epidemic, pandemic or Acts of God; performance shall be excused for the period of such delay. The affected Party shall promptly notify the other Parties in writing of such force majeure event. In case such a Force Majeure event continues for one hundred and twenty (120) days, the Sponsor shall retain the right to terminate the Agreement as provided under Section 6.2.

21.0 Entire Agreement: The Agreement and its Annexures constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes any prior agreement, understanding or arrangement between the Parties, whether oral or in writing. No representation, undertaking or promise shall be taken to have been given or be implied from anything said or written in negotiations between the Parties prior to this Agreement, except as expressly stated in this Agreement.

In witness whereof, the Parties have caused this Agreement to be executed by their authorized representative on the date, month and year first above mentioned.

HCL Technologies Ltd.

Authorized Signatory

Institution/ Hospital

01/11/23

Authorized Signatory

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Investigator

Authorized Signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ BW 624303

31 OCT 2022

NOVARTIS HEALTHCARE PRIVATE LIMITED (FIRST PART)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, (SECOND PART)

AND

Dr. Sanjeev Yadav (THIRD PART)

Novartis Healthcare Private Limited

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(30)

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of [21st NOV 2023] ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, 7th Floor, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Lucknow, Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Sanjeev Yadav as clinical practitioner in the field of ***Hematology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: **ianalumab, VAY736** (hereafter the "Trial Drug") in accordance with a protocol entitled **A phase 3, randomized, double-blind, study to assess efficacy and safety of ianalumab (VAY736) versus placebo in warm autoimmune hemolytic anemia (wAIHA) patients who failed at least one line of treatment (VAYHIA), CVAY736O12301** and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by Novartis.

all, as amended from time to time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments, unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Trial is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 5.3 (d) provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon signature by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

4.2 The following provisions shall survive the termination or expiry of this Agreement:

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Executive Registrar
SGPGIMS,Lucknow

understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not shall make payments for new Trial Subjects.

During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drugs (as defined hereunder) in sufficient quantity to conduct the Trial, unless specified in Protocol that one or more drugs is supplied locally. If Drugs are supplied locally, Novartis shall reimburse the Institution. Trial Drugs shall be defined as any investigational drug referred in the Protocol, which can include active ingredient, comparator, or placebo. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

(c) not permit Trial Drug to be used for any purpose other than the conduct of the Trial in

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(d) shall not make the Trial Drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(e) keep full and accurate records of who dispenses the Trial Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor entrusted with the oversight of the Trial ("Novartis Monitor") at any scheduled monitoring visit;

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

(g) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Trial Drugs to Novartis.

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the qualification of each prospective Trial Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Trial Subject's suitability for participation in the Trial, and abide by Novartis's decision as to whether or not to enrol that Trial Subject;

(c) ensure that, before their participation in the Trial, the Trial Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Trial that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Trial; and (ii) the collection, processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF") in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Trial Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with; and

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (e.g, 01 Subject/month) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

Novartis will review the Trial Subjects recruitment on an on-going basis to ensure that the enrolment continues at an acceptable rate. Novartis is empowered to discontinue the Trial at Institution medical facilities in case of no or poor enrolment.

In a multicentre trial, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrolment of Trial Subjects prior to enrolment of the targeted number of Trial Subjects. Institution and Principal Investigator undertake to cease such enrolment upon request of Novartis and further undertake not to seek any compensation thereof.

5.5 **Recordkeeping**

The Institution and the Principal Investigator shall perform the following recordkeeping and

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(a) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Trial Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial. If Novartis has any legal reasons to wish to access the documents for a longer period than described above, Novartis shall notify the Institution accordingly before the end of such period. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

(f) Make available all Records to Novartis, its nominee or Health Authorities promptly upon request for monitoring and/or auditing purposes;

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Trial; and

(b) Make the hospital notes and Case Report Forms for each Trial Subject available for source data verification or auditing purposes by representatives of Novartis and the officers of any competent regulatory authority.

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

The Institution and the Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given whether or not notification was initially given by telephone. This Section shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis.

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

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(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Trial Subject or which could result in a re-assessment of the risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per current ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the Protocol) in accordance with the trial Protocol, applicable trial procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

These reporting obligations shall survive expiration or earlier termination of the Agreement.

During the Trial Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Trial and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Trial procedures.

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annexure 1) and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug, unless otherwise specified in Protocol.

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto

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(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis. The Institution confirms that the Principal Investigator has appropriate medical liability insurance.

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

Study and Site Operations (SSO), India

7 floor, Inspire BKC, G Block,

BKC Main Road,

Bandra Kurla Complex , Bandra (East),

Mumbai – 400051

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of,

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purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

9. EQUIPMENT

9.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution, the Investigator and/or the designated Trial Staff: The Equipment shall only be used for the conduct of the Trial in accordance with the Protocol, Novartis instructions and until the Trial is completed or discontinued.

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall remain in the same condition during the Trial, with the exception of ordinary depreciation.

9.3 During the term of the Trial, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

9.4 Following completion of the Trial or upon discontinuation of the Trial for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

10. TERMINATION

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution accordingly. Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations, or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis

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the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution and/or Principal Investigator by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Trial or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion to any of its Affiliate or such third parties with no further payment or other obligation to the Institution and/or Principal Investigator. The Institution and/or Principal Investigator shall have no rights whatsoever therein

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1 shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those, which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

13. PUBLICATION

13.1 The term 'publications' is used interchangeably to refer to peer-reviewed scientific manuscripts (e.g. primary and secondary manuscripts, submitted to scientific or medical journals), scientific congress abstracts, and corresponding posters and oral presentations.

13.2 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary or confidential information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.3 Novartis follows the ICMJE authorship guidelines (www.icmje.org). All authors must therefore fulfill all four ICMJE authorship criteria during publication development to be included as authors on the publication, as follows:

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(a) Substantial contributions to conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

(b) Drafting the work or revising it critically for important intellectual content; AND

(c) Final approval of the version to be published; AND

(d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

13.4 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement prior to drafting the publication.

13.5 Authors will not receive remuneration for their writing of a publication, either directly from Novartis or through a professional medical writing agency.

13.6 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Trial are made available to Novartis, whichever is later.

13.7 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis. Publication of partial data sets shall not be made until the full data is released.

13.8 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.9 Novartis and its agents may list participating investigators and their institutional affiliations in the acknowledgement section of the manuscript or abstract submitted for publication according to the journal or congress guidelines.

13.10 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.11 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.12 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

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14. CONFIDENTIALITY

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14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or

shall be treated as confidential. The Institution agrees not to disclose to any third parties or to use any Information for any purpose other than the performance of the Trial. The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any, must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.

14.3 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

14.4 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said Information, its collection or creation did not occur during or in connection with the Trial;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning the Trial Subjects (such as gender, age, health status, etc) and the Trial Staff shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

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(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for sharing an appropriate privacy notice with such staff members following the framework attached as Annex 4.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual competent authorities or Applicable Laws, for example to report serious adverse events and comply with drug safety laws and regulations.

15.5 Retention of data. Personal data will be kept only for the period necessary to fulfil the purposes of the collection unless a longer retention period is required or permitted by Applicable Laws.

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution of its obligations hereunder.

Whenever a subcontractor is appointed and approved by Novartis, the Principal Investigator shall be responsible for the oversight of the subcontractor's personnel as part of the Trial Staff.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

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20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the Parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT OF INSTITUTION/PRINCIPAL INVESTIGATOR OR OTHER RESTRICTIONS FROM THE COMPETENT AUTHORITIES

(a) **Debarment**. The Institution and the Principal Investigator certify that they are not debarred or more generally under a prohibition under the relevant Applicable Laws to perform their activities. They certify that they will not use in any capacity the services of any person debarred (or otherwise under a prohibition to perform their activity) with respect to services to be performed under this Agreement. During the term of this Agreement and for three (3) years after its termination, the Institution and the Principal Investigator will notify Novartis promptly if this certification needs to be amended in light of new information. Principal Investigator also certifies that he/she does not have a revoked or suspended medical license or applicable certification.

(b) **Investigations, Inquiries, Warnings or Enforcement Actions Related to Conduct of Clinical Research**. The Institution and the Principal Investigator certify that they are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Competent Authority Action**") related to its conduct of clinical research that has not been disclosed to Novartis. The Institution and the Principal Investigator will notify Novartis promptly if it receives notice of or becomes the subject of any Competent Authority Action regarding its compliance with ethical, scientific, or regulatory standards for the conduct of clinical research, if the Competent Authority Action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

23. CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

23.1 The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

23.2 As the case may be, the Institution and the Principal Investigator shall ensure that the Principal Investigator and all Sub-Investigators involved in the Trial provide Novartis or its designee with the appropriate financial disclosures required by the U.S. Food and Drug Administration under 21 CFR Part 54, on such forms as Novartis or its designee may supply or approve. During the term of this Agreement and one (1) year following its expiration or earlier termination, the Institution and the Principal Investigator agree to assist the Sponsor or its designee in obtaining updated forms.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Trial; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required

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Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services. In addition, disclosures of transfers of value in accordance with national pharmaceutical industry association codes to which Novartis is a party shall also apply.

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy.

The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws or pharmaceutical industry codes applicable to Novartis. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Trial Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Trial Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. AUDITS AND INSPECTIONS

(a) Audit by Novartis and Records. The Institution shall grant access to its premises periodically as frequently as required for the proper performance and oversight of the Trial site in order to proceed with any and all monitoring activities required for the Trial. In addition, the Institution shall permit Novartis and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the Institution and the Principal Investigator in the course of conducting the Trial and to inspect the facilities at which the Trial is conducted to verify compliance with this Agreement, the Protocol, Applicable Laws and the accuracy of information provided in connection with the Trial. The Institution shall ensure that the Principal Investigator and other relevant staff is available for Novartis and its agents during an audit in order to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Novartis or its agents, the Institution and the Principal Investigator shall immediately correct any errors or omissions in such records and reports.

(b) Cooperation during Audit by Novartis. The Institution shall cooperate, and shall cause the Principal Investigator and the staff to cooperate, with Novartis and its contractors and agents in the event of any internal audits, upon reasonable notice and during normal business hours. The Institution shall furthermore make available to Novartis and its contractors and agents (for examination and duplication) all documentation, data and information relating to the Trial. Trial Subject medical records will be made available where appropriate for the purpose of source document verification procedures as part of the audit. The Institution also shall make the Principal Investigator and staff available to Novartis and its contractors and agents to explain and discuss such documentation, data and information. For the avoidance of doubt audits shall be supported at no cost by the Principal Investigator and investigational staff.

(c) Inspection by Competent Authority. The Institution and the Principal Investigator acknowledge that the Trial is subject to inspections by regulatory agencies worldwide, and that such inspections may also occur after completion of the Trial. In the event the Institution or the Principal Investigator receives notice that the Institution shall be the subject of an investigation or audit by any competent authority or Ethics Committee, as applicable, in relation to the Trial, it shall notify Novartis immediately within twenty four (24) hours the latest and shall obtain approval for Novartis or its agents to be present at the inspection or otherwise keep Novartis timely and constantly informed of the progress. In the event the Institution or the Principal Investigator does not receive prior notice of said inspection, it shall notify Novartis as soon as practicable after receiving knowledge of said inspection. Institution shall provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response. The Institution will promptly forward to Novartis copies of any inspection findings that the Institution receives from a competent authority or Ethics Committee, as applicable, in relation to the Trial. The Institution will provide Novartis with an opportunity to prospectively review any Institution responses to competent authority inspections in regard to the Trial

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(d) The Institution, the Principal Investigator and the staff shall cooperate with the relevant competent authorities or Ethics Committee, as applicable and comply with the legitimate requirements of an inspection. This also includes the making available (for examination and duplication) of documentation, data and information relating to the Trial. Subject medical records shall be made available where required for source document verification procedures as part of the inspection. The Institution also shall make the Principal Investigator and other staff available to the relevant competent authority to explain and discuss such documentation, data and information.

26. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The Parties hereby submit to the exclusive jurisdiction of Lucknow, India, without restricting any right of appeal.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in relation with trial procedures.

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(14)

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: **Saumya Mathew**
SSO Study Start-up ~~Team Lead~~

Title: _____

Date: 21st NOV 2023

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

Name: SHALEEN KUMAR

Title: Acting Director

Date: 16.1.24

Sanjay Gandhi Post Graduate Institute of Medical Sciences
Lucknow - 226014, INDIA

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Sanjeev Yadav

Title: Principal Investigator

Date: 28/11/23

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Annex1: Payment (and Equipment) Schedule

STUDY NUMBER: CVAY736O12301

STUDY NAME: A PHASE 3, RANDOMIZED, DOUBLE-BLIND, STUDY TO ASSESS EFFICACY AND SAFETY OF IANALUMAB (VAY736) VERSUS PLACEBO IN WARM AUTOIMMUNE HEMOLYTIC ANEMIA (WAIHA) PATIENTS WHO FAILED AT LEAST ONE LINE OF TREATMENT (VAYHIA)

Investigator's Name: Dr. Sanjeev Yadav

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Payee Name: Director, SGPGIMS Research Scheme Account

Pan Card Number: AAAJS3913N

GSTIN: 09AAAJS3913N2ZN

Committed Number of Study Subjects: 04

List of Equipments provided to Institution / Principal Investigator:

- e-PRO device - to be retrieved back post DBL
- Thermohygrometer – to be retrieved back post DBL

1. Payment shall be made directly by Novartis
2. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be any and all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial;
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved;
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.
- Sponsor shall reimburse patient's travel cost as per protocol, INR 1000 per visit (for local patient) & INR 2000 per visit (for outside patient) for which institution/PI shall provide original invoice along with the supporting receipts.
- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it

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- Supportive care and rescue treatments will be reimbursed during conduct of the trial as per protocol until the subjects enter the follow-up phase for which site has to submit invoice to sponsor.
- Day care charges will be paid as per actuals for which site has to submit invoice to sponsor.
- A non-refundable start-up fees of INR 75000 will be paid by sponsor for setting up trial at the site after SIV for which site has to provide Original invoice.
- Monthly study coordinator fees of INR 30000 per month will be paid from Site Initiation Visit to Site Close Out Visit for which site has to be submit invoice for processing.

The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Payment schedule

Visit		Investigator grant	IOH (25%)	Total	Per Patient Grant
Screening	SCR	16000	4000	20000	669250
Blinded Treatment Period	W1	17000	4250	21250	
	W3	10000	2500	12500	
	W5	17800	4450	22250	
	W7	9300	2325	11625	
	W9	17800	4450	22250	
	W11	9300	2325	11625	
	W13	17800	4450	22250	
	W15	9300	2325	11625	
	W17	12800	3200	16000	
End of Treatment	EOT	11200	2800	14000	
Open Label/Crossover Treatment Period	COW1	11000	2750	13750	
	COW3	4000	1000	5000	
	COW5	11000	2750	13750	
	C0W7	3600	900	4500	
	COW9	11000	2750	13750	
	COW11	3600	900	4500	
	COW13	11000	2750	13750	
	COW15	3600	900	4500	
	COW17	6700	1675	8375	
End of Treatment	EOT	11000	2750	13750	
Short Term Safety Follow-Up	STFU1	11000	2750	13750	
	STFU2	11000	2750	13750	
	STFU3	11000	2750	13750	
Long Term Safety Follow-up	LTFU1T	8000	2000	10000	
	LTFU2	8000	2000	10000	
	LTFU3	10000	2500	12500	
	LTFU4	8000	2000	10000	
	LTFU5	8000	2000	10000	
	LTFU6	10000	2500	12500	
	LTFU7	8000	2000	10000	
	LTFU8	8000	2000	10000	
	LTFU9	10000	2500	12500	
	LTFU10	8000	2000	10000	
	LTFU11	8000	2000	10000	
	LTFU12	10000	2500	12500	
	LTFU13	8000	2000	10000	
	LTFU14	8000	2000	10000	

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	LTFU16	8000	2000	10000
	LTFU17	8000	2000	10000
	LTFU18	10000	2500	12500
	LTFU19	8000	2000	10000
	LTFU20	9000	2250	11250
Long Term Safety Follow-up	LTFU22	6000	1500	7500
	LTFU23	6000	1500	7500
	LTFU24	7000	1750	8750
	LTFU25	6000	1500	7500
	LTFU26	6000	1500	7500
	LTFU27	7000	1750	8750
	LTFU28	6000	1500	7500
	LTFU29	6000	1500	7500
	LTFU30	5000	1250	6250
	LTFU31	5000	1250	6250
	LTFU32	5000	1250	6250
	LTFU33	5000	1250	6250
	LTFU34	5000	1250	6250
	LTFU35	5000	1250	6250
	LTFU36	5000	1250	6250
Endo of Study	EoS	14000	3500	17500
Unscheduled Visit	USV	5600	1400	7000

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(9)

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.

You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

□ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..

□ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.

□ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.

□ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

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SGPGIMS,Lucknow

Place and Date:

Healthcare Private Limited

Name: Dr. Sanjeev Yadav

Principal Investigator

ANNEX 3

Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:

(i) securing any improper advantage; or

(ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –

(i) transactions are executed in accordance with management's general or specific authorization;

(ii) transactions are recorded as necessary

(I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and

(II) to maintain accountability for assets;

(iii) access to assets is permitted only in accordance with management's general or specific authorization; and

(iv) the recorded accountability for assets is compared with the existing assets at reasonable

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ANNEX 4: Global Template - Privacy notice for clinical trial site personnel

[_____]

Month Year

This privacy notice is addressed to:

- **Clinical investigators** (principal investigator, sub-investigator or co-investigator);
- **Other Site staff** such as nurses, pharmacists or technicians, whose Personal Data may be processed in the course of the clinical trial sponsored by Novartis.

You are receiving this Privacy Notice because Novartis Healthcare Pvt LTD ("**Novartis**") will process information about you, which constitutes "Personal Data."

This privacy notice is provided to you to ensure transparency in relation to collection, use and disclosure of your Personal Data by Novartis for purposes related to the conduct of clinical trials sponsored by Novartis Healthcare Pvt LTD ("**Novartis Clinical Trials**") which are being carried at your Clinical Trial Site [(the "**Site**"). For the purposes described in this Privacy Notice, **Novartis** is responsible for the processing of your Personal Data acting as a "Controller".

Collection of Personal Data

For the purposes described in this Privacy Notice, we may collect the following information about you including:

- name, identification number, address and other contact details,
- financial information (e.g. bank account number, financial interests in any of the Novartis group companies),
- qualifications, publications and information contained in the CV you provide to us where necessary,
- previous experience in clinical trials within or outside of Novartis and type of the GCP training received,
- technical data related to your use of Novartis IT systems.

Purposes and legal basis for processing your Personal Data

Processing purpose	Legal basis
1. to conduct Novartis Clinical Trials in accordance with good clinical practice and applicable laws;	Novartis' legitimate interest to conduct clinical trials to test potential treatments as well as compliance with legal and regulatory obligations;
2. to support applications for and to comply with the conditions of any marketing approval granted in respect of any medication studied under a Novartis Clinical Trial ("**Study Medication**")	compliance with legal and regulatory obligations;
3. to support applications to vary the terms of any marketing approval granted in respect of a Study Medication;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
4. to carry out research related to the development of pharmaceutical products, diagnostics or medical aids and improve clinical trial practice;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
5. to comply with the US Financial Disclosure regulation, which is intended to ensure that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to the Federal Drug Administration of the	Legitimate interest and compliance with legal and regulatory obligations;

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U.S.A. ("FDA") are identified and disclosed to the FDA1;

6. to ensure traceability and follow-up of drug safety notification. compliance with legal and regulatory obligations.

If applicable to Novartis Clinical Trial, your Personal Data (name and contact information) may be incorporated in subject recruitment advertisements (print media or on Internet). Any such advertisement would be approved by the Ethical Committee before it is made public.

Sharing of Personal Data

In the course of our activities and for the purposes listed in this Privacy Notice, your Personal Data can be accessed by, or transferred to the following categories of recipients, on a need to know basis to achieve such purposes:

- the sponsor of the Clinical Trial,
- our personnel (including personnel, departments or other companies of the Novartis group),
- our independent agents or brokers (if any),
- our suppliers and services providers that provide services and products to us,
- our partners in the context of consortia or industry initiatives,
- our IT systems providers, cloud service providers, database providers and consultants,
- our business partners who offer products or services jointly with us or with our subsidiaries or affiliates,
- any third party to whom we assign or novate any of our rights or obligations ,our advisors and external lawyers in the context of the sale or transfer of any part of our business or its assets,
- national and/or international regulatory bodies or Ethics Committees.

The above third parties are obliged to protect the confidentiality and security of your Personal Data, in compliance with applicable laws.

If we transfer your Personal Data to other jurisdictions, we will make sure to protect your Personal Data by (i) applying the level of protection required under the local data protection/privacy laws applicable in the country of destination, (ii) acting in accordance with our policies and standards and, (iii) for entities located in the European Economic Area (i.e. the EU Member States plus Iceland, Liechtenstein and Norway, the "EEA"), unless otherwise specified, by transferring your Personal Data on the basis of standard contractual clauses approved by the European Commission. You may request additional information in relation to international transfers of Personal Data and obtain a copy of the adequate safeguard put in place by exercising your rights as described below.

For intra-group transfers of Personal Data, the Novartis group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of Personal Data outside the EEA and Switzerland. Read more about the Novartis Binding Corporate Rules at novartis.com/privacy-policy

Duration of storage

We will keep your Personal Data as long as needed for legal and regulatory requirements. Please note that we are required to retain Clinical Trial Documentation for a minimum of 25 years.

What are your rights and how can you exercise them?

Under conditions provided by the law, you have a right to request a copy of the personal information we hold about you. You may also object to its use or ask for it to be updated, restricted, deleted, or transferred to another organisation. If you wish to contact us regarding our use of your Personal Data or you wish to exercise your data privacy rights, you may send an email to < PI email ID >.

If you are not satisfied with how we process your Personal Data, please address your request to our Data Protection Officer at global.privacy_office@novartis.com, who will investigate your concern. In any case, you also have the right to file a complaint with a responsible supervisory authority, in addition to your rights above.

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1 **Clinical investigators:** principal investigator, sub-investigator or co-investigator who are directly involved in the treatment or evaluation of research subjects in NOVARTIS Clinical Trials affected by this law, must disclose information to

ANNEX 5:NOVARTIS PROFESSIONAL PRACTICES POLICY

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ BW 504524

उप कोषागार अधिकारी कल्याण

28 JUN 2023

NOVARTIS HEALTHCARE PRIVATE LIMITED (FIRST PART)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SECOND PART)

AND

Dr Narayan Prasad (THIRD PART)

Novartis Healthcare Pvt. Ltd. Mumbai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of [1st July 2023] ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr Narayan Prasad as clinical practitioner in the field of ***Nephrology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: **VAY736/ianalumab** (hereafter the "Trial Drug") in accordance with a protocol entitled "**A randomized, double-blind, parallel group, placebo-controlled, multicenter phase 3 trial to evaluate the efficacy, safety and tolerability of ianalumab on top of standard-of-care therapy in participants with active lupus nephritis (SIRIUS-LN), CVAY736K12301**" and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

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Executive Registrar
SGPGIMS,Lucknow

1. **CONFORMANCE WITH LAW AND ACCEPTED PRACTICE**

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by Novartis.

all, as amended from time to time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments, unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Trial is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 5.3 (d) provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon signature by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

4.2 The following provisions shall survive the termination or expiry of this Agreement: Section 11 (Intellectual Property), Section 13 (Publication), Section 14 (Confidentiality) and Section 15 (Data Privacy), as well as any other provisions which by their terms are

understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not shall make payments for new Trial Subjects.

During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drug in sufficient quantity to conduct the Trial. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

(c) not permit Trial Drug to be used for any purpose other than the conduct of the Trial in compliance with the Protocol;

(d) shall not make the Trial Drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(e) keep full and accurate records of who dispenses the Trial Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor entrusted with the oversight of the Trial ("Novartis Monitor") at any scheduled monitoring visit;

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

(g) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Trial Drugs to Novartis.

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the qualification of each prospective Trial Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Trial Subject's suitability for participation in the Trial, and abide by Novartis's decision as to whether or not to enrol that Trial Subject;

(c) ensure that, before their participation in the Trial, the Trial Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Trial that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Trial; and (ii) the collection, processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF") in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Trial Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with; and

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (1 Subjects per 3 months) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

Novartis will review the Trial Subjects recruitment on an on-going basis to ensure that the enrolment continues at an acceptable rate. Novartis is empowered to discontinue the Trial at Institution medical facilities in case of no or poor enrolment.

In a multicentre trial, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrolment of Trial Subjects prior to enrolment of the targeted number of Trial Subjects. Institution and Principal Investigator undertake to cease such enrolment upon request of Novartis and further undertake not to seek any compensation thereof.

5.5 **Recordkeeping**

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(a) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Trial Subject identification(s), medical notes, clinical observations, laboratory tests, and the receipt and

disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial. If Novartis has any legal reasons to wish to access the documents for a longer period than described above, Novartis shall notify the Institution accordingly before the end of such period. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

(f) Make available all Records to Novartis, its nominee or Health Authorities promptly upon request for monitoring and/or auditing purposes;

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Trial; and

(b) Make the hospital notes and Case Report Forms for each Trial Subject available for source data verification or auditing purposes by representatives of Novartis and the officers of any competent regulatory authority.

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

The Institution and the Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given whether or not notification was initially given by telephone. This Section shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis.

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Trial Subject or which could result in a re-assessment of the

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risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per current ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the Protocol) in accordance with the trial Protocol, applicable trial procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

These reporting obligations shall survive expiration or earlier termination of the Agreement.

During the Trial Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Trial and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Trial procedures.

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annex 1) and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto (but in any case within ten (10) days after the Indemnitee shall have received notice thereof);

(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

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(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

The PI of Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

6 & 7 floor, Inspire BKC, G Block,

BKC Main Road,

Bandra Kurla Complex , Bandra (East),

Mumbai – 400051

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

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9. EQUIPMENT

9.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution, the Investigator and/or the designated Trial Staff: The Equipment shall only be used for the conduct of the Trial in accordance with the Protocol, Novartis instructions and until the Trial is completed or discontinued.

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall remain in the same condition during the Trial, with the exception of ordinary depreciation.

9.3 During the term of the Trial, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

9.4 Following completion of the Trial or upon discontinuation of the Trial for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

10. TERMINATION

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution 07 days before the termination of the trial .Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations (as set out in Annex 3), or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis all documents, Trial results and material used, generated or referred to in the course of the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

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The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution and/or Principal Investigator by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Trial or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion to any of its Affiliate or such third parties with no further payment or other obligation to the Institution and/or Principal Investigator. The Institution and/or Principal Investigator shall have no rights whatsoever therein

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1 shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those, which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

13. PUBLICATION

13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary or confidential information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.2 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement.

13.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Trial are made available to Novartis, whichever is later.

13.4 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis.

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13.5 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.6 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.7 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.8 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

14. CONFIDENTIALITY

14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Trial (collectively "**Information**") shall be treated as confidential. The Institution agrees not to disclose to any third parties or to use any Information for any purpose other than the performance of the Trial. The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any, must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.

14.3 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

14.4 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said Information, its collection or creation did not occur during or in connection with the Trial;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

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(d) in case the disclosure of any such confidential information is in compliance of any law in force or consequent upon any direction of any governmental, statutory authority or a court of law or tribunal.

15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning the Trial Subjects (such as gender, age, health status, etc) and the Trial Staff shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for sharing an appropriate privacy notice with such staff members following the framework attached as Annex 4.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data.

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Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: **Murugananthan K.**
Country Monitoring Head

Title: _____

Date: 7th July 2023

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

Name: **Prof. R K Dhiman**

Title: **Director**

Date: _____

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

PRINCIPAL INVESTIGATOR

By: _____

Name: **Dr. Narayan Prasad**

Title: **Principal Investigator**

Date: 11.7.23

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Executive Registrar
SGPGIMS,Lucknow

Novartis Healthcare Pvt Ltd Mumbai

Annex1: Payment (and Equipment) Schedule

STUDY NUMBER: CVAY736K12301

STUDY NAME: A RANDOMIZED, DOUBLE-BLIND, PARALLEL GROUP, PLACEBO-CONTROLLED, MULTICENTER PHASE 3 TRIAL TO EVALUATE THE EFFICACY, SAFETY AND TOLERABILITY OF IANALUMAB ON TOP OF STANDARD-OF-CARE THERAPY IN PARTICIPANTS WITH ACTIVE LUPUS NEPHRITIS (SIRIUS-LN)

Investigator's Name: Dr. Narayan Prasad

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Payee Name: Director, SGPGIMS Research Scheme Account

Pan Card Number: AAAJS3913N

GSTIN: 09AAAJS3913N2ZN

Committed Number of Study Subjects: 6

List of Equipment provided to Institution / Principal Investigator:

- Kayentis ePRO-To be retrieved post DBL
- Thermohygrometer- To be retrieved post DBL

1. Payment shall be made directly by Novartis
2. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be any and all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial;
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved;
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will not receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting receipts.
- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- Prior to site closeout, sponsor shall provide INR 50,000/- for archival of study documents for 15 years.
- A non-refundable start-up fees of INR 50,000/- will be paid by sponsor for setting up trial at the site after SIV for which site has to provide original invoice.

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- Monthly CRC fees of INR 40,000 will be paid from site initiation visit to close out visit for which site has to submit invoice.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.

The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Study Budget:

Visit		Procedure Cost	Investigator Grant	Institutional Overhead (25%)	Total	Total Per Patient cost
Blinded Treatment Period-1	ENTSCR	5000	7000	3000	15000	681250
	BSL	5000	7000	3000	15000	
	W4	5000	7000	3000	15000	
	W8	5000	7000	3000	15000	
	W12	5000	7000	3000	15000	
	W16	5000	7000	3000	15000	
	W20	5000	7000	3000	15000	
	W24	5000	7000	3000	15000	
	W28	5000	7000	3000	15000	
	W32	5000	7000	3000	15000	
	W36	5000	7000	3000	15000	
	W40	5000	7000	3000	15000	
	W44	5000	7000	3000	15000	
	W48	5000	7000	3000	15000	
	W52	5000	7000	3000	15000	
	W56	5000	7000	3000	15000	
	W60	5000	7000	3000	15000	
	W64	5000	7000	3000	15000	
	W68	5000	7000	3000	15000	
	W68+3	2000	7000	2250	11250	
Blinded Treatment Period-2	W72	5000	7000	3000	15000	
	W76	5000	7000	3000	15000	
	W80	5000	7000	3000	15000	
	W84	5000	7000	3000	15000	
	W88	5000	7000	3000	15000	
	W92	5000	7000	3000	15000	
	W96	5000	7000	3000	15000	
	W100	5000	7000	3000	15000	
	W104	5000	7000	3000	15000	
	W108	5000	7000	3000	15000	
	W112	5000	7000	3000	15000	
	W116	5000	7000	3000	15000	
	W120	5000	7000	3000	15000	
	W124	5000	7000	3000	15000	
	W128	5000	7000	3000	15000	
	W132	5000	7000	3000	15000	
	W136	5000	7000	3000	15000	
	W140	5000	7000	3000	15000	
	W144-EOT	5000	7000	3000	15000	
Mandatory Post-treatment Follow up	FUP1	1000	7000	2000	10000	
	FUP2	1000	7000	2000	10000	
	FUP3	1000	7000	2000	10000	
	FUP4	1000	7000	2000	10000	
	FUP5	1000	7000	2000	10000	

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Conditional Post-treatment Follow-up	FUP6	1000	7000	2000	10000
	FUP7	1000	7000	2000	10000
	FUP8	1000	7000	2000	10000
	FUP9	1000	7000	2000	10000
	FUP10-EOS	1000	7000	2000	10000

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ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.

You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

- ☐ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..
- ☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.
- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date: 11.7.23

Name: **Dr. Narayan Prasad**

Principal Investigator

Novartis Healthcare Pvt. Ltd. Mumbai

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Executive Registrar
SGPGIMS,Lucknow

ANNEX 3: Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:

(i) securing any improper advantage; or

(ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –

(i) transactions are executed in accordance with management's general or specific authorization;

(ii) transactions are recorded as necessary

(I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and

(II) to maintain accountability for assets;

(iii) access to assets is permitted only in accordance with management's general or specific authorization; and

(iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

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ANNEX 4: Privacy notice. To be shared by the Principal Investigator with Trial Staff

[_____]

This privacy notice is addressed to:

- **Clinical investigators** (principal investigator, sub-investigator or co-investigator);
- **Other Site staff** such as nurses, pharmacists or technicians, whose Personal Data may be processed in the course of the clinical trial sponsored by Novartis.

You are receiving this Privacy Notice because Novartis Healthcare Pvt LTD ("**Novartis**") will process information about you, which constitutes "Personal Data."

This privacy notice is provided to you to ensure transparency in relation to collection, use and disclosure of your Personal Data by Novartis for purposes related to the conduct of clinical trials sponsored by Novartis Healthcare Pvt LTD ("**Novartis Clinical Trials**") which are being carried at your Clinical Trial Site [(the "**Site**"). For the purposes described in this Privacy Notice, **Novartis** is responsible for the processing of your Personal Data acting as a "Controller".

Collection of Personal Data

For the purposes described in this Privacy Notice, we may collect the following information about you including:

- name, identification number, address and other contact details,
- financial information (e.g. bank account number, financial interests in any of the Novartis group companies),
- qualifications, publications and information contained in the CV you provide to us where necessary,
- previous experience in clinical trials within or outside of Novartis and type of the GCP training received,
- technical data related to your use of Novartis IT systems.

Purposes and legal basis for processing your Personal Data

Processing purpose	Legal basis
1. to conduct Novartis Clinical Trials in accordance with good clinical practice and applicable laws;	Novartis' legitimate interest to conduct clinical trials to test potential treatments as well as compliance with legal and regulatory obligations;
2. to support applications for and to comply with the conditions of any marketing approval granted in respect of any medication studied under a Novartis Clinical Trial ("**Study Medication**")	compliance with legal and regulatory obligations;
3. to support applications to vary the terms of any marketing approval granted in respect of a Study Medication;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
4. to carry out research related to the development of pharmaceutical products, diagnostics or medical aids and improve clinical trial practice;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
5. to comply with the US Financial Disclosure regulation, which is intended to ensure that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to the Federal Drug Administration of the U.S.A. ("FDA") are identified and disclosed to the FDA1;	Legitimate interest and compliance with legal and regulatory obligations;
6. to ensure traceability and follow-up of drug safety notification.	compliance with legal and regulatory obligations.

1 **Clinical investigators:** principal investigator, sub-investigator or co-investigator who are directly involved in the treatment or evaluation of research subjects in NOVARTIS Clinical Trials affected by this law, must disclose information to Novartis regarding their financial interests in companies belonging to the Novartis group as well as those of their spouse and each dependent child

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If applicable to Novartis Clinical Trial, your Personal Data (name and contact information) may be incorporated in subject recruitment advertisements (print media or on Internet). Any such advertisement would be approved by the Ethical Committee before it is made public.

Sharing of Personal Data

In the course of our activities and for the purposes listed in this Privacy Notice, your Personal Data can be accessed by, or transferred to the following categories of recipients, on a need to know basis to achieve such purposes:

- the sponsor of the Clinical Trial,
- our personnel (including personnel, departments or other companies of the Novartis group),
- our independent agents or brokers (if any),
- our suppliers and services providers that provide services and products to us,
- our partners in the context of consortia or industry initiatives,
- our IT systems providers, cloud service providers, database providers and consultants,
- our business partners who offer products or services jointly with us or with our subsidiaries or affiliates,
- any third party to whom we assign or novate any of our rights or obligations ,our advisors and external lawyers in the context of the sale or transfer of any part of our business or its assets,
- national and/or international regulatory bodies or Ethics Committees.

The above third parties are obliged to protect the confidentiality and security of your Personal Data, in compliance with applicable laws.

If we transfer your Personal Data to other jurisdictions, we will make sure to protect your Personal Data by (i) applying the level of protection required under the local data protection/privacy laws applicable in the country of destination, (ii) acting in accordance with our policies and standards and, (iii) for entities located in the European Economic Area (i.e. the EU Member States plus Iceland, Liechtenstein and Norway, the "EEA"), unless otherwise specified, by transferring your Personal Data on the basis of standard contractual clauses approved by the European Commission. You may request additional information in relation to international transfers of Personal Data and obtain a copy of the adequate safeguard put in place by exercising your rights as described below.

For intra-group transfers of Personal Data, the Novartis group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of Personal Data outside the EEA and Switzerland. Read more about the Novartis Binding Corporate Rules at novartis.com/privacy-policy

Duration of storage

We will keep your Personal Data as long as needed for legal and regulatory requirements. Please note that we are required to retain Clinical Trial Documentation for a minimum of 25 years.

What are your rights and how can you exercise them?

Under conditions provided by the law, you have a right to request a copy of the personal information we hold about you. You may also object to its use or ask for it to be updated, restricted, deleted, or transferred to another organisation. If you wish to contact us regarding our use of your Personal Data or you wish to exercise your data privacy rights, you may send an email to < PI email ID >.

If you are not satisfied with how we process your Personal Data, please address your request to our Data Protection Officer at global.privacy_office@novartis.com, who will investigate your concern. In any case, you also have the right to file a complaint with a responsible supervisory authority, in addition to your rights above.

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ANNEX 5: NOVARTIS PROFESSIONAL PRACTICES POLICY

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ 47AA 885027

This Clinical Trial Agreement ("**Agreement**") is made as of 25 Jul 2023 ("**Effective Date**") by and between **Sanjay Gandhi Postgraduate Institute of Medical Sciences** ("**Institution**") with an address at **Raibareli Road Lucknow-226014**, **(Principal Investigator) Dr. Narayan Prasad**, an employee of Institution, **Leonard-Meron Biosciences, Inc.**("**Sponsor**") with an address at 11 Commerce Drive, First Floor, Cranford, NJ 07016 ,and **Biorasi Clinical Services Pvt Ltd. ("CRO")**, having its principal place of business at Unit B-3/06 B Wing, 8th Floor, Ashar IT Park Road no 16Z,Wagle Industrial Estate Thane West – 400604. CRO, Sponsor, Principal Investigator, and Institution are herein referred to collectively as "Parties." Individually, each of CRO and Institution is a "Party."

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Background:

CRO has been engaged by Sponsor to arrange and administer a multi-center clinical trial funded by Sponsor to determine the safety and efficacy of Sponsor's product.

Institution has appropriate facilities and personnel with the qualification, training, knowledge, and experience necessary to conduct such a clinical trial; and

The Study contemplated by this Agreement is of mutual interest and benefit to Institution and Sponsor and CRO;

NOW, THEREFORE, in consideration for the mutual promises made in this Agreement and for valid consideration, the Parties agree as follows:

1. Scope of Agreement

1.1. Institution will undertake a sponsored multicenter Clinical Trial (as defined in rule-122 DAA of the Drugs and Cosmetics Rule, 1945) ("**Study**") described in the protocol entitled, **A Phase 3, Multi-Center, Randomized, Open-Label, Assessor-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection** as may be amended from time to time and as approved by the Institutional Review Board ("**IEC**"), which is incorporated herein by this reference ("**Protocol**"). Institution will use its reasonable efforts to only recruit subjects in accordance with the Protocol. The Study will be conducted at the Institution under the direction of **Dr. Narayan Prasad**, A E.G., Faculty of Institution ("**Principal Investigator**"). Institution agrees to administer, and Investigator agrees to conduct, the Study at **Sanjay Gandhi Postgraduate Institute of Medical Sciences** Raibareli Road Lucknow-226014 insert address where Study will be conducted] (the "**Study Site**"). The Study Site may not be changed without Sponsor's prior written consent.

1.2. In the event of any conflict between the terms and conditions of this Agreement and the Protocol or between this Agreement and any of its Exhibits, the terms and conditions of the Protocol shall control with respect to matters of the clinical conduct of the Study, and the terms of this Agreement shall control with respect to all other matters.

1.3. Unless otherwise agreed to by the Parties, Sponsor and/or CRO will provide to Institution on a timely basis, without cost, the required quantities of properly-labeled Sponsor Investigational Product ("Study Drug") and/or if applicable, placebo, and other written materials (e.g., Investigator's Brochure, handling and storage instructions) necessary for Institution to conduct the Study in accordance with the Protocol. Unless stated otherwise in writing by Sponsor, all such items are and will remain the sole property of Sponsor until administered or dispensed to Study subjects during the course of the Study. Institution shall receive, store, and handle of Study Drug or Study Device in compliance with all applicable laws and regulations, the Protocol, and CRO's or Sponsor's written instructions.

1.4. Institution and Investigator shall carry out the Study in a competent manner and conduct all aspects of the Study in compliance with (a) the Protocol; (b) this

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Agreement; and in strict compliance with (i) applicable provisions of the Drugs and Cosmetics Act, 1940 ("**Act**"). the Drugs and Cosmetics Rules, 1945 ("**Rules**") including specifically Schedule Y, (ii) International Conference on Harmonization Good Clinical Practice (ICH GCP) guidelines, (iii) Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011; (iv) Indian Council of Medical Research (ICMR) Guidelines; (v) Good Clinical Practice (GCP) Guidelines, (vi) Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002; (vii) Indian Good Clinical Practice of the Central Drugs Standard Control Organization; (viii) WMA Declaration of Helsinki; (ix) OPPI Code of Pharmaceutical Practices 2019, (x) the New Drug and Clinical Trial Rules, 2019 ("**2019 Rules**"), and (xi) any additional laws, guidelines or regulations for the time being in force, which is applicable to the context and terms of this Agreement, Protocol and the Study (collectively, "**Applicable Laws**"). Institution will only allow its employees and staff(as applicable) ("**Study Personnel**") who are appropriately trained and qualified to assist in the conduct of the Study. Institution and Investigator will obtain and maintain all certifications, authorizations, permits and licenses required in connection with the conduct of the Study. Institution and Investigator will promptly complete, and ensure that relevant Study Personnel promptly complete, all Study-related regulatory forms. Investigator hereby represents that s/he has furnished an undertaking to Licensing Authority in the format given in Appendix VII of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

1.5. IEC Approval:

1.5.1 Institution shall obtain Institutional Ethics Committee ("**IEC**") approval for the Study prior to its initiation and written proof thereof shall be provided to CRO upon CRO's request. Initiation of the Protocol and Institution's obligation to conduct the Study shall not begin until IEC approval is obtained. Institution hereby represents that it has constituted the IEC as per the guidelines given in the Gazette of India and it has been registered with the Drug Controller General of India (DCGI) by letter No: ECR/1002/Inst/TN/2017/RR-20 dated 07-Oct-2020 Institution agrees any SOPs followed by the Institution shall be in compliance with Applicable Laws and it will ensure that the IEC will discharge its responsibilities as per provisions of of Clinical Trial Rules 2019 (Drug and Cosmetics Rules, 1945).

1.5.2 Prior to a subject's participation in the Study, Institution shall obtain from each subject, a signed informed consent and necessary authorization to disclose health information to CRO and/or Sponsor in a form approved in writing by the IEC and Sponsor, provided that the informed consent is consistent with Institution's policies, or a waiver of consent as directed by the IEC. Investigator shall ensure enrolment of Study Subjects after obtaining informed consent including audiovisual recording and informing the Study Subject of the provisions of adequate treatment and compensation for serious adverse events ("**SAEs**") as per VII Schedule of Clinical Trial Rules, 2019.

1.5.3 Any changes proposed by the Sponsor to the Protocol must be in writing and sent to the Institution and will not take effect until approved by the IEC. If such Protocol changes affect the contract terms (including the budget or payment

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terms), CRO agrees to promptly work with the Institution to execute an amendment to this Agreement.

1.6. Institution shall promptly inform Sponsor of all breaches of the Protocol of which Institution becomes aware.

1.7 The Principal Investigator shall report all serious and unexpected adverse events (as defined in the Protocol) and/or death to the Licensing Authority, Sponsor, and IEC as per Appendix XI of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945). The Principal Investigator shall forward its report on serious adverse event ("**SAE**") or death after due analysis of all factors with his/her opinion to the Chairman of IEC, the Chairman of Expert Committee and the Head of the Institution and the Licensing Authority as per Appendix X of Schedule Y (Drug and Cosmetics Rules, 1945). The Principal Investigator shall forward its report on SAE other than Death after due analysis of all factors with his/her opinion to the Licensing Authority, the Chairman of IEC and the Director of the Institution as per Appendix X of Schedule Y (Drug and Cosmetics Rules, 1945). During and following a Study Subject's participation in Study, the Principal Investigator shall ensure that adequate medical care is provided to the Study Subject for any SAEs.

1.8. Institution acknowledges CRO's right to assign or transfer, in whole or in part, with notice to Institution, any of its rights or obligations under this Agreement to the Sponsor or Sponsor's designate.

1.9 Sponsor hereby understands and represents that it has furnished an undertaking along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of Study-related injury or death for which Study Subjects will be entitled to compensation; as per provisions of rule 122 DAB (b) of Rules (Drug and Cosmetics Rules, 1945) and the 2019 Rules.

1.10 Sponsor shall submit a status report on the Study to the Licensing Authority at the prescribed time periods. If the Study is permanently discontinued for any reason, Sponsor shall submit a summary report to the Licensing Authority as per provisions of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

2. Payments

Sponsor will provide financial support for the Study and will provide such funds to CRO who will pay Institution in accordance with the budget attached a s **Exhibit A** ("**Budget& Payment**") on a prorated basis, according to the actual work completed and any non-cancelable obligated expenses, for subjects who are enrolled into the Study in accordance with this Agreement and the Protocol. The Parties acknowledge that the Budget amounts represent an equitable exchange for the conduct of the Study considering the professional time and expenses required for the performance of the Study.

In addition to other necessary routing information detailed in Exhibit A, each payment shall clearly reference the Study Protocol Number and PI name.

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3. Confidentiality

3.1. It is anticipated that in the performance of this Agreement, Sponsor and/or CRO on behalf of Sponsor may need to disclose to Institution information which is considered confidential. The rights and obligations of the Parties with respect to such information are as follows:

"**Confidential Information**" refers to information of any kind which is disclosed to the Institution by Sponsor and/or CRO on behalf of Sponsor for purposes of conducting the Study or Data (as defined below in Section 4) which:

(a) by appropriate marking, is identified as confidential and proprietary at the time of disclosure.

(b) if disclosed orally or visually, is identified in a marked writing within 30 days as being confidential: or

(c) in the absence of markings, is of such a nature that a reasonable person familiar with the Study would consider it to be confidential or proprietary from the context or circumstances of disclosure.

Notwithstanding the foregoing, Data and results generated by Institution in the course of conducting the Study are not considered Confidential Information for publishing purposes in accordance with Section 9 of this Agreement.

Institution agrees, for a period of five (5) years following either the early termination of the Study, or the completion of the Study at all sites identified by the locking of the database, that it will use reasonable efforts, no less than the protection given to its own confidential information, to not use or disclose the Confidential Information received from Sponsor and/or CRO on behalf of Sponsor, except as permitted under this Agreement.

Institution agrees to use Sponsor's Confidential Information solely as allowed by this Agreement, and for the purposes of conducting the Study. Institution agrees to make Sponsor's Confidential Information available only to those of its, or its affiliated hospitals 'Study Personnel, and approved subcontractors, as applicable, who require access to it in the performance of this Study and the Agreement and are subject to similar terms of confidentiality.

3.2. The obligation of nondisclosure does not apply with respect to any of the Confidential Information that:

(a) is or becomes public knowledge through no breach of this Agreement by Institution.

(b) is disclosed to Institution by a third party entitled to disclose such information without known obligation of confidentiality to Sponsor;

(c) is already known or is independently developed by Institution without use of Sponsor's Confidential Information as shown by Institution's

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contemporaneous written records or other verifiable evidence;

(d) is necessary to obtain IEC approval of the Study or is required to be included in the written information summary provided to Study subject(s) and/or informed consent form;

(e) is released with the prior written consent of the Sponsor; or

(f) is required to support the medical care of a Study subject.

3.3. Institution may disclose Confidential Information to the extent that it is required to be produced pursuant to a requirement of applicable law, regulation, an order by a government agency, IEC, an order of a court of competent jurisdiction, or a facially valid administrative, Congressional, or other subpoena, provided that Institution, subject to the requirement, order, or subpoena, promptly notifies Sponsor and CRO. Sponsor may seek to limit the scope of such disclosure and/or seek to obtain a protective order. Institution will disclose only the minimum amount of Confidential Information necessary to comply with law or court order as advised by Institution's legal counsel.

3.4. No license or other right is created or granted hereby, except the specific right to conduct the Study as set forth by the Protocol and under the terms of this Agreement, nor shall any license or other right with respect to the subject matter hereof be created or granted except by the prior written agreement of the Parties duly signed by their authorized representatives.

3.5 Without the permission of Sponsor and CRO, Institution may only disclose the existence of this Agreement and any additional information necessary to ensure compliance with applicable federal, state, or local laws, and Institutional policies, regulations, and procedures.

4. Data Use/Ownership

"**Data**" shall mean all data and information generated by Institution in the performance of the Study and required to be delivered in accordance with the IEC-approved Protocol. Data does **not** include original Study subject or patient medical records, research notebooks, source documents, or other routine internal documents kept in the Institution's ordinary course of business operations, which shall remain the sole and exclusive property of the Institution or medical provider. Sponsor shall own and have the right to use the Data in accordance with the signed informed consent and authorization form, applicable laws, and the terms of this Agreement. Notwithstanding any licenses or other rights granted to Sponsor herein, but in accordance with the confidentiality and publication sections herein, Institution shall retain the right to use the Data and results for, IEC, regulatory, legal, and for its own internal educational, patient care, and noncommercial research purposes, without the payment of royalties or other fees.

5. HIPAA Privacy/Data Security

5.1. Institution shall comply with applicable laws and regulations, as amended from time to time with respect to the collection, use, storage, and disclosure of personal health data (**PHI**). CRO and Sponsor (through its agreement with CRO),shall collect, use, store,

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access, and disclose PHI and other personal information collected from Study subjects only as permitted by the IEC approved informed consent form. Sponsor will collect, use, store, and disclose any Subject Material, defined in Section 15, it receives only in accordance with the informed consent form and, in any event, will not collect, use, store, or disclose any PHI attached to or contained within the Subject Material in any manner that would violate this Section of the Agreement.

(a) Principal Investigator or Institution shall assign a unique patient identification number ("**ID Number**") to each enrolled Study subject. Throughout the Study, each Study subject shall be identified inside and outside of the Institution using the assigned ID Number.

(b) Principal Investigator and Institution shall not disclose the personal data or PHI of a Study subject unless such disclosure is pursuant to a regulatory authority requirement or inquiry, or where such disclosure is necessary for the health and safety of the Study subject.

(c) Prior to providing copies of Study documentation which may include personal data or PHI of a Study subject, Principal Investigator and Institution shall ensure the Study documentation copies are redacted or "blacked out" where appropriate and the Study subject ID Number inserted.

(d) Principal Investigator and Institution shall exclusively provide to CRO data from patients that has previously been anonymized in such a way that personal data or PHI cannot be linked to an identifiable person.

5.3 [reserved]

5.2. CRO's ability to review the Study subjects' Study-related information contained in the Study subject's medical record shall be subject to reasonable safeguards for the protection of Study subject confidentiality and the Study subjects' informed consent form.

5.3. Neither CRO, nor Sponsor through its agreement with CRO, shall attempt to identify, or contact, any Study subject unless expressly permitted by the informed consent form.

6. **Record Retention**

As required by applicable law, Institution shall retain and preserve a copy of the Study records for the longer of:

(a) two (2) years after a marketing authorization for Study Drug has been approved for the indication for which it was investigated or Sponsor has closed the IND application with FDA.

(b) such longer period as required by federal regulatory requirements; or

(c) as requested in writing by Sponsor at Sponsor's reasonable storage expense.

Institution shall use reasonable efforts to notify Sponsor at least 45 days before the planned

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destruction of any Study records. Sponsor must make any request to Institution to retain the Study records for a longer period, in writing, within such 45-day period, with any continued record retention to be at Sponsor's sole expense. If Sponsor does not respond to Institution's notice within 45 days of its receipt or refuses to pay for the continued storage of Study records, Institution shall have the right to destroy such Study records, at its discretion.

7. Monitoring and Auditing

7.1. Site visits by Sponsor, CRO and/or another authorized designee (e.g., Study monitor) will be scheduled in advance for times mutually acceptable to the Parties during normal business hours. Sponsor's, CRO's and/or its authorized designee's access is subject to applicable Institution policies and procedures, including, but not limited to, reasonable safeguards to ensure confidentiality of medical records and systems, and safety of personnel and Study Subjects.

7.2. Unless otherwise prohibited by the United States Food & Drug Administration ("**FDA**" or any national local regulatory authority, upon becoming aware of an audit or investigation by a regulatory agency with jurisdiction, that is related to the Study, Institution agrees to provide CRO and Sponsor with prompt notice of the auditor investigation. CRO and/or Sponsor may be available on site for the purposes of making itself available to assist the Institution with any queries from the regulatory authority that may require or benefit from input from the Sponsor. If required by the regulatory agency or otherwise allowed by the regulatory agency, CRO and/or Sponsor may request to be present at such audit or investigation, but CRO and/or Sponsor agrees not to alter or interfere with any documentation or practice of Institution. Institution shall be free to respond to any regulatory agency inquiries and will provide CRO and/or Sponsor with a copy of any formal response or documentation to the regulatory agency regarding the Study.

7.3 In the event CRO, or CRO's representatives, affiliates, employees, independent contractors, or subcontractors, will monitor Institution Study subject data ("**Monitors**"),CRO agrees that it, and its Monitors will comply with all of Institution's applicable policies and procedures related to such monitoring, Monitors will be advised of relevant information at least 5 days prior to any planned monitoring activities.

8. Inventions, Discoveries and Patents

8.1. It is recognized and understood that certain existing inventions and technologies, and those arising outside of the research conducted under this Agreement, are the separate property of Sponsor or Institution and are not affected by this Agreement, and neither Sponsor nor Institution shall have any claims to or rights in such separate inventions and technologies.

8.2. Any new inventions, developments, or discoveries made during and in the performance of the Protocol ("**Inventions**") shall be promptly disclosed to Sponsor. Title to Inventions which are enhancements, modifications or improvements, of the Study Drug and that are made during and under this Agreement shall reside with Sponsor ("Sponsor Inventions"). Institution shall assign all Sponsor Inventions to Sponsor. Institution represents and certifies that all Institution personnel, including Principal Investigator,

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performing the Protocol have assigned to or are obligated to assign to Institution (or appropriate technology transfer office, on behalf of Institution), all their rights in or to Inventions that are necessary to enable Institution to grant Sponsor all rights to Inventions that Institution purports to grant under this Agreement. Title to Inventions other than Sponsor Inventions ("**Other Inventions**") shall reside with Sponsor if Sponsor personnel are the sole inventors, with Institution if Institution personnel are the sole inventors, and shall be held jointly if both Institution and Sponsor personnel are inventors. Institution's obligations under Sections 8.2 and 8.3 hereunder shall be performed by its appropriate office with technology transfer responsibilities, if required by and in accordance with Institution policies.

8.3. To the extent that Institution owns sole or joint title in any such Other Inventions, Sponsor is hereby granted, without option fee other than consideration of the Study sponsored herein and the reimbursement to Institution for patent expenses incurred prior to or during the option period, an option to acquire an exclusive, worldwide, royalty-bearing license to Institution's rights to any Other Invention, which option shall extend for no more than 90 days after Sponsor's receipt of an Invention disclosure from Institution ("**Option Period**"). Sponsor and Institution shall use their reasonable efforts to negotiate, for a period not to exceed 90 days after Sponsor's exercise of such option, a license agreement satisfactory to both Parties ("**Negotiation Period**"). In the event Sponsor fails to exercise its option within the Option Period, or Sponsor and Institution fail to reach agreement on the terms of such license within the Negotiation Period, Institution shall have no further obligation to Sponsor under this Agreement with regard to the specific Other Invention.

8.4. Institution shall have a right to use for its own internal noncommercial research, educational and patient care purposes, all Sponsor Inventions or Other Inventions licensed or assigned to Sponsor hereunder.

8.5. Nothing contained in this Agreement shall be deemed to grant either directly by implication, estoppel, or otherwise any license under any patents, patent applications, or other proprietary interest to any other inventions, discovery or improvement of either Sponsor or Institution.

8.6. CRO and Institution agree that the provisions of this Agreement are intended to be interpreted and implemented so as to comply with all applicable federal laws, rules, and regulations, including without limitation the requirements of Rev. Proc. 2007-47; provided, however, if it is determined by the Internal Revenue Service or any other federal agency or instrumentality (the "**Government**") that the provisions of this Agreement are not in such compliance, then the Parties agree to modify the provisions and the implementation of this Agreement so as to be in compliance with all applicable federal laws, rules, and regulations as determined by the Government.

9. Publication

9.1. Institution shall be free to publish, present, or use any Data and results arising out of its performance of the Protocol (individually, a "**Publication**") only after completion of the study. At least 30 days prior to submission for Publication, Institution shall submit to Sponsor any proposed oral or written Publication for Sponsor's review and

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comments ("**Review Period**"). Institution will consider any such comments in good faith but is under no obligation to incorporate Sponsor's suggestions. If during the Review Period, Sponsor notifies Institution in writing that: (i) it desires to file patent applications on any inventions disclosed or contained in the disclosures, Institution will defer Publication for a period not to exceed 60 days, to permit Sponsor to file any desired patent applications; and (ii) if the Publication contains Sponsor's Confidential Information as defined in Section 3 and Sponsor, in writing, requests Institution to delete such Sponsor's Confidential Information, then Institution agrees to do so only to the extent such deletion does not preclude the complete and accurate presentation and interpretation of the Study results.

9.2. If this Study is part of a multi-center clinical trial, Institution agrees that the first Publication of the results of the Study shall be made in conjunction with the presentation of a joint multi-center Publication of the Study results with the Principal Investigators from all sites contributing Data, analyses, and comments. Notwithstanding the foregoing, Institution may publish the Data and Study results individually in accordance with this Section 9 upon the first occurrence of one of the following: (i) multi-center Publication is published; (ii) no multi-center publication is submitted within 18 months after conclusion, abandonment, or termination of the Study at all sites; or (iii) Sponsor confirms in writing there will be no multi-center Publication.

9.3. If no multi-center Publication occurs within 18 months of the completion of the Study at all sites, upon request by Institution, Sponsor will provide Institution access to the aggregate results pursuant to the Protocol from all Study sites.

9.4. If the Institution, through its Principal Investigator, is identified to participate in the multi-center Publication: (i) Institution will have the opportunity to review the aggregate multi-center Data, upon request; and (ii) consistent with the International Committee of Medical Journal Editors (ICMJE) regulations, Institution will have adequate opportunity to review and provide input on any abstract or manuscript prior to its submission for Publication. Institution also retains the right, on behalf of its Principal Investigator, to decline to be an author on any Publication.

10. Use of Name

10.1. Neither Institution, sponsor nor CRO may use the name, trademark, logo, symbol, or other image or trade name of the other Party or its employees and agents in any advertisement, promotion, or other form of publicity or news release or that in any way implies endorsement without the prior written consent of an authorized representative of the Party whose name is being used. Such approval will not be unreasonably withheld.

10.2. Institution and Sponsor understand that the amount of any payment made hereunder may be disclosed and made public by the other party as required by law or regulation, including the Patient Protection and Affordable Care Act of 2010 ("**Disclosure Laws**"), provided that the disclosure clearly designates the payment as having been made to Institution for research and not to the physician. Institution acknowledges that, by Sponsor's disclosure of such payments, Sponsor must identify the Institution as the

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payment recipient, and may also need to identify the Principal Investigator in accordance with Disclosure Laws.

10.3. Institution may acknowledge the Sponsor's support, including but not limited to financial support as may be required by academic journals, professional societies, funding agencies, and applicable regulations. Notwithstanding anything to the contrary in this Agreement, Sponsor agrees to allow publicly registered information about the Study to appear on Institution's clinical trials directory/website. Additionally, notwithstanding anything herein to the contrary, Institution shall have the right to post Sponsor's and/or CRO's names, the Study title, and the Study period, and funding amount, on Institution's publicly accessible lists of research conducted by the Institution.

11. Indemnification and Limitation of Liability

11.1. Indemnification by Sponsor: In consideration of such participation by Institution and Principal Investigator, and subject to paragraph 11.2 below, Sponsor shall agrees to defend, indemnify, and hold harmless the Institution and its medical affiliates and affiliated hospitals, and each of their trustees, officers, directors, governing bodies, subsidiaries, affiliates, investigators, employees, IEC members, agents, successors, heirs and assigns, and the Principal Investigator (collectively referred to as "**Institution's Indemnitees**"), from and against any third party claims, loss, damage, cost and expense of claims (including reasonable attorney's fees) and suits ("**Claims**"), alleged to be caused by or arising from the conduct of the Study or use of the Study Drug under this Agreement or from the use of the Study results, regardless of the legal theory asserted.

11.2 Sponsor shall have no obligation to provide such indemnification to the extent that such Claim is solely caused by Institution's Indemnitee(s)': (1) failure to adhere to and comply with all material and substantive specifications and directions set forth in the Protocol (except to the extent such deviation is reasonable to protect the rights, safety and welfare of the Study subjects); (2) failure to comply with all applicable laws and regulations in the performance of the Study; or (3) if such claim is directly caused by the negligent acts or omissions of Institution's Indemnitees(s).

11.3. Indemnification by Institution: Subject to the limits and without waiving any immunities provided under applicable law (including constitutional provisions, statutes and case law) regarding the status, powers and authority of the Institution or the Institution's principal(s), Institution shall indemnify, hold harmless and defend Sponsor, its directors, officers, employees and agents, ("**Sponsor's Indemnitees**") from and against only those third party Claims to the extent directly attributable to Institution's negligence in its conduct of the Study. Notwithstanding the above, Institution shall have no obligation to indemnify Sponsor for any other Claims (including, but not limited to, infringement or product liability Claims).

11.4. Indemnification Procedure: The indemnified Party shall give notice to the indemnifying Party promptly upon receipt of written notice of a Claim for which indemnification may be sought under this Agreement, provided, however, that failure to provide such notice shall not relieve indemnifying Party of its indemnification obligations except to the

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extent that the indemnifying Party's ability to defend such Claim is materially, adversely affected by such failure. Indemnifying Party shall not make any settlement admitting fault or incur any liability on the part of the indemnified Party without indemnified Party's prior written consent, such consent not to be unreasonably withheld or delayed. The indemnified Party shall cooperate with indemnifying Party in all reasonable respects regarding the defense of any such Claim, at indemnifying Party's expense. The indemnified Party shall be entitled to retain counsel of its choice at its own expense. In the event a Claim falls under this indemnification clause, in no event shall the indemnified Party compromise, settle or otherwise admit any liability with respect to any Claim without the prior written consent of the indemnifying Party, and such consent not to be unreasonably withheld or delayed.

11.5. Limitation of Liability: EXCEPT FOR THE PARTIES' OBLIGATIONS TO INDEMNIFY EACH OTHER AS STATED ABOVE, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, CONSEQUENTIAL OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.

11.6. CRO expressly disclaims any liability in connection with the Study Drug, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, willful mis-conduct or breach of this Agreement by CRO.

11.7. Institution shall have no obligation to indemnify CRO and CRO shall have no obligation to indemnify Institution.

11.4 **NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, CONSEQUENTIAL, OR INCIDENTAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT, EVEN IF ADVISED OF THE POSSIBILITY OF THE SAME.**

12. Subject Injury

Sponsor agrees that any Study-related injury or death of the Study Subject as defined by the criteria for such in the provisions of the New Drug Clinical Trial 2019 Rules shall be compensated such that the Study Subject or his nominee, as the case may be, will be entitled to receive from the Sponsor financial compensation for such injury or death as per the notification of the Drug Controller General of India (DCGI) & Government of India issued from time to time. Study Subject Injury or Death shall not include complications from pre-existing medical conditions of the Study Subject or from the failure to follow the Protocol and Applicable Laws or the negligence by the Institution, the Principal Investigator or the Study Personnel.).

13. Insurance

13.1. Institution: Institution shall maintain during the term of this Agreement and for three (3) years thereafter institutional liability insurance including medical professional liability insurance with limits in accordance with local standards and Applicable Laws for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

13.2. CRO: CRO shall maintain an insurance policy or a program of self-insurance at levels

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sufficient to support its obligations assumed herein.

13.3 Sponsor: In order to provide insurance to Study Subjects in case of injuries or death, the Sponsor has contracted with insurance Bajaj Allianz General Insurance Company Limited which covers per Study Subject amount INR 10,000,000. This insurance is valid from the period from 25 March 2022 to 1 September 2023.This insurance shall be extended from time to time until the expiration of the Agreement.

13.4. Upon written request, a Party will provide evidence of its insurance or self-insurance reasonably acceptable to any other Party. Each Party shall provide prompt, written notice to the other Parties upon cancellation or material change to this insurance coverage. A Party's inability to meet its insurance obligation constitutes material breach of this Agreement.

14. Term and Termination

14.1. This term of this Agreement shall commence upon the Effective Date and terminate upon the completion of the Parties' Study-related activities under the Agreement, unless terminated earlier as further described in this Section.

14.2. CRO has the right to terminate this Agreement upon 30 days prior written notice to the Institution.

14.3 This Agreement may be terminated immediately at any time for any reason by the Institution or CRO when, in their judgment or that of the Principal Investigator, the Institution's IEC, Scientific Review Committee, if applicable, or the FDA, it is determined that termination is necessary in order to protect the Study subjects' rights, welfare, and safety, or the IEC otherwise disapproves the Study.

14.4 If for any reason Principal Investigator becomes unavailable to direct the performance of the work under this Agreement, Institution shall notify CRO. If the Parties are unable to identify a mutually acceptable successor Principal Investigator, this Agreement may be terminated by either Party upon 30 days written notice.

14.5. Notwithstanding the above, any Party may, in addition to any other available remedies:

(a) immediately terminate this Agreement upon the other Party's material failure to adhere to the Protocol, except for deviation required to protect the rights, safety, and welfare of Study subjects; and/or

(b) terminate this Agreement upon the other Party's material default or breach of this Agreement, provided that the defaulting/breaching Party fails to remedy such material default or breach within 30 business days after written notice thereof.

14.6. In the event that this Agreement is terminated for any reason prior to completion of the Study Institution shall:

(a) notify the IEC that the Study has been terminated;

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(b) cease enrolling subjects in the Study;

(c) cease treating Study subjects under the Protocol as directed by CRO to the extent medically permissible and appropriate;

(d) terminate, as soon as practicable, all other Study activities in accordance with the Protocol; and

(e) furnish to CRO any required final report for the Study in the form reasonably acceptable to CRO.

Promptly following any such termination, Institution will provide to CRO copies of Data collected pursuant to the Study Protocol. Upon Sponsor's or CRO's written request, Institution agrees to return all Confidential Information supplied to it by Sponsor or CRO, at Sponsor's expense, pursuant to this Agreement except that Institution may retain such Confidential Information in a secure location for purposes of identifying and satisfying its obligations and exercising its rights under this Agreement.

14.7. If this Study is terminated early by either Party, the Institution shall be reimbursed for all work completed, on a pro rata basis, and reasonable costs of bringing the Study to termination incurred through the date of termination, and for non-cancelable commitments properly incurred through that date. Upon receipt of notice of termination, Institution will use reasonable efforts to reduce or eliminate further costs and expenses and will cooperate with CRO to provide for an orderly wind-down of the Study.

14.8. Subsections 1.4, 1.6, and 14.6, and Sections 2, 3, 4, 5, 6, 7, 8, 9, 10, 11 (and the attached Letter of Indemnification), 12, 13, 15, 18,20, 21 and 24, shall survive any termination or expiration of this Agreement, except that Section 3 shall survive for the period stated in Section 3.1. Any provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

15. Subject Material

15.1. Subject Material means any biologic material of human origin including, without limitation, tissues, blood, plasma, urine, spinal fluid, or other fluids derived from the Study subjects as required by the Protocol ("**Subject Material**").

15.2. Institution agrees to make the Subject Material available to the Sponsor in accordance with the Protocol for the purposes of the Study. The Subject Material may be used by the Sponsor, central lab, or other contracted party only as allowed by the Study subject's informed consent form and/or research authorization. CRO, on behalf of Sponsor, agrees that any use of Subject Materials, other than as allowed by the Study subject's informed consent form and/or research authorization, will require additional Institutional review and approval.

16. Sponsor Equipment (if applicable)

Sponsor or CRO may provide equipment for the conduct of the Study as specified by the Protocol and described in Exhibit C ("**Equipment**") (optional). Institution agrees that such

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Equipment shall be used solely in connection with the Study during the term of this Agreement, unless the Parties have a separate written agreement that states otherwise.

17. **Subcontract/Assignment**

17.1. Institution has the right to subcontract to other sites to conduct the Study in accordance with the Protocol with terms consistent with this Agreement with written approval of the Sponsor, such approval not to be unreasonably withheld. If Institution subcontracts any Study related duties, Institution shall contract with such subcontractors incorporating terms substantially similar to the terms herein, and Institution remains responsible for any sub-contracted duties. Such subcontracts may be provided to the CRO upon written request. Institution may not assign this Agreement without CRO's prior written approval, such approval not to be unreasonably withheld.

17.2. CRO has the right to subcontract to a third-party and assign Study-related duties and rights to any CRO affiliate or third-party contractors. If CRO subcontracts any Study-related duties and rights, CRO remains responsible for any of those duties and rights. RO agrees to provide Institution with prompt, written notice of any assignment and/or subcontracting in accordance with the notice requirements under this Agreement.

17.3. No assignment and/or subcontracting shall relieve either Party of the performance of any accrued obligation that such Party may have under this Agreement.

17.4 The Parties acknowledge and agree that the Sponsor and each of its affiliates is a third-party beneficiary to this Agreement.

18. **Notices**

Any notice, authorization, approval, consent or other communication will be in writing and deemed given:
a) Upon delivery in person;
b) Upon delivery by courier;
c) Upon delivery date by a nationally-recognized overnight delivery service such as FedEx; or
d) Upon email delivery to the email address listed hereinbelow.

If to Sponsor:
Leonard-Meron Biosciences, Inc.
11 Commerce Drive
First Floor
Cranford, NJ 07016 USA
Attention: Alan Lader, Ph.D - Senior Vice-President
+1-908-967-6677
alader@citiuspharma.com

If to Institution:
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Dr. R. K Dhiman
Director
Sanjay Gandhi postgraduate institute of medical sciences raibareli road Lucknow - 226014
0522-2490001
director@sgpgi.ac.in

If to CRO:

With a copy to Principal Investigator:

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Executive Registrar
SGPGIMS,Lucknow

force and effect as manual signatures.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

The authorized representatives of the Parties have signed this Agreement as set forth below.

CRO
BY: BIORASI CLINICAL SERVICES PVT LTD

NAME: Dr Abhijit Damre
TITLE: Director, Clinical Operations
Date: 02/AUG/2023

INSTITUTION
SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

NAME: Dr R.K DHIMAN
Title: Director
Date:

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

SPONSOR

BY: LEONARD MERON BIOSCIENCES, INC

DocuSigned by:
Alan Lader
Signer Name: Alan Lader
Signing Reason: I approve this document
Signing Time: 27 July 2023 | 12:26:07 PM CDT
58DDD4611A9C4FD481B9AF6E80EE6756

Name: Alan S. Lader, Ph.D.
Title: Senior Vice-President of Clinical Operations and Quality Assurance

Date: 27 July 2023

Read and understood by
INVESTIGATOR

Signed:

Name: Dr. Narayan Prasad
Title: Professor & Head

Date: 14.8.23

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SGPGIMS,Lucknow

EXHIBIT A

Budget& Payment

For the purposes of the Agreement, the following Budget and Payment terms apply to the Institution and Principal Investigator (together, "**Site**"):

A. PRINCIPAL INVESTIGATOR INFORMATION

First Name	Narayan
Middle Name	Not Applicable
Last Name	Prasad
Medical Credentials	MD, DM

B. PAYEE DETAILS

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("**Payee**"):

Payee Name	Director SGPGIMS RESEARCH ACCOUNT
Payee Street Address	State Bank of India SGPGI Campus Raibareli Road Lucknow
Payee City, State ZIP	Lucknow UP-226014
Payee Tax ID	*Payee shall submit a W-9 (or equivalent) to AP@biorasi.com before any payment will be made. Payee shall maintain a current version of this document at all times; updates should be sent to AP@biorasi.com.*
Bank Name	State Bank of India, SGPGI Campus
Full Bank Address	State Bank of India, SGPGI Campus, Raibareli Road Lucknow-226014
Bank Routing Number	IFSC: SBIN0007789
Payee Bank Account	10095237491
Payee Contact information for recipient of payment notifications	Dr. R. K Dhiman Director director@sgpgi.ac.in

Single Payee: The Parties acknowledge that the designated Payee is authorized to receive all payments for the services performed under this Agreement. Principal Investigator acknowledges that if Principal Investigator is not the Payee, CRO will not pay Principal Investigator even if the Payee fails to reimburse Principal Investigator. If the Principal Investigator is not the Payee, then the Payee's obligation to reimburse the Principal Investigator, if any, is determined by a separate agreement between Principal Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by CRO to the Payee. Payee shall be solely responsible for the payment of all compensation and any other amounts due to all Investigators and Site staff performing services under this Agreement, and to Study Subjects.

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C. PAYMENT TERMS

CRO will administer payment to the Payee on a completed visit per subject basis in accordance with this Exhibit A and the Budget Table, below. Amounts listed herein include all applicable taxes. All payments will be paid by CRO electronically.

EDC: Site must complete the procedures in the appropriate sequence for each subject visit as set forth in the Protocol. Site shall complete the Electronic Data Capture ("**EDC**") data entry for each subject visit within 5 business days of the date of the specific visit to be eligible for payment. CRO monitors shall verify that the EDC data are accurate and complete. If a protocol procedure is not performed for any reason, Site shall document this in the CRF and EDC system to meet the "completed visit" requirements.

Payment: CRO shall make quarterly payments based on completed EDC data. CRO will withhold 10% of each site visit payment(the "**Retention Amount**") which will be paid upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by this Agreement, the return (or evidence of destruction) of all unused supplies to CRO at Sponsor's sole cost, performance/completion of end-of-Study protocol requirements and Site close-out activities as coordinated with CRO and upon satisfaction of all other applicable conditions set forth in the Agreement.

Reconciliation: EDC data will be verified by CRO during the study. If CRO discovers Site received unearned payment, CRO will deduct the unearned amount from the total payment issued to Site in the next payment cycle. At the conclusion of the Study, CRO shall reconcile payments made to Site. If it is determined the total amount of money paid exceeds the amount entitled to Site, CRO shall provide written notice for purposes of discussion and mutual agreement between the Parties. Where the Parties agree an overpayment has been made, the Retention Amount shall be adjusted accordingly.

Noncompliance: CRO reserves the right to withhold payment due to Site's non-compliance with any of the terms and requirements of this Agreement. **Major, disqualifying Protocol violations are not payable under this Agreement. Payments made by CRO for Subjects entered in violation of the Protocol or withdrawn from the Study due to Protocol violation may be required to be refunded by Site after evaluation on a case-by-case basis.**

Study Termination: In the event of any termination of the Study, the CRO will be responsible for all actual costs including non-cancelable obligations of the Institution if such costs were pre-approved by the Sponsor. In the event of early termination, the total sums payable by CRO shall be equitably pro-rated for actual work performed to the date of termination.

D. INVOICES

CRO shall review the EDC data for accuracy and completion at the end of each quarter for purposes of preparation of subject visit payment statements. Payments for all other fees/costs will be made only upon CRO's receipt of corresponding invoices, including back-up documentation where available, in the specified currency, as described below. Pass-through expenses must be substantiated by actual copy/ies of invoices or other documentation proving

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the expenditures were actual, reasonable, and verifiable in the amount submitted for reimbursement. Undisputed invoices will be payable within 45 days from the date of receipt by CRO of the invoice, including any applicable back-up documentation where available. Site shall submit all final invoices following the completion of the Study. Invoices received more than 30 days after completion of the requirements shall not be approved for payment.

Invoices for any payments in addition to those noted above (i.e., additional reimbursements) must also be sent to CRO and approved by Sponsor or CRO. All invoices shall be raised in the following manner:

Invoices to be billed to:
Biorasi Clinical Services Pvt Ltd.
Unit B-3/06 B Wing, 8th Floor, Ashar IT Park Road no 16Z,Wagle Industrial Estate Thane West – 400604, Maharashtra, India

Invoices to be sent to:
Biorasi Clinical Services Pvt Ltd.
Unit B-3/06 B Wing, 8th Floor, Ashar IT Park Road no 16Z,Wagle Industrial Estate Thane West – 400604, Maharashtra, India
AP@biorasi.com&CopytoStudy CTM

Site must include the following information on each invoice for payment to be made by CRO:

Biorasi Project Code:	177-1
Protocol Number:	MDA 2013-0039
Sponsor Name:	Leonard-Meron Biosciences, Inc
Site Number:	213
PI Name:	Dr. Narayan Prasad
Payee Name	Director SGPGIMS RESEARCH ACCOUNT
Site Name (if different):	Sanjay Gandhi Postgraduate Institute of Medical Sciences
Payee Address:	State Bank of India SGPGI Campus Raibareli Road Lucknow, Uttar Pradesh, Pin Code: 226014
Currency:	INR
	Invoice Date
	Invoice Number
	Payment Amount
	Complete details of services/ expense(s)

All invoice and payment related inquiries shall be addressed directly to Biorasi at AP@biorasi.com, telephone +1 786 388-0700.

E. PAYMENT DISPUTE

Payment of procedures or fees that are in dispute will be suspended until the Parties reach mutual agreement. Once agreement is reached, CRO will issue payment within 30 days from the date of dispute resolution. Site will have 45 business days from the receipt of final payment to dispute any payment discrepancies during the Study.

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F. SITE FEES

Site must submit invoices to CRO for payment of the following fees unless set forth otherwise below:

IEC Fees

CRO agrees to pay for Institution's initial IEC review regardless of whether the Study Protocol is approved. Local IEC/IEC costs will be reimbursed on a pass-through basis (actual costs, without overhead) upon CRO's receipt of invoice. Payment for Institutional IEC fees will be bundled within the same payment for other Study fees unless invoiced separately by the Site (or Institutional IEC if it requires direct payment).Any subsequent re-submissions or renewals will be reimbursed upon receipt and approval of the invoice by CRO and Sponsor.

Screening

Reimbursement for verified screen failures will be at the amount indicated for the screening visit within the below Budget Table. To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to CRO along with any additional information requested by CRO to appropriately document the subject screening procedures.

Unscheduled Visits

Site must receive prior written approval from CRO (pursuant to direction of Sponsor) for any planned unscheduled visits, tests or evaluations performed beyond the required scope of the Protocol. Payment for approved unscheduled visits, tests or evaluations will be based on the procedures actually performed and invoiced at the amounts indicated in the Conditional Procedures table below. Unscheduled visits shall be reimbursed upon receipt of a valid invoice. Subject number and visit/dates must be included on the invoice for payment to be issued.

Discontinued or Early Termination

Reimbursement for discontinued or early termination subjects will be prorated for actual work performed, based on the number of confirmed completed visits and/or procedures performed.

Administrative Study Start-Up Fee

A one-time, non-refundable payment as set forth in the Budget Table which includes overhead, to cover Study start-up activities will be made upon execution of this Agreement and receipt by CRO of proof that Institution has submitted all regulatory documentation required before the Site Initiation Visit, and receipt of an invoice. This fee does not include IEC review fees as noted above.

Study Subject Stipends

Stipends for patient travel to scheduled visits (inclusive of overhead) is included in the per visit cost outlined in the Budget Table. Additional patient travel expense stipends (inclusive of overhead) will be provided as outlined in *Conditional Costs*. Institution will generate payments to Study Subjects as outlined in the Informed Consent Form.

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Conditional Costs

Conditional costs will be reimbursed upon receipt of supporting invoices, at the rates listed in the Budget Table per occurrence which include overhead. Study Subject numbers and procedure date must be included on the invoice.

L. **BUDGET TABLE**

[see next page]

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED.

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A Phase 3, Multi-Center, Randomized, Open-Label, Assessor-Blind Study to Evaluate the Efficacy and Safety of Mino-Lok Therapy (MLT) in Combination with Systemic Antibiotics in the Treatment of Catheter-Related or Central Line-Associated Bloodstream Infection
PROTOCOL ID: MDA 2013-0039
LEONARD-MERON BIOSCIENCES, INC.

			Treatment							FUP visit		
Procedures	**Unit Cost**	**Screening**	Day1 T1	Day2 T2	Day3 T3	Day4 to Day 12 T4	Day5 to Day 13 T5	Day6 to Day 14 T6	Day7 to Day 15 T7 (EOT)	Week 6 TOC	ET	**Total**
Informed consent	₹ 4,000.00	₹ 4,000.00										₹ 4,000.00
Inclusion/exclusion review	₹ 2,500.00	₹ 2,500.00	₹ 2,500.00									₹ 5,000.00
Medical/Surgical History, Prior Concomitant Medications / Concomitant Non-Meds and Procedures	₹ 500.00	₹ 500.00	₹ 500.00	₹ 500.00	₹ 500.00			₹ 500.00	₹ 500.00	₹ 500.00	₹ 500.00	₹ 4,000.00
Height, Weight & Complete physical examination	₹ 500.00	₹ 500.00							₹ 500.00	₹ 500.00	₹ 500.00	₹ 2,000.00
Unblinded assessment of signs and symptoms of infection	₹ 800.00	₹ 800.00	₹ 800.00	₹ 800.00	₹ 800.00			₹ 800.00	₹ 800.00	₹ 800.00	₹ 800.00	₹ 6,400.00
Unblinded assessment of clinical outcome	₹ 800.00				₹ 800.00				₹ 800.00	₹ 800.00	₹ 800.00	₹ 3,200.00
Blinded assessment of signs and symptoms of infection	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00			₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 8,000.00
Blinded assessment of clinical outcome	₹ 1,000.00								₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 3,000.00
Vital signs	₹ 500.00	₹ 500.00	₹ 500.00	₹ 500.00	₹ 500.00			₹ 500.00	₹ 500.00	₹ 500.00	₹ 500.00	₹ 4,000.00
12 lead ECGo	₹ 1,000.00		₹ 1,000.00						₹ 1,000.00			₹ 2,000.00
Randomization	₹ 1,000.00		₹ 1,000.00									₹ 1,000.00
Pregnancy test	₹ 1,000.00	₹ 1,000.00							₹ 1,000.00		₹ 1,000.00	₹ 3,000.00
Clinical laboratory assessments	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00		₹ 1,000.00				₹ 1,000.00		₹ 1,000.00	₹ 5,000.00
PT or INR/PTTr	₹ 2,000.00	₹ 2,000.00										₹ 2,000.00
Chest x-ray or other radiologic imagings	₹ 1,000.00	₹ 1,000.00										₹ 1,000.00
Blood culture test	₹ 2,500.00	₹ 2,500.00	₹ 2,500.00		₹ 2,500.00				₹ 2,500.00	₹ 2,500.00	₹ 2,500.00	₹ 15,000.00
Retinal examination	₹ 1,500.00	₹ 1,500.00										₹ 1,500.00
Administration of antibiotic lock therapy	₹ 20,000.00		₹ 20,000.00									₹ 20,000.00
Antibiotic administration	₹ 5,000.00		₹ 5,000.00								₹ 5,000.00	₹ 10,000.00
Non-Procedures												₹ 0.00
Physician(s) Fee - PI	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 8,000.00	₹ 80,000.00
Physician(s) Fee - Sub I	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 3,000.00	₹ 30,000.00
Study Coordinator(s) Fee	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 1,500.00	₹ 15,000.00
Nursing Fee	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 1,000.00	₹ 10,000.00
Procedures SubTotal		₹ 16,800.00	₹ 35,800.00	₹ 2,800.00	₹ 7,100.00	₹ 0.00	₹ 0.00	₹ 2,800.00	₹ 10,600.00	₹ 7,600.00	₹ 14,600.00	₹ 1,00,200.00
Non-Procedures Sub Total		₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 13,500.00	₹ 1,35,000.00
Institute Overhead at	25%	₹ 4,700.00	₹ 8,950.00	₹ 700.00	₹ 1,775.00	₹ 0.00	₹ 0.00	₹ 700.00	₹ 2,650.00	₹ 1,900.00	₹ 3,650.00	₹ 25,025.00
Total (Procedures + Non-Procedures + Institute Overhead)		₹ 37,000.00	₹ 58,250	₹ 17,000	₹ 22,375	₹ 13,500	₹ 13,500	₹ 17,000	₹ 26,750	₹ 23,000	₹ 31,750	₹ 2,60,125
GST charges (Procedures + Non-Procedures + Institute Overhead)	18%	₹ 6,660.00	₹ 10,485.00	₹ 3,060.00	₹ 4,027.50	₹ 2,430.00	₹ 2,430.00	₹ 3,060.00	₹ 4,815.00	₹ 4,140.00	₹ 5,715.00	₹ 46,823
Total per subject grant		₹ 43,660.00	₹ 68,735.00	₹ 20,060.00	₹ 26,402.50	₹ 15,930.00	₹ 15,930.00	₹ 20,060.00	₹ 31,565.00	₹ 27,140.00	₹ 37,465.00	₹ 3,06,948

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Site Fees	Total
Administrative Start-up Fee (Non-refundable)	₹ 1,00,000.00
IRB Fee- Initial Review	as per Invoice
Long term record storage	₹ 75,000.00
Unscheduled Visit Fee	Per Procedure w/Overhead
Subject Travel Reimbursement	upto INR 2000
Cost for Standard of care will be as per actuals	as per Invoice

Footnotes:

1. *Screen failures will be paid on the basis of those procedures completed as verified by monitoring visits*
2. *Reimbursement predicated upon Site completing Visit procedures in appropriate sequence for each subject per the Protocol and as indicated in Budget plus EDC data being timely submitted.*
3. *All fees and payments outlined herein will be paid according to the terms and conditions as set forth in the CTA.*
4. *Reimbursement for discontinued or early termination subjects will be paid based on the total number of visits completed as of discontinuation or termination date.*
5. *Reimbursement for subjects enrolled in error or violation of the Protocol who are not allowed to continue the study and will not be paid*
6. *Budget prices are all inclusive of fees and costs to perform Study. Overtime and weekend work is not subject to separate compensation.*

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Certificate Of Completion

Envelope Id: 2C009DAF841048C890945F8412F23007 Status: Completed
Subject: Complete with DocuSign: Citius MDA 2013-0039_SGPGI LKO-20230621 -Final CTA with Budget- RTE.docx
Sponsor Project Code: 177-1
Quality Document Type:
Source Envelope:
Document Pages: 26 Signatures: 1 Envelope Originator:
Certificate Pages: 5 Initials: 0 Srinidhi Shetty
AutoNav: Enabled 18851 NE 29th Ave #800
EnvelopeId Stamping: Disabled Aventura, FL 33180
Time Zone: (UTC+05:30) Chennai, Kolkata, Mumbai, New Delhi sshetty@biorasi.com
IP Address: 103.121.75.45

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Signer Events	Signature	Timestamp
Alan Lader alader@citiuspharma.com Security Level: Email, Account Authentication (Required)	Alan Lader Signature Adoption: Pre-selected Style Signature ID: 58DDD461-1A9C-4FD4-81B9-AF6EB0EE6756 Using IP Address: 73.227.199.211 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 7/27/2023 6:52:34 PM Viewed: 7/27/2023 10:55:47 PM Signed: 7/27/2023 10:56:10 PM

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ID: 2282e431-2a43-4371-bfbe-602da438cbb2

In Person Signer Events	Signature	Timestamp
Editor Delivery Events	**Status**	**Timestamp**
Agent Delivery Events	**Status**	**Timestamp**
Intermediary Delivery Events	**Status**	**Timestamp**
Certified Delivery Events	**Status**	**Timestamp**
Carbon Copy Events	**Status**	**Timestamp**
Witness Events	**Signature**	**Timestamp**
Notary Events	**Signature**	**Timestamp**

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	7/27/2023 6:52:34 PM
Certified Delivered	Security Checked	7/27/2023 10:55:47 PM
Signing Complete	Security Checked	7/27/2023 10:56:10 PM
Completed	Security Checked	7/27/2023 10:56:10 PM

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Payment Events	Status	Timestamps
Electronic Record and Signature Disclosure		

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ELECTRONIC RECORD AND SIGNATURE DISCLOSURE

From time to time, Biorasi, LLC (we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to this Electronic Record and Signature Disclosure (ERSD), please confirm your agreement by selecting the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

Getting paper copies

At any time, you may request from us a paper copy of any record provided or made available electronically to you by us. You will have the ability to download and print documents we send to you through the DocuSign system during and immediately after the signing session and, if you elect to create a DocuSign account, you may access the documents for a limited period of time (usually 30 days) after such documents are first sent to you. After such time, if you wish for us to send you paper copies of any such documents from our office to you, you will be charged a $0.00 per-page fee. You may request delivery of such paper copies from us by following the procedure described below.

Withdrawing your consent

If you decide to receive notices and disclosures from us electronically, you may at any time change your mind and tell us that thereafter you want to receive required notices and disclosures only in paper format. How you must inform us of your decision to receive future notices and disclosure in paper format and withdraw your consent to receive notices and disclosures electronically is described below.

Consequences of changing your mind

If you elect to receive required notices and disclosures only in paper format, it will slow the speed at which we can complete certain steps in transactions with you and delivering services to you because we will need first to send the required notices or disclosures to you in paper format, and then wait until we receive back from you your acknowledgment of your receipt of such paper notices or disclosures. Further, you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

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Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. Thus, you can receive all the disclosures and notices electronically or in paper format through the paper mail delivery system. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact Biorasi, LLC:

You may contact us to let us know of your changes as to how we may contact you electronically, to request paper copies of certain information from us, and to withdraw your prior consent to receive notices and disclosures electronically as follows:
To contact us by email send messages to: mrudolph@biorasi.com

To advise Biorasi, LLC of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to us at mrudolph@biorasi.com and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address.

If you created a DocuSign account, you may update it with your new email address through your account preferences.

To request paper copies from Biorasi, LLC

To request delivery from us of paper copies of the notices and disclosures previously provided by us to you electronically, you must send us an email to mrudolph@biorasi.com and in the body of such request you must state your email address, full name, mailing address, and telephone number. We will bill you for any fees at that time, if any.

To withdraw your consent with Biorasi, LLC

To inform us that you no longer wish to receive future notices and disclosures in electronic format you may:

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i. decline to sign a document from within your signing session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent, or you may;

ii. send us an email to mrudolph@biorasi.com and in the body of such request you must state your email, full name, mailing address, and telephone number. We do not need any other information from you to withdraw consent.. The consequences of your withdrawing consent for online documents will be that transactions may take a longer time to process..

Required hardware and software

The minimum system requirements for using the DocuSign system may change over time. The current system requirements are found here: https://support.docusign.com/guides/signer-guide-signing-system-requirements.

Acknowledging your access and consent to receive and sign documents electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please confirm that you have read this ERSD, and (i) that you are able to print on paper or electronically save this ERSD for your future reference and access; or (ii) that you are able to email this ERSD to an email address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format as described herein, then select the check-box next to 'I agree to use electronic records and signatures' before clicking 'CONTINUE' within the DocuSign system.

By selecting the check-box next to 'I agree to use electronic records and signatures', you confirm that:

- You can access and read this Electronic Record and Signature Disclosure; and
- You can print on paper this Electronic Record and Signature Disclosure, or save or send this Electronic Record and Disclosure to a location where you can print it, for future reference and access; and
- Until or unless you notify Biorasi, LLC as described above, you consent to receive exclusively through electronic means all notices, disclosures, authorizations. acknowledgements, and other documents that are required to be provided or made available to you by Biorasi, LLC during the course of your relationship with Biorasi, LLC.

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Executive Registrar
SGPGIMS,Lucknow

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MoU) is entered on Dec 17, 2022 at Palo Alto, between SALOMI HEART FOUNDATION, California, USA a Company incorporated under the ~~Companies Act 2013~~ 501(c)(3), having its Corporate Office at San Jose, California, USA through _____ (herein after referred to as "Company" which expression shall unless repugnant to the context thereof include its successors) of the one Part

and

The Governor of Uttar Pradesh through _____ (herein after referred to as "GoUP" which expression shall unless **repugnant** to the context thereof include his successor in office) of the other Part.

Now, therefore, this MoU witnesses as follows:

1. Company wishes to establish the following Project in **Uttar Pradesh**:-

Project Name	Project Description incl Location	Proposed Investment (Rs in Cr)	Employment (Nos)	Proposed Year of Commencement
Centre of Excellence in Pediatric Cardiology	To build 200 bed Centre of Excellence in UP to train medical staff and treat children born with Congenital Heart Disease	480	5000	2024

2. For establishment of aforesaid Project, GoUP would facilitate Company to obtain necessary permission / registrations, approvals / clearances etc. as per the existing facilities / rules and regulations of the State GoUP and would also help to avail incentives under various schemes announced by State / Central Government, wherever applicable.

3. GoUP will facilitate Company to establish the **aforesaid** Project in the State of Uttar Pradesh in a time bound manner.

4. Parties to this MoU agree as Below:
   a. This MoU is not intended to provide any basis for any investment decision to be made by any interested parties and each prospective **interested** party must make their own independent assessment of the Project.

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b. None of the provisions of this MoU shall be deemed to constitute a Partnership between parties hereto, and no party shall have any authority to bind or shall be deemed to be agent of the other in any manner whatsoever.

c. In due course of time, if the GoUP undertakes a transparent competitive bidding process based on the feasibility reports to award the Projects, then the interested parties including Company may consider their participation as per their discretion.

IN WITNESS WHEREOF the Parties hereto have set and subscribed their respective hands on the day and the year first herein before written.

For and on behalf of
Government of Uttar Pradesh

(AUTHORISED SIGNATORY)
Name: ARVIND KUMAR
Designation: IAS, MD, UPSIDA
Contact No.: 7054444444
Email: psiidupa@gmail.com
Contact Address: 10B, C-Wing, Lok Bhawan, Lucknow

Witness:
Name: ANKUR AGGARWAL
Designation: DIRECTOR (I&T)
Contact No.: 9871222058

For and on behalf of
M/s. SALONI HEART FOUNDATION

(AUTHORISED SIGNATORY)
Name: MRINALINI SETH
Designation: Founder & President
Contact No.: +1-408-442-7163
Email: mili@saloniheartfoundation.org
Contact Address: P.O. Box # 23414
San Jose, CA-95160

Witness:
Name: BRATESH P. UPADHYAY
Designation: VOLUNTEER
Contact No.: 408.837.2725

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Executive Registrar
SGPGIMS,Lucknow

MEMORANDUM OF UNDERSTANDING

BETWEEN

CENTRAL UNIVERSITY OF PUNJAB

AND

SGPGI

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

1. **The Central University of Punjab,** hereinafter referred to as "CUPB" has been established through the Central Universities Act 2009 which received the assent of the President of India on 20th March 2009. Its territorial jurisdiction extends to the whole State of Punjab. This fast growing newly set up Central University at Bathinda is an important link in the recently set up chain of Central Universities created in the educationally backward areas throughout the country. This university is destined to emerge as a premier educational institution with the state of the art infrastructure to provice quality education and research in science and technology as well as humanities and social sciences.

2. **Sanjay Gandhi Postgraduate Institute of Medical Sciences** is a medical Institute under State Legislature Act, located in **Lucknow**, Uttar Pradesh. The institute is on a 550 acres (2.2 km2) residential campus at Raebareli Road, 15 km from the main city. The institute is rated amongst the top medical institutions in the country, delivering state-of-art tertiary medical care, super-specialty teaching, training and

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research. Dedicated faculty members endeavor to provide quality education, patient care and research and strive to meet the challenges and needs of the society. The institute offers DM, MCh, MD, PhD, Post-Doctoral Fellowships (PDF) and Post-Doctoral Certificate Courses (PDCC), and Senior Residency in various specialties. The Department of Critical Care Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow hereinafter referred to as "Critical Care Medicine" was established in the year 2002 with an aim to excel inclinical services, teaching & training, as well as basic & clinical research.

This MEMORANDUM OF UNDERSTANDING (MoU) in entered into on this day of _____.

BETWEEN

The Central University of Punjab being represented by its Registrar, having its office at Bathinda, Punjab in India hereinafter referred to as the PARTY OF THE FIRST PART.

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS),LUCKNOWbeing represented by its Director, having its office at Lucknow, Uttar Pradeshin India hereinafter referred to as the PARTY OF THE SECOND PART.

WITNESSETH that

WHEREAS, the Party of the First Part is an educational institution of national importance engaged in advancement of teaching and research in several branches of humanities, social sciences, science and languages. Reassuring its resolve and commitment and social responsibilities, towards the neighboring educational Institution needs of the area, adopted the Party of the Second part to help its constituents for the advancement of knowledge and creativity.

Whereas the Party of the 2nd part is a Medical Institution with a vision to provide excellent human resource throughdelivers tertiary medical care, super-specialty teaching, training and research.

WHEREAS both, Party of First Part and the Party of the Second Part with complimentary tasks have come to an understanding to promote cooperation between two organization in the field of education, research and development.

NOW, THEREFORE, IT IS HEREBY MUTUALLY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. This MoU is valid for a period of three years to promote the Innovation and research and which can be extendable.

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Executive Registrar
SGPGIMS,Lucknow

2. Both the parties will promote cooperation between two organization in the field of education, innovation and research in the field of Sciences, Humanities and Social Sciences.
3. Both the parties will work together to enhance the academic interchange between the two institutions to promote the teaching and research and to promote the standards.
4. The faculty and research scholars of the part one and part two will be mutually available for helping each other with the latest in the research areas. The teachers, staff and students of the institutions will have the liberty to use the facilities- Labs, library, equipment's, playground, Gymnasium, Auditorium etc. of the other party, if available, as per prescribed rules in force.
5. CUPB registered students and faculty under this MoU can use the SGPGI library and the designated laboratories for this purpose, as per prescribed rules in force.
6. The party of the First Part may allocate its students for research guidance and internships to the party of the Second Part. In all such mutually agreed instances, the faculty from First Party shall be the supervisor / guide while the faculty members from Second Party shall act as co-supervisor/co-guide. SEE IF YOU WANT TO ADD THIS
7. They can attend the seminars of the CUPB without any fee.
8. They can mutually invite faculty & research scholars to their institutions for interaction and for guidance as per the need and availability.
9. They can apply for research funding for collaborating research project on mutually agreeable basis.
10. There will not be any financial liability on either party.
11. Ownership of findings of any joint research shall be vested in both institutions and any publications regarding the same shall only be possible after prior approval from both institutions.
12. Both institutions agree and undertake to keep confidential, at all times, any information and / or data that may be exchanged, acquired and /or shared in connection with the area of cooperation as mentioned above unless otherwise the same information already exists in the public domain.

This MOU can also serve purpose of *Rastriya Aviskaar Abhiyaan* of MHRD through inspiring and motivating the young minds, teachers, and students for research and innovation.

TERMS AND CONDITIONS

1. The MoU shall be deemed to have been automatically rescinded after the expiry of the MoU period, unless renewed for further period as per mutually agreed upon terms at a later stage. It is further agreed that

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Executive Registrar
SGPGIMS,Lucknow

following the termination of the MoU, both the parties shall refrain from carrying out the balance of the activity agreed upon in this MoU.

2. Either of the parties hitherto shall be entitled to terminate the MoU at any time with valid reasons acceptable in writings to both parties and in such case, the MoU will terminate six months after the date of written notification or date of expiry of the MoU, whichever is earlier. In case of such premature termination of the MoU, all rights and obligations of both parties shall automatically cease except for those covered by written contracts including ongoing collaborative activity that can no longer be cancelled.
3. In case of any dispute that may crop up during execution of MoU, the matter would be settled through arbitration by referring to a committee jointly appointed by both parties.

IN WITNESS WHEREOF, the authorized representatives of both parties have hereinto affixed their signature at Bathinda on the date indicated below:

Registrar
Central University of Punjab

Director
Sanjay Gandhi Postgraduate
Institute of Medical Sciences,
Lucknow.

Date:
Place:

Date:
Place:

Signed in the Presence of

Vice Chancellor
Central University of Punjab

Signed in the Presence of

Director
Sanjay Gandhi Postgraduate Institute
of Medical Sciences, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (hereinafter called MOU) between **Sanjay Gandhi Post Graduate Institute of Medical sciences, Lucknow**, India (herein after called SGPGI) and **Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur** whose address is Civil Lines, Gorakhpur (U.P.) - 273009 India (herein after called "DDUGU") entered into on this .....(day) .....(month)..... (year).

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Preamble:

Whereas **SGPGI** is a superspeciality hospital, established by Govt. of Uttar Pradesh, as a centre of excellence for providing medical care, education and research of high order and is chartered to function as a university under this state act.

Whereas Deen Dayal Upadhyaya Gorakhpur University (DDUGU) is a residential-cum-affiliating State University established in 1957 by the Uttar Pradesh State Universities Act. It is first to be established in Uttar Pradesh after Independence, playing a significant role in imparting holistic education and research to contribute meaningfully to regional and national development for the people of the Eastern region since its inception.

Whereas (**SGPGI**) and (**DDUGU**) are willing to jointly participate in the development of collaborative research, academic exchanges and to explore other avenues for possible collaboration where expertise exists and can be mentored by either or both of them and also to provide higher education opportunities for faculty, support staff and students of SGPGIMS and DDUGU. A coordinator shall be appointed on each side to monitor and ensure progress during the MOU.

Scope of MOU

This MOU will cover the joint efforts of Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India and Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur in the area of communicable and non-communicable diseases, social health awareness programs, animal model development and collaborate to promote, facilitate and implement cooperation in the following programs and activities.

Furnish full details of the work to be done:

1. **Collaborative Research Programs in specific fields of interest** - SGPGI and DDUGU will jointly identify specific fields to conduct collaborative research programs of mutual interest and benefit to both parties. It should also include technical inputs for development of protocols for collaborative projects.

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Executive Registrar
SGPGIMS,Lucknow

2. **Submission of Joint projects**- Project proposals may be jointly submitted to UGC, SERB, ICMR, DBT, UPDST or any other funding agencies for extramural funding for carrying out further studies of selected project/fields.
3. **Faculty Exchange Programs**- SGPGI and DDUGU wish to develop academic exchanges and cooperation in teaching and research in furtherance of the advancement and dissemination of learning.
4. **Student Exchange Programs**- Exchange programs for students will be explored and conducted accordingly which will be mutually beneficial for both parties.
5. **Sharing of instrumentation facilities and Joint Programs**: Sharing of Instrumentation facility for research in various human diseases and organizing jointly symposia, workshops, scientific conference, and societal health awareness programs in the areas of mutual interest.

Responsibilities of SGPGI

1. SGPGI faculty and scientists will work towards joint projects with faculty members of Departments of Zoology, Biotechnology, Microbiology and Environmental science etc. of DDUGU, on request and subject to mutual using leading research facilities developed and to be developed at SGPGI, Lucknow and DDUGU.

2. The collaborators shall initiate the work after obtaining necessary approval of the research project from Institutional Human Ethics Committee and Institutional Animal Ethics Committee of SGPGI and DDUGU respectively.

3. A student working at SGPGI, Lucknow can be registered for Ph.D. degree at DDU Gorakhpur University provided he qualifies RET and is eligible for Ph.D. registration as per the Ph.D. ordinance of the university. In that case, a faculty member of the department, in which the student is registered, will be the supervisor and the concerned faculty/scientist from SGPGI will be the co-supervisor. In all cases, Ph.D. ordinance of the university will be applicable as and when required.

4. Research students of DDUGU working overlapping areas can do relevant Pre-PhD Course at SGPGI, Lucknow and their credit shall be counted.

5. The faculty and research students of the above-mentioned departments of DDUGU shall be allowed to use library of SGPGI subject to prior permission of the Director. Faculty and Ph.D.

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Executive Registrar
SGPGIMS,Lucknow

students of SGPGI shall likewise be given the library facilities at DDUGU with prior permission of competent authority.

Responsibilities of DDUGU

1. DDUGU will registered the research students for PhD with work place in SGPGI, While registering SGPGI students for PhD degree in DDUGU, the ordinance related to PhD degree of DDUGU will be applicable.

2. DDUGU will provide the place and existing instruments for the work of collaborative projects.

3. Both parties acknowledge the importance of protection of human and animal subjects in any research activity. Matters related to the transfer of biological material should receive prior approval on each side by the competent authority according to the existing rules and regulations of each party.

4. DDUGU will agree to ensure appropriate protection of Intellectual Property Rights generated from such cooperation consistent with their respective laws, rules and regulations and other international agreements to which both parties are signatories.

Administration:

Overall responsibilities of the project will rest with Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India & Deen Dayal Upadhyaya Gorakhpur University, Gorakhpur.

Financial Arrangements:

Funds for the projects will be distributes according to the mentioned in the applied funding agency-

1. Both parties shall take necessary financial approvals from the competent authority for fulfilling the objectives of the projects and applied for financial support from the funding agency as per utilization.

2. Both parties and their student can visit the collaborating institutes as per requirements of the project, and shall have adequate insurance coverage without any financial liability on each other.

4. Honorarium, TA/DA (if applicable) will be provided to the faculty members/scientists/technical staff of SGPGI, Lucknow and DDUGU, Gorakhpur.

5. Fellowship monitoring will be decided by the competent authority on the basis of activation of the fellowship (if candidates activate their fellowship from SGPGI, Lucknow then it is

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Executive Registrar
SGPGIMS,Lucknow

maintained by SGPGI and if activated in above mentioned departments of DDUGU then University will maintain the fellowship).

Intellectual Property rights:

1. The R & D information generated shall be shared by both the collaborating parties.
2. Any publication shall be by mutual consent of the coordinators.
3. Patents and other benefits, arising out of the project if any, shall be shared between the collaborating parties.
4. For projects identified as having a distinct potential generating know how leading to commercial applications *NRDC (National Research Development Corporation of India) guideline will be followed.

NRDC Guidelines:

1. To bring to notice of the investigator, prospective user of the technology being developed.
2. To do market research about the product and bring out a comprehensive study about the market potential for attending entrepreneur.
3. For effective coordination between the laboratory generating the know how and the entrepreneur.
4. To take such other steps as may facilitate the communication to know how.
5. NRDC will retain 40% of the royalty/permia and the remaining 60% will be sent to the institution generating the know how. The institute may decide the sharing of 40% between the institute and the project investigator team.

Duration of MOU:

This MOU will be force for the period of 05 (years from the date of its signing)
It is further agreed that the Director-SGPGI, Lucknow and Vice-Chancellor, DDUGU, Gorakhpur through periodic meetings will monitor the progress of this MOU. Any change or modification /termination as introduced/suggested by the review committee (Comprising of Director, SGPGI and Vice - Chancellor, DDUGU) will be binding to both the organizations.

Amendments to the MOU:

Amendments if any, before the authorized representative of SGPGI and DDUGU shall make the expiry of this MOU in writing after mutual agreement.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Resolution of Dispute:

Any dispute or difference between the collaboration parties shall be amicably resolved by either through mutual consultation or arbitration.

Seal of parties:

In witness therof parties hereto have signed this MOU on the day, month and year mentioned herein before.

Parties:

Signed and delivered for and behalf of SGPGI

Signature

Date

Name

Designation

Seal

Witness

1. U C Ghosh

2.

3.

Signed and delivered for and behalf of DDUGU

Signature

Date

Name

Designation

Seal

Witness

1.

2.

3.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Memorandum of Understanding (MOU)

FOR FACILITATING

COLLOBORATIVE SERVICES,TRAINING, EDUCATION AND RESEARCH

Between

Himalayan Institute of Medical Sciences, SRHU,

Dehradun

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences

Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Principal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEMORANDUM OF UNDERSTANDING (MOU)

This Memorandum of Understanding (MoU) is entered into on this **18th day of September 2021.**

This memorandum of understanding (MOU) is for cooperation in health services, education, training, research and for developing a collaborative arrangement, whereby the Institutions may participate in collaborative teaching, training, research and other agreed activities to further enhance relationship between two Institutions.

This MOU is entered between:

Himalayan Institute of Medical Sciences (HIMS), a constituent medical college of Swami Rama Himalayan University (SRHU) a University established under section 2(f) of UGC Act and enacted vide Uttarakhand Act No. 12 of 2013 having its registered office at Swami Ram Nagar, P.O. Jolly Grant, Dehradun, Uttarakhand, India, 248140, (herein after referred as "HIMS Dehradun"), through its **Principal**, which expression shall, unless repugnant to the context, include its successor, administrators, assigns or legal representatives.

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences situated at Raebareli Road, Lucknow-226014, India (herein after referred as "SGPGI Lucknow"), (The Institute shall be a body corporate and shall function as University established under UP Act. no. 30 of 1983, dated October 13, 1983. Acting through **Director**, which expression shall, unless repugnant to the context, include its successor, administrators, assigns or legal representatives.

Both institutions state that they:

Recognize the value of academic interchange and lively engagement in an national & international scholarly community by members of academic and research institutions.
Discern the significance and importance of collaboration in the pursuit of national & international cooperation and awareness by each institute's interest in and need for establishing and sustaining such cooperative ties.
Confirm the significance of the furthering of knowledge and the creative role of the national & international scholarly communication and collaboration in the development and dissemination of learning and research.

Hence, in the spirit of promoting exchanges between them in all pertinent area of health education, research, and service, both the institutions **agree as follows:**

A. **General Objectives**

i. To exchange information, articles, reports and teaching materials in order to support the educational programs of each institution in the field of the Professional Competencies (particularly the areas of Communication, Skills, Ethics, Professionalism).

ii. To strengthen and encourage communication and collaboration in education and research between members of the two institutions, particularly with respect to the Professional Competencies.

iii. To stimulate contacts between investigators in health science from the two institutions.

iv. To develop academic projects such as collaborative research, teaching, technical cooperative, evaluation and publication. The human and technical resources which will contribute in designing and operating the program shall be specified from each institution.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

v To promote bilateral co-operation in scientific research and education in different faculties involving:
   a. Teaching and exchange of scientific researchers
   b. Organizing lectures, seminars and scientific meetings
   c. Development of projects of common interest
   d. Visits of faculty and students for the mutual benefits of both institutions
   e. Co-operation in conduct of research (except finances).

B. Scholar Exchange and Education Collaboration

i. To develop learning opportunities through courses, seminars workshops, and other means from both institutions to pursue activities related to scholars' academic program, particularly with respect to the development of a Professional Competencies

ii. To facilitate visit by medical students between institutions vice versa who will assist with the roll-out of the Professional Competencies, as well as participating in clinical electives. In addition, to facilitate visits by students from other related disciplines like nursing.

iii. To facilitate the exchange of health science faculty members and visiting scholars dedicated to participating in teaching and research.

iv. In all cases, the exchange of faculty members and visiting scholars will occur within the regulation of each institution and will take place on an individual basis.

C. Legal Conditions

i. This MOU is a statement of intent and in no way intended to create legal or binding obligation on either Institutions and serves only as a record of the institutions' current intention to enhance the relationship of the institution going forward. This MoU does not create legally enforceable rights claim, interest, duty, or obligation in favour of either of the party as against other party.

ii. All co-operation is on self-finance basis and none of the institutions is obliged to support each other financially for the purpose of this MOU

iii. The Institutions agree to designate the following person as administrative focal point for any administrative aspects for this MOU:

a) For **HIMS, Dehradun**	b) For: **SGPGI Lucknow**
Professor Mushtaq Ahmad	Professor RK Dhiman
Principal	Director
Email: Principal.hims@srhu.edu.in	Email: director@sgpgi.ac.in
Ph: 0135-2471220	Ph: 0522-2494001/2494129

iv. All students and faculty exchanges will be approved at the departmental and faculty level through the appropriate mechanisms as per defined procedures.

v. For the purpose of coordinating visits, correspondence and projects, exchange visitors will communicate with a counterpart in the institutions where cooperative research or teaching occurs.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

xi. Both the parties shall appoint [illegible] Manager for [illegible] and [illegible] shall be responsible [illegible] this MOU.

xii. [illegible] shall be [illegible] by the Executive Director [illegible] and [illegible] this MOU.

xiii. This MOU [illegible] and [illegible] by both parties [illegible] of each party and shall be [illegible] by written agreement of both parties.

xiv. In case of any dispute [illegible] this MOU, both parties [illegible] to resolve the dispute [illegible] and [illegible].

xv. [illegible] by both parties [illegible] this MOU [illegible] and [illegible] by both parties [illegible] and [illegible].

xvi. [illegible] this MOU [illegible] and [illegible] MOU.

In witness whereof the parties hereto have executed this agreement on the day and the year first above written.

Signed for and on behalf of Himalayan Institute of Medical Sciences, [illegible] SKHU, Dehradun [illegible] Uttarakhand, INDIA - 248140	Signed for and on behalf of Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow INDIA 226014
Authorised Representative	Authorised Representative
Signature:	Signature:
Seal:	Seal:
Name: Prof. Mushtaq Ahmad Designation: Principal	Name: Prof. RK Dhiman Designation: Director
Date:	Date:
Witness 1:	Witness 1: UC Ghosal
Witness 2:	Witness 2:
DEPARTMENT OF [illegible]	

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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MEMORANDOM OF UNDERSTANDING

This agreement is made on ..20th..... day of September...2021

Between

BABASAHEB BHIMRAO AMBEDKAR UNIVERSITY, LUCKNOW

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW

on

ACADEMIC AND RESEARCH COLLABORATION AND COOPERATION

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

All disputes and differences concerning the validity, scope, meaning construction or effect of this MoU or any dispute or disagreement between the parties hereto as to any matter relating to this memorandum which cannot be settled by mutual discussion shall be settle by arbitration by 2 (two) arbitrators, appointed by each parties, in case of difference of opinion between the said two arbitrators to an umpire, who shall be appointed by arbitrators, and any such decision is binding on the parties.

9. The Memorandum of Understanding will be initially for three years in continuation of previous MoU& reviewed thereafter for continuation.

(Dr. R. K. Diman)
Director
SGPGIMS
Raebareli Road
Lucknow

S.G.P.G.I.M.S. Lucknow (U.P.) India
Director

(Prof. Victor Babu)
Registrar
B.B.A. University
Raebareli Road
Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH FU 356031

Memorandum of Understanding for Research Collaboration

Between

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow (SGPGI)

And

Indian Institute of Technology Kanpur

This Memorandum of Understanding ("MoU") is effective as of the 29-06-2021 ("Effective Date") by and between Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow (SGPGIMS) having its office at Lucknow, Uttar Pradesh, hereinafter referred to as SGPGI which term shall unless is repugnant to the context include its successors, representatives, administrators and permitted assigns of the FIRST PART,

And

Indian Institute of Technology Kanpur, is a body corporate incorporated under the Institutes of Technology Act, 1961 and having its office at P.O. IIT Kanpur, Kalyanpur Kanpur, Uttar Pradesh-208016, India, is a research and educational institution of national importance, hereinafter referred to as "IITK" which term shall unless is repugnant to the context include its successors, representatives, administrators and permitted assigns of the SECOND PART,

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

The aforesaid institutions are hereinafter referred to individually as the Party and collectively as the Parties.

Introduction

IITK is one of the premier institutes to provide meaningful education, to conduct original research of the highest standard and to provide leadership in technological innovation for the industrial growth of the country. IITK imparts and undertakes cutting-edge research in various areas of science, engineering, design, management, and humanities.

Whereas the SGPGIMS, Lucknow is tertiary care hospital and deemed to be medical university established under State of Uttar Pradesh Act engaged in super specialty medical education & training besides carrying out high level of medical research relevance to society. It has been engaged in Information Technology application research and deployment for over two decades and has established a "School of Telemedicine & Biomedical Informatics" in its campus which has been recognized as a National Resource Center by Ministries of Electronics & Information Technology (MeitY) and Ministry of Health & Family Welfare (MOH&FW), Govt. of India.

The faculty member(s) of IITK involved in this MoU or in any project specific agreement will receive/disclose Confidential Information on behalf of IITK. He / She / They will execute the obligations of non-disclosure of Confidential Information received from SGPGI.

The Parties wish to work in the areas of **Telemedicine and Robotics**. The degree of mutual interest is so great that considerable advantage may be gained from their pursuit on a collaborative basis.

NOW THEREFORE IN CONSIDERATION OF THE MUTUAL COVENANTS, CONTAINED HEREIN, THE PARTIES HERETO AGREE AS FOLLOWS.

1. Object:

Both the Parties agree to collaborative in the area of Telemedicine and Robotics with the goal of setting up a center of excellence at IIT Kanpur as given the Annexure. These activities will be carried out in the research areas of mutual interest, on a basis of equality and reciprocity.

The Parties shall seek to promote:

(i) Collaboration in research and development, and consultancy studies in the field of mutual interest,

(iii) The exchange of academic materials and publications,

(iii) Undertaking joint research, submission of joint proposal.

(iv) SGPGI will share the data on which IITK researchers will develop data analytics

(v) SGPGI and IITK will jointly set up many health care kiosks that will give rise to new model of smart health care through the creation of an eco-system - data analytics developed by IITK and medical experts from SGPGI within 5G framework.

(vi) The development of a customized telemedicine system in the Indian context will be a short term goal that will be demonstrated with the help of Government health-care system.

The Parties will work out a specific plan for any activity mentioned above; and mutually discuss the detailed arrangements for collaboration. The terms and conditions for such activity such as

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

deliverables, funding, developers, intellectual property will be specified in a separate project specific agreement.

2. Intellectual Property Rights:

Ownership of any background intellectual property (including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights) shall remain with the Party owning it.

Ownership of any intellectual property (including but not limited to confidential information, know-how, patents, copyrights, design rights, rights relating to computer software, and any other industrial or intellectual property rights) developed during the course of this MoU shall be decided through a separate project specific agreement.

3. Effective date, duration, termination of the MoU:

The MoU shall be effective from the effective date and shall remain in force for a period of Ten (10) years. The Party may extend the term in writing. The MoU may be terminated by either Party by giving a written notice of 60 days to the other Party, mentioning sufficient cause for such termination. However, both the Parties will ensure that the provisions of this MoU shall continue to apply to all activities in progress until their completion. Clauses 3, 5, 6, 7, 8, 9 and 10 shall survive the termination or expiration of this MoU.

4. Confidentiality:

a. Confidential information includes all communication of information disclosed in documentary or tangible form between the Parties, including oral, written and machine-readable form, pertaining to the above which is indicated as confidential. In the case of such information disclosed orally or visually, the Disclosing Party shall confirm in writing the fact and general nature of each disclosure within (30) days after it is made.

b. Confidential information includes information:

1. Disclosed by or on behalf of the Disclosing Party to the Receiving Party,
2. Otherwise learned or ascertained by the Receiving Party from inspection and/or evaluation of sample(s) identified by the Disclosing Party as confidential and provided to the Receiving Party by or on behalf of the Disclosing Party (sample(s)) and/or,
3. Otherwise learned or ascertained by the Receiving Party from the Disclosing Party.

c. The Receiving Party will not disclose confidential information of the Disclosing Party to any other person and use at least the same degree of care to maintain the information confidential as Receiving Party uses in maintaining as confidential its own confidential Information, but always at least a reasonable degree of care; due diligence will be taken by both the Parties in maintenance of confidential information.

d. The Receiving Party will use the confidential information only for the above mentioned purpose.

e. The Receiving Party will restrict disclosure of the confidential information of the Disclosing Party solely to those employees, subsidiaries, parent and affiliated companies of Receiving Party having a need to know such information in order to accomplish the purpose stated above.

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Institute of Medical Sciences

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f. This MoU imposes no obligations on Receiving Party with respect to any portion of the confidential information received from Disclosing Party which:

1. was known to Receiving Party prior to disclosure by Disclosing Party,
2. is lawfully obtained by Receiving Party from a third party under no obligation of confidentiality,
3. is or becomes generally known or publicly available other than by unauthorized disclosure,
4. is independently developed by Receiving Party,
5. is disclosed by Disclosing Party to a third party without a duty of confidentiality on the third party.
6. is required by law or decree.

g. The confidential information shall remain the sole property of the Disclosing Party.

h. The obligation of non-disclosure of confidential information shall survive for 3 years after expiry/termination of this MoU.

5. No Liability:

Neither Party, nor any of their affiliates nor their or their affiliates respective directors, officers, employees, subcontractors or agents shall be liable to the other Party for any special, incidental, indirect or consequential damages (including, but not limited to, contract, negligence and tort liability) in connection with or arising out of this MoU.

6. Publicity:

Neither Party shall use the name of the other Party or its employees in any advertisement, press release or publicity with reference to this MoU without prior written approval of the other Party, except for necessary governmental disclosures.

7. Independent Contractors:

For the purposes of this MoU, the Parties hereto are independent contractors and nothing contained in this MoU shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures.

8. Assignment:

This MoU shall not be assigned by either Party without the prior written consent of the other, to any third party. In case of any such assignment, the party taking up the assignment shall succeed to the rights, benefits, titles, duties, interest and obligations and liabilities of the Party making such an assignment under the MoU.

9. Amendment:

Any amendment or variation to this MoU shall be made by a written MoU between the Parties.

10. Arbitration and Governing Law:

This MoU shall be constructed, governed, interpreted and applied in accordance with the laws of India and the courts of Kanpur shall have the exclusive jurisdiction.

The Parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this MoU by negotiation. If the matter cannot be resolved in the normal course of business, within ten (10) days after the dispute arises, any interested Party shall give the other Party written notice of any such dispute not resolved, after which the dispute shall be referred to the Director, IITK and Director, SPGCI who will jointly resolve the dispute in a spirit of independence, mutual respect, and shared

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responsibility. In case an amicable settlement of any disputes arising out of or relating to this MoU is not achieved within thirty (30) days after written notice is received, such dispute shall be referred to arbitration under the Rules of Arbitration and Conciliation Act, 1996 (as amended from time to time), by one (1) sole arbitrator appointed in accordance with said Rules. The seat of the arbitration shall be Kanpur. The arbitration shall be conducted in the English language and the award shall be final and binding upon the Parties. Each Party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

In witness thereof, the Parties hereto have signed this MoU on the Effective Date mentioned hereinbefore.

For and on behalf of **SGPGI**

Signature

Name Prof R. K. Dhiman

Designation Director

Date S.G.P.G.I.M.S., Lucknow

Witness:

For and on behalf of **IITK**

Signature

अधिष्ठाता
DEAN
अनुसंधान एवं विकास
Research & Development
आई॰ आई॰ टी॰ कानपुर
I. I. T. KANPUR

Name: Prof. A. R. Harish

Designation: Dean of Research and Development

Date:

Witness: Prof. Laxmidhar Behera

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Annexure

Center of Excellence in Telemedicine and Robotics

Telemedicine

The World Health Organization has defined telemedicine as: "The delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities"

Four critical elements of an effective telemedicine systems are: 1. It's purpose is to provide clinical support. 2. It is intended to overcome geographical barriers, connecting doctors, health workers and patients who are not in the same physical location. 3. It involves the use of various types of information communication technology such as IoT devices, Sensors, Cloud and Internet. More importantly to create the telepresence of the doctor for a patient in a remote corner without creating any emotional barrier. 4. Its goal is to improve health outcomes.

In India context, we have situations where a child falling sick at night with no doctor and medicine around, a pregnant lady needs regular home check ups, elders and chronic patients need regular check ups for symptoms monitoring or village residents want a second opinion for better healthcare. Although many proof of concepts are already existing, acceptance by users through a proper business model needs following challenges to be sorted out:

1. One such challenge is a complex of human and cultural factors. Some patients and health care-workers resist adopting service models that differ from traditional approaches or indigenous practices, while others lack ICT literacy to use telemedicine approaches effectively.
2. Demonstrating solid business cases to convince policy-makers to embrace and invest in telemedicine.
3. As public and private sectors engage in closer collaboration and become increasingly interdependent in telemedicine, care must be taken to ensure that telemedicine will be deployed intelligently to maximize health services and optimal quality and guarantee that for-profit endeavours do not deprive citizens access to fundamental public health services. Issues pertaining to confidentiality, dignity, and privacy are of ethical concern with respect to the use of ICTs in telemedicine. It is imperative that telemedicine be implemented equitably and to the highest ethical standards, to maintain the dignity of all individuals and ensure that differences in education, language, geographic location, physical and mental ability, age, and sex will not lead to marginalization of care.

Objectives of this CoE

1. Develop cost effective telemedicine systems for different segments considering Indian rural sectors. Liaise with district level administrators for the field testing of the technology.
2. Introduce advance features such as telepresence doctors using concepts such as Avatar.
3. Liaise with start ups, Government and hospital to create a proper business model.

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Robotics in Health Care

Given COVID 2019 situation and beyond, we are going to see pervasiveness of robotics devices for health care. In health care situations, we need robots that can insulate health workers from the patients. We need telepresence robotics that can help nurses and doctors to provide care to patients without creating any emotional barrier. However, these robots need to work along with the humans. They must understand humans through interfaces such as voice, gesture, Brain Computer Interface, and haptics. These robots in some situations must learn to express humanly emotions as well. Such collaborative robots with human in the loop has following two distinct advantages:

1. These robots take guidance from the humans in complex and unknown situations. With human in the loop, we do not have to build fully autonomous systems and hence the effective cost of these devices will drastically come down. Simultaneously these devices can behave even smarter as they would embody human cognition.

2. There is a need to internalize the science of cognition. Robots are active agents that are more amenable to experimentally validate such studies.

Objectives CoE

1. Research in cognitive robotics involving multi-modal human-robot interactions will be given emphasis. The research problems will be identified by having collaborations with some of the renowned medical colleges and hospitals.
2. Robotic Nurse, Brain-wave controlled smart wheel chair, Companion Robots for elderly care, Rehabilitation robots, Robot assisted remote care for injured soldiers in remote location, will be some of the pet projects that will be implemented in this center leading to prototypes at the level of TRL 7.

Robotic Nurse

During a hospital stay, patients interact with nurses the most. They draw blood, check your vital signs, monitor your condition and take care of your hygiene if needed. What if we could design robotic systems with associated intelligence which can assist doctors to provide critical treatments to patients or can be deployed inside the hospital wards to replace health personnel? Such a technology would definitely revolutionize the applications of the modern robots and it would also open up new avenues in health-care application: the robot will be able to help the doctor to maintain social distance from the patients or doctor's assistant in real time; the robots can be deployed in the hospital ward to perform the tasks which are typically done by the nurses or can be used as tele-presence of the doctor to provide the consultation to the patient. However, successful execution of these tasks demands highly intelligent behavior from the robots, which are quite difficult to achieve with the current computational capabilities, numerical algorithms and commercially available robotic systems.
This project aims to solve these problems 1) by designing the necessary algorithms for robots, which will be useful to handle the challenges faced in this dynamic environment, 2) by developing intelligent motion planning, 3D localization / navigation for desired task execution and 3) by designing necessary grippers/hardware which are sometimes task specific. Robotic nurses will help carry this burden of a nurse while being monitored by the nurse/doctor. They will be designed to be able to carry out repetitive and monotonous tasks being guided remotely by the Nurse/Doctor. Using Avatar platform,

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they can express their care and empathy while effectively insulating health care professionals from the patients.

Brain Wave Controlled Wheel Chair (BCW)

Stroke patients and motor neuron patients are faced with a life quality devoid of autonomy, ease of communication and social interaction and entertainment. A person with lower limb disability is forced to use a wheelchair. In a traditional wheelchair the user spends time in a seated position most of the time. This gives rise to many physical as well as mental health related issues such as painful lesions on parts of the body, accumulation of pressure points leading to pressure sores, reduced blood circulation, and high dependence on other people for basic needs. We propose solutions to this problem by providing sensitive, flexible, easily calibratable mechanisms in the wheelchair to aid the MND subject to stand. This research work is aimed at developing brain computer interface (BCI) based human machine interface (HMI) that will enable these patients independently to perform their daily activities i.e. moving in a wheelchair to drink coffee and read a book etc. Last, but not the least it will also lead to activity dependent brain plasticity of the patients. The objective is to build a "cost-effective robotic wheelchair with bio-signal enabled control for motor neuron and stroke patients including elderly care". MND patients are not able to use devices like joysticks or buttons. Our goal is to develop a system usable in hospitals and homes with little hardware changes, which can help these people regain maneuverability. A proper brain computer interface system involves pre-processing EEG signal as these types of bio-signals are embedded in a kind of unknown stochastic noise of non-stationary type as well as classification of these processed signals. Algorithm based on recurrent quantum neural network has got significant attention from the researchers worldwide. Besides working on motor-imagery based deciphering EEG signal, hybrid models consisting of P300, SSVEP and MI needs to be developed to create a robust BCI system.

Cognitive Imitation Learning and Tele-Presence Mobile Manipulation.

Humans are gifted with the ability to adapt in uncertain and dynamic situations while performing a complex task using the a priori basic skills with little or no knowledge of the situations. They generalize and perform novel motions based on their previously learned motor skills. In contrast, current robots can only work efficiently in structured environments separated from humans and are limited to a small number of predefined tasks. The task is hard coded by a human expert after careful analysis of a robot's workspace. Thus, robots are still not able to adapt their skills to novel situations or to learn new motor tasks in real time. Issac Asimov envisioned robots as companions in the domestic environment, workers in automated commerce industries and soldiers in war. The solution to this problem is to learn new motor skills autonomously using prior learned basic skills and improve them over time. This poses an interesting scientific problem: can the robot observe humans doing such tasks and then imitate? Additionally, can we program the robot to exploit the knowledge of its own embodiment and dynamically adapt to moving obstacles, or people working in the same workspace? In this context, learning motor skills through human demonstrations needs to leverage prior information about the objects being picked, robot's movement capabilities and exploit abstract representation of the task that allows generalizing the learnt skill to novel situations. The robotic arm systems with a mobile base considered in this proposal has several redundant degrees of freedom and is equipped with depth-sensing camera to operate in an unstructured environment as well as distinctly identify, reach and manipulate different objects. Using these demonstrator platforms, our objective is to increase robustness and adaptability of autonomous solutions to robotic applications by addressing the following scientific goals:

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1. Represent the human demonstrations in a scalable, alternate relational space, that will allow us to transfer the task to heterogeneous robots robustly
2. Exploit offline computation to achieve fast, robust and collision-free motion planning in a dynamically changing environment
3. Enable robots to acquire visual servoing capabilities to reach any target and manipulate different objects
4. Equip the sensing system to visually perceive its unstructured workspace repeatedly and robustly
5. Write software that will allow us to learn, and transfer these skills across various robotic platforms, minimizing the platform-specific setup
6. In the context of various complex robotic automation, our techniques will be validated through mock-ups. We will use metrics such as success rate, accuracy, amount of demonstration data needed, motion power efficiency and runtime speed.

Most past work on robotic imitation learning has focused on having a robot literally copy/duplicate the human demonstrator's actions without any deeper "understanding" of the demonstrator's goals and intentions. In this context, the primary overall goal of this research project is to create and critically evaluate a general-purpose neurocognitive architecture for imitation learning by a semi-autonomous system. These learned skills shall be transferred to teleoperated robot using transfer learning framework.

Telepresence and Teleaction System for Robot Assisted Dentistry

In recent times, telepresence and teleaction (TPTA) systems have gained a lot of attention in the research community because of its many applications in various fields. TPTA systems allow a user to be present and active in a remote environment. Telemedicine (i.e., tele-diagnostics as well as tele-surgery) is one of its main applications. In hospitals, nurses typically spend a substantial amount of time with the patients to fulfil various needs such as, giving medicines or foods, checking vitals of the patients or responding to other requests from the patients. Also, the doctors are required to visit each patient to check their test reports, understand their complaints and symptoms while interacting personally with them. This poses risks to the nurses/health workers/doctors while treating patients with contagious diseases such as COVID-19 infection which has become a pandemic in present days. This kind of risk can be mitigated by introducing tele-presence robots between patients and health workers/doctors and thereby keeping the presence of the health personnel in the isolation ward at minimum level.

A typical telemedicine system (i.e., TPTA system) will consist of a human system interface connected to an operator, a communication medium, and /tele-robot as shown in Fig. WP3.1.1. The human system interface has input devices for position and orientation sensing, and output devices for displaying multiple modalities (i.e., vision, auditory, haptics, etc.). An operator is connected with the human system interface and commands the position/velocity to the teleoperator while observing the remote environment through the multi-modal feedback. The communication medium is used to transport the multimedia streams bidirectionally. Such TPTA systems will be developed for dentistry and will be further extended to other healthcare applications.

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Stamp Duty Paid By	:	JSS MEDICAL RESEARCH ASIA PACIFIC PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

CLINICAL REGISTRY AGREEMENT
(SITE)

This Tri-Partite Agreement ("the Agreement") is made on this 26th Day of Jul, 2022 ("Effective Date") at New Delhi.

Protocol Title : SHOCK/TL/R-2021-01: A Prospective, Observational, Single Arm, Multicenter Registry to evaluate clinical outcomes of the Shockwave Coronary Intravascular Lithotripsy (IVL) followed by stent implantation in Calcified Coronary Arteries in Real World Indian Patient Population.

Clinical Research Asia Pacific Pvt. Ltd. Faridabad

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Executive Registrar
SGPGIMS,Lucknow

BY AND BETWEEN

Translumina Therapeutics LLP, having its Registered Office at, Ground Floor, Metro Tower, Local Shopping Complex, MOR Land, New Rajinder Nagar, New Delhi – 110060, India, Phone: 91-11- 2874 (hereinafter referred to as "**Sponsor**") have delegated the above mentioned registry to CRO viz. **JSS Medical Research Asia Pacific Pvt. Ltd.**

Sponsor has contracted JSS Medical Research Asia Pacific Private Limited, having its registered office at corporate Head Office at Tower 2 ,1st South wing Floor, L & T Business Park, 6th Floor, Vatika Mindscapes, (Tower B), Plot 12/4, Sector 27D, Delhi Mathura Road, Near Saraj Khwaja Metro Station ,Faridabad-121003, as CRO (Hereinafter referred to as "CRO") to coordinate and/or perform activities on behalf of the Sponsor, required for the conduct of the Registry and for the purposes of this Agreement of the **FirstPart**

AND

Sanjay Gandhi Post Gradute Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014 (hereinafter referred to as "**Institution or site**"), which expression shall, unless repugnant to the context or meaning thereof shall be deemed to mean and include its affiliates and permitted assigns), **of the Second Part**

AND

Dr. Aditya Kapoor, DM (Cardiology) working as a Professor & Head (Cardiology) at Sanjay Gandhi Post Gradute Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014 (hereinafter referred to as "**Site Investigator**") which expression shall, unless repugnant to context or meaning thereof shall be deemed to mean and include its successors and assigns **of the Third Part**

The CRO, Institution and Site Investigator are henceforth referred to individually as and collectively as "Parties".

AND WHEREAS, the Institution represents and warrants that it is equipped to undertake the Registry along with the Purpose as envisaged in this Agreement and accordingly has the requisite experience and expertise for the above said.

Now, therefore, in consideration of the premises and the mutual promises and covenants expressed herein, Sponsor represented through its Lead Principal Investigator and/or CRO, the Site and/or the Site Investigator, hereby agrees to conduct the Registry on the following terms and conditions.

1. RULES FOR INTERPRETING THIS AGREEMENT

Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this Agreement, except where the context makes it clear that a rule is not intended to apply.

(a) reference to any statute, regulation, proclamation, ordinance, by-law, or guideline includes all statutes, regulations, proclamations, ordinances, by-laws or guidelines varying, consolidating or replacing them and a reference to a statute includes all regulations, proclamations, ordinances, by-laws or guidelines issued under that statute.

(b) Words importing the singular include the plural and vice versa and reference to one gender includes all genders.

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(c) a reference to a document or agreement including this Agreement includes a reference to that document or agreement as amended, supplemented, varied, or replaced from time to time.

(d) Where a word or phrase is given particular meaning, other parts of the speech or grammatical forms of that word or phrase have corresponding meanings.

(e) The whole and/or part of a recital or annexure forms part of this Agreement; and

(f) A reference to an individual or person includes a corporation, partnership, joint venture, association, authority, state or government and vice versa.

2. CONDUCT OF THE REGISTRY

2.1 The Site Investigator shall conduct the Registry at the Site according to the Registry protocol, the applicable laws and regulations of India, this Agreement, IRB/ IEC approved written instructions of CRO with respect to the Registry and terms of approval of the IRB/IEC (**"Institution Review Board/ Institutional Ethics Committee"**).

2.2 The protocol will be considered final following approval by the IRB/IEC. Any amendments in the Protocol may be carried out by the Site Investigator only after written consent of assigned CRO on behalf of lead investigator or as recommended by IRB/IEC.

2.3 In the event of a participant's medical emergency, the site Investigator, in all his prudence and due diligence deems it absolutely necessary, may, to that extent, cause and/or effectuate improvisations to the Protocol. The Site Investigator must immediately thereafter notify, in writing, the Sponsor, CRO, IRB/IEC of the above said subject to the terms and conditions of this Agreement and as per the regulatory timelines or as mentioned in the respective EC SOP.

2.4 Site Investigator shall fully comply with the SAE reporting provisions of the Protocol and all applicable Regulations and shall keep the IRB/IEC notified of the same.

2.5 The Site Investigator/Site will ensure that Eligible Patients (as per registry protocol) sign the written patient information sheet and informed consent form as provided by the CRO and approved and cleared by the respective IRB/IEC. The Site Investigator/Site will maintain a signed original of the consent form along with Patient's records in site master file.

2.6 Site Investigator shall maintain a Site master file which shall include all details about the conduct of the Registry including without limitation approvals of the IRB/IEC, final approved Protocol, consent forms, amendments to the above, correspondence, log of all site visits. Such Site master file will be maintained and retained as per ICH GCP requirements and all applicable Regulations. Site Investigator will, at CRO cost, retain the Site trial master and all Registry records in appropriate storage conditions, either at the Site or at a third-party location for a period of 2 years after Site Closeout. Site Investigator will contact CRO at least thirty (30) days before the planned destruction of any or all the Site master file, at which time CRO may request Site Investigator to deliver such records to CRO or its designee at Sponsor's cost. Site Investigator will notify lead investigator through CRO (if during the term of this Agreement) promptly in writing of any accidental loss or destruction of Registry records.

3. COVENANTS OF THE PARTIES

3.1 The Site and the Site Investigator undertake this Registry in furtherance of their goal of seeking data collection and to evaluate clinical outcomes of the Shockwave Coronary Intravascular Lithotripsy (IVL) C2 Coronary Catheter System in Calcified Coronary Arteries in Real World Indian Population and furthering their tasks and objectives as a research site and medical interventional center.

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3.2 Each Party warrants that it has power and authority to enter into and perform this Agreement and the Registry and services contemplated by this Agreement and its entry into, and performance of this Agreement and the acts contemplated by it, do not constitute a breach of any obligation or default of any other agreement/arrangement by which it is bound or of any applicable law, regulation or policy.

3.3 Each Party warrants that the person executing this Agreement on its behalf is duly authorized to do so and that nothing contained herein conflicts with any of the provisions of the Memorandum and Articles of Association or similar or other documents relating to the incorporation or of the rules and regulations governing the party.

3.4 That without prejudice to the terms and conditions of this Agreement, the Sponsor and/or CRO have in no manner whatsoever any vested interest/right in the results arising out of or in connection with the Registry.

3.5 It is agreed and understood that funding of the Registry in furtherance to the Purpose of this Agreement, by the Sponsor, is in no manner whatsoever, an act of guarantee with regard to the nature and extent of the outcome of the research registry.

3.6 The Site/ Site Investigator warrant that they have obtained all internal consents and approvals to carry out the Registry at the Site as per the Protocol.

3.7 The Site/ Site Investigator shall ensure that in the event of a temporary absence of the Site Investigator, a duly nominated and authorized substitute in the capacity of a 'Sub-Site Investigator' shall perform the functions of the Site Investigator. Further that during the period of such temporary absence of the Site Investigator, all obligations and representations of the Site Investigator under this Agreement shall continue to vest in the Site Investigator. That further such nomination/authorization will be done with the prior written approval of the Sponsor and/or CRO. If however a permanent substitution (replacement of site investigator) is required it will be notified to Sponsor and/or CRO who shall send a written approval only after consulting with the Investigator, otherwise the Registry will be suspended, till a replacement is found.

3.8 No Party hereto shall use the name of another Party hereto or the Sponsor either expressly or by implication in any news or publicity release, policy recommendation or commercial purpose without the express written approval of that Party or the Sponsor, as the case may be. Nothing herein shall be construed as a prohibition on the publication rights of the Sponsor/CRO.

4. MONITORING AND REPORTING

4.1 As per the Protocol, Site/ Site Investigator shall report any SAE suffered by a Patient during the Registry, whether or not causally related to the registry or Patient's participation in the Registry, promptly (within 48 hours) to CRO describing the circumstances under which the SAE occurred, and the remedies applied. Site/ Site Investigator shall follow-up such immediate report by sending a written report to Sponsor.

4.2 If in the medical judgment of the Site Investigator alternatives on or deviations from the Protocol are required due to a medical emergency, the alternatives and / or deviations and reasons for their use, will be documented and be forwarded to CRO at the earliest possible occasion following the occurrence of any such event, within two (02) days.

4.3 The Site/ Site Investigator shall notify CRO promptly if any Regulatory Authority requests permission to inspect the Site/ Site Investigator facilities, records regarding the Registry and shall permit such Regulatory Authority to conduct such inspection in accordance with and to the extent as permissible in law.. If the inspection occurs than the Site/ Site Investigator shall provide CRO with all materials, correspondence, statements, forms and records received from or exchanged with the Regulatory Authorities.

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4.4 Qualified personnel from the CRO (or their representatives) may call on Site periodically at any time during any working day convenient to all parties concerned to monitor and/or audit the Registry and ask procedural questions, inspect records and documents, which the Site/ Site Investigator will provide access to. Institution will make Registry records available for the CRO, only as far as permitted under the Protocol and in accordance with internal standard operating policies of the Institution and the requirements made by the IRB/IEC.

Furthermore, such records can only be made available as far as permitted and/or required by applicable Regulations including but not limited to the legislation regarding the privacy of persons and the protection of personal data.

4.5 If in accordance with Regulations, the facilities at the Site are determined as being inadequate for the purposes of the Registry or not as per the Protocol, and the Site/ Site Investigator do not remedy such inadequacies upon notice to them from either Sponsor, then Sponsor may in its discretion terminate this Agreement or refuse to commence or continue the Registry.

5. RECORDING AND PUBLICATION OF RESULTS

5.1 It is understood by all the Parties that the final report of the Registry is a scientific report. The report and analysis required to be submitted as per Regulations will be drafted by and under the full responsibility of Sponsor.

5.2 Site/ Site Investigator will report the findings of the Registry to CRO in the form of Registry reports. to be submitted to CRO at such stages or intervals as set out in the Protocol (including for instance the progress and the number of included patients) and/or as further agreed between the Parties.

5.3 The Parties acknowledge that Sponsor shall have the right to publish and present the results of the Registry. Sponsor shall take into account that these results represent a joint effort among Sponsor, lead investigator of registry, the Site and Site Investigator. Nothing in such publications shall contain any confidential information/material related to the Parties. unless otherwise agreed in writing by abd between the Parties. Sponsor shall mention the Site Investigator of the Site in a footnote in the manuscript as a member of the Registry.

5.4 The Site Investigator/Site shall not publish and present the results of the Registry unless approved or consented by the sponsor and steering committee members.

5.5 Sponsor shall retain ownership of all original CRFs, data, analyses and reports that result from the Registry.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 All rights, title and interest including, but not limited to, all Intellectual Property Rights of any nature whatsoever in the Registry, and all materials, data, reports and information connected thereto shall remain the sole and exclusive property of Sponsor and Site/ Site Investigator shall take all reasonable steps to protect such rights and intellectual property as and when required by the Sponsor and or CRO.

6.2 Any information, inventions or discoveries (whether patentable, copyrightable or not), innovations, communications and reports (collectively, "Inventions") conceived, reduced to practice, made or developed by Site/ Site Investigator as a result of conducting the Registry shall be promptly disclosed to Sponsor and shall be the sole property of Sponsor.

6.3 All data supplied by Sponsor/ lead investigator/CRO to the Site and Site Investigator, and all data generated in the conduction of the Registry, (collectively, "Data") shall be and remain the absolute and exclusive property of Sponsor. All copy rights and other rights of intellectual and industrial property with regard to the Data shall be vested in Sponsor.

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6.4 Site/ Site Investigator hereby assign to Sponsor all of their rights, title and interest in and to the Inventions and Data and further agree, upon request by Sponsor and at Sponsor's expense, to execute such documents and to take such other actions as Sponsor deems necessary or appropriate to affect such assignment and to obtain patent or other proprietary protection in Sponsor's name covering any of the foregoing.

7. FEE AND COMPENSATION

7.1 In consideration for the Registry, the Site will be paid fee/compensation in accordance with the approved payment rates detailed in the budget proposal attached hereto as **Exhibit B** and in accordance with the payment milestones mentioned therein (the "Payment Schedule"). The consideration mentioned under Exhibit B is the total consideration and includes the consideration for purchase of any equipment, infrastructure, admin overheads or hiring of any manpower required, if any, in connection with the Registry. The Payment Schedule may be modified only upon the prior written consent of Sponsor. Non-emergency additional tests or services (tests or services not required by the Protocol or performed in excess of Protocol requirements) shall not be compensated hereunder unless the written consent of Sponsor has been obtained prior to the administration of such tests or services.

7.2 In the event of Site Investigator recruiting more or less than minimum number of eligible patients, the consideration for the services will be pro-rated according to the actual number of Eligible Patients enrolled as per the agreed per patient fee which further will be limited on actual work done say number of visits completed by an enrolled patient.

7.3 Upon completion or termination of the Registry, the Site/ Site Investigator agrees to provide written acknowledgement to the CRO that all work requested under this Agreement has been completed and all monies due have been received. In any event, acceptance of payments as "final" constitutes such acknowledgement.

7.4 Sponsor further agrees to reimburse the Site for the actual cost of diagnostic procedures and medical treatment necessary to treat a Patient injury related to the Registry, subject to adjudication by clinical events committee and confirmation that the event is a device related injury or death. Patient injury means harm or loss that occurs to an individual as a result of participation in research, which would not occur otherwise in standard clinical practice, irrespective of the manner in which it has occurred, and is only limited to adverse events and serious adverse events related to the subject's participation in the registry. There is no provision for medical management and /or compensation for events including serious events or death which are listed in the Instructions for Use, however, reasonable financial support will be provided to the Site and Site Investigator for medical management and compensation for the device related injury or death as awarded by the IEC as per applicable laws and regulations, subject to adjudication by clinical events committee and confirmation that the event is a device related injury or death.

8. TERM AND TERMINATION

8.1 The Registry will be deemed to be concluded on the day when the final and complete report of the Registry is sent by the Site Investigator to the CRO.

8.2 The Parties have agreed that all reasonable efforts will be made to complete the Registry within the mutually agreed period, unless agreed otherwise explicitly between Parties.

8.3 The Registry and this Agreement may be terminated by prior written notice of 30 (thirty) days from Sponsor to Site/ Site Investigator, for any of following reasons but not limited to these:

a. Notification by Sponsor to terminate the Registry.
b. Notification by an IRB/IEC to terminate the Registry with relevant report.

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c. Determination by Sponsor that Site Investigator is not performing the Registry as required in the Protocol.
d. Failure of the Site Investigator/ Site to provide access to any and all original medical records necessary to verify entries on Registry CRF's
e. Failure of Site Investigator/Site to comply with all Regulations
f. Unauthorized replacement of Site Investigator.
g. CRFs provided to Site Investigator for use in the registry, are not completed and forwarded to CRO, within the timelines prescribed in the Protocol.
h. Failure of Site Investigator/Site to enroll patients

Immediately upon receipt of a notice of termination, Site Investigator shall cease entering new patients into the Registry, cease conducting procedures to the extent medically permissible on the existing subjects already entered into the Registry and shall initiate the process of their safe withdrawal from the Registry as per the prevailing medical standard and Site Investigator's medical judgment.

8.4 The Registry may be suspended by written notice from Site/ Site Investigator to CRO, with immediate effect, if in the Site Investigator's reasonable medical opinion for such suspension is necessary to protect patient safety. Promptly after CRO's receipt of such notice, representatives of the Parties and CRO shall meet (in person or via teleconference) to discuss in good faith Site Investigator's concerns and an appropriate resolution to such concerns, which may include mutual termination of the Registry and this Agreement upon discussion with the Sponsor.

8.5 The Registry and this Agreement may be terminated by a prior written notice of 30 (thirty) days from the Site/ Site Investigator to CRO if CRO commits any material breach of this Agreement which it does not remedy within 30 days of receipt of written notice from the Site/ Site Investigator specifying the breach and requiring remedy; provided that Site/ Site Investigator shall not be entitled to serve such notice of termination until (i) Site/ Site Investigator has notified Sponsor in writing that CRO has failed to remedy the specified breach within such 30 day period and (ii) either the breach has been remedied or this Agreement has been assigned to Sponsor within 30 days of Sponsor's receipt of such notice from Site/ Site Investigator.

8.6 In the event of termination, any funds not due but already paid shall be returned to Sponsor by the Site.

8.7 Upon completion or termination of the Registry," **Director SGPGI Research Account**" (Payee name) agrees to provide written acknowledgement to CRO that all work requested under this Agreement has been completed and all pending payments have been received. In any event, acceptance of the payments as "final" constitutes such acknowledgement. At the time of termination, a detailed account of work completed by site as per clause 8.3 will be prepared and any balance payment to be made to the site, will be done by sponsor. In case, site has received excess money that amount shall be remitted by the Institution to the Sponsor.

9. INDEMNITY AND INSURANCE

9.1 Sponsor shall indemnify, defend and hold harmless the Site Investigator, Institution, Directors, Co-investigator, Coordinators & ethics committee, from and against any third party loss, claim, cost (including reasonable attorney fees) or demand (collectively, "Claims") arising out of or in connection with (i) the administration of the Registry in accordance with the Protocol at the Site including an injury to a Patient arising from the use of the Registry Material in the Registry; (ii) any breach of this Agreement by Sponsor or its employees or agents, or (iii) any breach by Sponsor of any representation, warranties or covenants set forth herein, except to the extent the same is

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caused by the gross negligence or willful misconduct of Site Investigator; however, that any such liability, loss, or damage resulting from (1) a failure to adhere to the terms of the protocol, or this Agreement or IRB/ IEC approved written instructions of the Sponsor's with respect to the Registry (2) failure to obtain the Patients' informed consent (3) failure to comply with any applicable governmental requirements; or (4) negligence or willful malfeasance by the Site, the Site Investigator or associated staff is excluded from this Agreement to indemnify and hold harmless.

It is hereby clarified that the Site/ Site Investigator's aggregate liability under this Agreement (whether under contract, tort or otherwise) shall be limited to the amount of consideration actually received by the Site under this Agreement.

The Site and the Site Investigator agree to notify Sponsor as soon as they become aware of a claim or action as to which Sponsor has indemnification obligations under this Agreement and to cooperate with and to authorize Sponsor to carry out the sole management and defense of such claim or action. Sponsor agrees, at its own expense, to provide attorneys to defend against any such claim or action, whether or not such claim or action is rightfully brought or filed. Neither the Site, Site Investigator nor associated staff shall compromise or settle any claim or action without the prior written approval of Sponsor.

10. CONFIDENTIALITY

10.1 In handling a Patient's medical records, the Site/ Site Investigator and associated staff shall hold in strict confidence the identity of the patient, and shall comply fully with any and all Regulations regarding the confidentiality of such records and data protection.

10.2 The Site/ Site Investigator shall be responsible for effecting and maintaining all registrations for the processing of personal data that are required by Regulations, including under the Drugs and Cosmetics Rules 1945. Site Investigator hereby consents for CRO and CRO's affiliates to collect and/or otherwise process personal data provided by or relating to Site Investigator for purposes of sharing such personal data with Regulatory Authorities and for any use by CRO and its affiliates. Site Investigator agrees that CRO and CRO's affiliates may transfer such personal data to CRO's facilities, and to Regulatory Authorities, if asked by authority in future.

10.3 The Site/ Site Investigator acknowledge and agree that all information disclosed to them by or on behalf of Sponsor or developed by the Site or Site Investigator in connection with the Registry is the proprietary information of Sponsor and shall be deemed to be Sponsor's Confidential Information and each undertakes to Sponsor, for its own benefit and for the benefit of Sponsor. that it will ensure that such information is kept confidential, for a period of 05 (five) years even after expiry or termination of this Agreement and is not disclosed to any third party without prior written consent of Sponsor. The Site/ Site Investigator will hold in strictest confidence and will not directly or indirectly, disclose, reveal, report, use, lecture, broadcast, transfer, disseminate in any form, upon or publish any Confidential Information of CRO or Sponsor.

10.4 The Site/ Site Investigator shall limit access to the Confidential Information of Sponsor to their officers, directors and employees (collectively "Representatives") who require access to such Confidential Information in order to effectuate the purposes of this Agreement. The Site/ Site Investigator agrees and shall obligate their Representatives to agree, that they will use the same degree of care and discretion as they use to protect their own Confidential Information.

10.5 The Site/ Site Investigator shall use the Confidential Information of Sponsor only for the purpose of fulfilling their obligations under this Agreement. The Site/ Site Investigator shall not be entitled

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to use any of the results or data, or any other information, resulting from or related to the Registry for own research or other purposes, nor shall the Site Investigator be involved in such research, without having obtained the prior written consent of Sponsor.

10.6 Excluded from the above confidentiality obligations shall be information which, may be demonstrated by the Site/ Site Investigator to the reasonable satisfaction of Sponsor, as the case may be:

(i) was already in possession of the Site/ Site Investigator at the time of disclosure or acquisition in connection with the Registry;

(ii) was at the time of such disclosure or acquisition already in the public domain or subsequently enters the public domain without default on the part of the Site/ Site Investigator; or

(iii) was received from a third party, who does not owe an obligation of confidentiality to the Sponsor.

10.7 Consent shall be deemed to have been given by Sponsor to the following disclosures of their respective Confidential Information:

(i) Disclosure of such Confidential Information to employees or consultants of the Site/ Site Investigator provided that the Site/ Site Investigator ensures that such employees or consultants are bound by obligations of confidentiality no less strict than those set out herein and that they require the information disclosed for the purposes of the Registry;

(ii) Disclosure of such information to the extent required by law or by any Regulatory Authority, provided that Sponsor, as the case may be, is informed of such requirements and in so far as practicable, the Site/ Site Investigator arranges for the disclosure to be made in confidence.

11. RESEARCH DELIVERABLES

In this undertaking the Site Investigator agrees to perform the work required by this Agreement (more specifically as defined under **Exhibit A** attached herewith) and the Site Investigator has fully understood the service deliverables under this Agreement. Site Investigator representing that he is duly authorized by the Ethics Committee of the Institution to do so, agrees to make reasonable endeavors to enroll minimum 25 Patients or such higher numbers as agreed upon with Sponsor from time to time to meet the patient selection criteria described in the Protocol. Site Investigator acknowledges that enrollment for the Registry is competitive, and that the enrollment period may be terminated at any time. The estimated registry duration is 24 months including pre-& post registry period and extended follow up (telephonic) is 1 month and 365 days for OCT sub study group subjects.

12. GENERAL PROVISIONS

12.1 Notices: Unless otherwise provided herein, any notice required or permitted to be given hereunder shall be in writing and faxed/emailed, mailed by registered mail, or delivered by hand to the party to whom such correspondence is required or permitted to be given hereunder at the addresses set out above (or such other address as a party may designate by notice in writing).If delivered by registered mail, any such correspondence shall be deemed to have been delivered after three business days from dispatch, and if delivered by hand, any such correspondence shall be deemed to have been delivered on receipt, and if faxed, any such correspondence shall be deemed to have been delivered immediately upon successful facsimile/email transmission.

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12.2 Governing law: This Agreement, and any disputes arising hereunder, shall be governed by and interpreted in accordance with the **laws of India** and the PARTIES submit to the exclusive jurisdiction of the courts of **Lucknow.**

12.3 Entire Agreement: This Agreement sets forth the entire Agreement and understanding of the Parties relating to the subject matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, between the Parties.

12.4 Severability: If any provision of this Agreement shall be held invalid, illegal or unenforceable, such provision shall be enforced to the maximum extent permitted by law and in compliance with the Parties' intent, and the remaining provisions shall not be affected or impaired.

12.5 Amendments, Waivers: This Agreement may be amended, modified, superseded, cancelled, renewed or extended, and the terms or covenants hereof may be waived, only by a written instrument (which identifies this Agreement and states the plan or intent to modify) executed by all Parties hereto, or in the case of a waiver, by the Party waiving compliance.

12.6 Assignment: Site/ Site Investigator may not assign this Agreement to any party and may not subcontract any of their obligations under this Agreement, unless prior written consent for the same has been obtained from CRO

12.7 Survival: Notwithstanding the termination of this Agreement, obligations which have accrued or have application beyond the term including without limitation those relating to confidentiality, intellectual property, publications, indemnification and enforcement of Parties' rights, shall survive the expiration or earlier termination of this Agreement.

12.8 Relationship of the Parties: The Parties agree that Site/ Site Investigator shall their respective roles and obligations as memoralised under the terms of this Agreement perform services hereunder as an independent contractor, and not as an agent, retaining control over and responsibility for its own operations and personnel. Site/ Site Investigator shall not, and will ensure that its Representatives shall not, represent themselves to be the agents, employees, partners or joint ventures of Sponsor and shall not otherwise cause Sponsor to be liable under any contract or otherwise.

12.9 Attachments: **Exhibits A & B** form an integral and substantial part of this Agreement.

12.10 Force Majeure: Except CRO on behalf of sponsor's obligation to make payment to the Site in accordance with Exhibit B, no Party hereto shall be liable for damages or have the right to cancel this Agreement for any delay or default in performing its obligations hereunder, if such delay or default is caused by conditions beyond its control, including but not limited to natural disasters, acts of God, government restrictions/policy, laws, wars, terrorist acts, or insurrections. Whichever of Site/ Site Investigator and CRO is affected by such circumstances (the "Affected Party") shall promptly notify the other (the "Non-Affected Party") in writing when such circumstances cause a delay or failure in performance ("a Delay"). In the event of a Delay lasting for four (4) weeks or more the Non-Affected Party shall have the right to terminate this Agreement by notice of 30 (thirty) days in writing to the Affected Party.

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IN WITNESS WHEREOF the parties hereto have accepted and executed this Agreement as of the day and year first set above. This Agreement has been executed in **Triplicate**; each party having received one original.

ACCEPTED AND AGREED:

SITE INVESTIGATOR:

Name: Dr. Aditya Kapoor

Date: 3 Aug 2022

Title: Professor & Head

INSTITUTION:

Name: Prof. R.K. DHIMAN, Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, LUCKNOW-226 014, INDIA

Date: 01.09.2022

Title: -

CRO

Name: Mr. Kishor Kumar

Date: 26th July'2022

Title: Chief Financial Officer

JSS Medical Research Asia Pacific Pvt. Ltd. ★ Faridabad

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EXHIBIT – A

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LIST OF SERVICES

1. Scientific clearance for conduction of registry at investigator site (if applicable)
2. Ec approval of registry documents like protocol, informed consent document etc.
3. Identification of eligible patients for the registry
4. Obtaining of informed consent process
5. Treat registry participants as hospital standard of care & adequate follow up
6. Collection of complete medical history of the patients
7. Recording of physical examination – signs and symptoms of all the patients and other related information on source / e-CRF
8. Reporting of adverse events and serious adverse events reporting as per regulatory/ec sop -timelines
9. Writing the patient registry summary-completion of source documentation
10. Supporting and coordinate with CRO's/ sponsor monitor to monitor the registry
11. Supporting and coordinate with CRO's/ sponsor auditor for the registry audit.
12. Supporting and coordinate with CRO's/ sponsor for registry closeout at end of the registry

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EXHIBIT – B

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BUDGET AND PAYMENT SUMMARY:

COMPETITIVE ENROLLMENT OF 25 PARTICIPANTS IN THE REGISTRY.

BUDGET AND PAYMENT SCHEDULE:

Registry Financial Grant: Per patients enrolled and upon COMPLETION (INR) = ₹ 15000 as per the following:

(SUMMARY)	
Description	**Amount Rs. (Excl. TDS & GST)**
TOTAL PER PATIENT REGISTRY GRANT IN INR	
Investigator/ CRC Fees per patient inclusive Investigation/Laboratory costs	₹ 15,000/ participant (Includes PI fee, CRC fee and Institute Overhead)
REGISTRY GRANT PAYMENTS & MILESTONES	
Schedule Registry grants release milestones	**Milestone & registry Grant amounts**
Upon initiation of Shock India Registry site	Investigator and CRC Fees per Patient inclusive Laboratory Costs
Screening & Enrolment (pre procedure)	₹ 15000 / patient
Index Procedure	
Post Procedure (Discharge)	
1 Month clinic FU/ Telephonic Call	
1 year clinic FU/ Telephonic Call for first 100 patients with OCT imaging	
CRC fee for data entry into eCRF and other registry related work	

Note:

- As Per sponsor request, archival of the documents will be at third party outside vendor, hence archival fee will not be applicable for this registry.
- TDS if applicable, will be deducted at prevailing applicable percentage rates.
- GST is NIL on Investigation/Laboratory Costs.
- GST @ 18% if applicable, as per prescribed rates.

* Laboratory tests (Hemoglobin, Platelet, Serum creatinine and CK-MB, 2D ECHO, 12 Lead ECG) if done, as part of the standard of care prior to the registry screening date, will be considered as valid for the registry and will not be compensated for.
* Similarly, all investigations required as part of the registry follow up, and if done as part of the standard of care will be considered as valid and will not be compensated for.

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A. PAYMENT TERMS:

All payments are based on enrolled patients' actual registry visits (Registry visits are as defined in the protocol scheduled visits). The total payment will be dependent on the total number of patient visits which are captured in the CRF, and source data verification based.

All payments under this Agreement shall be subject to deduction of tax at source, wherever applicable and, as per applicable Indian laws, for which if required, a TDS certificate will be issued by the CRO on behalf of sponsor to the Site/ Site Investigator within the time permissible under applicable laws.

B. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

No payment will be made in the event of a failure to follow the registry procedure as defined by the protocol, except where such failures are beyond the reasonable control of the Site. Reimbursement will not be provided for patients who enter the registry but fail to meet all the inclusion and exclusion criteria. Reimbursement for discontinued or early termination patients will be prorated based on the number of confirmed completed visits.

C. IRB/EC PAYMENT:

IRB/EC costs will be reimbursed on a pass-through basis and are not included in the attached budget. The nature of this registry being purely academic, CRO on behalf of sponsor will not pay for any EC renewal fees.

D. PAYEE INFORMATION

The parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee (the "Payee").

Payments will be issued by the CRO within 30 (thirty) days from the date of receipt of invoice from the Payee according to visits completed, as verified by the registry monitor in the electronic data captured tool E-CRF records. Payments will be made by cheque / wire transfer in favor of this agreement payee details.

PAYEE NAME:	Director SGPGI Research Account
PAYEE ADDRESS:	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, UP-226014, India
PAYEE ACCOUNT NUMBER	10095237491
BRANCH ADDRESS	State Bank of India, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, UP- 226014, India
IFSC CODE	SBIN0007789
PERMANENT ACCOUNT (PAN) OF PAYEE	AAAJS3913N
(GST NO), if applicable	09AAAJS3913N2ZN

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Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ BH 103139

कोषागार कार्यालय ठाणे

जिल्हा कोषागार कार्यालय, ठाणे
10 JAN 2022

NOVARTIS HEALTHCARE PRIVATE LIMITED (First Part)

AND

Dr. Sanjeev (Second Part)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Third Part)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of *[__ _____ 22_]* ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Lucknow*** ("**Institution**") registered under state legislature Act, 1983 and having its address at Raebareli road, Lucknow 226014 which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Sanjeev, assistant professor, Department of Haematology as clinical practitioner in the field of ***Haematology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: **Crizanlizumab, SEG101** (hereafter the "Trial Drug") in accordance with a protocol entitled "***An Indian Multi-centric Phase IV study to assess the safety of Crizanlizumab with or without hydroxyurea therapy in sickle cell disease patients with vaso-occlusive crises', Protocol No-CSEG101A2403"*** and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

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. TNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed ,heir duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: _____

Title: _____

Date: _____

Murugahanthan K.
Country Monitoring Head
27 Jan 2022

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

Name: _____

Title: _____

Date: _____

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Sanjeev

Title: Principal Investigator

Date: 17/02/2022

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

सत्यमेव जयते

₹100

e-Stamp

Certificate No.	:	IN-DL05054049809906U
Certificate Issued Date	:	16-Mar-2022 01:32 PM
Account Reference	:	IMPACC (IV)/ dl700603/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL70060398783511234109U
Purchased by	:	DATT MEDIPRODUCTS PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DATT MEDIPRODUCTS PVT LTD
Second Party	:	DIRECTOR SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES AND PROF GYAN CHAND SGPGIMS
Stamp Duty Paid By	:	DATT MEDIPRODUCTS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

₹100

₹100 ₹100 ₹100

Please write or type below this line IN-DL05054049809906U

This non-judicial stamp paper forms an integral part of clinical trial agreement (CTA) executed between Datt Mediproducts Pvt. Ltd., Director (SGPGIMS) & Prof. Gyan Chand, Dept. of Endocrine Surgery, SGPGIMS Lucknow

(Principal Investigator) (Institute/Hospital) (Sponsor)

Clinical Trial Agreement

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

(39) Certificate No.: IN-DL05054049809906U

CLINICAL TRIAL AGREEMENT

Clinical Investigation Plan/Protocol Title:	A randomized, open label, single centre Post Market Surveillance Study to evaluate the efficacy and safety of a new antimicrobial wound dressing (VELVERT) compared to standard dressing (SD) in the treatment of Diabetic foot ulcer.
Clinical Investigation Plan/Protocol Number:	**Protocol No.: DMPL/CIP-02-2020/CT/VV; Version No.: 1.0, Date: 03-Sep-2020**
Date of Agreement:	17-Mar-2022
SPONSOR	
Name:	Datt Mediproducts Pvt. Ltd.
Address:	**Registered office:** Gazraj Chambers, 2B, Second Floor, 86 B/2, Topsia Road (South), Kolkata, 700046. **Corporate office:** 56, Community Center, East of Kailash, D Block, New Delhi, Delhi 110065.
PRINCIPAL INVESTIGATOR	
Name:	Prof. Dr. Gyan Chand
Address:	Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli road, Lucknow,226014, Uttar Pradesh.
INSTITUTION	
Name:	Prof. R K Dhiman
Address:	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India.

(Principal Investigator) (Institute/Hospital) (Sponsor)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Certificate No.: IN-DL050540498099O6U

This Clinical Trial Agreement ("Agreement" is made between **DATT MEDIPRODUCTS PRIVATE LIMITED**, (hereinafter referred to as **"SPONSOR"**) a company incorporated under the COMPANIES ACT 1956, having registered office at **Gajraj Chambers, 2B, second floor, 86 B/2, Topsia Road (South), Kolkata 700046** and corporate office at **56, Community Center, East of Kailash, New Delhi – 110065**, on the First Party.

AND

Director, SGPGIMS (hereinafter referred to as "Investigation Site"), which is located at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India., on the Second Party.

AND

Prof. Gyan Chand, whose designation is **"Professor"** at **Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences,** (herein after referred to as "Principal Investigator" (PI), which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executers, administrators and successors) of the Third Party;

Sponsor, Principal Investigator (PI) and Institution shall individually be referred as **"Party"** and collectively as "Parties".

RECITALS:

WHEREAS,

A. **SPONSOR,** is inter-alia, engaged in the business of manufacturing and marketing of medical device along with research, product development & clinical research,
B. The **INVESTIGATOR** is engaged in the treatment of subjects with potential exposure to the indication intended for treatment, at an Institution/hospital;
C. The **INSTITUTION** is the facility where the clinical trials and study will be conducted ethically and as per the approved Clinical Investigation Plan/protocol;
D. **SPONSOR** is willing to engage the **Principal Investigator** and **Institution** to conduct the clinical trial and the study on non-exclusive basis and Institution and **Principal INVESTIGATOR** are willing to carry out the study on the terms set out in this Agreement.
E. The purpose of this **AGREEMENT** is to agree on terms and conditions, as well as procedures, according to which the clinical trials and the study will be conducted, and on the division of duties and responsibilities between the parties conducting the said trials/study.
F. The **SPONSOR** is desirous of conducting the study as per **IEC** approved protocol.

(Principal Investigator) (Institute/Hospital) (Sponsor)

DATT MEDIPRODUCTS PVT. LTD. New Delhi

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

G. The clinical trials/study will be initiated at the site only after an approval from the registered ethics committee of the institute.

H. On the faith and strength of the aforesaid representations and warranties, the **SPONSOR** has agreed to appoint the institution and Investigator for the conduct and supervision of the clinical trial/study in accordance with the approved **Clinical Investigation Plan/protocol,** subject to the terms and conditions hereinafter appearing.

NOW THEREFORE, the Parties agree as follows:

1. DEFINITIONS:

1.1 "Adverse Event (AE)" means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH-GCP Guidance page-2 section-1.2) for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

1.2 "Affiliate" means with respect to an entity, any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such entity. "Control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean (a) the power to direct the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance, resolution, regulation or otherwise, or (b) to own 50% or more of the outstanding voting securities or other ownership interest of such entity. "Entity" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

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(Principal Investigator) (Institute/Hospital) (Sponsor)

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1.3 **"Applicable law"** means the Drugs & Cosmetics Act, 1940, Drugs & Cosmetics Rules, 1945 with its amendments and any other law or rules for the time being in force in India.

1.4 **"Case Report form"** means a printed, optical or electronic document or database designed to record subject information.

1.5 **"Confidential information"** means any or all data or information whether oral, written or in electronic form disclosed by sponsor and its affiliates to Principal Investigator and/or to the Institution, including – **i.** all information collected in the course of, resulting from, or arising directly from the study; **ii.** Clinical Investigation Plan/protocol, Investigator's Brochure, study materials and Investigational Product, business plans, sales or marketing methods; **iii.** Information, ideas, concepts, IPR, technical and operational information, scientific or technical processes or techniques, product composition or details owned by the sponsor and its affiliates; **iv.** Know-how, methodology, trade secrets, sequences and structure of the study; and v. Information concerning the business affairs or clients and its affiliates.

1.6 **"Fees"** shall mean the milestone payments agreed by the parties of the study.

1.7 **"Force Majeure Event"** shall mean circumstances beyond reasonable control of a party, including but not limited to, change in government policy, fire, flood, epidemic, act of God, war and riot;

1.8 **"GCP"** means good clinical practices guidelines issued by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. of India and under applicable Laws;

1.9 **"GLP"** shall mean good laboratory practices guidelines issued by the Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Govt. of India and under applicable Laws;

1.10 "ICH-GCP" shall mean International Conference of Harmonization of Technical Requirements for Pharmaceuticals for Human Use – Good Clinical Practice Guidelines, is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of Human subjects;

1.11 "IEC" shall mean Institutional Ethics Committee of the Institution;

1.12 "Investigational Product" shall mean an allogenic cell based wound dressing (VELVERT), which will use, as how it will be used.

1.13 "IPR" shall mean patent, copyright, trademark, service mark, service name, trade name, interned domain name, brand name, trade dress, label, logo, know-how, technical and non-technical information, trade secret, formulae, technique, sketch

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drawing, model, invention, design, specifications, processes, apparatus, equipment, database, research, experimental work, development, study materials and Investigational Product and all the confidential or proprietary information obtained by the Principal Investigator and Institution from the Sponsor or generated or created by Principal Investigator and Institution as a direct or sole result of performing clinical trial/study under this agreement, including, without limitation results of the clinical trial/study, data generated, confidential proprietary, commercial, scientific, medical or technical information.

1.14 **"Party"** shall individually mean sponsor or Principal Investigator or Institution.

1.15 **"Parties"** shall collectively mean Sponsor, Principal Investigator and Institution.

1.16 **"Clinical Investigation Plan/protocol"** shall mean a document that states the background, objectives, rationale, design, methodology and statistical considerations of the study.

1.17 **"Regulatory Authorities"** means the Drugs Controller General (India), Directorate General of Health Services, Ministry of Health and family Welfare, Drug Advisory Committee and relevant government authority having jurisdiction under applicable Laws.

1.18 **"Representative"** shall mean the employees, directors and officers of a party.

1.19 **"Serious Adverse Event"** means an untoward medical occurrence that leads to,— (i) a death; or (ii) a serious deterioration in the health of the subject that either- (A) resulted in a life-threatening illness or injury; or (B) resulted in a permanent impairment of a body structure or a body function; or (C) required in-patient hospitalization or prolongation of existing hospitalization; or (D) resulted in medical or surgical intervention to prevent life threatening illness or injury or permanent impairment to a body structure or a body function; or (iii) foetal distress, foetal death or a congenital abnormality or birth defect;

1.20 **"Study site"** shall mean the Institution facility (Department of Endocrine Surgery), Located at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow– Uttar Pradesh, India.

"Clinical trial/Study" means the clinical trial/study (A randomized, open label, single centre Post Market Surveillance Study to evaluate the efficacy and safety of a new antimicrobial wound dressing (VELVERT) compared to standard dressing (SD) in the treatment of Diabetic foot ulcer.

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1.21) to be conducted on eligible subjects by the Principal Investigator and Institution to test the Safety and Efficacy of the study device.

1.22 Study completion occurs when the final **Clinical Study Report (CSR)** is signed by the Principal Investigator and Institution and Sponsor. Data generated in the clinical trial/study has been locked and provide to Sponsor, including a copy of approval letter of IEC acknowledgment of final report.

1.23 Study Material means Medical Device VELVERT).

1.24 Subject means patient enrolled in said study.

2. SCOPE AND CONDUCT OF THE STUDY:

2.1 Sponsor hereby engages the Principal Investigator and Institution to conduct the Clinical trial/study on non-exclusive basis.

2.2 Institution agrees to provide all the facilities to the Principal Investigator and confirms that the study shall be conducted at the study site under the direction of Principal Investigator.

2.3 Principal Investigator shall conduct the study in accordance with the Clinical Investigation Plan/protocol, GCP, Regulatory Authority requirements including ICH-GCP, institution standard Operating procedures and other applicable laws.

2.4 Institution shall perform the Clinical Trial/Study under the direct supervision and control of Principal Investigator. If Principal Investigator is unwilling or unable to perform the study, Institution shall refer alternative Investigator to Sponsor as replacement of Principal Investigator and based on Sponsor's written approval, such Investigator shall be engaged as Principal Investigator for the clinical trial/study. If a mutually acceptable Principal Investigator is not referred by the Institution, then the study may be continued with **Prof. Gyan Chand** until the Sponsor suspends or terminates the study or till completion of the study.

2.5 Sponsor will not accept the study until relevant milestones are achieved as identified in the Clinical Investigation Plan/protocol. In the event of any actual or anticipated failure by Site to perform the Clinical Trial/Study in strict compliance with the standards specified in the Clinical Investigation Plan/protocol or otherwise described in this Agreement for any reason other than Sponsor's acts or omissions, Sponsor shall be entitled to, at it's sole option, require the Principal Investigator and Institution to re-perform the relevant milestone in the study without any additional cost to the Sponsor within timelines specified by the Sponsor

3. SUBJECT RECRUITMENT:

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3.1 Principal Investigator shall enroll the Subjects in the study after IEC approval.

3.2 Principal Investigator shall ensure that all Subjects comply with Clinical Investigation Plan/protocol.

3.3 It shall be the responsibility of the Institution and Principal Investigator to notify Sponsor and IEC of any significant deviation from Clinical Investigation Plan/protocol and/or Applicable and Regulatory Authority guidelines including without limitation to Serious Adverse Events within Forty-eight (48) Hours.

3.4 Principal Investigator and Institution shall enroll **100 patients at site. If additional subjects are enrolled or less subjects are enrolled then, it should be communicated with sponsor.**, additional Subjects may be recruited only upon Sponsor's prior written consent.

3.5 Principal Investigator and Institution agrees that Sponsor can limit or stop Subject inclusion in the Study at any time for any reasons. If Sponsor limits Subject inclusion in the Study, milestone Fees under the payment schedule shall be paid by Sponsor based on the milestones achieved by the Principal Investigator and Institution as defined in Annexure - I. Should there be no Subject enrollment or there is no Study kick-off by Principal Investigator and Institution in accordance with the Agreement, entire milestone Fees paid by Sponsor shall be refunded immediately.

3.6 If a Subject suffers with any Study related injury, Principal Investigator and Institution shall notify Sponsor within 24 hours, however, Principal Investigator and Institution shall be responsible to provide complete medical treatment to the Subject. Sponsor will bear actual medical expenses incurred by the Principal Investigator and Institution for the Subject as a result of any study related injury. In case of death of Subject due to Study related injury, Principal Investigator and Institution shall immediately notify the Sponsor and Sponsor will pay the financial compensation as a result of Study related death as provided under Regulatory Authority guidelines and Applicable Law.

4. RESPOSNIBILITIES OF PARTIES:

4.1 PRINCIPAL INVESTIGATOR & INSTITUTION:

4.1.1 Principal Investigator and Institution shall be responsible to conduct the said Study at the Study Site.

4.1.2 Principal Investigator and Institution shall not subcontract the Study to any third party, except with prior written consent of Sponsor.

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4.1.3 Principal Investigator and Institution shall provide preliminary and final detailed reports to Sponsor as per the timelines specified in the Protocol.

4.1.4 Principal Investigator and Institution shall be responsible to provide daily updates in respect of Serious Adverse Events, milestones pending, completed and safety issues.

4.1.5 Principal Investigator and Institution agrees that the Investigational Product and Study Materials are owned by Sponsor and all unused Investigational Product and Study Materials shall be returned to Sponsor on Study Completion. However, Institution is responsible to maintain full and accurate records for the use of Investigational Product and Study Materials in the Study.

4.1.6 Principal Investigator and Institution shall be responsible to notify Sponsor and IEC if there is a requirement for change in Clinical Investigation Plan/Protocol. Principal Investigator shall carry out the modifications and/or amendments in the Clinical Investigation Plan/Protocol based on the approval of IEC and Sponsor.

4.1.7 Principal Investigator and Institution agrees that Sponsor can monitor the Clinical Trial/Study and advise Principal Investigator and Institution on cessation of the Clinical Trial/Study or withdrawal of Investigational Product and Study Materials for safety reasons.

4.1.8 Principal Investigator and Institution shall maintain all Study Materials, including copies of signed consent forms, Case Report Forms, Protocol and information relating to Investigational Product and Study Materials in safe custody always locked.

4.2 PRINCIPAL INVESTIGATOR:

4.2.1 Principal Investigator thoroughly familiarizes him/herself with the appropriate use study materials/Investigational Product (**VELVERT**) and described in Clinical Investigation Plan/Protocol, Informed Consent Documents and Case Report Form.

4.2.2 Principal Investigator shall be responsible to coordinate with the research staff and Institution and deliver all reports, data, statement and deliverables of the Clinical Trial/Study to the Sponsor.

4.3 INSTITUTION:

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4.3.1 Institution is responsible to ensure that Principal Investigator is conducting the study under this agreement is not debarred by the Regulatory Authority or under applicable laws.

4.3.2 If Principal Investigator leaves the Institution or otherwise ceases to be available, then the Institution must consult with the Sponsor and use reasonable endeavors to nominate as soon as possible, a replacement reasonably accepted to both parties; and the Sponsor many require recruitment into the study by the Institution to cease, or move the study to a different study site.

4.3.3 The Institution shall be responsible for ensuring sufficient, appropriate and necessary facilities, equipment and resources for the conduct of the trials/Study, and all other resources reasonably required to complete the Study and that no other than legal obligations or commitments of the Institution cause unreasonable damage to or delay in conducting the said trial/Study as set forth in this agreement.

4.3.4 Institution will ensure that the Study is subject to the continuing oversight of the Principal Investigator and IEC throughout the Study Completion.

4.3.5 Institution shall be responsible to retain archival records of the Study including the original or a copy of al Subject consent forms in conformance with applicable regulations for a minimum free storage period of **fifteen (15) years.**

4.3.6 Institution shall notify Sponsor before destroying any Study Materials and retain the Study Materials for such longer period as reasonably required by the Sponsor at the mutually agreed costs after completion of free storage period of **fifteen (15) years.**

4.4 SPONSOR:

4.4.1 Sponsor will provide study materials to the Principal Investigator and Institution for the purpose of conducting the Clinical Trial/Study.

4.4.2 Sponsor will share relevant information of study materials and Investigational Product with Principal Investigator and Institution.

5. REGULATORY AUTHORITY:

5.1 Principal Investigator and Institution shall obtain IEC approval and Sponsor will obtain regulatory authority clearance under applicable law as specified in Clinical Investigation Plan/Protocol.

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5.2 If Principal Investigator and Institution fails to obtain the IEC approval within the agreed timelines stated in the Clinical Investigation Plan/Protocol, Sponsor shall at its sole option, immediately suspend or terminate the Clinical Trial/Study and terminate this Agreement as per Section 13 Principal Investigator and Institution shall notify sponsor within twenty-four (24) hours upon receipt of written communication from Regulatory Authority inspection or inquiry related to the Clinical Trial/Study.

5.3 Principal Investigator and Institution shall cooperate with Sponsor from time to time in inquiry, investigation, audit or proceedings of Regulatory Authority without additional cost to Sponsor.

6. REPRESENTATION & WARRANTIES:

6.1 Parties represent and warrant that they are authorized to execute this agreement and that the terms of this agreement are not in violation of any contract to which they are a party.

6.2 Principal Investigator and Institution represents and warrants that they have relevant skill, experience, expertise, regulatory approvals/licenses and facilities to conduct the Clinical Trials/Study as required by Sponsor from time to time.

6.3 Institution represents and warrants that the processes and clinical tools used by Principal Investigator to perform the Study herein does not infringe any Intellectual Property Rights including patent, copyright, trade secret, industrial rights or other proprietary right of any third party.

6.4 Institution warrants that Principal Investigator, and all Representatives deputed for performing the Study shall possess relevant skills and qualifications and the Clinical Trial/Study shall be rendered in a professional and workmanlike manner.

6.5 Principal Investigator and Institution shall diligently and timely respond to all queries and requests of Sponsor.

6.6 Principal Investigator and Institution shall comply with all Applicable laws including data privacy, confidentiality and data security policies from time-to-time.

7. INTELLECTUAL PROPERTY:

7.1 All rights, title and interests resulting from the said Clinical Trials/Study, Study Materials and Investigational Product including IPR whether created, developed, generated, modified or improved by Principal Investigator and/or Institution shall be the exclusive property of Sponsor. Principal Investigator and Institution agrees that Sponsor owns the right, title and interest in any inventions, designs, discoveries, improvements, developments, innovations and works of authorship

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produced as a result of the Study. Principal Investigator and Institution shall irrevocably transfer and assign all rights, title and interest in IPR in favor of Sponsor.

7.2 Principal Investigator and Institution shall not use the Confidential Information and IPR and/or data generated from the study directly or indirectly for any purpose other than the Clinical Trial/Study.

7.3 Principal Investigator and Institution agrees that all inventions, data, works, discoveries, technology and innovations or improvements in relation to the study and IPR, whether or not subject to any protection by statute which are conceived of, made, reduced to practice, created, written, designed or developed, authored or made by Principal Investigator and/or Institution either alone or in combination, in the course of the performance of study under this Agreement including modifications or improvements to any proprietary technology, information or materials provided by Sponsor to Principal Investigator and Institution shall be the exclusive property of Sponsor. The Inventions are to be promptly reported to Sponsor. Sponsor is free to use the results of the Clinical Trial/Study without any further communication to Principal Investigator and Institution.

7.4 Principal Investigator and Institution agrees to cooperate with Sponsor and its nominees to obtain patents or register copyrights in any and all countries for the inventions and IPR and to execute all documents for use in applying for and obtaining such protection thereon as Sponsor may desire, together with assignments thereof to confirm Sponsor's ownership. In the event that any improvements, innovations or developments do not qualify to be work for hire, Principal Investigator and Institution herby irrevocably transfers, assigns and conveys, all rights, title and interest in such improvements or developments to Sponsor free from all encumbrances and agrees to execute and shall cause it's representative to execute, all necessary documents in favor of Sponsor.

8. FEES:

8.1 Principal Investigator and Institution shall submit any invoice to the Sponsor for conducting the said Clinical Trial/Study. Principal Investigator and Institution agrees that the payment made by Sponsor for conducting the Clinical Trial/Study is fair as mutually agreed by the parties as per **Annexure I.**

8.2 Principal Investigator consideration of the Clinical Trial/Study, Sponsor will pay the Fees/ charges to the Institute on completion of relevant milestones as specified in **Annexure I.**

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8.3 Institute shall submit to Sponsor the invoices for Clinical Trial/Study completed till the relevant milestones. All invoices shall be approved by the Sponsor representative. Principal Investigator shall give supportive documents upon successful completion of deliverables within the agreed timelines. Sponsor will make payments against undisputed invoices within thirty (30) business days from the date of receipt of invoice. If there is any discrepancy in the invoice submitted by the Institute, Sponsor will notify Institute within fifteen (15) business days from the date of receipt of such invoice and withhold disputed invoice amounts until resolved by the Parties. However, pending resolution of any dispute under this Agreement, Principal Investigator and Institution shall proceed diligently with its performance of Clinical Trial/Study and complete the Clinical Trial/Study during dispute proceeding, unless otherwise instructed by the Sponsor.

8.4 All payments made by Sponsor to Institute shall be subject to tax deduction at source, service tax and payments, other applicable taxes as per their applicable rates, shall be paid extra by Sponsor.

8.5 Institute has provided NEFT/RTGS/wire transfer details to the Sponsor for processing the payments and subject to undisputed invoices, payment will be processed by the Sponsor.

All invoices to be sent to:

SPONSOR:	Datt Mediproducts Private Limited
BILLING ADDRESS:	Datt Mediproducts Private Limited, 56, Community Center, East of Kailash, New Delhi – 110065, India
ATTENTION OF:	Dr. Rajan Datt
TELEPHONE:	+91 – (11) 47191777
EMAIL:	lifescience@dattmedi.com

All invoices will be sent to the Sponsor via email and the electronic version of the invoices will be considered as the original and hard copies of the invoices will be shared by Institute on above address.

9. PUBLICATION:

9.1 Principal Investigator and Institution shall not, without prior written consent of the Sponsor, report or publish or make available the data, results or any report of the

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Clinical Trial/Study conducted under this Agreement to any third party or in any journal, book, magazine etc.

9.2 Accordingly, Study results may be published in medical journals or presented at a public forum such as conferences only after Sponsor's written consent and Sponsor has determined that such publication will not compromise IPR issues and/or confidentiality issues associated with the Clinical Trial/Study and approved or consented in writing that the Principal Investigator and Institution may publish or report the data, results or any report of the Clinical Trial/Study.

The Principal Investigator and Institution shall declare that Sponsor has provided her/him with funding for the Study whenever she/he writes or speaks in public about a matter that is the subject of this Agreement or about any other issue relating to Sponsor.

9.3 In all publications, the Sponsor's support of the Study shall be acknowledged. The Study will be clinically and statistically evaluated collaboratively by the Sponsor, Principal Investigator and on behalf of Institution and manuscript shall be prepared for submission to a peer-reviewed journal, subject to written approval of Sponsor.

9.4 Authorship credits shall, upon mutual consent between the Institution and the Sponsor, shall be decided considering all those participating in the Study program. The Sponsor may freely use, copy and disseminate any manuscript following its publication in a journal without further obligation to the Principal Investigator & Institution or disclosure. All communications in relation to the Clinical Trial/Study such as press release or responses to inquiries from media should receive prior written approval from the Sponsor.

10. CONFIDENTIALITY:

10.1 Principal Investigator and Institution agrees that CONFIDENTIAL information shall be used only for rendering the services. Principal Investigator and Institution shall keep CONFIDENTIAL information strictly confidential, protect from unauthorized use, reproduction, access and damage or destruction and employ the same degree of care as it would employ to protect its own confidential Information.

10.2 Principal Investigator and Institution shall limit disclosure of Confidential Information only to its Representatives who necessarily require access to render the Services, provided that –

(a) Principal Investigator and Institution first require each of them to agree in writing, either as a condition of their service to Principal Investigator and Institution or in order to obtain Confidential Information, to be bound by terms

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and conditions substantially similar to those terms and conditions applicable to Principal Investigator and Institution under this Agreement, and

(b) Principal Investigator and Institution shall maintain a record of Confidential Information disclosed to the Representatives and such record shall contain the name, designation of the Representatives and details of Confidential Information disclosed, which shall be made available to Sponsor upon request. However, Principal Investigator and Institution shall, under all circumstances, continue to be liable as a principal party.

10.3 In the event Principal Investigator and Institution becomes legally compelled by government or judicial process to disclose any Confidential Information, Principal Investigator and Institution will provide prior written notice thereof to Sponsor before making any disclosures, to enable Sponsor to seek protective order or other appropriate remedy to minimize disclosure and Principal Investigator and Institution shall disclose only such portion of Confidential Information absolutely necessary in the opinion of its legal counsel to comply with the process.

10.4 All Confidential Information is provided "as is", without any warranty, express, implied or otherwise, regarding its accuracy or performance and in no event shall Sponsor be liable to Principal Investigator and Institution for disclosure of Confidential Information under this Agreement.

10.5 Upon the first written request of Sponsor at any time during the term or immediately upon expiry or earlier termination of the Agreement, Principal Investigator and Institution shall return **within fifteen (15) days** all Confidential Information to Sponsor, by registered mail/courier of international repute, and/or destroy such Confidential Information as per the directions and instructions of Sponsor and provide written certification to Sponsor. Principal Investigator and Institution may, however, retain one copy of such Confidential Information in its legal archives solely for legal compliance purposes, under strict obligations of confidentiality as stated in this Agreement.

10.6 All obligations contained in the Agreement shall however survive the expiry or early termination of this Agreement and the Parties shall always remain bound by the same.

11. INDEMNITY:

Sponsor shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

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11.1 The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Datt Mediproducts Pvt. Ltd.;

11.2 The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Sponsor consent;

11.3 The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

11.4 An adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

11.5 Sponsor is immediately informed of the claim and all pertinent information relating thereto (but in any case, within ten (10) days after the Indemnitee shall have received notice thereof);

11.6 The Indemnitee provide such information and assistance to Sponsor in connection with such claim as is reasonably requested by Sponsor and its representatives;

11.7 Sponsor is permitted to handle and control such claim in its sole discretion.

11.8 An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

11.9 The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Datt Mediproducts Pvt. Ltd. in respect of all claims.

12. TERM:

This agreement shall commence from the effective date and shall be valid for a period of Two (02) Years or on Clinical Trial/Study completion or unless sooner terminated by Sponsor in accordance with section 13, whichever is applicable. Parties may renew this Agreement upon mutually agreed terms & conditions.

13. TERMINATION:

13.1 Sponsor shall be entitled to terminate this Agreement in the following circumstances:

13.2 Without cause at any time by giving seven (7) days' prior written notice to the Principal Investigator and/or Institution.

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13.3 In the event of breach by Principal Investigator and Institution that is not cured within thirty (30) days from the date of written notice by Sponsor.

13.4 Immediately, if Principal Investigator and Institution fails to obtain ethics committee clearance.

13.5 Immediately, if Institution becomes insolvent or files for bankruptcy.

13.6 In the event of change of control of Institution, unless Sponsor decides otherwise, in which case, the acquiring entity undertakes in writing to assume all liabilities and responsibilities of Institution under this Agreement.

13.7 If this Agreement is terminated by Sponsor and/or Principal Investigator, Institution:

13.8 If Sponsor terminate the study: Fees for successful completion of Study till the date of termination as per the relevant milestone shall be paid by Sponsor.

13.9 If Principal Investigator/Institution terminate the study: Principal Investigator and Institution shall be liable to reimburse the Fees and expenses to Sponsor as a result of Sponsor retaining third party contractor to complete the Study.

13.10 Should Sponsor retain a third party for completion of the Study, then Principal Investigator and Institution shall provide transition services to such third party within the timelines specified by Sponsor without any costs thereon.

13.11

13.12

13.13 INSURANCE:

13.14 Sponsor shall secure and maintain in full force and effect throughout the performance of the Study, insurance coverage from a reputed insurance company to cover its obligations including the Principal Investigator and Representatives and all the claims arising out of Subjects injury and/or death.

14. NOTICE:

14.1 Any notice given under this Agreement shall be in writing and signed by or on behalf of party giving it and may be served by delivering it personally or sending it by pre-paid recorded delivery or registered post or by email or fax to the address and for the attention of the relevant **Party.** Any changes in address shall be notified by a **Party** to the other.

14.2 Any such notices be deemed to have been received;
-If delivered personally at the time of delivery;

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-In the case of registered airmail, pre-paid recorded delivery or registered post-upon receipt;
-In the case of fax, at the time of transmission

The addresses, Email IDs and fax number of **Parties** for the purpose of any written notice is as follows:

FOR SPONSOR	FOR PRINCIPAL INVESTIGATOR
DATT MEDIPRODUCTS PRIVATE LIMITED 56, COMMUNITY CENTER, EAST OF KAILASH, NEW DELHI – 110065, INDIA TELEPHONE: +91 (11) 47191777 EMAIL: lifescience@dattmedi.com	**Dr. GYAN CHAND.** DEPARTMENT OF ENDOCRINE SURGERY, SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW.

14.3 This agreement and the Parties rights and obligations hereunder shall be governed by and interpreted in accordance with the laws of India.

14.4 All disputes arising under this Agreement shall be mutually settled by the Parties within **thirty (30) days**, failing which, shall be finally resolved by arbitration under the Rules as per Lucknow Court by one/sole arbitrator appointed in accordance with its Rules. The language of the arbitration proceedings shall be Hindi/English. The place of arbitration shall be at Lucknow and verdict passed by the arbitrator shall be final and binding on the Parties.

15. GENERAL PROVISION:

15.1 The relationship between Sponsor is Institute is of independent contractor.

15.2 A Party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by a Force Majeure Event provided that the affected **Party** promptly notifies the other of the occurrence of Force **Majeure Event.**

15.3 Principal Investigator and Institution shall not assign this Agreement to any person without prior written consent of Sponsor.

15.4 Any waiver by a **Party** of any provisions of this Agreement shall not operate or De construed as a waiver of any subsequent breach of such provision or any other provision hereof by such Party.

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15.5 The invalidity or unenforceability of any provision of this Agreement shall not in any way affect, impair or render unenforceable this Agreement or any other provision contained herein, which shall remain in full force and effect.

15.6 No amendment to this agreement shall be valid unless mutually agreed in writing and executed by the parties.

15.7 This Agreement represents the entire engagement between parties and supersedes all prior negotiations, understanding the agreements, written or oral, relating to the subject matter herein.

In Witness, whereof, the Parties herby sign and execute this Agreement as of Effective Date.

FOR SPONSOR:

Signature: Siddharth Pandey

Name: Dr Siddharth Pandey

Title: Vice president & RND Head

Address: Datt Mediproducts Pvt. Ltd., 56, Community Center, East of Kailash, New Delhi – 110065, India

FOR SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES:

Signature: _____

Name: Prof. R K Dhiman

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014 (U.P.)

Title: Director

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow- 226014, Uttar Pradesh, India.

FOR PRINCIPAL INVESTIGATOR:

Signature: _____

Name: Dr. Gyan Chand

Dr. Gyan Chand
Professor
Dept of Endocrine Surgeon
S.G.P.G.I M.S., Lucknow

Title: Professor

Address: Department of Endocrine Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences,

(Principal Investigator) (Institute/Hospital) (Sponsor)

DATT MEDIPRODUCTS PVT. LTD. New Delhi

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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ANNEXURE I

Study Title:
A randomized, open label, single centre Post Market Surveillance Study to evaluate the efficacy and safety of a new antimicrobial wound dressing (VELVERT) compared to standard dressing (SD) in the treatment of Diabetic foot ulcer.

Fixed cost as investigators includes both investigators Principal and Co-Investigator fee: Datt Mediproducts Pvt. Ltd. will pay maximum up to INR 700/ per visit upon achieving the milestones listed below.
Clinical research coordinator shall be provided by the sponsor and cost of the same shall be borne by the sponsor.

1. Payment Milestones

As per monthly invoice generated by site. Invoice will be clear by sponsor within 30 days of receipt of invoice.

2. Allocated study budget (B)

Particulars	Per visit	Cost Per subject
Investigators Fee	INR 700/	**INR 10,500/-**
Institutional charges @ 25% of total Budget	-	*25% Institutional overhead*
Grand Total	-	

3. Bank details for payment transfer:

Beneficiary Name	Director SGPGI Research Account
Bank Name	State Bank of India
Bank Address	Sanjay Gandhi PGIMS, Rae Bareli Road, Lucknow, Uttar Pradesh, India 226014
Account No.	10095237491
Account Type	Current
NEFT/ IFC / RTGS code	IFSC code. SBIN0007789

(Principal Investigator) (Institute/Hospital) (Sponsor)

DATT MEDIPRODUCTS PVT. LTD. New Delhi

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Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ BG 124182

उप कोषागार कार्यालय कल्याण

उप कोषागार अधिकारी कल्याण

29 JUN 2022

Novartis Healthcare Private Limited (FIRST PART)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SECOND PART)

AND

Dr. Jayantee Kalita (THIRD PART)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of [22 NOV 2022] ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Jayantee Kalita as clinical practitioner in the field of ***Neurology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug **LOU064/remibrutinib** (hereafter the "Trial Drug") in accordance with a protocol entitled **"A randomized, double-blind, double-dummy, parallel-group study, comparing the efficacy and safety of remibrutinib versus teriflunomide in participants with relapsing multiple sclerosis, followed by extended treatment with open-label remibrutinib.", CLOU064C12301"** and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

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SGPGIMS,Lucknow

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by Novartis.

all, as amended from time to time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments, unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Trial is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 5.3 (d) provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon signature by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

4.2 The following provisions shall survive the termination or expiry of this Agreement:

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understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not shall make payments for new Trial Subjects.

During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drug in sufficient quantity to conduct the Trial. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

(c) not permit Trial Drug to be used for any purpose other than the conduct of the Trial in compliance with the Protocol;

(d) shall not make the Trial Drug available to any third party other than as specified in the

(e) keep full and accurate records of who dispenses the Trial Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor entrusted with the oversight of the Trial ("Novartis Monitor") at any scheduled monitoring visit;

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

(g) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Trial Drugs to Novartis.

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the qualification of each prospective Trial Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Trial Subject's suitability for participation in the Trial, and abide by Novartis's decision as to whether or not to enrol that Trial Subject;

(c) ensure that, before their participation in the Trial, the Trial Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Trial that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Trial; and (ii) the collection, processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF") in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Trial Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with; and

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (1 subject screening per month) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

Novartis will review the Trial Subjects recruitment on an on-going basis to ensure that the enrolment continues at an acceptable rate. Novartis is empowered to discontinue the Trial at Institution medical facilities in case of no or poor enrolment.

In a multicentre trial, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrolment of Trial Subjects prior to enrolment of the targeted number of Trial Subjects. Institution and Principal Investigator undertake to cease such enrolment upon request of Novartis and further undertake not to seek any compensation thereof.

5.5 **Recordkeeping**

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(a) Preparation and maintenance of complete, accurately written and electronic records,

disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial. If Novartis has any legal reasons to wish to access the documents for a longer period than described above, Novartis shall notify the Institution accordingly before the end of such period. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

(f) Make available all Records to Novartis, its nominee or Health Authorities promptly upon request for monitoring and/or auditing purposes;

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Trial; and

(b) Make the hospital notes and Case Report Forms for each Trial Subject available for source data verification or auditing purposes by representatives of Novartis and the officers of any competent regulatory authority.

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

The Institution and the Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given whether or not notification was initially given by telephone. This Section shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis.

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including

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risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per current ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the Protocol) in accordance with the trial Protocol, applicable trial procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

These reporting obligations shall survive expiration or earlier termination of the Agreement.

During the Trial Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Trial and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Trial procedures.

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annex 1) and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto (but in any case within ten (10) days after the Indemnitee shall have received notice thereof);

(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

The PI of Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

6 & 7 floor, Inspire BKC, G Block,

BKC Main Road,

Bandra Kurla Complex , Bandra (East),

Mumbai – 400051

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

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Executive Registrar
SGPGIMS,Lucknow

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9. **EQUIPMENT**

9.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution, the Investigator and/or the designated Trial Staff: The Equipment shall only be used for the conduct of the Trial in accordance with the Protocol, Novartis instructions and until the Trial is completed or discontinued.

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall remain in the same condition during the Trial, with the exception of ordinary depreciation.

9.3 During the term of the Trial, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

9.4 Following completion of the Trial or upon discontinuation of the Trial for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

10. **TERMINATION**

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution 07 days before the termination of the trial .Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations (as set out in Annex 3), or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis all documents, Trial results and material used, generated or referred to in the course of the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

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The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution and/or Principal Investigator by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Trial or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion to any of its Affiliate or such third parties with no further payment or other obligation to the Institution and/or Principal Investigator. The Institution and/or Principal Investigator shall have no rights whatsoever therein

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1 shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those, which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

13. PUBLICATION

13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary or confidential information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.2 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement.

13.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Trial are made available to Novartis, whichever is later.

13.4 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis.

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13.5 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.6 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.7 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.8 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

14. CONFIDENTIALITY

14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Trial (collectively "**Information**") shall be treated as confidential. The Institution agrees not to disclose to any third parties or to use any Information for any purpose other than the performance of the Trial. The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any, must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.

14.3 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

14.4 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said Information, its collection or creation did not occur during or in connection with the Trial;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

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15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning the Trial Subjects (such as gender, age, health status, etc) and the Trial Staff shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for sharing an appropriate privacy notice with such staff members following the framework attached as Annex 4.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual competent authorities or Applicable Laws, for example to report serious adverse events and comply with drug safety laws and regulations.

15.5 Retention of data. Personal data will be kept only for the period necessary to fulfil the purposes of the collection unless a longer retention period is required or permitted by Applicable Laws

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SGPGIMS,Lucknow

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution of its obligations hereunder.

Whenever a subcontractor is appointed and approved by Novartis, the Principal Investigator shall be responsible for the oversight of the subcontractor's personnel as part of the Trial Staff.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the Parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT OF INSTITUTION/PRINCIPAL INVESTIGATOR OR OTHER RESTRICTIONS FROM THE COMPETENT AUTHORITIES

(a) **Debarment**. The Institution and the Principal Investigator certify that they are not debarred or more generally under a prohibition under the relevant Applicable Laws to perform their activities. They certify that they will not use in any capacity the services of any person debarred (or otherwise under a prohibition to perform their activity) with respect to services to be performed under this Agreement. During the term of this Agreement and for three (3) years after its termination, the Institution and the Principal Investigator will notify Novartis promptly if this certification needs to be amended in light of new information. Principal Investigator also certifies that he/she does not have a revoked or suspended medical license or applicable certification.

(b) **Investigations, Inquiries, Warnings or Enforcement Actions Related to Conduct of Clinical Research**. The Institution and the Principal Investigator certify that they are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Competent Authority Action**") related to its conduct of clinical research that has not been disclosed to Novartis. The Institution and the Principal Investigator will notify Novartis promptly if it receives notice of or becomes the subject of any Competent Authority Action regarding its compliance with ethical, scientific, or regulatory standards for the conduct of clinical research, if the Competent Authority Action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

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23. CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

23.1 The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

23.2 As the case may be, the Institution and the Principal Investigator shall ensure that the Principal Investigator and all Sub-Investigators involved in the Trial provide Novartis or its designee with the appropriate financial disclosures required by the U.S. Food and Drug Administration under 21 CFR Part 54, on such forms as Novartis or its designee may supply or approve. During the term of this Agreement and one (1) year following its expiration or earlier termination, the Institution and the Principal Investigator agree to assist the Sponsor or its designee in obtaining updated forms.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Trial; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services. In addition, disclosures of transfers of value in accordance with national pharmaceutical industry association codes to which Novartis is a party shall also apply.

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy. This term is mandatory for clinical studies that have sites in China as they have to be registered in the "Drug Clinical Trial Registry", and this registration includes investigator's personal data. Please inform clinicaltrial.cn@novartis.com if this term could not be included due to Local Regulations on Data Privacy so that individual consent request could be administered.

The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws or pharmaceutical industry codes applicable to Novartis. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Trial Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Trial Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. AUDITS AND INSPECTIONS

(a) Audit by Novartis and Records. The Institution shall grant access to its premises periodically as frequently as required for the proper performance and oversight of the Trial site in order to proceed with any and all monitoring activities required for the Trial. In addition, the Institution shall permit Novartis and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the Institution and the Principal Investigator in the course of conducting the Trial and to inspect the facilities at which the Trial is conducted to verify compliance with this Agreement, the Protocol, Applicable Laws and the accuracy of information provided in connection with the Trial. The Institution shall ensure that the

during an audit in order to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Novartis or its agents, the Institution and the Principal Investigator shall immediately correct any errors or omissions in such records and reports.

(b) Cooperation during Audit by Novartis. The Institution shall cooperate, and shall cause the Principal Investigator and the staff to cooperate, with Novartis and its contractors and agents in the event of any internal audits, upon reasonable notice and during normal business hours. The Institution shall furthermore make available to Novartis and its contractors and agents (for examination and duplication) all documentation, data and information relating to the Trial. Trial Subject medical records will be made available where appropriate for the purpose of source document verification procedures as part of the audit. The Institution also shall make the Principal Investigator and staff available to Novartis and its contractors and agents to explain and discuss such documentation, data and information. For the avoidance of doubt audits shall be supported at no cost by the Principal Investigator and investigational staff.

(c) Inspection by Competent Authority. The Institution and the Principal Investigator acknowledge that the Trial is subject to inspections by regulatory agencies worldwide, and that such inspections may also occur after completion of the Trial. In the event the Institution or the Principal Investigator receives notice that the Institution shall be the subject of an investigation or audit by any competent authority or Ethics Committee, as applicable, in relation to the Trial, it shall notify Novartis immediately within twenty four (24) hours the latest and shall obtain approval for Novartis or its agents to be present at the inspection or otherwise keep Novartis timely and constantly informed of the progress. In the event the Institution or the Principal Investigator does not receive prior notice of said inspection, it shall notify Novartis as soon as practicable after receiving knowledge of said inspection. Institution shall provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response. The Institution will promptly forward to Novartis copies of any inspection findings that the Institution receives from a competent authority or Ethics Committee, as applicable, in relation to the Trial. The Institution will provide Novartis with an opportunity to prospectively review any Institution responses to competent authority inspections in regard to the Trial.

(d) The Institution, the Principal Investigator and the staff shall cooperate with the relevant competent authorities or Ethics Committee, as applicable and comply with the legitimate requirements of an inspection. This also includes the making available (for examination and duplication) of documentation, data and information relating to the Trial. Subject medical records shall be made available where required for source document verification procedures as part of the inspection. The Institution also shall make the Principal Investigator and other staff available to the relevant competent authority to explain and discuss such documentation, data and information.

26. JURISDICTION, APPLICABLE LAW, AND DISPUTE RESOLUTION.

This Agreement shall be governed by and construed in accordance with the laws of India. The Parties hereby submit to the exclusive jurisdiction of Lucknow, India, without restricting any right of appeal.

In the event of dispute arising under the agreement, the parties shall be resolve the dispute in good faith through mutual consultation. In case the dispute is not resolved within 7 days, the parties agree that the competent courts of Lucknow India shall have jurisdiction to decide any dispute related to this agreement.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in relation with trial procedures.

Lt Col Varun Baipai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: **Murugananthan K.**

Title: Country Monitoring Head

Date: 22 Nov 2022

Sanjay Gandhi Post Graduate Institute of Medical Science

By: _____

Name: Prof R.K Diman

Title: Director

Date: _____

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Jayantee Kalita

Title: Professor

Date: 10 Feb 2023

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annex1: Payment (and Equipment) Schedule

STUDY NUMBER: CLOU064C12301

STUDY NAME: A RANDOMIZED, DOUBLE-BLIND, DOUBLE-DUMMY, PARALLEL-GROUP STUDY, COMPARING THE EFFICACY AND SAFETY OF REMIBRUTINIB VERSUS TERIFLUNOMIDE IN PARTICIPANTS WITH RELAPSING MULTIPLE SCLEROSIS, FOLLOWED BY EXTENDED TREATMENT WITH OPEN-LABEL REMIBRUTINIB

Investigator's Name: Dr. Jayantee Kalita

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Payee Name: Director, SGPGIMS Research Scheme Account

Pan Card Number: AAAJS3913N

GSTIN: 09AAAJS3913N2ZN

Committed Number of Study Subjects: 6

List of Equipment provided to Institution / Principal Investigator:

- eCOA Phone: To be retrieved post DBL
- ECG: To be retrieved post DBL
- Signant eCOA Tablet: To be retrieved post DBL
- Thermohygrometer: To be retrieved post DBL

1. Payment shall be made directly by Novartis

2. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be any and all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial.
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved.
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will not receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting receipts.
- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it

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The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Study Budget:

Assessment Schedule, Core Part

Visit		Investigator Fees	Protocol Procedures	EDSS Rater	Coordinator Fees	Institutional Overhead @ 25%	TOTAL (INR)	Total Per patient cost
Screening	Screening	5000	32000	1500	2500	10250	51250	**549375**
Treatment	D1	5000	20000	1500	2500	7250	36250	
	M1	5000	12000	-	2500	4875	24375	
	M3	5000	32000	1500	2500	10250	51250	
	M6	5000	32000	1500	2500	10250	51250	
	M9	5000	12000	1500	2500	5250	26250	
	M12	5000	18000	1500	2500	6750	33750	
	M15	5000	12000	1500	2500	5250	26250	
	M18	5000	12000	1500	2500	5250	26250	
	M21	5000	12000	1500	2500	5250	26250	
	M24	5000	32000	1500	2500	10250	51250	
	M27	5000	8000	1500	2500	4250	21250	
	M30 / EOS[4]	5000	32000	1500	2500	10250	51250	
	EOT	5000	32000	1500	2500	10250	51250	
Follow-up	Follow-up	5000	8000	1500	2500	4250	21250	

Assessment Schedule, Extension Part

Visit Name	Investigator Fees	Protocol Procedures	EDSS Rater	Coordinator Fees	Institutional Overhead @ 25%	TOTAL (INR)	Total Per patient cost
EP Day 1	5000	14000	1500	2500	5750	28750	**387500**
EP M1	5000	7000	1500	2500	4000	20000	
EP M6	5000	14000	1500	2500	5750	28750	
EP M12	5000	14000	1500	2500	5750	28750	
EP M18	5000	8000	1500	2500	4250	21250	
EP M24	5000	14000	1500	2500	5750	28750	
EP M30	5000	8000	1500	2500	4250	21250	
EP M36	5000	35000	1500	2500	11000	55000	
EP M42	5000	8000	1500	2500	4250	21250	
EP M48	5000	14000	1500	2500	5750	28750	
EP M54	5000	14000	1500	2500	5750	28750	
EP M60/EOS	5000	35000	1500	2500	11000	55000	
EP Follow-up	5000	8000	1500	2500	4250	21250	

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Executive Registrar
SGPGIMS,Lucknow

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.

You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

☑ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above.

☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.

☑ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.

☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date: 10 Feb 23

Name: **Dr. Jayantee Kalita**

Principal Investigator

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 3: Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:

(i) securing any improper advantage; or

(ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –

(i) transactions are executed in accordance with management's general or specific authorization;

(ii) transactions are recorded as necessary

(I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and

(II) to maintain accountability for assets;

(iii) access to assets is permitted only in accordance with management's general or specific authorization; and

(iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

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Executive Registrar
SGPGIMS,Lucknow

ANNEX 4: Privacy notice. To be shared by the Principal Investigator with Trial Staff

[Feb 23]

(Month/Year)

This privacy notice is addressed to:

- **Clinical investigators** (principal investigator, sub-investigator or co-investigator);
- **Other Site staff** such as nurses, pharmacists or technicians, whose Personal Data may be processed in the course of the clinical trial sponsored by Novartis.

You are receiving this Privacy Notice because Novartis Healthcare Pvt LTD (**"Novartis"**) will process information about you, which constitutes "Personal Data."

This privacy notice is provided to you to ensure transparency in relation to collection, use and disclosure of your Personal Data by Novartis for purposes related to the conduct of clinical trials sponsored by Novartis Healthcare Pvt LTD (**"Novartis Clinical Trials"**) which are being carried at your Clinical Trial Site [(the **"Site"**). For the purposes described in this Privacy Notice, **Novartis** is responsible for the processing of your Personal Data acting as a "Controller".

Collection of Personal Data

For the purposes described in this Privacy Notice, we may collect the following information about you including:

- name, identification number, address and other contact details,
- financial information (e.g. bank account number, financial interests in any of the Novartis group companies),
- qualifications, publications and information contained in the CV you provide to us where necessary,
- previous experience in clinical trials within or outside of Novartis and type of the GCP training received,
- technical data related to your use of Novartis IT systems.

Purposes and legal basis for processing your Personal Data

Processing purpose	Legal basis
1. to conduct Novartis Clinical Trials in accordance with good clinical practice and applicable laws;	Novartis' legitimate interest to conduct clinical trials to test potential treatments as well as compliance with legal and regulatory obligations;
2. to support applications for and to comply with the conditions of any marketing approval granted in respect of any medication studied under a Novartis Clinical Trial (**"Study Medication"**)	compliance with legal and regulatory obligations;
3. to support applications to vary the terms of any marketing approval granted in respect of a Study Medication;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
4. to carry out research related to the development of pharmaceutical products, diagnostics or medical aids and improve clinical trial practice;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
5. to comply with the US Financial Disclosure regulation, which is intended to ensure that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to the Federal Drug Administration of the U.S.A. ("FDA") are identified and disclosed to the FDA1;	Legitimate interest and compliance with legal and regulatory obligations;
6. to ensure traceability and follow-up of drug safety notification.	compliance with legal and regulatory obligations.

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SGPGIMS,Lucknow

1 **Clinical investigators**: principal investigator, sub-investigator or co-investigator who are directly involved in the treatment or evaluation of research subjects in NOVARTIS Clinical Trials affected by this law, must disclose information to

If applicable to Novartis Clinical Trial, your Personal Data (name and contact information) may be incorporated in subject recruitment advertisements (print media or on Internet). Any such advertisement would be approved by the Ethical Committee before it is made public.

Sharing of Personal Data

In the course of our activities and for the purposes listed in this Privacy Notice, your Personal Data can be accessed by, or transferred to the following categories of recipients, on a need to know basis to achieve such purposes:

- the sponsor of the Clinical Trial,
- our personnel (including personnel, departments or other companies of the Novartis group),
- our independent agents or brokers (if any),
- our suppliers and services providers that provide services and products to us,
- our partners in the context of consortia or industry initiatives,
- our IT systems providers, cloud service providers, database providers and consultants,
- our business partners who offer products or services jointly with us or with our subsidiaries or affiliates,
- any third party to whom we assign or novate any of our rights or obligations ,our advisors and external lawyers in the context of the sale or transfer of any part of our business or its assets,
- national and/or international regulatory bodies or Ethics Committees.

The above third parties are obliged to protect the confidentiality and security of your Personal Data, in compliance with applicable laws.

If we transfer your Personal Data to other jurisdictions, we will make sure to protect your Personal Data by (i) applying the level of protection required under the local data protection/privacy laws applicable in the country of destination, (ii) acting in accordance with our policies and standards and, (iii) for entities located in the European Economic Area (i.e. the EU Member States plus Iceland, Liechtenstein and Norway, the "EEA"), unless otherwise specified, by transferring your Personal Data on the basis of standard contractual clauses approved by the European Commission. You may request additional information in relation to international transfers of Personal Data and obtain a copy of the adequate safeguard put in place by exercising your rights as described below.

For intra-group transfers of Personal Data, the Novartis group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of Personal Data outside the EEA and Switzerland. Read more about the Novartis Binding Corporate Rules at novartis.com/privacy-policy

Duration of storage

We will keep your Personal Data as long as needed for legal and regulatory requirements. Please note that we are required to retain Clinical Trial Documentation for a minimum of 25 years.

What are your rights and how can you exercise them?

Under conditions provided by the law, you have a right to request a copy of the personal information we hold about you. You may also object to its use or ask for it to be updated, restricted, deleted, or transferred to another organisation. If you wish to contact us regarding our use of your Personal Data or you wish to exercise your data privacy rights, you may send an email to < PI email ID >.

If you are not satisfied with how we process your Personal Data, please address your request to our Data Protection Officer at global.privacy_office@novartis.com, who will investigate your concern. In any case, you also have the right to file a complaint with a responsible supervisory authority, in addition to your rights above.

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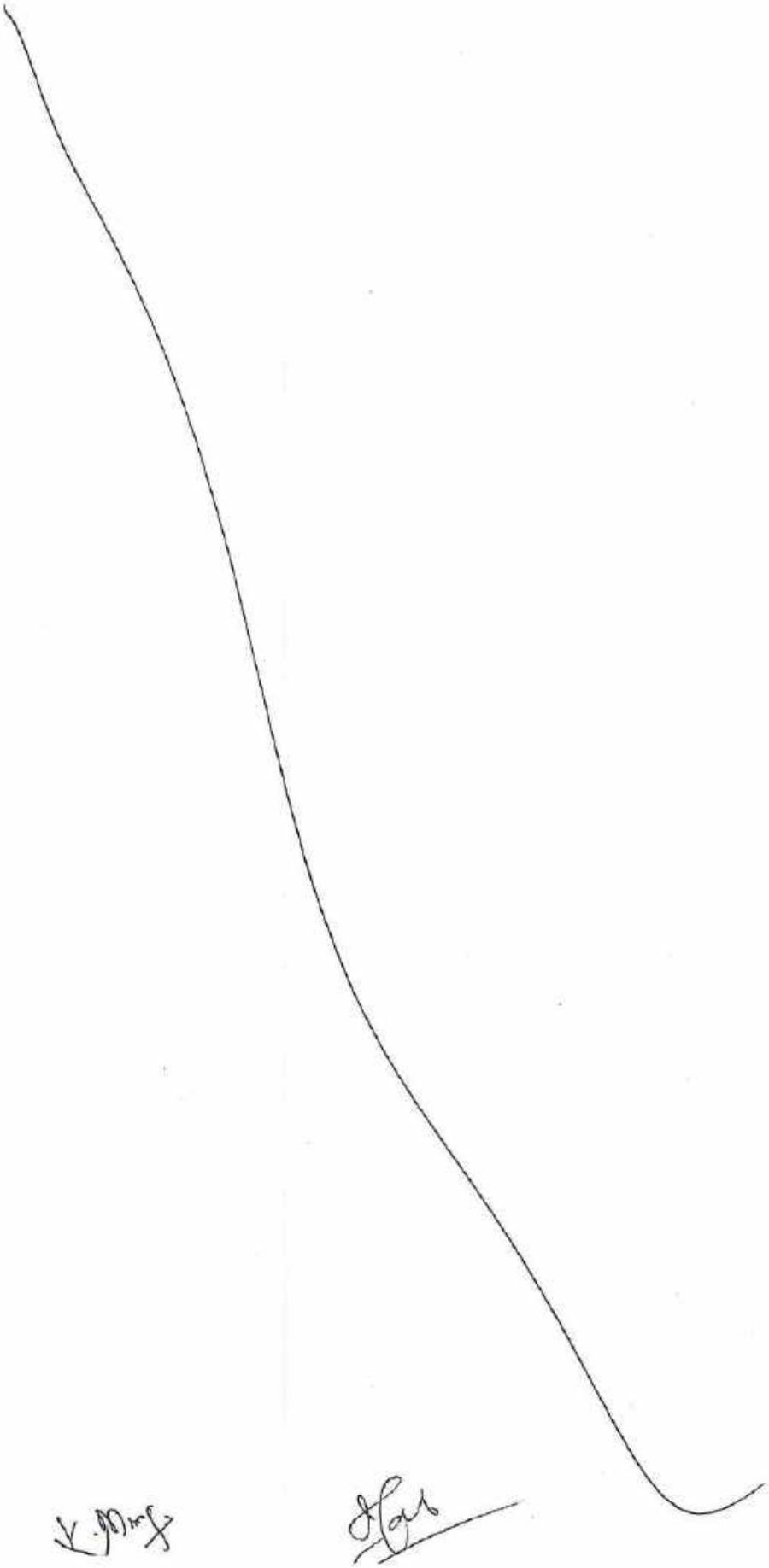
Executive Registrar
SGPGIMS,Lucknow

ANNEX 5: NOVARTIS PROFESSIONAL PRACTICES POLICY



INDIA NON JUDICIAL

Government of Uttar Pradesh

IN-UP01247166819988V

e-Stamp

Certificate No.	:	IN-UP01247166819988V
Certificate Issued Date	:	14-Dec-2023 04:40 PM
Account Reference	:	NEWIMPACC (SV)/ up14733204/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14733204982705329731 89V
Purchased by	:	ANSHIKA SRIVASTAVA
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description.	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	ANSHIKA SRIVASTAVA
Second Party	:	Not Applicable
Stamp Duty Paid By	:	ANSHIKA SRIVASTAVA
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

CHANDRA PRAKASH DIXIT * LUCKNOW * SHCILACC CODE UP14733204

Please write or type below this line

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this Fourteen December day of Two thousand and Twenty Three BY AND BETWEEN President of India, acting through Secretary, Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India, a society under the Societies Registration Act --

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

1860, having its registered office in/at **Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India,** hereinafter referred to as **SGPGIMS** (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART; (154)

WHEREAS DBT being desirous of **Human genetics and cardiomyopathies** decided to support a project submitted by **Dr. Anshika Srivastava, Assistant Professor, Department of Medical Genetics, SGPGIMS, Lucknow, India** for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **"Harnessing Genome sequencing and engineering (CRISPR/Cas9) technologies for identification of shared genetic and molecular etiology in pediatric and adult Cardiomyopathies."**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs. 86,60,988.00 (Rupees Eighty Six Lakhs Sixty Thousand Nine Hundred and Eighty Eight Only)** over a period of **Three (03)** years from the date of sanction of the project **Sanction Letter No.- (BT/PR38372/GET/119/329/2020) dated 06.01.2022**, from 06.01.2022 to 05.01.2025 **(Dr. Anshika Srivastava, SGPGIMS, Lucknow** for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India

2.1. To provide their contribution of (NIL) for *(duration in years)* years from date of sanction of the project as detailed in Annexure – II. *(Provide the cost in place of NIL if a jointly supported project).*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

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SGPGIMS,Lucknow

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

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3.0 DURATION OF PROJECT

3.1 Duration of project shall be **Three (03)** years from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by **SGPGIMS, Lucknow** will be the joint property of **SGPGIMS, Lucknow** and DBT, Government of India. It shall be the responsibility of **Sanjay Gandhi Postgraduate Institute of Medical Sciences(SGPGIMS), Raebareli Road, Lucknow-226014, UP, India** to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **SGPGIMS, Lucknow** under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of the project investigator (s) and **SGPGIMS, Lucknow** to ensure that support of DBT is suitably acknowledged in the in scientific publication/ patents/ technology transfer documents etc. arising out of the PROJECT. It shall also be the responsibility of the project investigators and institute to ensure the inclusion of reference/ grant number and duration of the financial support while making the acknowledgement of the financial support received from DBT.

Anshika

Dr. Anshika Srivastava
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
LUCKNOW-226014, INDIA

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of **SGPGIMS, Lucknow** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, **SGPGIMS, Lucknow** shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and **SGPGIMS, Lucknow.**

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Signed by ----------

(Designation)
For and on behalf of The President of India

Signatures of two witnesses (from DBT):

i.

ii.

Signed and stamped by: 10/1/24
(Director, SGPGIMS, Lucknow)

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

For and on behalf of SGPGIMS, Lucknow

X

Name, Signature and stamp of Two Witnesses (from *Institute/ University/ Organization)*):

i. Deepti Saxena

Dr. Deepti Saxena
Associate Professor
Dept. of Medical Genetics
S G P G I M S.
Lucknow-226014

ii. Somya Srivastava

Dr. Somya Srivastava
Assistant Professor
Department of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226014 (U.P.) INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – I of MoA

Detailed Project Activities

Details of the activities to be undertaken by Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP, India under the project entitled "Harnessing Genome sequencing and engineering (CRISPR/Cas9) technologies for identification of shared genetic and molecular etiology in pediatric and adult Cardiomyopathies".

Objective 1: Determine the pathogenic mechanism of chromatin modifier ASXL3 induced pediatric cardiomyopathy

hESCs ASXL3-mutation models and successful cardiac directed differentiation: I will create patient specific mutations (c.1448dupT; T484NfsX5 and c.1897_1898delCA; Q633VfsX13) in human embryonic stem cells (HUES9) using CRISPR/Cas9. As shown in our previous studies performed in patient fibroblasts that heterozygous mutations in *ASXL3* results in nonsense mediated decay and both the mutations are associated with congenital HCM as evident through our *Asxl3*$^{+/-}$ mice. hESCs will undergo cardiac-directed differentiation using sequential application of a highly efficient protocol relying on application of cytokines at specific time points hESCs.

Immunohistochemistry (IHC): A hypertrophic phenotype will be validated using cell size quantification with immunofluorescence imaging and with a qRT-PCR assay of NPPA. I will quantify the human cardiomyocytes diameter with WGA. Ki67 and PH3 staining will quantify proliferation and cells undergoing mitosis defects.

RNA-seq analysis: RNA will be isolated from three biologic replicates for each genotype (wildtype, heterozygous and homozygous). Random culture condition effects will be minimized by pooling samples from at least 3 different differentiation batches. Three biologic replicates will be obtained for each model to maximize the accuracy of RNA-Seq analysis at 30M paired end reads per sample. I will employ an existing RNA-Seq processing pipeline to map RNA-Seq reads (STAR) and quantify mRNA transcript abundance (RSEM). I will assess differential expression for each target gene using the software package EBSeq and control for false discovery rate (FDR) using established methods. Enrichment of differential expression signals at the pathway level (gene set enrichment analysis, or GSEA) will be performed using Fisher's exact test.

ATAC-seq: ATAC-seq will be performed on three biologic replicates for each genotype (wildtype, heterozygous and homozygous) in parallel with RNA-seq sample collection as above. Nuclei will be isolated and a transposase reaction performed using protocol outlined by Scott LJ et al. Analysis of ATAC-seq data will focus on quantification of availability of transcription factor binding sites that are known recognition sequences for hypertrophic signaling transcription factors and/or transcription factors that are differentially expressed based on the RNA-seq data. For the former, quantification of binding site availability is important since the transcription factor may be activated through phosphorylation (or other post-translational modification) but may not necessarily be upregulated at the mRNA level thus, the ATAC-seq methodology will be able to detect this level of activation that would be missed by solely RNA-seq analysis.

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Objective 2. Determine the pathogenic mechanism of MYBPC3 induced pediatric cardiomyopathy:

hESCs MYBPC-mutation models: I will create patient specific mutations using CRISPR/Cas9 and will perform the cardiac differentiation as outlined in objective 1.

Immunohistochemistry: IHC analysis will be performed as outlined in objective 1.

RNA-seq: Experiments will be performed and analyzed as outlined in objective 1.

ATAC-seq: ATAC sequencing will be performed as outlined in objective 1.

Objective 3. Contrast signaling mechanisms of hypertrophy in hESC-CM models with sarcomere gene mutations vs mutation in the chromatin modifier ASXL3.

This objective directly compares two different genetic models of cardiac hypertrophy – one with a mutation in the contractile gene *MYBPC3* and one with a mutation in the chromatin modifier *ASXL3*. I hypothesize that there will be both shared and distinct hypertrophic pathways activated between the two models. Distinction of these pathways will have implications for therapeutic intervention for cardiac hypertrophy. The RNA and ATAC sequenced data from objective 1 and 2 will be intersected using custom R scripts. Common and distinct dysregulated genes and pathways will be analyze on Microsoft excel whereas regions of open chromatin and transcription factor binding will be visualized on https://epigenomegateway.wustl.edu website.

Objective 4. Develop a cohort of PHCM and adult-onset cardiomyopathies for expanding diseases mutation spectrum and validating the upstream and/or regulators identified through RNA and ATAC sequencing in objective 3.

Study Population The study population will be individuals of Indian origin who visit the hospitals for treatment and may encompass the north, northwest and north eastern and central parts of India. Pediatric and adult onset cardiomyopathy patients and their family members attending cardiology clinic of Sanjay Gandhi post-graduate institute of medical sciences (SGPGIMS) Lucknow, will be enrolled in this study after obtaining informed consent. Since pediatric cardiomyopathies have an annual incidence of 1.1-1.5 per 10,000 we will recruit PHCM from both cardiology and medical genetic clinic of SGPGIMS. Dr. Kausik will evaluate patients with pediatric cardiomyopathy at medical genetics clinic. In case of adult-onset HCM each patient will undergo heart catheterization for the angiographical exclusion of coronary artery disease in the same procedure. All the patients will undergo a physical examination, following by ECG, and trans-thoracic echocardiography and Doppler studies.

From all the patients complete information about medical history, complications associated with the disease will be noted. All the participants of the study will undergo a standardized interview using a questionnaire on family history, demographic profile, and lifestyle habits. Incase of PHCM, the guardian will fill out questionnaire. The questionnaire will include following details:

- Medical history of the participant, of family members, medication intake, and other
- Demographics, such as gender, age, place of birth, education
- Anthropometric data, such as weight, height, for calculation of BMI

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- Associated risk factors as hypertension, diabetes mellitus, and smoking in case of adult-onset HCM
- Dietary and tobacco habits

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Echocardiography: Standard views for M-mode and two-dimensional studies will be obtained. For all cardiomyopathy patients end diastolic left ventricular wall thickness will be recorded at the level of the mitral valve and papillary muscle in the anterior, posterior, septal, and lateral walls using short-axis two-dimensional images. Anterior and posterior septal thickness at the apex will be assessed from apical short-axis view. The maximum left ventricular wall thickness will be defined as the maximal measurement recorded in any of the myocardial segments studied. Left ventricle inflow and outflow velocities will be determined using continuous and pulse wave Doppler echocardiography.

Sample Size: The proposed sample size is ~ 100 subjects i.e., 20 families with PHCM (trio-WES will be performed father, mother-proband) and 50 individuals with adult-onset cardiomyopathy.

Whole exome sequencing: DNA extraction will be performed using the QIAamp DNA Mini Kit (Qiagen, Germany). The quantity and purity of DNA will be checked by measuring optical density (OD) at 260 nm and 280 nm. The ratio of absorbance at 260 and 280 nm of DNA is around 1.7-1.9. The quality and purity will be also confirmed by 1% agarose gel electrophoresis in 1 X TBE buffer. Whole-exome sequencing (WES) will be performed to identify causative variations responsible for pediatric and adult-onset HCM. Genomic DNA (~5µg) will be used for library preparation followed by enrichment of the libraries using "Agilent SureSelectXT Target Enrichment System" (Agilent Inc). Enriched libraries will be equenced on Illumina Hiseq2000 platform. Identified variations/ mutations in different genes will be analyzed using different bioinformatics tools and pipelines.

Pathogenic variant prioritization: Every exome contains hundreds of variants, with few variants predicted to be pathogenic with known significance. We will use custom scripts in python and R and publically available GEMINI tool to prioritize the variants. During the variant prioritization if we identify variant of unknown significance (VUS) in novel PHCM and adult-onset HCM genes, it will be further annotated to determine if: (1) zygosity of variants are tolerated (EXAC) (3) predicted functional impairment correlates with phenotype (literature search, OMIM), (4) organ system involvement is conserved in model organisms (mouse & zebrafish databases, published literature), (5) similar pathology is observed for mutations in associated gene families or protein complexes (Phenominer, OMIM, literature), and (6) filter out variants associated with unrelated phenotypes (OMIM).

Genetic Validation: Sanger sequencing will be used to validate the variations identified and to check for segregation in other family members and controls.

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Executive Registrar
SGPGIMS,Lucknow

Annexure – II of MoA

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Details of Funds

Dr. Anshika Srivastava, Assistant Professor, Department of Medical Genetics, Sanjay Gandhi Postgraduate Institute of Medical Sciences(SGPGIMS), Raebareli Road, Lucknow-226014, UP, India

Items	*I year*	*II year*	*III year*	Total
Non-recurring (Equipment etc.)	600000.00			600000.00
Manpower	486996.00	486996.00	486996.00	1460988.00
Consumables	2000000.00	2000000.00	2000000.00	6000000.00
Travel	50000.00	50000.00	50000.00	150000.00
Contingencies	50000.00	50000.00	50000.00	150000.00
Overhead	100000.00	100000.00	100000.00	300000.00
Others (If applicable)				
Total	**3286996.00**	**2686996.00**	**2686996.00**	**8660988.00**

Anshika

Dr. Anshika Srivastava
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
LUCKNOW-226014, INDIA

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with MoA)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

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Executive Registrar
SGPGIMS,Lucknow

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

Lt Col Vasun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The Memorandum Agreement, to be sent to Department of Biotechnology should be on Non- Judicial stamp paper of Rs. 100/-.

23. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

10/01/24

Signature of Executive Authority of Institute/ University With seal:(Director, SGPGIMS, Lucknow)

Prof [illegible] NIGAM
Sanjay [illegible] Post Graduate
Institute [illegible] Medical Sciences
LUCKNOW-226 014, INDIA

Date :

Signature and seal of Project Coordinator (If applicable)
Date:

Signature and seal of all Principal Investigator(s)/ Co- PI (s):
Date : 28.12.2023

Anshika

Dr. Anshika Srivastava
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences.
LUCKNOW-226014, INDIA

Signature and seal of all Co-Investigator (s)
Date :

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

FY 346730

22 MAR 2021

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this **11 of January** of Two Thousand Twenty One and **Director, SGPGIMS Lucknow** BY AND BETWEEN President of India, acting through **Director**, Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

AND

Sanjay Gandhi Postgraduate of Institute of Medical Science, Lucknow (SGPGI, hereafter), a society under the Societies Registration Act – 1860, having its registered office in/at **Lucknow**, hereinafter referred to as **SGPGIMS** (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of **Basic Science Research** decided to support a project submitted by **Dr. Alok Kumar, Associate Professor, Department of**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Molecular Medicine & Biotechnology and Dr. Shantanu Pande, Department of Cardiovascular and Thoracic Surgery, SGPGIMS, Lucknow for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot"**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs.66,50,240/- (Rupees Sixty Six Lakhs Fifty Thousand Two Hundred and Forty Only)** over a period of **Three** years from the date of sanction of the project, to **Dr. Alok Kumar, Associate Professor, Department of Molecular Medicine & Biotechnology and Dr. Shantanu Pande, Department of Cardiovascular and Thoracic Surgery, SGPGIMS, Lucknow** for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF SANJAY GANDHI POSTGRADUATE OF INSTITUTE OF MEDICAL SCIENCE, LUCKNOW (Institute)

2.1. To provide their contribution of **nil** for **3** years from date of sanction of the project as detailed in Annexure – II. *(if a jointly supported project)*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

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2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be 3 years from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by SGPGIMS will be the joint property of SGPGIMS and DBT, Government of India. It shall be the responsibility of SGPGIMS to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of SGPGIMS under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of SGPGIMS to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.) arising out of the PROJECT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of **this research project at SGPGIMS** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, **SGPGIMS** shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain in force for the duration of the project and until all claims are settled between DBT and **SGPGIMS.**

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final

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Executive Registrar
SGPGIMS,Lucknow

and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

1.

2.

Signed by ----------

(Designation) ----------

For and on behalf of The President of India

Witnesses:

1.----------
(Dr. Alok Kumar)

2.----------
(Dr. Shantanu Pande)

3.----------
(Dr. Surendra Kumar Agarwal)

4.----------
(Dr. Vikas Agarwal)

Signed by ---------- 22/11/22

(Designation) **DIRECTOR**

For and on behalf of SGPGIM, LKo

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(23)

Check list for Sending MoA

1.	No portion of the MoA has been modified in any way	**Yes/No**
2.	The MoA has been **signed on stamp paper at an appropriate value of Rs. 100/-.**	**Yes/No**
3.	Blank spaces have been filled	**Yes/No**
4.	MoA is **signed and stamped by PI and competent authority** on every page.	**Yes/No**
5.	A copy of terms and condition **signed and stamped by PI and competent authority is attached as annexure**	**Yes/No**
6.	A copy of sanction order **signed and stamped by PI and competent authority** on every page is attached as an annexure	**Yes/No**

Signature and stamped of Principal Investigator
Date : 11.04.2022

Dr. Alok Kumar..... Dr. Shantanu Pande.....

Signature and stamped of Co-Investigator
Date : 11.04.2022

Prof. Surendra Kumar Agarwal..... Prof. Vikas Agarwal.....

Signed and stamped of Director
Date : 11.04.2022

Prof. R. K. Dhiman..... 22/4/22

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

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Executive Registrar
SGPGIMS,Lucknow

(9c)

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

22/4/22

Signature of Project Coordinator
(applicable only for multi-institutional projects)

Date :

Signature of Executive Authority of Institute/ University With seal

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date :

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(19)

Witnesses:

Signature and stamped of Principal Investigator

Date : 09.04.2022

Dr. Alok Kumar ..... Dr. Shantanu Pande.....

Signature and stamped of Co-Investigator

Date : 09.04.2022

Prof. Surendra Kumar Agarwal..... Prof. Vikas Agarwal.....

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(18)

No. BT/PR42952/MED/97/569/2021
E-Office No. RAD-21/56/2021-MED-DBT (Computer No. 15167)

GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: 09.03.2022

ORDER

Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Powers Rules ,1978 , for the implementation of the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot"** for a period of 3 Year 0 Month at a total cost of **Rs. 6650240/-** (Rupees Sixty Six Lakhs Fifty Thousand Two Hundred and Forty Only) on the terms and conditions detailed here under:-

2 The Project :

2.1 Title : Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot

2.2 Details of the Investigators:

Dr. Alok Kumar
Ramalingaswami re-entry fellow and Associate Professor
Molecular Medicine and Biotechnology
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

Dr. Shantanu Pande
Professor
Cardiovascular and Thoracic Surgery
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

CO-PI:

Prof. Surendra Kumar Agarwal
Professor
Department of CVTS,
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

Prof. Vikas Agarwal
Professor
Department of Clinical Immunology & Rheumatology
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Lucknow, Uttar Pradesh-226014

2.3 Objectives:

1. To determine that host immune responses involve in distortion of native pulmonary valve of Tetralogy of Fallot's Patients.
2. To determine that treatment of phosphodiesterase 5 inhibitor and 5-hydroxytryptamine receptor 2B inhibitor helps in maintaining the morphology of the neo pulmonary valve keeping it free of retraction and distortion

2.4 Time Schedule:

The duration of the project is 3 Year 0 Month from the date of this sanction order.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.5 Project Cost:

The total cost of the project is Rs. **6650240/-**(Rupees Sixty Six Lakhs Fifty Thousand Two Hundred and Forty Only) as per details given below:

Budget Head	Year I	Year II	Year III	Total(Rs.)
Equipment	1900000.00	0.0	0.0	**1900000.00**
Manpower	431520.00	431520.00	487200.00	**1350240.00**
Consumables	1000000.00	500000.00	1000000.00	**2500000.00**
Contingency	50000.00	50000.00	50000.00	**150000.00**
Overhead	50000.00	50000.00	50000.00	**150000.00**
Travel	30000.00	30000.00	40000.00	**100000.00**
Outsourcing	0.0	500000.00	0.0	**500000.00**
Total (Rs.)	**3461520.00**	**1561520.00**	**1627200.00**	**6650240.00**

2.6 Equipment

The details of the equipment sanctioned for the implementation of the project at **Annexure-I**

2.7 Manpower:

The details of the manpower sanctioned for the implementation of the project at **Annexure-II**

2.8 Quarterly Milestones and Deliverables:

The details of the Quarterly Milestones and Deliverables sanctioned for the implementation of the project at **Annexure-III**

3. Head of Account:

The **Non-Recurring** expenditure involved is debitable to:

Demand No. 89	Department of Biotechnology
3425	Other Scientific Research 2021-2022
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance to Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

The **Recurring** expenditure involved is debitable to:

Demand No. 89	Department of Biotechnology
3425	Other Scientific Research 2021-2022
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance to Research and Development
3425.60.200.29.17.31	Grants -in-Aid General

4. Terms & Conditions:

(i) In case the whole or a part of the amount of the grant-in-aid is being refunded, an interest at the rate of ten percent thereon shall be recovered.
ii) Grantee Institution is a public funded organization.
iii) The equipment sanctioned under the project should be purchased within 18 months from the date of the release of the grant.
iv) The expenditure to be made as per the EAT module of the Government of India.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.1 The other terms and conditions governing this sanction are attached at **Annexure- III.**

4.2 A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee institution on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/installment will be made only after signing of MoA between the grantee institutions and DBT. In case of NGO's and Private Institution's, execution of MOA is mandatory before first release. A format of the MoA is enclosed in **Annexure-IV.**

4.3 The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The interest earned should be remitted to the Consolidated fund of India through Bharat Kosh portal (www.bharatkosh.gov.in) as per GFR-2017-230(8) after finalization of the account for a given Financial Year.

5. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.

6. The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh would be responsible for submission of Statements of Expenditure (SoE), utilization certificates (UC), Assets Certificates, Manpower staffing & expenditure details in prescribed DBT formats to DBT in respect of grants released in this project from time to time.

7. PIs of DBT sponsored projects can consider appointment of JRF from Category-II merit list of DBT-BET exam so that candidates can be paid fellowships at par with NET/GATE/BET qualified candidates as per DST OM No. A.SR/S9/Z-08/2018 dated 30 Jan 2019. However, there is no compulsion on PI's to select candidates for JRF in their projects from Category-II of DBT-BET.

8. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organizations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG (DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organizations is called upon to do so.

9. If the Research Project involves biological resources, the obligations under the Biological Diversity Act 2002 as applicable shall be complied with by the Project Investigator, the details of such obligations can be accessed at www.nbaindia.org

10 (I) "The PIs/Implementing Agencies shall strictly adhere to the GoI instructions issued vide OM No.F.4.1.2021-PPD dated 30.6.2021 in the matter of issue of Global tender Enquiry with special reference to instructions contained under para 4 of the said OM for procurement of equipments, spares and consumables for research purposes and shall not issue Global Tenders Enquiries before seeking the approval of the competent authority".

(II) "After incurring the expenditure on import of such items and at the time of submission of UCs to the department next year, the PIs will also furnish the copy of the approval sought from the competent authority for issue of the GTE for such items of import. The release of next installment of grant will the subject to the fulfillment of the above condition."

11. This issues under the powers delegated to this Department as per IFD order No. G-17012/1/2020-IFD-DBT dated 15.02.2022 and with the concurrence of IFD. This has been noted in IFD at SAN No. **102/IFD/SAN/3085/2021-2022** dated **08.03.2022.**

12. This sanction order has been noted at serial no. 93 in the Register of Grants.

(Dr. Neha Bansal)
डॉ. नेहा बंसल/Dr. NEHA BANSAL
वैज्ञानिक 'सी'/Scientist 'C'
जैव प्रौद्योगिकी विभाग/Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
Page No. [3 / 8]
Scientist 'C'

Generated through eProMIS

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

BT/PR42952/MED/97/56

To,
The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
3 Dr. Alok Kumar, Ramalingaswami re-entry fellow and Associate Professor, Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
4 Dr. Shantanu Pande, Professor, Cardiovascular and Thoracic Surgery, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
5 Prof. Surendra Kumar Agarwal, Professor, Department of CVTS, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
6 Prof. Vikas Agarwal, Professor, Department of Clinical Immunology & Rheumatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh
7 Cash Section, DBT (2 copies).
8 Sanction Folder.
9 File Copy.

(Dr. Neha Bansal)
Scientist 'C'

डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
जैव प्रौद्योगिकी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
ब्लॉक-2, कॉम्प्लेक्स, लोधी रोड, नई दिल्ली-110003
Block-2, C.G.O. Complex, Lodhi Road, New Delhi-110003

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

(K)

BT/PR42952/MED/97/569/2021

Annexure -I

Details of the Equipment sanctioned for the implementation of the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot":**

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow			
SNo.	**Name of Equipment**	**No.**	**Cost(Rs.)**
1.	RCCSMAX-HV Perfusion loop RotaryCell Culture System	1	1500000.00
2.	Small equipments: westernblot, shaker, vortex mixer, ph meter, 4°C freezer, variable single channel micropipette etc.	1	400000.00
		Total	**1900000.00**

Annexure –II

Details of the manpower sanctioned for the implementation of the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot":**

Head	**No. of Position**	**Year I**	**Year II**	**Year III**	**Total (Rs.)**
JRF @ (Rs. 31,000/- pm + 16% HRA for 1st and 2nd year = Rs. 35960/- pm and SRF @ Rs. 35,000/- pm + 16% HRA for 3rd year = Rs. 40600/- pm	1	431520	431520	487200	**1350240**
Total (Rs.)		**431520**	**431520**	**487200**	**1350240**

Emoluments detail of research personal(s) mentioned in table(s) of Annexure-II shall be applicable only if candidate(s) met educational qualification and eligibility criteria as per DST OM No. SR/S9/Z-08/2018 dated 30.01.2019 for JRF/SRF/RA

(Dr. Neha Bansal)
Scientist 'C'

डॉ. नेहा बंसल / Dr. Neha Bansal
वैज्ञानिक 'सी' / Scientist 'C'
बायोटेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
सी.जी.ओ. कॉम्प्लेक्स, लोधी रोड, नई दिल्ली–110003
C.G.O. Complex, Lodhi Road, New Delhi-110003

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure III

Title of the project: "Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot."

Quarterly Milestones

Quarter-wise	Action plan	Deliverables
Objective 1: To determine that host immune responses involve in distortion of Native pulmonary valve of Tetralogy of Fallot's Patients.		
	Aim 1: Host immune response characterization of a distorted pulmonary heart valve.	
Q1-Q8 (0-32 months)	Key activities: (1) Surgery will be performed to obtain distorted pulmonary heart valve from TOF patients; (2) Intra-operative harvesting of pericardium will be performed for valve designing and treatment	
Q3, Q4	(2) Immune cell activation profile will be examined by using nanostring analysis.	Gene signatures of individual immune cells will be identified to predict disease-specific biomarkers
Q3, Q4	(3) Host immune cell activation such as macrophages (CD45+/CD14+/CD64+, CCR2+/-), classical (CD14+CD16neg) and non-classical monocytes (CD14+CD16+/Ly-6Clow), neutrophils (Ly6G+), B-cell population (CD19+, CD27+, IgD+IgM+, IgD+IgM-, IgD-IgM+) and T-cell subsets (CD3+, CD8+, CD4+ IFN-γ+, CD4+IL-4+, CD4+IL-17+, and CD4+CD25+Treg) will be studied by using flow cytometry.	Host activated immune cells will be identified by using flow cytometry
Q3, Q4	(4) Activated immune cells will be sorted, and detailed proteomic and phosphor-proteomic analyses will be performed using LC-MS/MS.	Key protein signatures involved in isolated immune cell activation will be identified
Q3, Q4	(5) Further target validation will be performed using western blot analysis and ELISA kits as per the manufacturer's protocol.	Host immune response will be identified in distortion of pulmonary heart valve of Tetralogy of Fallot's Patients.

1

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SGPGIMS,Lucknow

Objective 2: To determine that treatment of phosphodiesterase 5 inhibitor and 5-hydroxytryptamine receptor 2B inhibitor creates a competent pulmonary heart valve and reduces pulmonary heart valve pathophysiology.

Q1-Q8 (0-32 months)	**Key activities:** (1) Surgery will be performed to obtain distorted pulmonary heart valve from TOF patients (2) Intra-operative harvesting of pericardium will be performed for valve designing and treatment	
Q2, Q3	(2) Valve designing and treatment with phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor	
Q2, Q3, Q4 Q6, Q7	(3) Biocompatibility assessment will be performed through co-culture of human endothelial cells and treated pericardium heart valve. A. Cytotoxicity assay; B. Hemocompatibility assay; C. Biocompatibility assessment through in vitro 3D cell culture model of an interstitial treated pericardium heart valve by using perfusion bioreactor	Biocompatibility of the treated molecule of phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor will be examined in the heart valve
Q5, Q6	(4) Activated immune cells will be sorted from distorted heart valve, and treatment of phosphodiesterase 5 and 5-Hydroxytryptamine receptor 2B inhibitor will be performed	Modulation of immune cell activation by the treated molecule of phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor will be examined
Q5, Q6	(5) Host immune cell activation such as macrophages (CD45+/CD14+/CD64+, CCR2+/-), classical (CD14+CD16neg) and non-classical monocytes (CD14+CD16+/Ly-6Clow), neutrophils (Ly6G+), B-cell population (CD19+, CD27+, IgD+IgM+, IgD+IgM-, IgD-IgM+) and T-cell subsets (CD3+, CD8+, CD4+ IFN-γ+, CD4+IL-4+, CD4+IL-17+, and CD4+CD25+Treg) will be examined by using flow cytometry.	

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SGPGIMS,Lucknow

Q1, Q2, Q3, Q4	(6) Activation of Human valve interstitial cells (VICs) by using TNFα , IFNγ, and treatment of phosphodiesterase 5 inhibitor & 5-hydroxytryptamine receptor 2B inhibitor will be performed	Utility of treated molecule of phosphodiesterase 5 inhibitor and 5-Hydroxytryptamine receptor 2B inhibitor in the modulation of fibrotic genes and involved in driving potential signaling (which can be beneficial for the heart valve modulation) will be examined by using VICs cell culture
Q1, Q2, Q3, Q4	**Outcome measures:** 1. Real-time quantitative PCR for pro-fibrotic [pCollagen Type I Alpha 1 Chain (Col1a1), Collagen Type I Alpha 2 Chain (Col1a2), Smooth Muscle Alpha (a)-2 actin (ACTA2), Connective Tissue Growth Factor (CTGF) and Fibronectin-1(FN1) genes] and anti-fibrotic genes [Matrix Metalloproteinase 2 (MMP2), Tissue inhibitor of metalloproteinases-1 (TIMP1) expression] will be performed.	
Q5, Q6, Q7, Q8	(7) Potential signaling of TGF-beta and Smad3 and their modulation after treatment will be evaluated by using the gene knockdown/siRNA approach	

Q-Quarter wise	Months
Q1	0-4
Q2	05-08
Q3	09-12
Q4	13-16
Q5	17-20
Q6	21-24

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

No. BT/PR42952/MED/97/569/2021
E-Office No. RAD-21/56/2021-MED-DBT (Computer No. 15167)
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, (6-8th Floors)
CGO Complex, Lodhi Road,
New Delhi- 110 003
Date: 09.03.2022

RELEASE ORDER

In continuation of this Department's sanction order of even number dated 09.03.2022 sanction of the President is hereby accorded, under Rule18 of the Delegation of Financial Powers Rule, 1978, for the release of **Rs. 1561520.00/-** (Rupees Fifteen Lakhs Sixty One Thousand Five Hundred and Twenty Only) being the first year release for the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot"**, being implemented by:

Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.

The detailed break-up is as given below:

SN	Institute Name	Recurring						Total Release Amount (Rs)
		Manpower	Consumable	Travel	Contingency	Others	Overhead	
1	Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	431520.00	1000000.00	30000.00	50000.00	0.00	50000.00	1561520.00

2. The amount of **Rs. 1561520.00/- (Rupees Fifteen Lakhs Sixty One Thousand Five Hundred and Twenty Only)** will be directly credited by the Pay & Accounts Officer, DBT in the account as detailed below:

The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh

Bank Name :State Bank of India
Branch Name :SGPGIMS LUCKNOW
A/c No. :10095237491
IFSC Code :SBIN0007789
MICR Code :226002034

3. The expenditure involved is debitable to:

Demand No. 89	**Department of Biotechnology**
3425	Other Scientific Research 2021-2022
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance to Research and Development
3425.60.200.29.17.31	Grants -in-Aid General

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4. The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh will submit audited utilization certificates and statements of expenditure in respect of the above-mentioned amount.
5. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organisations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG (DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organisation is called upon to do so.
6. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.
7. The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The interest earned should be remitted to the Consolidated fund of India through Bharat Kosh portal (www.bharatkosh.gov.in) as per GFR-2017-230(8) after finalization of the account for a given Financial Year.
8. (i) In case the whole or a part of the amount of the grant-in-aid is being refunded, an interest at the rate of ten percent thereon shall be recovered.
   ii) Grantee Institution is a public funded organization.
   iii) The expenditure to be made as per the EAT module of the Government of India.
   The other terms and conditions governing the financial sanction will remain unaltered.
9. This issues under the powers delegated to this Department as per IFD order No. G-17012/1/2020-IFD-DBT dated 15.02.2022 and with the concurrence of IFD. This has been noted in IFD at SAN No. **102/IFD/SAN/3086/2021-2022** dated **08.03.2022.**
10. This sanction order has been noted at serial no. 94 in the Register of Grants.

(Dr. Neha Bansal)
Scientist 'C'
डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
...विभाग / Department of Biotechnology
...और प्रौद्योगिकी मंत्रालय
...stry of Science & Technology
...सरकार / Govt. of India
...110003
...O. Complex, Lodhi ... 110003

To,

The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow – 226014, Uttar Pradesh.
3 Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
4 Dr. Shantanu Pande, Professor, Cardiovascular and Thoracic Surgery, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
5 Cash Section, DBT (2 copies).
6 Sanction Folder.
7 File Copy.

(Dr. Neha Bansal)
Scientist 'C'
डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
...टेक्नोलॉजी विभाग / Department of Biotechnology
विज्ञान और प्रौद्योगिकी मंत्रालय
Ministry of Science & Technology
भारत सरकार / Govt. of India
...लोधी रोड, नई दिल्ली–110003
...O. Complex, Lodhi Road, New Delhi-110003

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(13)

BT/PR42952/MED/97/569/2021

No. BT/PR42952/MED/97/569/2021
E-Office No. RAD-21/56/2021-MED-DBT (Computer No. 15167)
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, (6-8th Floors)
CGO Complex, Lodhi Road,
New Delhi- 110 003
Date:09.03.2022

RELEASE ORDER

In continuation of this Department's sanction order of even number dated 09.03.2022 sanction of the President is hereby accorded, under Rule18 of the Delegation of Financial Powers Rule, 1978, for the release of **Rs. 1900000.00/-** (Rupees Nineteen Lakhs Only) being the first year release for the project entitled **"Determination and establishment of key molecular therapeutic approach for remodelling of pericardial heart valve of Tetralogy of Fallot"**, being implemented by:

Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.

The detailed break-up is as given below:

SN	Institute Name	Non Recurring		Total Release Amount (Rs)
		Equipment	Other	
1	Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow	1900000.00	0.00	**1900000.00**

2. The amount of **Rs. 1900000.00/- (Rupees Nineteen Lakhs Only)** will be directly credited by the Pay & Accounts Officer, DBT in the account as detailed below:

The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh

Bank Name :State Bank of India
Branch Name :SGPGIMS LUCKNOW
A/c No. :10095237491
IFSC Code :SBIN0007789
MICR Code :226002034

3. The expenditure involved is debitable to:

Demand No. 89	**Department of Biotechnology**
3425	Other Scientific Research 2021-2022
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance to Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

4. The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh will submit audited utilization certificates and statements of expenditure in respect of the above-mentioned amount.

Lt Col Varun Bajpai (Retd)
Executive Registrar
SGPGIMS,Lucknow

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5. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organisations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG (DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organisation is called upon to do so.
6. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.
7. The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The interest earned should be remitted to the Consolidated fund of India through Bharat Kosh portal (www.bharatkosh.gov.in) as per GFR-2017-230(8) after finalization of the account for a given Financial Year.
8. (i) In case the whole or a part of the amount of the grant-in-aid is being refunded, an interest at the rate of ten-percent thereon shall be recovered.
   ii) Grantee Institution is a public funded organization.
   iii) The equipment sanctioned under the project should be purchased within 18 months from the date of the release of the grant.
   iv) The expenditure to be made as per the EAT module of the Government of India.
   The other terms and conditions governing the financial sanction will remain unaltered.
9. This issues under the powers delegated to this Department as per IFD order No. G-17012/1/2020-IFD-DBT dated 15.02.2022 and with the concurrence of IFD. This has been noted in IFD at SAN No. **102/IFD/SAN/3087/2021-2022** dated **08.03.2022.**
10. This sanction order has been noted at serial no. 95 in the Register of Grants.

(Dr. Neha Bansal)
Scientist 'C'
डॉ. नेहा बंसल / Dr. NEHA BANSAL
वैज्ञानिक 'सी' / Scientist 'C'
विभाग / Department of Biotechnology
और प्रौद्योगिकी मंत्रालय
of Science & Technology
सरकार / Govt. of India
सी.जी.ओ. कॉम्प्लेक्स, लोधी रोड, नई दिल्ली-110003
G.O. Complex, Lodhi Road, New Delhi-110003

To,

The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 The Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow - 226014, Uttar Pradesh.
3 Dr. Alok Kumar, Department of Molecular Medicine and Biotechnology, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
4 Dr. Shantanu Pande, Professor, Cardiovascular and Thoracic Surgery, Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow - 226014, Uttar Pradesh.
5 Cash Section, DBT (2 copies).
6 Sanction Folder.
7 File Copy.

(Dr. Neha Bansal)
डॉ. नेहा बंसल / Dr. NEHA BANSAL
Scientist 'C'
वैज्ञानिक 'सी' / Scientist 'C'
विभाग / Department of Biotechnology
और प्रौद्योगिकी मंत्रालय
of Science & Technology
सरकार / Govt. of India
सी.जी.ओ. कॉम्प्लेक्स, लोधी रोड, नई दिल्ली-110003
G.O. Complex, Lodhi Road, New Delhi-110003

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

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सत्यमेव जयते

Certificate No.	:	IN-UP48166778929699T
Certificate Issued Date	:	31-Aug-2021 11:26 AM
Account Reference	:	NEWIMPACC (SV)/ up14267604/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP1426760485102997461551T
Purchased by	:	SGPGIMS LUCKNOW
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	SGPGIMS LUCKNOW
Second Party	:	DBT NEW DELHI
Stamp Duty Paid By	:	SGPGIMS LUCKNOW
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

----------Please write or type below this line----------

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this ____ day of Two thousand and Nineteen BY AND BETWEEN President of India, acting through Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART:

AND

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert

Sanjay Gandhi postgraduate Institute of Medical Sciences, Raiberali Road, Lucknow, UP Act No 30 of 1983(2906(2)/XVII---1-1(Ka)-29-82) dated Oct 13, 1983 having its registered office at *Lucknow* hereinafter referred to as "**SGPGIMS**" (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART:

WHEREAS DBT being desirous of **(Centres of Excellence (COE) on Translational Research on Bio-inspired Nanomaterials and Drugs from endophytes)**, decided to support a project submitted by ***Dr Sanjay Gambhir*** *(Project Co-Investigator)* ***and Dr Manish Dixit*** *(Project Co-Investigator)* for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto:

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the "**Centres of Excellence (COE) on Translational Research on Bio-inspired Nanomaterials and Drugs from endophytes** ***(sanction Order No.*** **102/IFD/SAN/295/2018-19)**".

NOW THE PARTIES HERE TO AGREE AS FOLLOWS:

1.0 ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of 43,75,000.00 ***(Forty Three Lakh seventy five Thousand rupees only)*** over a period of ***five years*** from the date of sanction of the project, to ***SGPGIMS*** for undertaking activities as detailed in Annexure-I. Details of the funds to be provided are given in Annexure-II.

2.0 ROLE OF Sanjay Gandhi postgraduate Institute of Medical Sciences, Raiberali Road, Lucknow.

2.1 To provide their contribution of ***NIL*** for 05 years from date of sanction of the project as detailed in Annexure II. *(if a jointly supported Project).*

2.2 To provide existing facilities as mentioned in the project document.

2.3 To be responsible for accomplishing objectives identified and activities listed.

2.4 To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5 To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6 To prepare and submit all periodical reports and other documents that would be required by DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.7 To maintain a separate audit head of account for the grants received from DBT for the project.

2.8 To submit an annual audited statement of expenditure incurred under the project.

2.9 To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10 The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contact for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be ***Five (05)*** years from the date the Project has been sanctioned by DBT-New Delhi.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by ***Dr Sanjay Gambhir*** *(Project Co-Investigator)* ***and Dr Manish Dixit*** *(Project Co-Investigator)* will be the joint property of ***SGPGIMS-Lucknow*** and DBT, Government of India. It shall be the responsibility of ***Dr Sanjay Gambhir*** *(Project Co-Investigator) and* ***Dr Manish Dixit*** *(Project Co-Investigator)*, **SGPGIMS-Lucknow** to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **SGPGIMS-Lucknow** under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of SGPGIMS-Lucknow to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.) arising out of the Project.

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of ***SGPGIMS-Lucknow*** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, ***Dr Sanjay Gambhir*** *(Project Co-Investigator)* ***and Dr Manish Dixit*** *(Project Co-Investigator)* shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain in-force for the duration of the project and until all claims are settled between DBT and ***SGPGIMS-Lucknow***.

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

9.0 GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

1.

2.

Signed by _____

(Designation) _____

For and on behalf of The President of India

Witnesses:

1. Dr Sanjay Gambhir 06/09/2021

2. Dr Manish Dixit

Signed by _____ 14/9/21

(Designation) _____

For and on behalf of SGPGIMS-Lucknow

Prof. R. K. DHUMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure - I

Detailed Project Activities

Details of the activities to be undertaken by *SGPGIMS-Lucknow* under the project entitled "**Centres of Excellence (COE) on Translational Research on Bio-inspired Nanomaterials and Drugs from endophytes**"

Objectives:

Radiolabelling of nanoparticles/nano-drug formulates and animal studies to see their bio-distribution and clearance time from blood.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Details of Funds

Items	*I year*	*II year*	*III year*	IV year	V year	Total
Non-recurring	0	0	0	0	0	0
Manpower	300000.00	300000.00	300000.00	300000.00	300000.00	1500000.00
Consumables	500000.00	500000.00	500000.00	500000.00	500000.00	2500000.00
Travel	25000.00	25000.00	25000.00	25000.00	25000.00	125000.00
Contingency	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Total	**875000.0**	**875000.0**	**875000.0**	**875000.0**	**875000.0**	**4375000.0**

Dr Sanjay Gambhir
(Project Co-Investigator)
Department of Nuclear Medicine.
Rai-Berali Road. **SGPGIMS-Lucknow**

Dr Manish Dixit
(Project Co-Investigator)
Department of Nuclear Medicine.
Rai-Berali Road. **SGPGIMS-Lucknow**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure - III

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilize funds from any other organization (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at Appendix-'A') shall be maintained by the Institute. The term "assets" means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/-. The grant will not be utilized for construction of any immovable property. Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Department of Biotechnology, be disposed of, or encumbered or utilized for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale/disposal of these assets. The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed / monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realization of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Department of Biotechnology a Utilization Certificate and an audited statement of expenditure (necessary formats can be obtained from the dealing officer of DBT) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Department of Biotechnology on receipt of the Cheque/Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Department of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Department of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilization for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Department of Biotechnology projects should acknowledge the financial support received from the Department of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://dbtindia.nic.in, http://www.btisnet.ac.in.

14. Investigators/Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Department of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators/Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure – VI.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

16. The Govt. of India (Department of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Department as per the format enclosed at Annexture VII. More information on commercialization can be found at the website http://www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project will not be the concern/responsibility of the Govt. of India. The Organization may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Department of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on Project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance, if any.

22. The organization should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

Manish Dixit

Signature of Co-Investigator

Date: 06/9/24

Signature of Co-Investigator

Date:

16/9/24

Signature of Executive Authority of Institute/ University with seal

Prof R K DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Certificate No.	:	IN-UP67093582423558U
Certificate Issued Date	:	16-Apr-2022 01:58 PM
Account Reference	:	NEWIMPACC (SV)/ up14238304/ MOHANLALGANJ/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14238304254061207373 86U
Purchased by	:	DR AMITA MOIRANGTHEM
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	DR AMITA MOIRANGTHEM
Second Party	:	Not Applicable
Stamp Duty Paid By	:	DR AMITA MOIRANGTHEM
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this 30th March day of Two thousand and twenty two BY AND BETWEEN President of India, acting through _____, Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or

Sworn & Verified Before Me

16/04/2022

AKHILESH KUMAR
ADVOCATE & NOTARY

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, a society under the Societies Registration Act – 1860, having its registered office in/at Raebareli Road, Lucknow, Pin 226014, Uttar Pradesh, hereinafter referred to as SGPGIMS (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of Clinical research Project decided to support a project submitted by Dr Amita Moirangthem, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the Mission Project on Pediatric Rare Genetic Disorders.

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of _____over a period of five years from the date of sanction of the project, to Dr Amita Moirangthem, SGPGIMS for undertaking activities as detailed in Annexure I. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF SGPGIMS..... (Institute/NGO)

2.1. To provide their contribution of ____(NIL)____ for five years from date of sanction of the project as detailed in Annexure – II. *(provide the cost in place of NIL if a jointly supported project).*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be five years from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by SGPGIMS will be the joint property of SGPGIMS and DBT, Government of India. It shall be the responsibility of SGPGIMS to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of SGPGIMS under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

It shall be the responsibility of the project investigator (s) and SGPGIMS to ensure that support of DBT is suitably acknowledged in the in scientific publication/ patents/ technology transfer documents etc. arising out of the PROJECT. It shall also be the responsibility of the project investigators and institute to ensure the inclusion of reference/ grant number and duration of the financial support while making the acknowledgement of the financial support received from DBT.

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of SGPGIMS for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, SGPGIMS shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and SGPGIMS.

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice, Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made there under shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF the parties hereto have signed, scaled and delivered this Agreement on the day, month and year first above written in presence of:

Signed by ----------

(Designation)

For and on behalf of The President of India

Signatures of two witnesses (from DBT):

i.

ii.

Signed and stamped by:

(Director Please also mentioned name and designation of Executive Authority of Institute/ University/ Organization)----------

Acting Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Lucknow-226014, INDIA

NOTARY
Mukesh Kumar
Govt. of U.P. India

For and on behalf of-- ***Sanjay Gandhi Postgraduate Institute of Medial Sciences, Lucknow***

--- (Please mentioned here name of Institute/ University/ Organization)-------

Name, Signature and stamp of Two Witnesses (from ***Institute/ University/ Organization)***):

i.

ii.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – I of MoA

Detailed Project Activities

Details of the activities to be undertaken by *SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, RAEBARELI ROAD, LUCKNOW, UTTAR PRADESH* **under the project entitled** *" MISSION PROGRAM ON PEDIATRIC RARE GENETIC DISORDERS (PROJECT TITLE)"*

Objectives:

1. Recruitment of patients with pediatric rare genetic disorders
2. Awareness programmes- workshops/training programs, webinars, community genetics awareness-open day programmes, lectures in schools/colleges

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NOTARY

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure – II of MoA

Details of Funds

DR AMITA MOIRANGTHEM, DEPARTMENT OF MEDICAL GENETICCS, SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, RAEBARELI ROAD, LUCKNOW-226014, UTTAR PRADESH.

Items	*I year*	*II year*	*III year*	*IV year*	*V year*	Total
Non-recurring (Equipment etc.)	NIL	NIL	NIL	NIL	NIL	NIL
Manpower	1016160.00	1016160.00	1016160.00	1016160.00	1016160.00	5080800.00
Consumables	900000.00	900000.00	900000.00	900000.00	900000.00	900000.00
Travel	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Contingencies	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Overhead	100000.00	100000.00	100000.00	100000.00	100000.00	100000.00
Others (If applicable)	NIL	NIL	NIL	NIL	NIL	NIL
Total	2116160.00	2116160.00	2116160.00	2116160.00	2116160.00	10580800.00

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with MoA)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilize funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The Memorandum Agreement, to be sent to Department of Biotechnology should be on Non- Judicial stamp paper of Rs. 100/-.

23. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

NOTARY
Akhilesh Kumar
Advocate & Notary
GOVT. OF INDIA

27.4.2022
Acting Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow - 226014, INDIA

Signature of Executive Authority of Institute/ University With seal:

Date :

Signature and seal of Project Coordinator (If applicable)
Date:

Signature and seal of all Principal Investigator(s)/ Co- PI (s):
Date :

16/04/2022
AKHILESH KUMAR
ADVOCATE & NOTARY
Tahsil Mohanlalganj, Lucknow

16/4/2022
Dr. Moirangthem Amita
Assistant Professor
Department of Medical Gen
Sanjay Gandhi Post Grad
Institute of Medical Scie
LUCKNOW-226014 (U.P.)

19/4/22

Signature and seal of all Co-Investigator (s)
Date :

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

I identified the deponent/executant/party who has Signed/put T.I. before me.

1.1.2 **Trial Staff and Facilities.** Institution and/or Investigator will provide an adequate number of qualified Trial Staff, and adequate facilities and will require the Trial Staff and facilities to conduct the Trial properly and safely and in accordance with the Protocol and Applicable Law (as defined below under Section 1.1.4). "Trial Staff" means any employees of Institution or Investigator, and/or contractors engaged by Institution or Investigator, who are involved in performing the Trial, including, without limitation, any sub-investigator(s), study coordinator(s), and any other contractors, agents and employees of Institution or Investigator who assist Institution and Investigator with the Trial. Institution and Investigator shall inform Sponsor and CRO promptly in writing about all changes impacting the Trial Staff and/or facilities.

1.1.3 **Performance and Delegation.** Any and all research and procedures pertaining to the Trial will be performed only by the Investigator or Trial Staff assigned thereto by Institution and/or Investigator and Investigator will personally supervise the work of all assigned Trial Staff, and neither Institution nor Investigator may delegate this duty. Notwithstanding the foregoing, Institution may delegate other duties of Investigator and/or duties of Institution's assigned Trial Staff under this Agreement to third-parties provided that (i) Investigator will personally supervise the work of the third-party; (ii) the third-party will only assign and/or delegate Trial related activities to its own employees; *(iii)* the third-party will be deemed Institution's agent, and Institution will remain fully responsible for the performance of such third-parties under this Agreement; *(iv)* Institution and the third-party have entered into a written agreement (the "Side Agreement") that *(a)* binds such third-party to terms and conditions that are at least as stringent as those contained in this Agreement, including, but not limited to, those regarding Trial conduct, confidentiality, intellectual property, use of information, record retention, and monitoring, and *(b)* does not conflict with any of Sponsor's or CRO's rights and obligations under this Agreement; and *(v)*, (if applicable under Applicable Law, as defined below) Sponsor will be deemed a third-party beneficiary of the Side Agreement and will be entitled to enforce any applicable terms thereunder as related to this Agreement and/or the Trial. Institution will provide a copy of any Side Agreement to Sponsor and/or CRO.

1.1.4 **Compliance.** Institution and Investigator will (and warrant that the Trial Staff will) conduct the Trial in a diligent, efficient, and skillful manner, consistent with sound scientific procedures and in strict accordance with

(i) this Agreement,
(ii) the Protocol including any amendments / modifications (the "Protocol"),
(iii) the Investigator Site File ("ISF"),
(iv) any specific Trial instructions, other than the Protocol, issued by Sponsor;
(v) any applicable international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, ordinance, guideline or official publication that applies, directly or indirectly, to any party or to the conduct of clinical trials, this Trial, or this Agreement, as amended from time to time, in particular, without being limited to, New Drugs and Clinical

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

Trials Rules, 2019 including the gazette notification as issued from time to time, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017, Indian GCP guidelines released by CDSCO, the International Conference on Harmonisation Harmonised Tripartite Guideline for Good Clinical Practice ("ICH GCP"), the principles laid down in the Declaration of the Helsinki, most current version (as long as local laws do not require to follow other versions), and, where applicable, the rules governing good manufacturing practice and good laboratory practice, and rules governing the collection and storage of human tissue samples and the performance of DNA testing as well as related governmental and regulatory authorities' regulations, any conditions imposed by a competent Institutional Review Board/ Ethics Committee ("IRB/EC"), as well as all applicable drug, data protection/privacy, anti-competitive, anti-corruption, anti-bribery and anti-kickback law and all industry regulations on the cooperation of the pharmaceutical industry with the medical profession, including but not limited to, the IFPMA Code of Marketing Practices, the EFPIA Code of practice on the promotion of medicines, the PhRMA Code on Interactions with Health Care Professionals and the German FSA Code of Conduct, the Singapore Association of Pharmaceutical Industries Guiding Principles on Ethical Conduct on Promotion (SAPI Code of Marketing Practices), OPPI Code of Pharmaceutical Practices India, if applicable (e.g. for investigator meetings) (in the following collectively "Applicable Law").

1.2 **Qualification of Investigator and other Trial Staff.**

1.2.1 **Qualification.** Institution will ensure that the Investigator and Trial Staff are, at all times during the term of this Agreement, qualified by education, training and experience with appropriate expertise to conduct the Trial in accordance with this Agreement and the Protocol. If the Investigator is, at any time, no longer qualified or unable to perform any of the activities of the Trial, Institution, Sponsor and CRO may mutually agree to a substitute Investigator. Institution will notify Sponsor and CRO in writing, immediately upon learning that the Investigator is or will be unable to perform any of the activities of the Trial. Institution will use its best efforts to identify and obtain a substitute Investigator acceptable to Sponsor within thirty (30) days following such notice to Sponsor and CRO. If an acceptable Investigator cannot be obtained within thirty (30) days, CRO with written authorization from Sponsor may, at its discretion, immediately terminate this Agreement in accordance with Section 14.3 below. Prior to assuming the role of Investigator, the substitute Investigator must agree in writing to be bound by all obligations, terms and conditions of this Agreement.

1.2.2 **Curriculum Vitae.** Institution and/or Investigator will provide an up to date curriculum vitae for Investigator, any sub-investigators as well as other relevant documentation requested by competent IRB/ECs, regulatory authorities, CRO or Sponsor needed for the conduct of the Trial.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1.3 Notifications and Submissions

1.3.1 **Notification/Submission to Authorities and IRB/EC.** In accordance with Applicable Law, before initiating and during the conduct of the Trial, Institution and Investigator will ensure that *(i)* all necessary submissions, notifications and/or application(s) have been made, *(ii)* all necessary documentation and information is available, and *(iii)* all required reviews and approvals (or favourable opinions) by applicable regulatory authorities and competent IRB/EC have been obtained.

1.3.2 **Agreement.** Institution and Investigator agree that this Agreement may be forwarded to competent regulatory authorities as well as competent IRB/ECs, where requested by such.

1.4 Recruitment and Enrollment of Trial Participants.

1.4.1 **General.** Investigator will enroll subjects as participants in the Trial ("Trial Participants") in accordance with the terms and conditions of the Protocol and this Agreement. Investigator will enroll Trial Participants in strict compliance with the exclusion and inclusion criteria set forth in the Protocol without deviation or exception.

1.4.2 **Recruitment Phase.** The planned recruitment phase of this multi-center Trial at a global level will be from Dec 2020 to Dec 2021. Institution shall use reasonable endeavors to recruit or cause the Investigator to use reasonable endeavors to recruit approximately up to 13 randomized Trial Participants within this phase. The recruitment and inclusion of Trial Participants by the Investigator above and beyond this number, or any adjustment of this number, shall be subject to prior written approval of Sponsor.

1.4.3 **Competitive Recruitment.** Institution and Investigator acknowledge and agree that the Trial will involve the participation of multiple sites and recruitment will be competitive and closed when the desired overall number of evaluable Trial Participants has been obtained.

1.5 Informed Consent, Data Protection / Privacy.

1.5.1 **Trial Participant Consent.** Institution and Investigator shall ensure to have

(i) all requirements for obtaining informed consent and data protection/privacy related documents are satisfied,

(ii) he/she has obtained from each Trial Participant prior to enrolling such subject in the Trial a valid, dated, signed informed consent (the "IC") covering *(a)* Trial Participant's participation in the Trial, and *(b)* collection, storage and processing of Trial Participant's personal data in relation with the Trial (and a separate consent for future research/biobanking, where applicable), in accordance with the IC form provided by Sponsor and approved by the competent IRB/EC, and

(iii) the respective data collection form on file before the Trial Participant begins to participate in the Trial.

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1.5.2 **Data Protection Laws.** During the term of this Agreement, BI and Institution/Investigator may collect, share, process or use certain personal data (as the term is defined in the Data Protection Laws). "Data Protection Laws" means *(i)* any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the processing of personal data to which a Party is subject, in particular, Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data (the "General Data Protection Regulation – GDPR"); and *(ii)* any code of practice or guidance published by a relevant regulatory body from time to time. Institution and Investigator will only process personal data as permitted under applicable Data Protection Laws.
Under this Agreement, Sponsor and Institution/Investigator are Joint-Controllers, Covance is the Processor of personal data.

1.5.3 **Notification and Cooperation.** Investigator and/or Institution shall notify the Sponsor about the identity of the Data Protection Officer / Data Privacy Officer appointed at Investigator/Institution. Institution and Investigator shall notify Sponsor immediately in writing (but in no event later than three (3) days from the date) of any *(i)* loss or misuse (by any means) of personal data of Trial Participants or of the Sponsor's personnel; *(ii)* inadvertent, unauthorized, and/or unlawful processing, collection, storage, disclosure, access, alteration, corruption, transfer, or sale or rental, destruction, or use of personal data of Trial Participants or of the Sponsor's Personnel; or *(iii)* any other act or omission that compromises the security, confidentiality, or integrity of personal data of Trial Participants or of the Sponsor's Personnel to enable the Sponsor to consider what action is required in order to resolve the issue in accordance with applicable Data Protection Laws. If requested by Sponsor in order to enable Sponsor to comply with applicable Data Protection Laws, Institution and Investigator will, and will cause its Trial Staff to assist and cooperate with Sponsor to address any data protection/privacy issue relating to the Trial.

1.5.4 **Contact Point.** Under the IC Institution will be appointed as the point of contact for any data protection related requests concerning Institution or Sponsor in connection with the Trial and any use of personal data according to the IC. Institution shall be responsible to handle such requests (including sharing such requests with Sponsor, where required) and communicate with Trial Participants; Sponsor will provide reasonable assistance where required to ensure compliance with Trial Participants' rights under applicable Data Protection Laws.

1.6 Adverse Event Reporting. Investigator will collect, document and report information on all adverse events, serious and non-serious, as defined in the Protocol ("Adverse Events"), that occur for each Trial Participant from the point the Trial Participant signs the informed consent until completion of the Trial, including any post treatment period specified in the Protocol, in accordance with the instructions provided in the Investigator Site File ("ISF"), Applicable Law and any condition imposed by the IRB/EC, or any (sub)investigators, or the competent regulatory or governmental authority. This includes provision of available follow-up case data and detailed medical information.

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1.7 Use of Investigational Product and Other Materials

1.7.1 **Definition Trial Drug.** Sponsor provide the Investigational Product to be used in the Trial in accordance with the Protocol. The Investigational Product collectively referred to herein as "Trial Drug".

1.7.2 **Use of Trial Drug.** Institution and Investigator will ensure that any Trial Drug is administered only to Trial Participants in strict accordance with the Protocol and only under the supervision of Investigator. At no time will any Trial Drug be employed for any purpose other than as described in the Protocol.

1.7.3 **Storage, Accounting, Return and Destruction.** Institution and Investigator will be responsible for *(i)* storing the Trial Drug in a secure, limited access area under appropriate climate conditions specified in the Protocol and *(ii)* accounting for all Trial Drug whether or not such Trial Drug is used which will be documented in the Trial Drug accountability log. Upon completion or termination of the Trial, Institution and Investigator will account for all quantities used of the Trial Drug and shall return, retain or destroy, at Sponsor's option, all unused Trial Drug in accordance with instructions to be provided by Sponsor and/or CRO at Sponsor's sole expense.

2. OBLIGATIONS OF SPONSOR

2.1 **Supply of Trial Drug.** Sponsor will supply that may be done through third party providers the Investigational Product, if applicable, for use in the Trial at no cost to Institution or Investigator. Sponsor may also supply or arrange for the provision of any other Trial Drug to be used in the Trial at no cost to Institution or Investigator, either through provision of such Trial Drug by Sponsor or reimbursement to Institution by a third party payor.

2.2 **Information of Investigator.** Sponsor and/or CRO will provide Investigator with the current Investigator Brochure containing information about the chemical, pharmaceutical, toxicological, pharmacological and clinical data concerning the Trial Drug.

2.3 **Notification/Submission to Authorities and IRB/EC.** In accordance with Applicable Law, before initiating and during the conduct of the Trial, Sponsor will ensure that *(i)* all necessary submissions, notifications and/or application(s) have been made, *(ii)* all necessary documentation and information is available, and *(iii)* all required reviews and approvals (or favourable opinions) by applicable regulatory authorities and competent IRB/EC have been obtained.

2.4 Compensation

2.4.1 **Budget.** As compensation for all Trial services performed under this Agreement, Sponsor or Sponsor's designee, acting on behalf of Sponsor, will compensate Institution at fair market value according to the itemized "Clinical Trial Budget and Payment Schedule" attached as Appendix 1. Such amounts are fully inclusive for all services provided by Institution and Investigator in connection with the Trial and include all applicable direct

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and indirect costs, overhead, fees, and other assessments due to Institution, Investigator and other persons or entities providing any services or goods in connection with the Trial, but does not include standard of care costs. Except as specifically agreed to by Sponsor and/or CRO in writing, neither Institution, nor Investigator, nor any other person or entity will be entitled to any payments in connection with the Trial or activities conducted pursuant to this Agreement in addition to the amounts set forth in the Clinical Trial Budget. Any Party to this Agreement shall bear its own costs arising in connection with the preparation, negotiation, execution and performance of this Agreement, including but not limited to, all legal fees, auditor's fees and other professional fees.

2.4.2 **Invoices**. All payments due according to Appendix 1 shall be made to Institution within forty five (45) days of receipt of an invoice by Institution detailing goods and services tax (GST) separately to a bank designated by Institution. For the purpose of this agreement, the term 'GST' shall include the Central Goods and Services Tax ('CGST'), the State Goods and Services Tax ('SGST'), Integrated Goods and Services Tax ('IGST'), Union Territory Goods and Service Tax ('UTGST') and any other taxes levied under the GST related legislations in India as may be applicable. The term 'GST legislation/s' should be accordingly interpreted.

2.4.3 Invoices shall be made in accordance with the specifications set forth in the Clinical Trial Budget, which shall be modified in the event of a change in the applicable legal requirements. The Institution and Investigator shall be responsible for identifying the Place of supply of services supplied to Sponsor/CRO in accordance with the provisions of GST law.

(a) CRO hold right to hold further payments till the completion of following events;

1. Invoice details are reflected in GSTR-2 of CRO and payment of GST is made by Institution or Investigator; or

2. If not reflected in GSTR-2, amendments made by CRO in its GSTR-2 are accepted by Institution and Investigator and payment of GST is made; or

3. In case GST is actually paid by the Institution and Investigator, then the same can be deducted from subsequent payments if credit is not available

2.4.4 All invoices, debit notes, credit notes and receipts against advances, etc. issued to Covance India Pharmaceutical Services Pvt. Ltd. should be in accordance with the format prescribed under the GST Invoice Rules with the correct GST registration numbers to ensure that entire input tax credit is available.

2.4.5 **Overpayment, Final Accounting and Payment.**

(i) If during the course of the Trial Sponsor and/or CRO compensates Institution any funds in excess of the amount due under the Clinical Trial Budget,

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Institution will return such excess funds to Sponsor within sixty (60) days of written notification by Sponsor and/or CRO to Institution or Institution's discovery of such overpayment, whichever first occurs.

(ii) Final payment hereunder will be expressly conditioned upon receipt by Sponsor and/or CRO of any and all required data or other information from Institution and Investigator in a timely manner and as required by this Agreement and the Protocol, in a form satisfactory to Sponsor and CRO. The final payment will be processed by CRO after Sponsor's close-out visit to Institution, when all (original paper and electronic) case report forms (the "CRFs/eCRFs") have been completed and logged for all Trial Participants enrolled at Institution, all queries to Institution have been resolved, and Institution's data, including the Trial data accountability log, has been reviewed and accepted by the Sponsor or CRO clinical monitor. The final payment will include any remaining approved interim Trial Participant visit fees and/or any remaining approved invoiceable items noted on the Clinical Trial Budget.

(iii) Within ninety (90) days following the earlier of the date of termination of this Agreement or completion of the Trial by Institution and Investigator, Sponsor or CRO will submit to Institution a final report and documentation of all costs incurred and all funds received by Institution pursuant to this Agreement. Subject to the limits set forth in the Clinical Trial Budget and, (a) if the payments previously made by Sponsor/CRO to Institution exceed Institution's costs and allowable commitments incurred, such report will include a request for refund to Sponsor/CRO by the Institution, which refund will be made within sixty (60) days following the date of such report, or (b) if the payments previously made by Sponsor/CRO to Institution are less than Institution's costs and allowable commitments incurred, Sponsor/CRO will issue payment to Institution within sixty (60) days following the date of such report in the amount by which its costs and allowable commitments incurred exceed the payments previously made by CRO to Institution..

(iv) Except as otherwise provided in this Agreement, the failure of Institution to make demand for payment within the earlier of twelve (12) months of termination of this Agreement, or completion of the Trial by Institution and Investigator will be considered a waiver by Institution of its right to receive payment.

2.4.6 **Taxes.**

(i) **General.** All payments under or in connection with this Agreement shall be inclusive of any Taxes and each party shall be responsible for and shall bear, pay or set-off its own Taxes assessed by a tax or other authority except as otherwise set forth in this Agreement. "Taxes" mean all present and future taxes, import deposits assessments, and other governmental charges and any related penalties and interest not attributable to the fault or delay of a party.

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"Taxes" shall mean all forms or preliminary or finally imposed taxation, domestic and foreign taxes, fees, levies, duties and other assessments or charges of whatever kind (including but not limited to sales, use, excise, stamp, transfer, property, value added, goods and service, withholding and franchise taxes) together with any interest, penalties or addition payable in connection with such taxes, fees, levies, duties and other assessments or charges.

(ii) If Applicable Law requires withholding (of licensee) of any taxes imposed upon (by licensor) on account of any royalties and other payments, paid under this Agreement, such taxes shall be retained (by licensee) as required by law from such remittable royalty and other payment and shall be paid (by licensee) to the proper tax authorities on account of (licensor). Official receipts of payment of any retained local withholding tax shall be secured and sent to (licensor) as evidence of such payment. The parties shall cooperate and exercise their best efforts to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of any relevant double tax treaty.

(iii) **GST or similar Taxes.** All payments due to the terms of this agreement are expressed to be exclusive of indirect taxes (e.g. goods and service tax). GST/indirect taxes shall be added to the payments due to the terms if legally applicable.

(iv) The GST amounts of invoices received by Institution and Investigator are not billable to Sponsor as far as Institution and Investigator have an input GST deduction, i.e., Institution and Investigator are able to receive a refund by the competent authority. If GST is not refundable because of legal restrictions, which are not caused by Institution or Investigator, the GST amounts are billable to Sponsor/CRO. Prior to the invoicing of the aforementioned billable amounts written approval of Sponsor and/or CRO is mandatory. Legal restrictions which are caused by Institution or Investigator and lead to a non-billable amount to BI shall be the following, but not limited to, (i) failure of Institution or Investigator of adhering to applicable statutes of limitations, or (ii) inaccurate documents in order to receive the input GST deduction.

I. In cases, where Institution and Investigator is GST unregistered, Institution and Investigator should declare the same at the time of Clinical trial agreement sign off and should not charge any tax on service to CRO. Where the Institution/ site fails to inform CRO that they are GST unregistered, the Institution and Investigator shall be liable to reimburse for loss of any input tax credit, interest or penalty levied by the tax authorities on such supplies of services.

II. In respect of notified supplies of services received by CRO/Sponsor, where Sponsor may be required to deduct tax at source (under GST law) on certain payments made to the Investigator and Institution, Sponsor/CRO shall deposit such amount with appropriate government within 10 days after the end of the month in which such deduction is made. Sponsor/CRO shall also furnish a certificate in Form GSTR 7A to the Institution and Investigator against such deduction. The

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Institution and Investigator shall be responsible for providing the correct details of address, GSTIN, HSN code and other details as may be required to be mentioned by Sponsor/CRO in the certificate to be issued in Form GSTR 7A. In case of any incorrect / incomplete details provided by the Institution and Investigator which results in denial of credit (of TDS deducted) by the authorities to the Institution and Investigator along with levy of interest or penalty on the Institution and Investigator for incorrect availement or utilization of credit, Sponsor/CRO shall not be responsible to reimburse the same to the Institution and Investigator

III. If the Institution and Investigator is a composition dealer, Institution and Investigator should declare the same at the time of Clinical trial agreement sign off. Where composite scheme is availed without informing Sponsor/CRO, Institution and Investigator is liable to reduce the price to the extent of tax applicable on similar services.

(v) The Investigator/Institution shall support Sponsor/CRO on various aspects to comply with the transitional provisions under GST and assist Sponsor/CRO in identifying tax benefits or refunds as the case may be, that may accrue on stocks, credits, taxes, etc. on the GST implementation appointed date and pass-on the same to Sponsor/CRO.

(vi) The Investigator/ Institution shall pass on to Sponsor/CRO all the benefits of either reduction in tax rates, exemptions, concessions, rebate, set off, credits, etc. or introduction of new tax rates, exemptions, concessions, rebate, set off, credits etc. pertaining to all taxes, duties, imposts, fees and levies in respect of the supplies of services or performance of obligations including reduction in procurement price, including reduction of tax rates as a result of statutory changes or judicial rulings and reduction in price where the Investigator/ Institution is benefited due to reduction in taxes.

3. TRIAL DOCUMENTS

3.1 **Collection and Storage.** Institution and Investigator will accurately maintain, organize, keep current, complete and preserve all essential documents relating to the Trial which allow verification of the conduct of the Trial and the quality of the data generated (Investigator Site File), including, but not limited to, *(i)* written or electronic records, copies of paper original and electronic CRFs, accounts, notes, reports, materials and data collected or performed as part of the Trial under this Agreement, including clinical data and patient medical care records and progress reports for each Trial Participant (including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images); *(ii)* and any other records, data or reports related to or generated as part of the Trial (e.g., Protocol, informed consent form, source data, documents facilitating identification of Trial Participants); required by Applicable Law, in full compliance with the Protocol.

3.2 **Document Storage and Protection.** Institution and Investigator shall *(i)* maintain and store such documents in a secure manner appropriate to the applicable data type and in accordance with Applicable Law, and *(ii)* protect the documents from unauthorized use, access, duplication, disclosure, loss and damage. Institution and Investigator will make all documents available for review, copying, audit, and inspection in accordance with Article 4 hereof.

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3.3 **Retention and Destruction.** Institution and Investigator will archive the Investigator Site File containing all essential documents which allow the verification of the conduct of the Trial and the quality of the data generated in their original format for fifteen (15) years After the expiration of the retention period required above, Institution and Investigator shall provide written notice to the Sponsor or its designated party and destroy all essential documents.

3.4 **Access to Documents.** Institution and Investigator must not transfer or make in any other way accessible to Sponsor and/or CRO any essential documents containing personal data of Trial Participants, unless such data has been pseudonomized (de-identified) or if such disclosure is required under Applicable Law or requested by the competent authorities. Sponsor may assign certain of its employees, CRO employees or external vendors (clinical research associates, the "CRAs") to review and control accuracy and completeness of the essential documents in order to comply with Applicable Law at Institution or Investigator; however, such CRAs are restricted from disclosing any personal data of Trial Participants to the Sponsor stored at Institution or Investigator.

3.5 **Information Delivery to Sponsor and/or CRO.** Institution and/or Investigator will provide to Sponsor and/or CRO completed CRFs/eCRFs, as applicable, for each Trial Participant and other such reports when and as required by the Protocol and Applicable Law. Institution and Investigator warrant that all eCRFs or CRFs submitted to Sponsor/CRO are true, complete, correct and accurately reflect the results of the Trial. Within sixty (60) days following the completion of the Trial by Institution and Investigator or the earlier termination of this Agreement, Institution and Investigator will provide to Sponsor/CRO any and all data required pursuant to the terms of this Agreement and the Protocol.

3.6 **Incomplete Data.** In the event that essential documents and any other original records and data related to or generated as part of the Trial are either incomplete or out-of-date, Sponsor/CRO may retain trained health care professionals to assist in satisfactory completion of such documents. The cost of such professional assistance (which will be reasonable in the circumstances) will be charged to Institution and may be offset against compensation owed to Institution hereunder.

4. MONITORING, AUDITS AND INSPECTIONS

4.1 **Access.** Sponsor, CRO and/or their agents and, when applicable, IRB/EC and regulatory authorities, including foreign regulatory authorities, may, at any time during normal business hours, (i) inspect any facilities used for the conduct of the Trial, (ii) monitor and/or audit the conduct of the Trial, (iii) inspect, audit and/or copy any and all Trial documents, source data/documents, medical records, work product, and required licenses, certificates and accreditations, or (iv) interview any person involved in the Trial. Additionally, during the term of this Agreement and for a period of twenty-four (24) months after completion of the Trial, Sponsor and/or its designee shall be entitled to inspect Institution's financial accounts directly related to the Trial. Institution and Investigator will, and will cause its Trial Staff to, cooperate with any of the foregoing activities and will provide timely access to requested documentation and facilities.

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4.2 **Electronic Records System.** Without limiting the foregoing, if Institution stores and retains its records in an electronic records system, Institution will promptly upon request allow access to Trial documents and other required documents and information through such electronic records system. In the event it is not possible, after exercise of commercially reasonable efforts, to allow access to Trial documents in Institution's electronic records system without jeopardizing data protection or privacy rights of other patients of Institution, Institution will print and provide to the requestor certified hardcopies of all relevant documents and information. Institution will maintain, create, modify, archive, retrieve and transmit, and make available for inspection by regulatory authorities, all electronic records in compliance with any Applicable Law, including, but not limited to, Title 21 U.S. Code of Federal Regulations, Part 11 "Electronic Records; Electronic Signatures."

4.3 **Regulatory Authority Inspections.**

4.3.1 **Notification.** Institution and/or Investigator will notify Sponsor and CRO immediately by telephone, facsimile or email if, in connection with the Trial or in connection with any matter that may affect Institution's or Investigator's performance of the Trial, a governmental or regulatory authority requests permission to or does inspect Institution's and/or Investigator's facilities or research records.

4.3.2 Copies. In accordance with Applicable Law, Institution and/or Investigator will provide in writing to Sponsor and/or CRO copies of all materials, reports, correspondence, statements, forms and records which Institution and/or Investigator receives, obtains or generates pursuant to any such inspection in connection with the Trial, or in connection with any matter that may affect Institution's or Investigator's performance of the Trial.

4.3.3 **Sponsor Attendance.** Institution and Investigator shall permit Sponsor and/or its designees to attend any such inspection unless prohibited by Applicable Law or the competent governmental or regulatory authority. If any proposed correspondence from Institution and/or Investigator to a governmental or regulatory authority relates directly or indirectly to Institution's and/or Investigator's activities under this Agreement, Sponsor and/or its designee(s) will have the right to review such correspondence and request reasonable revisions thereto.

5. CONFIDENTIALITY

5.1 **Non-Disclosure and Non-Use Obligation.** Institution and Investigator shall keep any and all data, know-how, substances and all other information (including, but not limited to, documents, descriptions, data, (e)CRFs, photographs, videos and instructions), and material (including, but not limited to, the Investigational Product and comparator products), provided to or made available, no matter how it is disclosed (e.g. in writing or electronically), to Institution or Investigator by Sponsor, CRO or their Affiliates, or their agents, and/or generated under this Agreement and/or relating to the Trial (collectively referred to as "Sponsor Confidential Information") confidential and shall not (i) disclose the Sponsor Confidential Information to any third party without the prior written approval of Sponsor, or (ii) use the Sponsor Confidential Information for any purpose other than for the conduct of the Trial and its obligations under this Agreement. Sponsor Intellectual Property (as

defined in 6.2.1) and Results (as defined in 6.3) shall be considered Sponsor Confidential Information; provided that Results shall not be considered Sponsor Confidential Information for the sole purpose of publication in accordance with the terms set forth in Article 7. For the purpose of this Agreement, "Affiliate" or "Affiliates" shall mean any person or entity controlled by, controlling, or under common control with either Sponsor or Institution. For this purpose, "control" means direct or indirect beneficial ownership of at least fifty percent (50%) interest in the voting stock (or the equivalent) of such person or entity or having the right to direct, appoint or remove a majority or more of the members of its board of directors (or their equivalent), or having the power to control the general management of such person or entity, by contract, law or otherwise.

5.2 **Dissemination to Others.** Institution and Investigator will restrict the dissemination of Sponsor Confidential Information to those persons participating in the Trial on behalf of Institution and/or Investigator who have a need to know and will ensure that each such person is contractually bound by confidentiality and non-use obligations at least as onerous as those set forth in this Agreement before being engaged or involved in the Trial.

5.3 **Non-Written Information.** If Sponsor Confidential Information is disclosed by Sponsor or its Affiliates to Institution and/or Investigator other than in written or electronic form, then Institution and/or Investigator 's obligations of confidentiality and non-use shall only apply if the respective Sponsor Confidential Information is indicated upon disclosure as being confidential and is then summarised electronically or in writing and provided to Institution and/or Investigator within thirty (30) days after initial disclosure, except for any such Sponsor Confidential Information that, based on the nature of the information, a reasonable person would understand is the confidential information of Sponsor.

5.4 **Return of Sponsor Confidential Information.** Institution and Investigator agree and bind themselves, either immediately upon request of Sponsor or upon expiry or termination of this Agreement, to return all Sponsor Confidential Information to Sponsor, except for those documents generated by Institution or Investigator necessary to comply with applicable record retention requirements or procedures, but only to the extent required by Applicable Law, and all such retained documents will continue to be subject to the confidentiality provisions of this Agreement.

5.5 **Exemption.** These confidentiality and non-use obligations do not apply to: (i) information already in the possession of Institution and/or Investigator prior to its disclosure by Sponsor or its Affiliates as evidenced by written records, (ii) information which comes into the public domain by publication or otherwise through no breach by Institution and/or Investigator or others involved in the Trial, (iii) information which has been disclosed to Institution and/or Investigator from another source free from any obligation of confidentiality and which was not directly or indirectly obtained from Sponsor or its Affiliates, or (iv) information required to be disclosed under Applicable Law or for making applications or submissions to or otherwise dealing with an IRB/EC or competent regulatory authority in connection with the Trial provided, however, that such information shall be disclosed only to the extent reasonably necessary (v) information required to be disclosed under the order of a court of competent jurisdiction, provided that Institution and/or promptly notifies Sponsor of such obligation beforehand and the information to be disclosed and fully cooperates with Sponsor, if so requested, in maintaining the confidentiality of such information by applying for a protective order or any similar legal instrument.

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5.6 **Encryption Technology.** Institution and Investigator undertake to protect Sponsor Confidential Information (including but not limited to patent-relevant, scientific or technical information) against unauthorized access by third parties. If Sponsor Confidential Information is communicated via internet mail, use of internet mail encryption technology is compulsory (for direct communication between the Parties, Sponsor provides for a suitable technology at http://guides.boehringer-ingelheim.com free of charge).

5.7 **Breach Notification.** Institution and/or Investigator will notify Sponsor immediately of any loss, compromise, or unauthorized use or disclosure of any part or all of Sponsor Confidential Information.

6. INTELLECTUAL PROPERTY

6.1 Background IP

6.1.1 **Ownership.** Each Party and or its Affiliates shall be and shall remain the owner of any data, documents, know-how, information, material, substances, including but not limited to the Investigational Product, and any other intellectual property, which are provided to the other party for use in the Trial (the "Background Intellectual Property") and this Agreement shall not affect the ownership of any Background Intellectual Property.

6.1.2 **Licence Grant.** Each party grants the other party a royalty free, non-exclusive license to use its or its Affiliates' Background Intellectual Property only for the purpose of carrying out the Trial. Neither Party may grant any sublicense to use the other Party's Background Intellectual Property, except that Sponsor may allow its Affiliates or any third party working for or on behalf of Sponsor or its Affiliates to use the Institution and/or Investigator's Background Intellectual Property for the purpose of carrying out the Trial. Additionally, Institution and Investigator shall and hereby grant Sponsor and its Affiliates a worldwide, perpetual, irrevocable, sub-licensable, fully paid-up, non-exclusive license to use its Background Intellectual Property as may be necessary for Sponsor and/or its Affiliates to fully exploit Sponsor's and/or its Affiliates rights in and to any Sponsor Intellectual Property and the Results as defined below.

6.2 Foreground IP

6.2.1 **Definition "Sponsor Intellectual Property".** As used herein, "Sponsor Intellectual Property" shall mean all rights, title and interest in and to the intellectual property and materials that are the subject of the Trial or the Protocol, including, without limitation: (i) all intellectual property rights in the Investigational Product, (ii) all data, technical information, inventions, discoveries, developments, improvements, enhancements, software, know-how, methods, techniques, formulae, data, processes and other proprietary ideas (whether or not patentable or registrable under any patent, copyright or

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similar laws) and materials related to the Investigational Product or its uses, the Trial or the Protocol, (iii) all intellectual property otherwise derived, conceived, discovered, developed or reduced to practice as a direct or indirect result of the Institution or Investigator's performance of any services under or pursuant to this Agreement or during the course of or in connection with the Trial and relating to or incorporating the Investigational Product or its use, including but not limited to any such intellectual property generated upon any review or other use of Trial data, and (iv) any intellectual property incorporating or derived from Sponsor Confidential Information, whether generated or developed by Institution, Investigator or Sponsor or their respective agents, employees or contractors, either solely or jointly with others.

6.2.2 **Ownership.**

(i) Sponsor Intellectual Property is the sole and exclusive property of Sponsor. Institution and Investigator shall assign and hereby assign to Sponsor all of their right, title and interest in Sponsor Intellectual Property. Institution will ensure that the Investigator and all Trial Staff or other persons carrying out Institution's obligation under or pursuant to this Agreement have already assigned to the Institution, by their employment obligations or otherwise, or shall assign to the Institution all right, title and interest that they may have in Sponsor Intellectual Property in order to give full effect of the foregoing assignment of rights to Sponsor.

(ii) All intellectual property derived, conceived, discovered, developed or reduced to practice solely by Institution and as a direct or indirect result of the Institution or Investigator's performance of any services under or pursuant to this Agreement or during the course of or in connection with the Trial, but that is not within the scope of Sponsor Intellectual Property as defined in Section 6.2.1, is the sole and exclusive property of Institution ("**Institution Intellectual Property**"). Institution hereby grants to Sponsor a worldwide, perpetual, irrevocable, sub-licensable, fully paid-up and royalty free, non-exclusive license to use such Institution Intellectual Property as may be necessary or useful for Sponsor and/or its Affiliates to fully exploit Sponsor's and/or its Affiliates rights in and to Investigational Product, any Sponsor Intellectual Property and Results.

(iii) All intellectual property derived, conceived, discovered, developed or reduced to practice jointly by Institution and Sponsor under or pursuant to this Agreement or during the course of or in connection with the Trial, but that is not within the scope of Sponsor Intellectual Property as defined in Section 6.2.1, is the joint property of Institution and Sponsor ("**Joint Intellectual Property**"). Sponsor is hereby granted an option to negotiate an exclusive, worldwide, compensation-bearing license under Institution's rights to any Institution Intellectual Property or Joint Intellectual Property, which option shall extend for one-hundred and eighty (180) days following of the relevant intellectual property. Upon Sponsor's exercise of the option the Parties shall promptly negotiate a license agreement in good faith.

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6.8 **No Conflict.** Institution and Investigator warrant by the execution of this Agreement, that neither they nor any Trial Staff involved in the Trial have entered, and that none of them will enter, into any contractual agreement or relationship which would in any way conflict with or compromise Sponsor's proprietary interest in, or rights to, any Sponsor Intellectual Property, Institution Intellectual Property, Joint Intellectual Property or Results existing at the time of the execution of this Agreement or arising out of or related to its performance thereunder.

7. PUBLICATION, PUBLICITY AND TRANSPARENCY

7.1 **Publication.**

7.1.1 **Publication by Sponsor.** Sponsor shall have unrestricted publication rights for the Results and may give the data to third parties for publication.

7.1.2 Publication by Institution or Investigator. Sponsor acknowledges that Institution and Investigator have the right to publish the results that Institution and Investigator contribute and generate as a result of the Trial for non-commercial purposes with due regard to the protection of Sponsor Confidential Information and consistent with the below paragraph regarding joint multi-center publications. If Institution and/or Investigator publish the results of the Trial, Sponsor is hereby granted a perpetual, royalty-free license to make, display and distribute copies of such publications under any copyright rights or privileges of Investigator or Institution.

7.1.3 **Good Publication Practice.** For all publications relating to the Trial or including any Trial data, Sponsor, Institution and Investigator agree to comply with the Good Publication Practice Guidelines (found at: http://www.ismpp.org) and all ethical standards concerning publications and authorship, including the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" as established by the International Committee of Medical Journal Editors ("ICMJE") (found at http://www.icmje.org).

7.1.4 Submission of Publications. Prior to submission for any written, electronic, oral or audio-visual publication, Institution and/or Investigator shall first submit to Sponsor a copy of any proposed abstract, poster, presentation slides, manuscript or any other material at least sixty (60) days in advance of such proposed date of submission for publication for review by Sponsor. Unless Sponsor informs Institution and/or Investigator in writing during the sixty (60) day period, that the proposed publication must be (i) delayed in order to protect a potentially patentable invention or (ii) changed to avoid the potential disclosure of Sponsor Confidential Information, Institution and/or Investigator shall be free to proceed with the proposed publication. Institution and/or Investigator shall remove from any proposed publication material all Sponsor Confidential Information identified by Sponsor in writing to Institution and/or Investigator during the sixty (60) day period. In no event will any Sponsor Confidential Information be included in any published material without the prior written approval of

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Sponsor. For the sole purpose of publications approved by Sponsor under this Article 7, all data and results generated by Institution and/or Investigator during the performance of the Trial shall not be considered Sponsor Confidential Information. If within the sixty (60) day review period Sponsor notifies Institution that it desires to file a patent application covering a potentially patentable invention disclosed in the publication Institution and Investigator shall withhold such submission for publication for an additional period agreed upon in good faith by the Parties, however no longer than eighteen (18) months after the filing of the patent application covering the respective invention.

7.1.5 Multi-Center Publication. Institution and Investigator acknowledge that if the Trial is part of a multi-center trial, Sponsor anticipates a joint multi-center primary full publication. Therefore, Institution and Investigator agree not to publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement before such multi-center publication has been published. Without limiting the foregoing, if there is no joint multi-center publication within eighteen (18) months after completion of the Trial at all sites, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Results generated and contributed by them, subject to review and comment as set forth in the preceding paragraph.

7.1.6 Authorship. Authorship of any publications relating to the Trial should be determined by mutual agreement. Sponsor has the right to name co-authors.

7.2 Publicity.

7.2.1 **Use of Trial Information.** Neither Institution nor Investigator will use any information regarding the Trial, including, but not limited to, the existence of the Trial or other publicly available information in any publicity, advertising or subject recruitment materials without Sponsor's prior written consent.

7.2.2 Use of Name, Logo and Trademarks. No Party hereto shall use the other party's/parties' or its Affiliates' name(s), logo(s), trademark(s), physical likeness, employee name, owner symbol, or other image in any press release, advertising or other form of publicity without prior written consent of the other party/parties, except as otherwise required by Applicable Law. Sponsor may use the name of Institution's and/or Investigator's name and other identifying information in Trial publications and communications, including clinical trial websites and Trial newsletters, applications or forms, or other materials submitted to any regulatory authority and/or other disclosures required by Applicable Law such as disclosures in clinical trial registries. (for e.g. Indian clinical trial registry; http://www.ctri.nic.in/

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7.3 Transparency.

7.3.1 Registry and Reporting. Sponsor will adhere to the ICMJE requirements on clinical trial registration and represents that the Trial will be registered according to ICMJE applicable requirements and all applicable laws regarding clinical trial registration prior to the recruitment of the first Trial Participant and will report the results of the Trial publicly when and to the extent legally required.

7.3.2 Data and Document Sharing. Institution and Investigator acknowledge that, Sponsor may, in accordance with the joint 'Principles for Responsible Clinical Trial Data Sharing' by EFPIA and PhRMA (found at: www.efpia.eu or www.phrma.org), share the clinical study report, related clinical documents, and patient-level clinical study data with third party requestors (more information to be found at http://trials.boehringer-ingelheim.com/transparency_policy.html).

8. PROVISION OF EQUIPMENT AND REMOTE DATA CAPTURE

8.1 Use of Computer and Remote Data Capture. If computer systems are used for Remote Data Capture ("RDC") by Institution and/or Investigator for the Trial (own computer or notebook computer supplied by Sponsor), Institution and Investigator will ensure that all requirements for RDC are in place and comply with the RDC terms and conditions set forth in Appendix 2 "Remote Data Capture (RDC) – Terms and Conditions" and the RDC User Guide provided by Sponsor or CRO.

8.2 Use of other Equipment. If Sponsor or its designees provide(s) Institution and/or Investigator with any other equipment ("Equipment") for use in connection with performance of services in the Trial, Institution and/or Investigator will document the Equipment in the "Equipment Loaned Log" which is part of the ISF. The terms and conditions for provision of Equipment are set forth in Appendix 3 of this Agreement.

9. TRIAL PARTICIPANT INJURY, INSURANCE INDEMNIFICATION AND LIABILITY

9.1 **Trial Participant Injury.** Institution and or Investigator shall promptly notify Sponsor and/or CRO in writing of any claim of illness or injury actually or allegedly due to their participation in the Trial and allow Sponsor to handle such claim (including settlement negotiations), and shall cooperate fully with Sponsor and CRO in its handling of the claim. Institution will provide to Sponsor and/or CRO sufficient documentation to review and process any Trial Participant injury reimbursements, provided, however, that any and all patient identifiers will be removed from any documentation submitted to Sponsor and/or CRO.

9.2 **Liability Insurance.** Institution and Investigator will each secure and maintain in full force and effect throughout the performance of the Trial, at their own expense, insurance or self-insurance that provides appropriate coverage for claims for damages arising out of acts or omissions of Institution, Institution's employees and/or agents, and/or Investigator, Investigator's employees

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and/or agents in the Trial and in their performance of this Agreement. Institution and Investigator shall promptly provide evidence of its insurance upon request by Sponsor/CRO.

9.3 **Clinical Trial Insurance.** Sponsor, where required by Applicable Law, has affected sufficient insurance to compensate damages suffered by Trial Participants as a direct result of their participation in the Trial. To that extent, such clinical trial insurance may also cover the relevant liability of Institution or Investigator. However, the Parties understand that the clinical trial insurance is not intended as nor is a substitute for full and complete malpractice and other forms of liability insurance.

9.4 **Indemnification**

9.4.1 Covance and Sponsor shall not be responsible for, and Investigator shall indemnify, defend and hold Covance and Sponsor harmless from any loss or third party claim resulting from Investigator's or Research Staff's negligence, willful misconduct, or their breach of this Agreement.

9.4.2 **Institution Indemnification.** Institution will indemnify, defend and hold harmless Sponsor, Covance and their Affiliates, their directors, their officers, managers, agents and employees and their respective successors (collectively "Sponsor Indemnitees" and/or "CRO Indemnitees") from any Losses incurred by or imposed upon a Sponsor/CRO Indemnitee as a result of any third party claim made or suit brought against the Sponsor and/or CRO Indemnitee to the extent the same is arising directly from any injuries or damages that are a result of *(i)* the negligence or willful misconduct of any Institution Indemnitee; *(ii)* research activities conducted by any Institution Indemnitee contrary to or outside the scope of the Protocol, this Agreement or; or *(iii)* actions by any Institution Indemnitee in violation of Applicable Law, this Agreement or any written instruction relating to the conduct of the Trial.

9.4.3 **Conditions of Indemnity.** Either party (herein referred to as the "Indemnified Party") wishing to be indemnified by the other will: *(i)* promptly and in no event longer than ten (10) days after receipt of notice of any claims and/or legal proceedings, notify the other party thereof in writing and enclose a copy of all papers served, and *(ii)* allow the other party to retain exclusive control of the defense against such legal proceedings and claims without limitation the right to select defense counsel and to settle such legal proceedings and claims at its sole discretion, provided that the other party will not make any settlement which admits fault on the part of the Indemnified Party or could reasonably be expected to have a negative effect on the reputation of the Indemnified Party without the prior written consent of the Indemnified Party, which will not be unreasonably withheld. Institution and Investigator undertake to fully cooperate with Sponsor and/or Covance to determine the actions in the cases referred to above, and take no action that could harm the interests of Sponsor in Covance.

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11. DEBARMENT

11.1 **Representation and Warranty.** Institution and Investigator each represent and warrant that Institution, Investigator and their respective employees, contractors, and agents, including sub-investigators, have not been restricted, debarred, suspended, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment, or otherwise subject to any restrictions or sanctions by the U.S. FDA or any other governmental or regulatory authority or professional body with respect to the performance of scientific or clinical investigations.

11.2 **Notification.** Institution and/or Investigator shall notify Sponsor immediately in writing if Institution, Investigator or any of their respective employees, contractors or agents, including sub-investigators, is so restricted, debarred, suspended, disqualified or banned or becomes subject to an investigation for debarment, or becomes otherwise subject to any restrictions or sanctions.

11.3 **Termination.** Debarment, suspension or proposed debarment of Institution, Investigator or their employees by any any governmental or regulatory authority will constitute grounds for automatic termination of this Agreement by Sponsor, in Sponsor's sole discretion, in accordance with Article 13 below.

12. ANTI-BRIBERY AND ANTI-CORRUPTION

12.1 **Prohibition.** Institution and Investigator each represents and warrants that it, its owners, directors, officers, employees, sub-contractors and agents will act in full compliance with any applicable anti-corruption laws and regulations, industry and professional codes of practice (MCI code of Ethics, OPPI code) and will not offer, promise, pay or arrange for payment or giving of any benefit or advantage to any individual or entity, including but not limited to Public Officials, as defined below, in exchange for an improper advantage in any form either directly or indirectly. In particular, Institution and Investigator may not offer, promise or pay a bribe in order to fulfil, obtain or retain *(i)* regulatory requirements, *(ii)* any kind of business including any commercial transaction to which Sponsor and/or CRO is a party, or *(iii)* any other improper advantage in connection with the business of Sponsor and/or CRO. Institution and Investigator are prohibited to request, accept a promise of or receive any payment, benefit or advantage from any individual or entity for oneself or for a third party in return for giving another person or entity unfair preferences in the procurement of goods or commercial or other services. In case of any doubt regarding the question whether or not a particular transaction may be regarded as a bribe, Institution and Investigator must seek prior advice and approval of the Sponsor and/or CRO.

12.2 **Public Official.** For the purpose of this Agreement, "Public Official" means any officer or employee of a local or foreign government or any department, agency, or instrumentality thereof, or of a public international organization as well as any person acting in an official capacity for or on behalf of any such government, department, agency, or instrumentality, or for or on behalf of any such public international organization as well healthcare professionals, working in healthcare institutions, in which the central, regional or local government owns an interest or has control or which are paid partly or as a whole by the government. Regardless of whether or not such transfer might constitute a bribe, Institution and Investigator may not transfer anything of value to a Public Official without

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the prior approval of the Sponsor and/or CRO. Institution and Investigator may not transfer anything of value to agents for the purpose of offering, promising, paying, receiving, soliciting, or arranging for the payment of, or reimbursing anyone for payment of, a bribe or a transaction of anything of value to a Public Official.

12.3 **Reporting to Sponsor and CRO.** Institution and Investigator shall report any suspicion of past, actual or potential violations of this Section to the Sponsor and the CRO. If Institution is in doubt whether a certain act violates its obligations under this Section, Institution shall contact the Sponsor and CRO and shall delay the decision before taking the action.

12.4 **Consequences of Violation.** Any violation of this Section constitutes a material breach of this Agreement. In addition to any other sanction provided by Applicable Law and/or this Agreement, CRO, with written authorization by Sponsor, may terminate this Agreement after giving an opportunity to the institution/Investigator to explain their position in that regard for cause and with immediate effect, if Institution violates its obligations under this Section. I nstitution and Investigator shall indemnify and hold Sponsor and CRO harmless for any loss or damage resulting of a breach by the Institution and Investigator, its directors, officers, employees, sub-contractors and agents of this Section or of any Applicable Law.

12.5 **Certificate.** Upon Sponsor's request from time to time, Institution and Investigator agree to certify compliance with the foregoing in a form suitable for Sponsor.

13. EXPORT CONTROL

13.1 **Sponsor/CRO provides items.** Institution and Investigator understand and agree that the items incl. goods, software, technology (specific technical information necessary for the development, production, or use of a product) and technical services provided by the Sponsor or by CRO, acting on behalf of the Sponsor or by their third party vendors under this Agreement may be subject to international, India and US Export Control laws and regulations (hereinafter "Laws") restricting exports, re-exports, transfers or disclosures, regardless of the mode of provision (hereinafter "Transactions"). Institution and Investigator shall comply with all such Laws. Institution and Investigator shall not, without first obtaining permission to do so from the appropriate authorities, perform any further Transactions of items provided by the Sponsor and/or CRO under this Agreement *(i)* if the item is controlled under the Laws; *(ii)* to any country, person or other party that is ineligible to receive such item, i.e. sanctioned by any embargo or sanctioned party list (hereinafter: "Sanctioned Party") under the Laws; or *(iii)* to a person or other party if Institution and Investigator know or have reason to assume that such person or party intends to provide the item to any such country, person or party, or intends to use or allow others to use the item for activities related to military or otherwise restricted use.

13.2 **Sponsor receives items.** Institution and Investigator understand and agree that the items incl. goods, software, technology (specific technical information necessary for the development, production, or use of a product) and technical services (hereinafter "Item") provided to Sponsor/CRO under this Agreement may be subject to Laws restricting Transactions. Institution and Investigator shall comply with all such Laws. Institution and Investigator shall determine whether an item is

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controlled under the Laws and identify the specific export control status of the item. If the item is subject to any restrictions or license requirements under the Laws, Institution and Investigator shall notify Sponsor/CRO about these restrictions prior to providing the item to Sponsor, incl. information on where the controlled item is listed (e.g., U.S. Commerce Control List). Institution and Investigator shall cooperate with Sponsor by providing upon request information and other assistance necessary for the classification (e.g., on the US Export Control List), export documentation, license determination, export licensing etc. of items provided to Sponsor under this Agreement.

14. TERM, TERMINATION AND EFFECTS OF TERMINATION

14.1 **Term.** This Agreement will become effective on as of the last date of signature (the "Effective Date") and shall continue until completion of the Trial (i.e. until the close-out visit date at the site has been performed), unless earlier terminated as provided herein below.

14.2 **Termination by CRO.** CRO, with written authorization from Sponsor, may terminate this Agreement or terminate or suspend enrollment or randomization of Trial Participants for any reason and upon at least thirty (30) days prior written notice to Institution and/or Investigator. The date of termination will be the date specified in such notice.

14.3 Immediate Termination initiated by Sponsor or CRO. CRO may terminate this Agreement or Sponsor may terminate or suspend enrollment or randomization of Trial Participants immediately upon written notice to Institution and/or Investigator if within the first three (3) months after Trial initiation Institution or Investigator *(i)* fails to enroll any patient or recruits such a low number of patients that it can be assumed that the agreed number of Trial Participants will not be reached during the global recruitment phase as specified in the Protocol and this Agreement, *(ii)* Sponsor becomes aware of any efficacy or safety information that could significantly affect or alter continuation of the Trial, *(iii)* Sponsor terminates its conduct of the entire Trial in Sponsor's sole discretion; or *(iv)* there is a violation or a suspected violation by Institution or Investigator of any Applicable Law, the Protocol or this Agreement, as determined within Sponsor's reasonable discretion. The date of termination will be the date specified in such notice, (v) if Sponsor terminates its services agreement with Covance for the conduct of the Trial.

14.4 **Termination by Institution.** Institution may terminate this Agreement effective upon written notice to Sponsor and CRO if Sponsor and/or CRO materially breaches any of the terms or conditions of this Agreement, and fails to cure such breach within thirty (30) days after receiving written notice thereof from Institution specifying the breach alleged by Institution. Further, if Institution has indication of serious physical harm being suffered by any of the Trial Participants at its site, it may immediately suspend enrollment of Trial Participants at its site. In such event, Institution will immediately notify Sponsor of any such indication and its determination to suspend enrollment of Trial Participants at its site but will continue to perform follow-up procedures as set forth hereunder.

14.5 **Effects of Suspension or Termination of Enrollment.** If enrollment or randomization of Trial Participants has begun and enrollment or randomization of additional Trial Participants is

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terminated or suspended, Institution and Investigator will either terminate or suspend enrollment, as appropriate, and will continue to conduct the Trial in accordance with the Protocol and this Agreement for all Trial Participants then enrolled, except if the safety of such Trial Participants could be endangered thereby or if the Institution and Investigator are otherwise instructed by Sponsor that may be communicated via CRO.

14.6 Effects of Termination. The effect of any such termination will be as follows

14.6.1. Continued Monitoring and Data Maintenance. Upon receipt of notice of termination by Sponsor, Institution and Investigator will terminate enrollment or randomization and will terminate treatment of all Trial Participants pursuant to the Protocol, except if the safety of such Trial Participants could be endangered or if the Institution and Investigator are otherwise instructed by Sponsor, that may be communicated via CRO. Following such termination, Institution and Investigator will continue to monitor Trial Participants and maintain clinical data as set forth in the Protocol and in accordance with ICH GCP.

14.6.2 Provision of Data and Medical Records. Institution and Investigator will *(i)* provide to Sponsor any and all data required pursuant to the terms of this Agreement and/or the Protocol, and *(ii)* provide Sponsor representatives access, both prior to and following final payment, to data and medical records for review and completion of necessary documentation and appropriate transfer or discontinuation of Trial Participants' participation in the Trial.

14.6.3. Reimbursement of Costs. Upon early termination for any reason, Institution and Investigator will use their best efforts to promptly limit or terminate any outstanding commitments and to conclude the work. Except as specifically set forth herein in regards to termination by Sponsor pursuant to Sections 11.3 and 14.3(iv), all costs incurred by Institution prior to such termination and authorized under the Protocol and Clinical Trial Budget will be reimbursable, including, without limitation, all non-reimbursable costs and non-cancelable commitments incurred in accordance with the Clinical Trial Budget prior to the receipt of the termination notice.

Notwithstanding the foregoing, if this Agreement is terminated by Sponsor pursuant to Section 14.3.(iv) as a result of a violation by Institution or Investigator of any applicable laws or regulations or ICH GCP Guidelines and such violation negatively affects the integrity of the Trial data and/or results generated by Institution, Institution will reimburse Sponsor any and all amounts paid (other non-cancelable expenses) by Sponsor and/or CRO to Institution under this Agreement within thirty (30) days following written request by Sponsor and/or CRO.

15. CONCLUDING PROVISIONS

15.1 **No Violation.** Institution and Investigator represent and warrant that the execution, delivery, and performance of this Agreement by such party do not *(i)* require the consent, waiver, approval, license, or authorization of any person or public authority which has not heretofore been obtained; *(ii)* violate any provision of law applicable to such party; *(iii)* conflict with or result in a default under any agreement or instrument; or *(iv)* violate any judicial or administrative decree, regulation, or any other restriction of any kind or character to which such party is a party or by which such party is bound.

15.2 **Conflict of Interest.** Institution and Investigator represent and warrant that neither Institution nor Investigator and/or any Trial Staff have any conflict of interest that would affect conduct of the Trial and that neither Institution nor Investigator have received any extra benefits from Sponsor or any of its Affiliates for participation in the Trial, including offers to family members. Institution and Investigator will promptly notify Sponsor in writing if any conflict of interest arises during the term of this Agreement.

15.3 **Assignment.** Neither Institution nor Investigator shall be entitled to assign, to sub-contract or otherwise transfer its rights and obligations under this Agreement in whole or in part to any third party without the prior written consent of Sponsor and CRO. Any such consent shall relieve neither Institution nor Investigator of its obligations hereunder. It is understood by the Parties that any right or obligation of Sponsor and/or CRO under this Agreement may be assigned to any of their Affiliates or a third party upon written notice to Institution, and that any right or obligation of Sponsor and/or CRO under this Agreement may be performed by any of its Affiliates or a third party. Any legal successor of Sponsor and/or CRO shall be deemed an Affiliate of Sponsor and/or CRO, as applicable, for the purpose of this Agreement.

15.4 **Entire Agreement.** This Agreement sets forth the entire agreement between the Parties and supersedes all previous agreements, written or oral, regarding the subject matter hereof. This Agreement may be amended only by an instrument in writing duly executed on behalf of the Parties.

15.5 **Conflict.** In case of inconsistencies between this Agreement and any Appendix hereof, the terms of this Agreement shall prevail unless agreed to explicitly that the Appendix should prevail. In the event there is a discrepancy between this Agreement and the Protocol, the Protocol will govern with respect to medical and scientific issues and the Trial conduct, and this Agreement will govern with respect to all other issues.

15.6 **Force Majeure.** If the performance by either Party of any of its obligations under this Agreement is delayed or prevented by circumstances beyond its reasonable control, that Party will not be in breach of this Agreement because of that delay in performance. However, such Party shall promptly give to the other Party written notice claiming force majeure and shall use its best efforts to eliminate the effect of such force majeure, insofar as is possible and with all reasonable dispatch. If the period of delay or failure should extend for more than three (3) months then the non-defaulting Party shall have the right to terminate this Agreement forthwith upon written notice at any time after expiration of said three (3) months period.

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15.7 **Waiver.** Any waiver shall be made in writing for it to be effective and unless expressly stated shall not be a continuing waiver nor shall it prevent the waiving Party from enforcing any term or condition of this Agreement not so waived.

15.8 **Severability.** The invalidity of any provision of this Agreement or any loophole in this Agreement shall not affect the validity of any other provision hereof. The Parties undertake to replace the invalid provision or close the loophole in the Agreement with another provision which reflects legally the originally intended commercial objectives of the Parties as closely as possible.

15.9 **Independent Contractors.** In the performance of this Agreement each party shall be an independent contractor, and therefore, no Party shall be entitled to any benefits applicable to any employees of the other Party. In particular, this agreement gives the Investigator no right of employment to the Sponsor or CRO. No Party is authorized to act as an agent for the other Party for any purpose, and no Party shall enter into any contract, warranty or representation as to any matter on behalf of the other Party.

15.10 **Survival.** The terms and conditions of the Sections titled Compliance; Safety Reporting; Overpayment, Final Accounting and Payment; Reporting of Payments; Trial Documents; Effects of Termination; Data Protection / Privacy; Confidentiality; Sponsor Intellectual Property; Publication, Publicity and Transparency; Monitoring, Audits, and Inspections; Indemnification; Insurance; and Financial Disclosure will survive termination or completion of this Agreement.

15.11 **Notice.** Any notice under this Agreement will be mailed (by certified or registered mail, postage prepaid, return receipt requested) or delivered by a reputable overnight courier service. Notices will be directed to the name and address set forth below: Either party may change its notice address by sending written notification to the other party clearly indicating the change.

If to Institution:

Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences
Address: Rae Bareli Road, Lucknow, UP – 226014, India
Attention: Prof. R.K. Dhiman (Director of SGPGIMS)

If to Investigator:

Name: Dr. Sudeep Kumar,
Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, UP – 226014, India
Office: +91 522 2495198
Fax: +91 522 2668017
Email: sudeepkum@yahoo.com

If to Sponsor:

Boehringer Ingelheim India Private Limited

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Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the Parties have executed this Agreement in 3 originals by their duly authorized representatives.

Covance India Pharmaceutical Services Pvt. Ltd.

DocuSigned by:
By: Dr. Shekhar Dawkhar
Name: Dr. Shekhar S Dawkhar
Title: Senior Director
Date: 6/21/2022

INSTITUTION

By:
Name: Prof. R.K. Dhiman
Title: Director
Date: 11/7/22

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

INVESTIGATOR:

By:

Name: Dr. Sudeep Kumar

Date: 27 June 2022

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Should any remote visits be done on site - the visit cost provided in the visit schedule will be reimbursed

Table 2: Payment Per Visit: Optional Visits

Visit Description	Payment INR
Screening done remotely (instead of on-site)	18,266.00
Visit 4 done remotely (instead of on-site)	9,930.00
Unscheduled visit	10,450.00
Randomised Treatment Period: 6 monthly visits; Visit 5 onwards	10,450.00

For each Evaluable Patient, payment will be made according to actual visits performed and the evaluable data produced and entered correctly in the eCRF.

It is understood and agreed that no payment will be made by Covance for any visits performed after screening in relation to any Trial Participant who does not conform to the Protocol's inclusion and exclusion criteria or in relation to whom serious deviations from the Protocol have been made.

2. Conditional Procedures

Table 3: Conditional Procedures

Description	Detail (Maximum per Trial Participant)	Cost Per Procedure INR	Total Cost per Trial Participant (INR)
Re-consent (due to protocol amendment)	All will be reimbursed	1,224.00	1,224.00
SAE	All will be reimbursed	2,792.00	2,792.00
Shipment of IMP, if Trial Participant cannot attend an on-site visit	actual cost upon invoice will be reimbursed	NA	NA
Urine pregnancy test	2	1,020.00	2,040.00
Dispense Trial medication visits at follow-up: If the trial is prolonged additional medication kits can be assigned	1	1,038.00	1,038.00

(a) Patient Travel Costs

Patient travel expenses and associated other reasonable out of pocket expenses (e.g. parking) will be paid to a maximum of 500 INR per visit per Trial Participant upon Covance's receipt of an invoice detailing **actual** amounts from Institution, which shall be supported by appropriate documentation. Higher expenses exceeding 500 INR per visit can only be reimbursed prior written approval from Covance is obtained.

Reimbursement payments under this section 2 (a) are payable quarterly upon receipt of an invoice detailing actual amounts reimbursed by Institution to each patient in the preceding quarter. All payments are subject to verification.

पश्चिमबङ्गा पश्चिम बंगाल WEST BENGAL AG 794091

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("Agreement") is made as of _____ (the "Effective Date") by and among

1. **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014**, hereafter referred to as **Institution**.

   And

2. **Dr.Ujjala Ghoshal**, Professor and HOD, Department of Microbiology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014, India , hereafter referred to as **Principal Investigator (PI)**

   And

3. **Medclin Research Pvt. Ltd.** Having its registered office at Acropolis, unit 10/5, 10th floor 1858/1, Rajdanga Main Road, Kol-107, hereafter referred to as **Clinical Research Organization (CRO)**

Ughoshal

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SGPGIMS,Lucknow

WHEREAS,

Sponsor (Alkem Laboratories, Alkem House, Senapati Bapat Marg,Lower Parel, Mumbai – 400013) based on the representation and warranties given by the CRO, desires to engage CRO on non-exclusive basis to initiate study of "In vitro susceptibility of Ceftriaxone or Ceftriaxone combination with Sulbactam & Tazobactam in community acquired and nosocomial infections against gram-negative and gram -positive bacteria." (Hereinafter referred to as the "Study")

a. The CRO has approached the Institution and Principal Investigator to perform the study in accordance with the corresponding Protocol, and all applicable rules and regulations. The Institution and PI agree to conduct the study in accordance with the same.

b. The Institution is equipped to undertake the Study and the Institution, CRO and Principal Investigator have agreed to perform the Study according to the terms and conditions hereinafter set forth.

1. REPRESENTATIONS AND WARRANTEES:

a. Each party represents and warrants to and covenants with the other that:

i. It has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this agreement; wherever applicable,

ii. It has the corporate power and authority to enter into and perform its obligations under this Agreement, whenever applicable,

iii. This Agreement has been duly authorized, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

iv. Neither the execution and delivery of this Agreement by either party, nor the performance by such party of its obligations here under nor compliance by such party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any indenture, mortgage, lease, agreement, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such party;

b. Institution represents that

i. It is entitled to procure the services of Principal investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.

ii. The Institution shall notify Medclin if the Principal Investigator ceases to be employed by or associated with the Institution and shall use its best endeavors to find a replacement acceptable to both The Sponsor and CRO. In order to ensure high standard of clinical trials, if no mutually acceptable replacement can be found, The CRO may terminate this agreement pursuant to clause 19(c).

c. Principal Investigator represents:

i. A competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub investigators and research staff and the Institution.

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vii. The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India, and agrees to immediately inform The Sponsor/CRO if such cases arise.

viii. The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with the Protocol and all other terms of this Agreement; Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs; Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP; All applicable laws and regulations.

b. Principal Investigator:

i. Will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub investigators or research staff. The duties and responsibilities delegated will be only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.

ii. Will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is accountable for the compliance of Investigators to the terms of this Agreement.

iii. Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from Sponsor and CRO.

iv. Will comply with the policies and procedures of the organization / institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify CRO promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

v. Shall be responsible for obtaining and maintaining all approvals from the relevant local research ethics committee/other Authorities for the conduct of the Clinical Trial keeping The CRO fully apprised of the progress of ethics committee submissions. The written evidence of review shall be provided prior to initiation. All other communications, upon request be made available to Medclin. Investigator will notify The CRO and the responsible Institutional Review Board as soon as possible. The Protocol may be modified only by a written amendment ("Protocol Amendment"), signed by Sponsor and the Principal Investigator. If applicable, the Parties acknowledge that Protocol Amendments are also subject to approval by the responsible Independent or Institutional Ethics Committee ("IEC") and/or Regulatory Authority ("RA").

vi. The PI and Institution will provide for (i) access to the research subject's medical records by Sponsor/CRO and other appropriate regulatory agencies and (ii) the facilities where the Study is being conducted (iii) Raw data (iv) the use of Study data by Sponsor/CRO for any purpose that it deems appropriate provided that the research subject's personal identifying information has been removed. In the event of a conflict between terms of the Protocol and this Agreement, the terms of this Agreement shall govern (v) any other relevant information necessary for Sponsor, other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations.

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iv. Any income tax, withholding tax or similar taxes deductible from the payment will be deducted by CRO.

4. NO ADDITIONAL RESEARCH: The Institution & Principal Investigator ensures that no additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol.

5. ETHICS COMMITTEE ("EC"): Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct

6. STUDY APPROVAL: If, through no fault of Investigator, the Study is disapproved by EC, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 18(a).

7. DATA PROTECTION: The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of data. The Sponsor / CRO will take appropriate measures to protect the confidentiality and security of all data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any other requirements. Such data may be disclosed or transferred to other members of sponsor team, to representatives and contractors working on behalf of The Sponsor.

8. CONFIDENTIAL INFORMATION: During the course of the Study, Investigator may receive or generate information that is confidential to The Sponsor. Any information marked by The Sponsor as confidential and provided to the investigator before the execution of this agreement will also be treated as confidential information

9. OBLIGATIONS OF CONFIDENTIALITY: Unless the Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the EC or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 16, Publications, of this Agreement.

9.1 Disclosure Required by Law: If disclosure of Confidential Information to any party other than the EC is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator:

a) Notifies the sponsor in writing in 15 working days advance of the disclosure so as to allow The Sponsor to take legal action to protect its Confidential Information,

b) Discloses only that Confidential Information required to comply with the legal requirement, and

c) Continues to maintain the confidentiality of this Confidential Information with respect to all other parties.

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study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify the Sponsor and CRO before destroying any Study data after the required retention period. Investigator further agrees to permit The Sponsor to ensure that the records are retained for a longer period, if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

12. MONITORING AND AUDITS:

12.1 Monitoring and Audits: The Sponsor / CRO shall be entitled at its absolute discretion (and in such form as the Sponsor / CRO sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit The Sponsor's / CRO's representatives' access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by Sponsor / CRO will relieve the Investigator of any of its obligations hereunder.

a) **Cooperation.** Investigator will cooperate with the Sponsor / CRO in the conduct of audits and will ensure that Study Records are maintained in a way that facilitates such activities.

b) **Resolution of Discrepancies.** Investigator will promptly resolve any discrepancies that are identified within the study data.

c) **Study Conduct Evaluations.** The Sponsor / CRO may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor / CRO or its representative will use these evaluations solely for internal purposes

13. INVENTIONS:

13.1 Notification. If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the Sponsor and CRO.

13.2 Assignment. Investigator will assign all interest in any such Invention to the Sponsor, or its representative free of any obligation or consideration beyond that provided for in this Agreement.

13.3 Assistance. Investigator will provide reasonable assistance to the Sponsor or its representative in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

14. PUBLICATIONS: The findings of this study may be published in a scientific journal or presented at a scientific meeting with prior permission from Sponsor and CRO. The Sponsor reserves the right to review all manuscripts prior to submission for publication or any paper before it is presented. In accordance with standard editorial and ethical practice, the Sponsor will generally support publication of multicentric trials only in their entirety and not as individual center data. Authorship will be determined by mutual agreement between The Sponsor in conjunction with the CRO and the Principal investigator(s).

15. DEBARMENT AND EXCLUSION: Investigators certify that s/he is not debarred and that s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and after its termination, Investigator will notify the Sponsor/CRO promptly if either of these certifications needs to be amended in light of new information.

16. USE OF NAME: Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify The PI and Investigator in association with a listing of the Protocol

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h) **Return of Materials**. Unless The Sponsor / CRO instructs otherwise in writing, Investigator will promptly return all materials supplied by The Sponsor / CRO for Study conduct, other study related material and any The Sponsor / CRO - supplied Equipment.

i) **Survival of Obligations**. Obligations relating to Funding, Confidential Information, Study data, Inventions, Publications, Indemnification, and Debarment and Exclusion survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

19. FORCE MAJEURE: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, and flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance causes a delay or failure in performance ('a Delay') and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator / Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to Sponsor / CRO. Sponsor / CRO shall have the right to terminate an agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

20. NOTICE: Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to Institution:
Name: Prof. R.K.Dhiman (Director, SGPGIMS, Lucknow)
Phone: 05222494001/2/3
OR
If to Principal Investigator:
Name: Dr. Ujjala Ghoshal
Phone: 7706997492

OR
If to CRO:
Dr Monjori Mitra (Research Director, Medelin Research Pvt. Ltd);
Phone: +91 9831075734

21. ENTIRE AGREEMENT: This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements (If any) between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.
To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial will be retained for a period as per required Regulations after the completion/termination of the study whichever is later. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform The Sponsor, the Parties shall discuss in good faith in order to find an alternative solution for the proper archiving of these elements in. Subjects' files should be retained as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of The Sponsor.

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Executed by the parties
INSTITUTION, PRINCIPAL INVESTIGATOR and the CONTRACT RESEARCH ORGANIZATION.

The Institution: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow**	**The Principal Investigator**	**CRO** **Medclin Research Pvt. Ltd., Kolkata**
Signature: Prof. R.K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA	Signature: Ujjala Ghoshal	Signature: Monjori Mitra
Name: Prof. R.K. Dhiman	Name: Dr. Ujjala Ghoshal	Name: Dr. Monjori Mitra
Designation: Director	Designation: Principal Investigator	Designation: Research Director
Date:	Date: 8/9/2022	Date: 13/07/2022.
Stamp:	Stamp: Dr. Ujjala Ghoshal Professor & Head Dept. of Microbiology SGPGIMS., Lucknow-14.	Stamp: MEDCLIN RESEARCH PVT. LTD.

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Executive Registrar
SGPGIMS,Lucknow

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Government of Karnataka

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Description	:	AGREEMENT
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CLINICAL REGISTRY AGREEMENT

Please write or type below this line

THIS AGREEMENT IS MADE ON THE 07 Apr 2021 AT Bangalore.

BY AND BETWEEN

Dr. Rajiv Parakh, Chairman having his office at Division of Peripheral Vascular & Endovascular Sciences, Medanta- The Medicity, Sec-38, Gurgaon, Haryana - 122001, India (hereinafter referred to as "NATIONAL INVESTIGATOR", which term shall also include his heirs, representatives, successors, permitted assigns) of the One Part;

National Investigator

BioQuest Solutions Pvt. Ltd. Bangalore

Principal Investigator

Head of Institution

Dr. RAJIV PARAKH, M.S., M.Ch. Chairman, Division of Peripheral Vascular & Endovascular Surgery Medanta - The Medicity Sec-38, Gurugram Haryana, India

Lt Col Varun Bajpai VSM Executive Registrar SGPGIMS,Lucknow

AND

BIOQUEST SOLUTIONS PRIVATE LIMITED, a company registered under the Companies Act, 1956, having its registered office at #24, wellington street, Richmond town, Bangalore - 560 025 (hereinafter referred to as **"BIOQUEST"**, which term shall also include its successors or permitted assigns) of the **Second Part**

AND

Dr. Raghunandan Prasad, Associate Professor, Department of Radiodiagnosis, Sanjay Gandhi Postgraduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India. (hereinafter referred to as the **'Principal Investigator'** which expression shall wherever the context so requires mean and include his legal heirs, administrators, executors, representatives, successors and permitted assigns) of the Third Part

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India. (hereinafter referred to as **'Participating Institution'** which expression shall wherever the context so requires mean and include its doctors, their respective legal heirs, administrators, executors, representatives, successors and permitted assigns) of the Third Part

National Investigator, BioQuest, Participating Institution and Principal Investigator are referred to individually as a "**Party**" and collectively as the "**Parties**".

WHEREAS:

1. The National Investigator has engaged BioQuest for conducting observational registry titled "A Prospective, Multicentric, Non-Interventional, Real-World, Data Collection Registry to Evaluate the Effectiveness, Safety and Durability of SUPERA Stent for the Treatment of De Novo or Restenotic Superficial Femoral Artery or Complex Femoropopliteal Artery Lesions in Indian patients" through its separate agreement dated 13th Feb 2020 between National Investigator and BioQuest.

2. The Participating Institution and Principal Investigator have the qualified personnel and the facilities equipped according to Good Clinical Practices (GCP) to undertake the registry (defined herein below);

3. **NOW THEREFORE**, it is agreed as follows between the Parties hereto:

1 **DEFINITIONS** In this agreement, unless the context otherwise requires, the following words shall have the meanings ascribed to them in this Clause.

1.1 "**Agreement**" means this Agreement, including its appendix, if any and all amendments and modifications thereto made in accordance with the provisions hereof or which are incorporated herein expressly by reference.

1.2 "**Force Majeure**" means labour disturbances, riots, war, unexpected weather conditions for the time and location of the Services, or any other cause beyond the reasonable control of the affected Party which by exercise of reasonable diligence could not have been prevented or provided against, except financial distress.

1.3 Site/Registry Site means the participating institutions that take part in the registry.

1.4 In this Agreement, unless the context otherwise requires, the singular includes the plural and vice versa, references to persons includes corporations, words importing the

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

Dr. RAJIV PARAKH, M.S., FRCS
Chairman, Division of Peripheral Vascular & Endovascular Surgery
Medanta - The Medicity

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Executive Registrar
SGPGIMS,Lucknow

masculine gender include the feminine and neuter gender and vice versa and a month means a calendar month.

1.5 Headings to clauses, sub-clauses and schedules are for convenience only and shall not be used in the construction or interpretation of this Agreement.

1.6 National Investigator means the Sponsor Investigator who is receiving the grant for conducting the registry. In this registry, it is **Dr. Rajiv Parakh**

2 **REGISTRY, SCOPE, ROLES AND RESPONSBILITIES OF PARTIES:**

The registry shall be conducted, under the direction of the Principal Investigator, in the treatment of patients in accordance with this Agreement and the protocol identified as Protocol No. **iSUPREME/01/2019**, titled "A Prospective, Multicentric, Non-Interventional, Real-World, Data Collection Registry to Evaluate the Effectiveness, Safety and Durability of SUPERA Stent for the Treatment of De Novo or Restenotic Superficial Femoral Artery or Complex Femoropopliteal Artery Lesions in Indian patients". The Registry will be monitored on behalf of the National Investigator by BioQuest. The roles and responsibilities of National Investigator, BioQuest and Principal Investigator are described below.

2.1 **Responsibilities of National Investigator**

- Approval of Essential documents (Protocol, CRF and ICF)
- To provide support in case of any comments from Ethical committee
- Review and approve all registry related documents (clinical registry report and article for publication)

2.2 **Responsibilities of BIOQUEST**

- To liaise with participating investigators and brief about the proposed registry
- To collect and prepare Ethics committee documents/ dossiers.
- Co-ordination with National Investigator and participating investigators for clarifying any registry related queries from Ethics committee
- To register registry in CTRI
- Making necessary amendments to Essential documents (protocol, CRF and ICF), if any
- Train designated registry site staff for this registry on eCRF portal and share usernames and passwords for accessing the portal
- Handling registry site queries
- Continually monitor registry progress and update all investigators periodically
- To perform registry site monitoring (source document verification)
- TO liaise with independent lab
- To close all registry sites and archive documents at site and centrally
- To perform data review and analysis
- To prepare Clinical registry report
- To develop manuscript and submit it to Publication
- To process payments to Ethics committee and Investigator as and when registry milestones are achieved

2.3 **Principal Investigator:**

- Review of Essential documents (protocol, CRF and ICF)
- Providing Ethics committee (EC) SOP for preparation of Dossier
- Submission of dossier to EC
- Be present in EC meeting if required
- Identify and consent patients for registry participation
- Data collection and entry into eCRF portal

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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- Clarify and help resolve all data related queries
- Maintain registry files at the registry site
- Support BioQuest and National investigator in all registry related activities
- Report all AEs/SAEs as per registry protocol to BioQuest and National investigator

3 **Activity**

3.1 **Adherence:** Participating Institution, Principal Investigator and their personnel shall render service under this Agreement in accordance with the protocol approved by the Institutional Review Board and according to Good Clinical Practice Standards. Participating Institution, Principal Investigator and their personnel shall comply with: (i) all applicable local, state and federal laws, regulations, and guidelines; (ii) good clinical practices; (iii) the applicable requirements of the concerned Regulatory Authorities ("Applicable Regulatory Authorities"); and the Institutional Review Board (or ethics board, as applicable) (for the purposes of this Agreement, the "IRB")

4 **Registry Details**

4.1 **Registry Initiation.** The Principal Investigator shall initiate the Registry at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

4.2 **Enrolment.** Principal investigator shall enroll the patients as described in the registry protocol.

4.3 **Registry Documents.** electronic case record forms (eCRF) to be used for this registry will be duly filled by the registry team within 3 working days after the registry patient's visit. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the National Investigator in the eCRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed/scanned/emailed to National Investigator and BioQuest within 24 hours of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized.

4.4 **Registry Completion.** The Participating Institution shall complete the enrollment of all the patients within the specified timeline given or informed by the National Investigator/ BioQuest. The Participating Institution shall input all final CRF data and complete the final eCRFs not later than five days after the last patient's last visit.

5 **Payment**

5.1 **Budget and Payment.** BioQuest shall pay the Participating Investigator in accordance with the Milestone set out in Annexure A - Budget and Payment Schedule hereto. On completion of each milestone the Participating Investigator shall raise an invoice on BioQuest which shall be cleared within 30 days of receipt of the same.

5.2 **Payment of Costs outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the National Investigator and/or BioQuest.

5.3 **Reimbursement.** BioQuest shall make payment in relation to the IEC/IRB approvals for conducting the Registry. BioQuest on receipt of any invoice from the Principal Investigator shall also forward the same to the National Investigator. All such approval costs and related expenses or invoices shall be communicated in writing by BioQuest to the National Investigator and the same shall be reimbursed by invoice, and in no event later than 30 days from the receipt of such intimation or invoice.

National Investigator	BioQuest Solutions	Principal Investigator	Head of Institution

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SGPGIMS,Lucknow

6 Principal Investigator & Institution's Obligations.

6.1 IRB/ Ethics Committee Approval. Principal Investigator shall obtain IRB approval for the registry protocol and associated submission documents. Principal Investigator shall send BioQuest, a copy of the written IRB approval when obtained, and any other relevant documents. Further, Principal Investigator shall promptly provide to BioQuest, a copy of any follow-up reports or submissions provided to the IRB. The Principal Investigator or the Participating Institution shall inform BioQuest before beginning the data collection activity if the Principal Investigator or the Participating Institution or the IRB determines that the activity is a significant risk activity. If the IRB withdraws approval at any time, the principal investigator shall within twenty-four (24) hours notify BioQuest and provide a written explanation of the circumstances leading to the withdrawal. In the event the IRB requires changes in the protocol, Principal Investigator shall immediately notify BioQuest, and provide a written explanation of the reasons for the changes. Any modifications to the protocol must be approved in advance by the National Investigator and BioQuest. Participating Institution and Principal Investigator shall not modify the protocol without the prior written approval of the National Investigator and BioQuest. Modifications to the protocol shall not be implemented by the Principal Investigator until receipt of any necessary IRB approvals.

6.2 Reports. Upon request of National Investigator and BioQuest, Principal Investigator shall cooperate with National Investigator and BioQuest in the preparation or review of any reports and to facilitate reporting to the regulatory body/bodies. In addition, Principal Investigator shall submit the progress reports and / or final report upon closure of the registry to IRB as per the standards of the IRB. The same report shall be submitted to National Investigator and BioQuest for the records purpose.

6.3 Meetings. Principal Investigator shall attend activity-related meetings, training sessions (including self-study training sessions), or conference calls (collectively the "Meetings") when requested by National Investigator and BioQuest.

6.4 Warranties and Covenants.
Participating Institution and Principal Investigator/s each warrant and covenant, on behalf of itself and its personnel, that: (a) it has not been found by the Applicable Regulatory Authorities and state regulatory or governmental officials, to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations; (b) it has not received an Applicable Regulatory Authorities warning or other regulatory letter; (c) it has not been terminated from any investigation or research project for reasons other than completion of the research project, and it and the IRB have not been disqualified by the Applicable Regulatory Authorities; and (d) it is not currently and has not been the subject of a proceeding by any Board of Medical Examiners or similar agency. Participating Institution and Principal Investigator each agree that if the foregoing warranties or covenants set forth in this Section should change, Participating Institution or Principal Investigator, shall notify National Investigator and BioQuest in writing within 7 (seven) business days of such change. If Principal Investigator or any individual, corporation, partnership or association providing services to the Participating Institution which directly or indirectly relate to the Participating Institution's activities pursuant to this Agreement becomes disqualified or receives notice of action or threat of action with respect to disqualification, in such an event the National Investigator and BioQuest shall have the right to terminate this Agreement with immediately effect.

7 Replacement of Principal Investigator

7.1 Replacement. If the Principal Investigator is unable to continue to serve as the Principal Investigator of the activity, or otherwise unable to fulfill his/her duties under this Agreement, he/she can notify by providing 15 days prior written notice to the IRB and National Investigator and BioQuest, the Principal Investigator shall also promptly

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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propose to appoint another appropriately qualified successor to assume the duties of Principal Investigator under this Agreement. National Investigator and BioQuest shall determine, whether the proposed replacement is acceptable. The appointment of a successor shall not relieve the preceding Principal Investigator of his duties under this Agreement. The new Principal Investigator shall provide a letter to the IRB, National Investigator and BioQuest accepting the appointment. By accepting such appointment, the new Principal Investigator shall assume the duties, representations and warranties of the Principal Investigator under this Agreement. If National Investigator BioQuest and Participating Institution are unable to promptly agree on an acceptable successor, this Agreement may be terminated at either National Investigator and/or BioQuest's discretion.

7.2 **Records.** Principal Investigator and Participating Institution shall promptly contact National Investigator and BioQuest in writing if the Principal Investigator leaves or will be leaving the Participating Institution, so that National Investigator and BioQuest can determine, whether the activity and the records relating thereto can be transferred to another party affiliated with Participating Institution or the departing Principal Investigator.

8 **Records and Access**

8.1 **Records».** Principal Investigator/s and Participating Institution shall maintain the following records relating to the activity: (i) all correspondence with the IRB, National Investigator, BioQuest, the Applicable Regulatory Authorities, or another investigator involved in the activity, including required reports; (ii) the protocol with documents showing the dates of and reasons for each deviation from the protocol; and (iii) other records that the Applicable Regulatory Authorities require to be maintained regarding the activity. Principal Investigator shall maintain such records during the activity and for a period of three (3) years after the termination or completion of the activity, whichever is later.

8.2 **Access.** Principal Investigator and Participating Institution each agree to permit National Investigator and BioQuest, its designated representatives, or appropriate representatives of regulatory agencies, at reasonable times and in a reasonable manner, to inspect facilities and to make all documents (including electronic records) available for review, comparison and/or copying if requested. Participating Institution and Principal Investigator shall notify National Investigator and BioQuest immediately by telephone (with a follow-up by mail) upon, but not later than twenty-four (24) hours after, learning that an Applicable Regulatory Authorities or other regulatory agency inspection is scheduled to take place, or, if there is no prior notice by the Applicable Regulatory Authorities or other regulatory agency, that an inspection has commenced Participating Institution and Principal Investigator shall make all reasonable efforts to coordinate any scheduling of Applicable Regulatory Authorities or other regulatory agency inspections to permit National Investigator and BioQuest and its representatives to attend such inspections.

9 **National Investigator and BioQuest Property.**

National Investigator and BioQuest shall provide the documents necessary for carrying out the activity to the Principal Investigator and Participating Institution at no charge. Participating Institution shall keep all such details and documents in a locked, secured area at all times (provided that all software, if any, may be loaded onto computers with appropriate physical and technical security restrictions) and shall maintain accurate records showing the disposition and return of any document. The documents and other property provided by or on behalf of National Investigator and BioQuest to the Participating Institution or Investigators in connection with this Agreement shall be and remain the exclusive property of the National Investigator and BioQuest. Participating Institution and Investigators shall use documents and other property only for the purposes of this Agreement and shall not use and/or mis-use the documents

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

BioQuest Solutions Pvt. Ltd. Bangalore

Dr. RAJIV PARAKH, M.S. FRCS
Chairman, Division of Peripheral Vascular & Endovascular Surgery
Medanta - The Medicity
Sector-38, Gurugram Haryana, India

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

unless authorized in writing to do so by National Investigator and BioQuest. Should any document be damaged or explanted for any reason, Participating Institution and Investigators shall promptly return such documents or information to National Investigator and BioQuest or, at National Investigator and BioQuest's direction, send it to a third party for analysis.

10 **Indemnification.**

10.1 **Indemnification by BioQuest.**
BioQuest here by agrees to indemnify, defend and hold harmless, Participating Institution and Investigators (the "Institution Indemnitees") from and against any and all liability, claims, causes of action, lawsuits, losses, damages, costs, and expenses, including reasonable attorneys' fees and court costs, and other losses (collectively "Claims") asserted by any individual or entity or incurred by any Institution Indemnitee directly resulting from or arising out of the performance of the activity in accordance with the protocol; provided that BioQuest shall not be responsible for any Claims that are the result of: (1) the gross negligence or intentional misconduct of any of the Institution Indemnitees otherwise entitled to such indemnification; (2) except as otherwise specifically provided below, Institution Indemnitees activities under this Agreement conducted contrary to the provisions of this Agreement or the protocol, or outside the scope of the protocol; (3) actions by any Institution Indemnitees in violation of applicable laws or regulations; or (4) unauthorized warranties by any Institution Indemnitees relating to the activity.

10.2 **Indemnification by Participating Institution and Principal Investigator/s.** Participating Institution and Principal Investigator/s hereby agree to indemnify, defend and hold harmless, National Investigator and BioQuest, and as applicable, its respective shareholders, directors, officers, employees, contractors, agents and representatives who are in any manner connected with the Activity (collectively, the "National Investigator and BioQuest Indemnitees") from and against any and all Claims asserted by any individual or entity or incurred by any National Investigator and BioQuest Indemnitees directly resulting from or arising out of the negligence or willful misconduct of Participating Institution or Principal Investigator; provided that Participating Institution and Principal Investigator/s shall not be responsible for any Claims that are the result of: (1) the gross negligence or intentional misconduct of any of the National Investigator and BioQuest Indemnitees otherwise entitled to such indemnification; (2) except as otherwise specifically provided below, National Investigator and BioQuest Indemnitees activities under this Agreement conducted contrary to the provisions of this Agreement or the protocol, or outside the scope of the protocol; (3) actions by any National Investigator and BioQuest Indemnitees in violation of applicable laws or regulations; or (4) unauthorized warranties by any National Investigator and BioQuest Indemnitees relating to the activities.

10.3 In no event will either party be liable for any incidental, special, punitive, exemplary, or consequential damages arising out of or in connection with this Agreement or otherwise, including without limitation, liability for lost profits, business interruption, or loss of business, arising from any cause of action whatsoever, including contract, warranty, tort, or strict liability, even if a party has been notified of the possibility of such damages." The Indemnity or Liability damages payable by either party under this Agreement shall in no event exceed the total value of this agreement.

10.4 The provisions of this Section shall survive the expiration or termination of this Agreement with respect to any loss, damage, injury, or loss of life that occurred during the term of this Agreement.

10.5 **Claim of Indemnification».** The Party claiming a right of indemnification or defense under this Agreement shall provide the indemnifying Party prompt notice (in all events within fifteen (15) days) of any such claim, including a copy thereof, served upon it,

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

BioQuest Solutions Pvt. Ltd. Bangalore

Dr. RAJIV PARAKH, M S, FRCS
Chairman, Division of Peripheral Vascular & Endovascular Surgery
Medanta - The Medicity
Sector-38, Gurugram Haryana, India

Dr. Raghunandan
Associate Professor
Dept. of C

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

and shall cooperate fully with the indemnifying Party and its legal representatives in the investigation of any matter regarding the subject of indemnification, at the Indemnifying Party's expense. The indemnifying Party shall have the right to exercise sole control over the defense and settlement of any such complaint or claims for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; provided that the indemnifying Party shall not enter into any non-monetary settlement or admit fault or liability on the indemnified Party's behalf without the prior written consent of the indemnified Party, which consent shall not be unreasonably withheld or delayed. In the event a claim or action is or may be asserted, the indemnified Party shall have the right to select and to obtain representation by separate legal counsel. If the indemnified Party exercises such right, all costs, expenses and risks incurred by the indemnified Party for such separate legal counsel shall be borne by the indemnified Party unless the indemnifying Party is adjudicated liable by a court of competent jurisdiction for such injury or death, in which case the indemnifying Party shall be responsible for such indemnified Party's separate legal counsel's costs and expenses.

10.6 National Investigator/ BioQuest shall in addition has subscribed to a clinical trial insurance policy which covers all the registry subjects for bodily injury resulting or alleged to have resulted from the registry, subject to the terms and conditions of the insurance policy.

11 Term and Termination

11.1 **Term.** The term of this Agreement shall commence on the Effective Date and shall continue until all responsibilities of the Parties as described in this Agreement and the protocol have been completed, unless earlier terminated as set forth herein.

11.2 **Termination.** National Investigator and/or BioQuest may temporarily halt or terminate the activity at any time, with or without cause. National Investigator and BioQuest may terminate this Agreement if the Principal Investigator does not meet minimal requirements set forth in the protocol. If National Investigator and BioQuest discovers that Principal Investigator or Participating Institution is not complying with this Agreement, the protocol, or any applicable law or regulation, National Investigator and/or BioQuest may, at its sole discretion: (i) immediately terminate the Principal Investigator's participation in the Activity; or (ii) take other corrective actions as National Investigator and / or BioQuest determines appropriate.

11.3 **Effect of Termination.** Upon termination, the Parties shall notify the IRB that the activity has been terminated, immediately stop and cease conducting procedures in connection with the activity. Principal Investigator and Participating Institution shall return to National Investigator and/or BioQuest any materials and Confidential Information provided for the conduct of the activity. In the event of termination of this Agreement prior to completion of the activity, the Participating Institution, Primary Investigator shall make all reasonable efforts to minimize further costs. National Investigator shall reimburse Principal Investigator for any work performed by Principal Investigator prior to termination and all required follow-up testing.

BioQuest Solutions Pvt. Ltd. Bangalore

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

Dr. Raghunandan Prasad, I.D
Associate Professor
Deptt. of Radiotherapy
SGPGIMS, Lucknow (India)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

12 **Ownership.**

12.1 **Pre-existing Intellectual Property».** Ownership of inventions, technologies, know-how, ideas, processes, techniques, algorithms, programs, discoveries, improvements, devices, biologics, products, concepts, designs, prototypes, samples, models, technical information, materials, drawings, specifications and other works of authorship existing as of the Effective Date hereof, and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "Pre-existing Intellectual Property"), is not affected by this Agreement, and no Party shall have any claims to or rights in any Pre-existing Intellectual Property of any other Party, except as may be otherwise expressly provided in any other written agreement between two or more Parties.

12.2 **Research Results».** The National Investigator shall solely own all right, title and interest in and to any and all information, data or other materials delivered to the Participating Institution or the Principal Investigator by or on behalf of the National Investigator as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Registry, including, without limitation, the Registry Records, data entered in eCRF, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the National Investigator. Accordingly, the National Investigator shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the regulatory agencies, if applicable. If Principal Investigator wants to publish his part, the prior written approval from National Investigator is required.

13 **Confidential Information.**

13.1 **Definition of Confidential Information.**
"Confidential Information" shall be the confidential and proprietary information of National Investigator and BioQuest, and shall mean: (a) the terms and conditions of this Agreement; (b) all information disclosed by or on behalf of National Investigator and BioQuest to Participating Institution, Principal Investigator, or their personnel, including without limitation, the Product, technical information relating to the Product, and all Pre-Existing Intellectual Property of National Investigator and BioQuest; (c) the protocol, information pertaining to the status of the activity, communications to and from the Applicable Regulatory Authorities, information relating to the documents regulatory status and correspondence to or from any clinical events committee or data safety monitoring board; (d) results; and (e) any activity-related information that was previously disclosed to any Party in contemplation of this Agreement or that was subject to a confidential disclosure agreement between two or more of the Parties. Confidential Information shall not include information that: (i) can be shown by documentation to have been public knowledge prior to or after disclosure to the Participating Institution, Principal Investigator, other than through acts or omissions attributable to Participating Institution, Principal Investigator or their personnel; (ii) can be shown by documentation to have been in the possession of Participating Institution, Principal Investigator or their personnel from sources other than National Investigator and BioQuest that did not have an obligation of confidentiality to National Investigator and BioQuest prior to disclosure; or (iii) can be shown by documentation to have been independently developed by Participating Institution, Principal Investigator or their personnel prior to disclosure.

13.2 **Obligations.** Participating Institution and Principal Investigator shall not, and shall require their respective personnel not to, use the Confidential Information for any purpose other than the performance of the activity or disclose the Confidential Information to any third party, except as otherwise expressly permitted by this Agreement or as otherwise required by law or authorized in writing by National Investigator and BioQuest. To protect Confidential Information, Participating

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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Institution, Principal Investigator agree to: (a) limit dissemination of Confidential Information to only those personnel having a "need to know"; (b) advise all personnel who receive Confidential Information of the confidential nature of such information; (c) have appropriate agreements with such personnel sufficient to enable them to comply with the confidentiality and nondisclosure obligations contained herein; and (d) use reasonable measures to protect the information from disclosure.

13.3 Compelled Disclosure. In the event that Participating Institution, Principal Investigator receive notice of a third party seeking to compel disclosure of any Confidential Information, they shall provide National Investigator and BioQuest with prompt notice so that National Investigator and BioQuest may assist Participating Institution, Principal Investigator in seeking a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, Participating Institution, Principal Investigator shall furnish only that portion of the Confidential Information which it is advised by its counsel, in consultation with National Investigator and BioQuest, is legally required to be disclosed, and shall exercise its best efforts to obtain reliable assurance that confidential treatment shall be afforded the Confidential Information.

14 Governing Law and Arbitration

14.1 This Agreement shall be governed by and construed in accordance with the laws of - India

14.2 Arbitration. Any dispute, controversy or claim arising out of or relating to this Deed, or breach, termination or invalidity thereof, shall be referred to binding arbitration in accordance with the country's Arbitration and Conciliation Act, / or equivalent as at present in force, and/or any amendments thereto, from time to time. Parties shall attempt to nominate a sole arbitrator failing which each shall appoint an arbitrator of its choice and the two arbitrators shall appoint the third arbitrator. The place of arbitration shall be Lucknow, India. The proceedings shall be in English language.

14.3 The courts of Lucknow shall have the Jurisdiction to try these cases.

15 Entire Agreement

This Agreement constitutes the entire agreement between the parties concerning the subject matter and this Agreement may only be modified or amended in writing and signed by all parties.

16 Non-Assignment

Principal Investigator shall not assign rights or duties under this Agreement without the prior written approval of National Investigator and BioQuest. The terms of this Agreement shall be binding upon and inure to the benefit of the Parties hereto and their successors and permitted assigns. Any attempted pledge, transfer, sublicense, or transfer in violation of this paragraph shall be void and of no force or effect.

17 Notices

Any notices under this Agreement shall be in writing and delivered to the Parties at the postal addresses set forth below, or to the postal address subsequently provided by a Party in accordance with this paragraph, by (a) first class certified mail, return receipt requested, with notice deemed given three (3) business days following the date of mailing; (b) a nationally-recognized overnight courier service, with notice deemed given on the date of receipt as indicated on the courier's receipt, or (c) by facsimile (with a follow-up by mail):

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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Executive Registrar
SGPGIMS,Lucknow

If to National Investigator	:	Dr. Rajiv Parakh, Chairman Division of Peripheral Vascular & Endovascular Sciences, Medanta- The Medicity, Sec-38, Gurgaon, Haryana - 122001, India
If to BioQuest	:	BIOQUEST Solutions Private Limited, #24, wellington street, Richmond Town, Bangalore - 560 025, India.
If to Participating Institution	:	Sanjay Gandhi Postgraduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India.
If to Principal Investigator	:	Dr. Raghunandan Prasad, Associate Professor, Department of Radiodiagnosis, Sanjay Gandhi Postgraduate Institute of Medical Sciences, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh 226014, India.

18 **Third Party Beneficiaries**
Nothing in this Agreement, whether expressed or implied, is intended to confer any rights or remedies under or by reason of this Agreement on any persons other than the Parties to this Agreement and to their respective successors and assigns.

19 **Independent Contractors**
The Parties agree that the relationship between National Investigator, BioQuest, the Participating Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor the Participating Institution may create or assume any obligation on National Investigator and/or BioQuest's behalf.

20 **Use of Name or Marks**
Neither Party shall have the right to use the name, symbols, trademarks or service marks of the other Party in advertising or promotional materials or otherwise without receiving the prior written approval of such other Party.

21 **Severability**
If any provision of this Agreement is held invalid, illegal or unenforceable by a court of competent jurisdiction, the remainder of the Agreement shall be valid and enforceable and the Parties shall negotiate in good faith a valid and enforceable substitute provision which most nearly affects the Parties' intent in entering in this Agreement.

22 **Modification; Waiver**
This Agreement may not be altered, amended, or modified in any way except in a writing signed by the Parties. The failure of a Party to enforce any provision of this Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce that provision or any other provision or right.

23 **Multiple Counterparts.**
This Agreement may be executed in multiple counterparts, each of which shall be deemed to be an original and all of which taken together shall constitute a single instrument.

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

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Executive Registrar
SGPGIMS,Lucknow

24 **Changes to the Protocol.** If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between National Investigator and Participating Institution and the Principal Investigator. If such changes affect the cost of the Registry, PI/ Participating Institution will submit to National Investigator a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

25 **Safety and Reporting.**
The recording of adverse events (AEs) is an important aspect of the Registry documentation. It is the Principal Investigator's responsibility to document all AEs according to the guidelines of the Protocol.

By signing this Agreement, each Party confirms that it has read this Agreement and agrees to all responsibilities and requirements described by each document.

1. National Investigator

Name	Title	Signature	Date
Dr. Rajiv Parakh	National Investigator		13-08-2021

2. BioQuest Solutions Pvt. Ltd

Name	Title	Signature	Date
Hanumanthu Reddy	Group Head - BRS		07 Apr 21

3. Principal Investigator

Name	Title	Signature	Date
Dr. Raghunandan Prasad	Principal Investigator		

4. Participating Institution

Name	Title	Signature	Date

National Investigator | BioQuest Solutions | Principal Investigator | Head of Institution

12

Prof. R. KRISHNAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014 INDIA

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Executive Registrar
SGPGIMS,Lucknow

Annexure A: BUDGET AND PAYMENTS SCHEDULE

For each completed patient, PI will receive any amount of Rs. 10000. This amount will be paid as per the schedule detailed below. The fee is inclusive of institutional overheads, if any.

Set forth milestones will be considered for payment at the submission of an invoices on a quarterly basis to BioQuest and it will be processed after review and approval from National Investigator.

Milestone payments:

Milestone	Value (inclusive of TDS, if any)
Upon enrolment of a patient(s)	50%
Upon Completion of final FU visit	50%

All payment in the above Milestone Table shall be inclusive of institutional overheads, if any and any applicable taxes will be deducted as per applicable local tax laws. Whereas GST, 18% will be in additional to the above-mentioned investigator fees.

Any Fee charged by Ethics committee will be paid directly by BioQuest on behalf of National Investigator.

Payment Recipient and Mailing Address. All cheque shall be made payable to the entity / person mentioned here.

The mailing address for cheque shall be:

Address:

The further details for the payments should be provided as:

Payee Name (Account name)	Director, SGPGIMS, Research Account
Account Number	10095237491
Bank Name	State Bank of India
Branch Name	SGPGIMS, Lucknow
Branch Code	007789
IFSC Code	SBIN0007789
PAN Number*	AAAJS3913N

The Amount paid under this Agreement shall be subject to statutory deduction of tax at source.

National Investigator

BioQuest Solutions

Principal Investigator

Head of Institution

Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014. INDIA

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Executive Registrar
SGPGIMS,Lucknow

தமிழ்நாடு तमिलनाडु TAMIL NADU

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10/10/23

CMC
VELLORE

C. EDWIN EZHILARAS
STAMP VENDOR
License No. 23/VLR/20
Vellore - 632 001.

MEMORANDUM OF AGREEMENT -- HYPORT ADJUVANT

This MEMORANDUM OF AGREEMENT is made on this 20th May Two thousand and twenty-three

BY AND BETWEEN Dr Selvamani B, Professor, Department of Radiation Oncology, Christian Medical College, hereinafter referred to as the 'CMC'

AND

Dr Sanjoy Chatterjee, Senior Consultant, Tata Medical Center, Kolkata, hereinafter referred to as 'TMC'.

AND

The Institution Tata Medical Center, situated at 14, MAR, Rajarhat, New Town, Kolkata-700160, hereinafter referred to as 'TMC'.

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the HYPORT Clinical Trial

TATA MEDICAL CENTER KOLKATA

NOW THE PARTIES HERE TO AGREE AS FOLLOWS: -

1. **ROLE OF TATA MEDICAL CENTER, KOLKATA**

To provide funds as support / unrestricted grant to the extent of Rs 20,000 per month from 01st June 2023 over a period of 2 years or might be less from the date of signature of MOU to CMCtowards data operator fee and others. This will be bank transfer in the Institution bank accountafter TMC receives a request for transfer every 3 months along with utilization certificate of previous three months.

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2. DURATION OF PROJECT

The duration of the project shall be 2 years from the date the MOU has been sanctioned. The duration of the project could be increased in case the recruitment has not been completed.

3. ROLE OF CHRISTIAN MEDICAL COLLEGE, VELLORE

To utilize the funding received from TMC towards the data operator fees and submit the utilization report signed by authorized signatory and finance head of institution.

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

1. Dr. Rajesh. B

2. Mrs. Vinolia Vincy. L
Secretary

Signed by Dr. Selvamani B

Professor and Head
Department of Radiation Oncology
Christian Medical College, Vellore

Dr. SELVAMANI B, MBBS, MD, DIp.NB..
Regn. No. 50921
Professor
Department of Radiation Oncology - Unit - III,
Christian Medical College
Vellore-632 004, Tamil Nadu, India.

Witnesses:

1.

2.

Signed by Dr. Sanjoy Chatterjee

Senior Consultant, Radiation Oncology
Tata Medical Center, Kolkata

Signed by Mr. Sanjeev Kumar Agarwal

Chief Financial Officer
Tata Medical Center, Kolkata

For TATA MEDICAL CENTER
Sanjeev Kumar Agarwal
Chief Financial Officer
27/12/23

Signed by Dr. P Arun

Director
Tata Medical Center, Kolkata

27/12/23

Dr. P. Arun
Director
Tata Medical Center
Kolkata

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Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA023279409025357
Certificate Issued Date	:	15-Apr-2021 05:23 PM
Account Reference	:	NONACC (FI)/ kacrsf08/ PADMANABHANAGAR3/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08754206840993117
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	SANJAY GANDHI POST GRADUATE INSTITUTE
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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DRB-3/RSG/02/42156/2017-18

IQVIA RDS INDIA PRIVATE LIMITED IN-KA023279409025357 RS. 100 15-APR-2021 05:23 PM

Please write or type below this line

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

AMENDMENT NUMBER ONE
TO CLINICAL TRIAL AGREEMENT

This Amendment One (this "**Amendment #1**") to the Clinical Trial Agreement (the "**Agreement**"), dated 07Apr2021 by and between **Sanjay Gandhi Post Graduate Institute of Medical Sciences**, with business address located at Raebareli Road, Lucknow- 226014, Uttar Pradesh, India. ("**Institution**"), and **IQVIA RDS (India) Private Limited,** having a place of business at Omega Embassy Tech Square Marathahalli- Sarjapur Outer Ring Road, Kadubeesanahalli Bangalore- KA- 560103, India ("**IQVIA**") and **Dr. Jayantee Kalita,** with business address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014, Uttar Pradesh, India. ("**Investigator**"), and is effective as of the date last signed below ("**Effective Date**"). All capitalized terms used but not otherwise defined herein shall have the meaning set forth in the Agreement.

WHEREAS, IQVIA, and Institution and Investigator entered into the Agreement, pursuant to which the Parties agreed that Institution would conduct the following clinical trial sponsored by Merck Healthcare KGaA for the conduct of the study with details below:

Protocol Number : MS200527_0082

Principal Investigator : Dr. Jayantee Kalita; and

Protocol Title : "A Phase III, Multicenter, Randomized, Parallel Group, Double Blind, Double Dummy, Active Controlled Study of Evobrutinib Compared with Teriflunomide, in Participants with Relapsing Multiple Sclerosis to Evaluate Efficacy and Safety"

WHEREAS, the parties wish to amend the Agreement due to the Protocol Amendment dated 09 December 2020 / Version 2.0 and effect the required budget changes;

NOW THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:

1. **Section D,** as found in Attachment A is hereby amended by deleting it in its entirety and replaced with the section below.

DOUBLE BLIND PERIOD

Visit	Cost/Unit (including Overhead) INR
Screening Visit	41414.75
Baseline Visit	47446.75
Week 2	18131.1
Week 4	22293.7
Week 6	18131.1
Week 8	18131.1
Week 10	18131.1
Week 12	35934.6
Week 14	18131.1
Week 16	18131.1
Week 18	18131.1

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Week 20	18131.1
Week 22	18131.1
Week 24	71007.95
Week 28	18131.1
Week 32	18131.1
Week 36	33757.1
Week 40	18131.1
Week 44	18131.1
Week 48	72515.3
Week 52	7963.8
Week 56	7963.8
Week 60	33757.1
Week 64	7963.8
Week 68	7963.8
Week 72	36523.5
Week 76	7963.8
Week 80	7963.8
Week 84	33757.1
Week 88	7963.8
Week 92	7963.8
Week 96/Early Discontinuation	73000.85
Total Cost Per Patient:	**800823.4**
Week 108*	36338.9
Safety Follow-up	34414.9
AEP**	749.45
Teriflunomide level**	3108.3
Telephone Visit	7963.8

* W108 is applicable only for a subset of participants who have disability progression between 72 and 96 weeks
** AEP and Teriflunomide level in case needed at early discontinuation

* W108 is applicable only for a subset of participants who have disability progression between 72 and 96 weeks
** AEP and Teriflunomide level in case needed at early discontinuation

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OLE PERIOD

Visit	Cost/Unit (including Overhead) INR
Week 2	18131.1
Week 4	18131.1
Week 6	18131.1
Week 8	18131.1
Week 10	18131.1
Week 12	18131.1
Week 14	18131.1
Week 16	18131.1
Week 18	18131.1
Week 20	18131.1
Week 22	18131.1
Week 24	67594.8
Week 28	18131.1
Week 32	18131.1
Week 36	33757.1
Week 40	18131.1
Week 44	18131.1
Week 48	67594.8
Week 52	7963.8
Week 56	7963.8
Week 60	18131.1
Week 64	7963.8
Week 68	7963.8
Week 72	34346
Week 76	7963.8
Week 80	7963.8
Week 84	18131.1
Week 88	7963.8
Week 92	7963.8
Week 96	69587.7
Week 100	7963.8
Week 104	7963.8
Week 108	30342
Week 112	7963.8
Week 116	7963.8
Week 120	34346
Week 124	7963.8

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Week 128	7963.8
Week 132	7963.8
Week 136	7963.8
Week 140	7963.8
Week 144/Early Discontinuation	69587.7
Total Cost Per Patient:	**866395.4**
AEP visit*	2448.55
Teriflunomide level	3108.3
Baseline visit after AEP	71219.2
Baseline visit for female participants not undergoing AEP	4124.9
Week 148 Safety Follow-up	34414.9
Telephone Visit	7963.8

* AEP visit is applicable only for male participants before to enter OLE. It is optional for female.

3. **Section J. Conditional Procedures**. In accordance with the changes outlined above, the Section titled- **Conditional Procedures** of the Budget & Payment Schedule is hereby amended as follows:

J. CONDITIONAL PROCEDURES (WITH INVOICE)

The following conditional procedure costs will be reimbursed on a pass-through basis upon receipt of invoice in the amount indicated in the table below (which includes overhead) and as verified by IQVIA conditional procedures occurred, and the site has completed relevant data entry. Subject number and procedure dates must be included on the invoice for payment to be issued.

Conditional Procedure	Cost/Unit (including Overhead) INR
Optional pharmacogenetics consent; DNA consent	850
Healthy volunteer dummy run MRI informed consent	850
Pregnant partner informed consent	850
Full physical examination: A comprehensive history; A comprehensive physical examination; one set of vital signs; weight	5,645

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Blood draw, phlebotomy, routine venipuncture for collection of specimen(s), simple for central laboratory (teriflunomide levels if applicable; serum pregnancy if applicable; tuberculosis test; ferritin and transferrin saturation; HIV, HBV and HCV testing; Evobrutinib concentration; Biochemistry; Hematology; Supplemental LFT; Hepatic Panel; Coagulation; Immunoglobulin levels; Novel liver function protein/genomic biomarkes); PD substudy samples if applicable : Includes preparation of specimen; Blood Sampling	1,337
Lab handling and/or shipping of specimen(s) to central laboratory, simple -	677
Urine pregnancy, gonadotropin chorionic (hCG) (BetahCG); qualitative (local lab) -	1,133
Tuberculosis test, cell mediated immunity antigen response measurement; enumeration of gamma interferon-producing T-cells in cell suspension (T-SPOT)(local lab)	2,144
Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis B virus (local lab); HCV RNA, quantification (local lab)	4,129
Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton)	49,099
Interpretation and Report; Magnetic resonance imaging, brain including brain stem (MRI); with contrast material(s) (eg, proton) -	8,291
Magnetic resonance imaging, brain including brain stem (MRI); without contrast material (eg, proton) - healthy volunteer dummy run	39,628
Copies of Diagnostic Films, Complex - Per Copy - for sharing MRI scans with central reviewer	2,053
Urine collection for local (urinalysis and urine pregnancy if applicable) and central laboratory (microscopis exam if applicable)	342
Lab handling and/or shipping of urine specimen(s) to central laboratory, simple -	455
Single 12-lead ECG: Includes tracing, interpretation and report -	1,901
Health resource utilization -	692
Columbia Suicide Severity Rating Scale, physician administered	1,982
Electronic Extended Disability Status Scale (EDSS); rater-administered -	6,252

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Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the parties hereto have caused this Amendment #1 to be executed by their duly authorized representatives as of the effective date first set forth above.

AKNOWLEDGED AND AGREED BY THE PARTIES BELOW

IQVIA RDS (INDIA) PRIVATE LIMITED

Signature: _____

Name (Print): Shweta Pradhan

Title: Director & Head, Site Management

Date: 28 | Apr | 2021

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES

Signature: _____ 27/5/21

Name (Print): Prof. R K Dhiman

Title: Director, SGPGIMS

Date: _____

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

INVESTIGATOR

Signature: Dr. Jayantee Kalita

Name (Print): Principal Investigator

Title: Professor

Date: 07 | may | 2021

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ 54AA 348725

Amendment #1
Clinical Study Agreement

This amendment dated 30 March 2023 to the Clinical Study Agreement (the "Amendment") is entered into by and between Sanjay Gandhi Postgraduate Institute of Medical Sciences, a clinical research site with its principal office and place of business at Raibareily Road, Lucknow - 226014, Uttar Pradesh, India (**"Institution"**), Dr. Jayantee Kalita, having an address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareily Road, Lucknow - 226014, Uttar Pradesh, India (**"Principal Investigator"**) and Medpace Clinical Research LLC, located at 5375, Medpace Way, Cincinnati, Ohio 45227 ("Medpace"), collectively, (the "Parties").

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WITNESSETH:

WHEREAS, the Parties entered into a Clinical Study Agreement as of 28 January 2021 (the "Agreement") pursuant to which Institution is conducting a Study based on Protocol No. VIB0551.P3.S1, entitled "A Randomized, Double-Blind, Multicenter, Placebo-Controlled Phase 3 Study With Open-Label Period To Evaluate The Efficacy And Safety Of Inebilizumab In Adults With Myasthenia Gravis", (the "Protocol"); and

WHEREAS, the Parties desire to amend the Agreement to amend the budget in Schedule A of the Agreement contained therein.

NOW THEREFORE, the Parties hereby agree as follows:

1. Schedule A of the Agreement shall be deleted in its entirety and replaced with the Schedule A appended to this Amendment.

2. All other provisions of the Agreement shall remain unchanged and in effect.

[SIGNATURE PAGE TO FOLLOW]

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(34)

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment by proper persons thereunto duly authorized

FOR MEDPACE, ON ITS OWN BEHALF AND AS PAYMENT AGENT OF SPONSOR

By: _____

Name: Taher Sadriwala

Title: Sr. Associate Director – Clinical Trial Management

Date: 01/Jun/2023

INSTITUTION

By: _____ 03/07/23

Name: _____

Title: Prof. R.K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA

Date: _____

Read and Acknowledged by:
Principal Investigator

By: _____

Name: Prof. Jayantee Kalita

Date: 16/Jun/2023

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

VIELA BIO

PROTOCOL ID: VIB0551.P3.S1

// DR JAYANTEE KALITA //

PROTOCOL VERSION 6.0

SITE: //4105//

SCHEDULE A VERSION: VERSION #2.0

COUNTRY: INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SCHEDULE A

A1 STUDY BUDGET

Medpace, as Sponsor's payment agent, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. All fees listed include overhead, taxes, and subject stipend or travel reimbursement, as applicable. VAT is not applicable because Medpace Clinical Research, LLC is a US-based corporation. Should any changes to VAT law occur during the term of this Agreement, the party legally responsible shall be liable for VAT. Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject (Including 25% IOH and 18% GST)

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit 2/Day 1.

1.1.1	*Randomized Control Period-AcHR-Ab+ Population*	*INR 670,107.00*
1.1.2	*Randomized Control Period-MuSK-Ab+ Population*	*INR 473,031.00*
1.1.3	*Open Label Period*	*INR 554,746.03*

A2 SETUP FEES & VISIT PAYMENTS

☒ Please check box if Payee must submit an invoice to Medpace prior to receiving payment. Payment will be made within forty-five (45) days of receipt of invoice.

A2.1 Setup Fees

2.1.1	*Administrative Fee*	*INR 40,000 + 18% GST*
2.1.2	*Pharmacy Start-Up Fee*	*INR 75,000 + 18% GST*

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation;
- IRB/EC approval; and
- Medpace's receipt of the fully executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

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Table 1 - Fees for Completed Clinical Visits for Randomized Control Period- ACHR-Ab+ Population

VISIT	VISIT FEE		25% IOH FEE		VISIT FEE INCLUDING 18% GST	
Visit 1/Screening	INR	30,797	INR	7,699	INR	45,476
Visit 2/Day 1	INR	64,262	INR	16,066	INR	94,786
Visit 3/Day 15	INR	43,778	INR	10,945	INR	64,573
Visit 4/Day 29	INR	34,622	INR	8,656	INR	51,067
Visit 5/Day 57	INR	28,622	INR	7,156	INR	42,217
Visit 6/Day 85	INR	34,784	INR	8,696	INR	51,306
Visit 7/Day 126	INR	27,476	INR	6,869	INR	40,527
Visit 8/Day 183	INR	59,010	INR	14,753	INR	87,040
Visit 9/Day 225	INR	27,950	INR	6,988	INR	41,226
Visit 10/Day 267	INR	34,671	INR	8,668	INR	51,140
Visit 11/Day 309	INR	27,476	INR	6,869	INR	40,527
Visit 12/Day 365	INR	40,862	INR	10,216	INR	60,271
TOTAL PER PATIENT	**INR**	**4,54,310**	**INR**	**1,13,578**	**INR**	**6,70,107**
Remote Visit due to COVID-19	INR	17,592	INR	4,398	INR	25,948

Table 2 - Fees for Completed Clinical Visits for Randomized Control Period- MuSK-Ab+ Population

VISIT	VISIT FEE		25% IOH		VISIT FEE INCLUDING 18% GST	
Visit 1/Screening	INR	30,797	INR	7,699.25	INR	45,425.58
Visit 2/Day 1	INR	64,262	INR	16,065.50	INR	94,786.45
Visit 3/Day 15	INR	43,778	INR	10,944.50	INR	64,572.55
Visit 4/Day 29	INR	34,622	INR	8,655.50	INR	51,067.45
Visit 5/Day 57	INR	28,622	INR	7,155.50	INR	42,217.45
Visit 6/Day 85	INR	34,784	INR	8,696.00	INR	51,306.40
Visit 7/Day 126	INR	27,476	INR	6,869.00	INR	40,527.10
Visit 9/Day 183	INR	56,358	INR	14,089.50	INR	83,128.05
TOTAL PER PATIENT	**INR**	**3,20,699**	**INR**	**80,175**	**INR**	**4,73,031**
Remote Visit due to COVID-19	INR	17,592	INR	4,398.00	INR	25,948.20

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

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Table 3- Fees for Correlated Clinical Visits for Open Label Period

VISIT	FEE	25% IOH	FEE INCLUDING 18% GST
Visit 1/OLE Day 1	INR 27,505.00	INR 6,876.25	INR 40,569.88
Visit 2/OLE Day 15	INR 33,784.00	INR 8,446.00	INR 49,831.40
Visit 3/OLE Day 92	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 4/OLE Day 183	INR 55,018.00	INR 13,754.50	INR 81,151.55
Visit 5/OLE Day 275	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 6/OLE Day 365	INR 36,810.00	INR 9,202.50	INR 54,294.75
Visit 7/OLE Day 456	INR 29,310.00	INR 7,327.50	INR 43,232.25
Visit 8/OLE Day 547	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 9/OLE Day 730	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 10/OLE Day 911	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 11/OLE Day 1093/ET	INR 33,013.00	INR 8,253.25	INR 48,694.18
TOTAL PER PATIENT	**INR 3,76,099.00**	**INR 94,024.75**	**INR 5,54,746.03**
Safety Follow up	INR 22,199.00	INR 5,549.75	INR 32,743.53

A2.3 Screen Failures

Table 4 - Screen Failures

VISIT OF FAILURE	COST	25% IOH	COST INCLUDING 18% GST
Visit 1/Screening	INR 30,797	INR 7,699.25	INR 45,425.58

Payment for a max of 10 screen failures will be made for whom Medpace has received all appropriate documentation of procedures/visits completed with the next scheduled payment owed to the Payee. Eligible screen failure payment will be based on the order (by date) of when the subject is consented. Payment for additional screen failures must be pre-approve by Medpace/Sponsor.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Medpace after:

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor.
- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A2.5 Archiving Fee — 350,000 plus 18% GST

Payable with final payment. The expectation is that the study site will be responsible to maintain study documents for 25 years after site closure unless notified by the sponsor.

The final payment shall be reconfirmed and paid as per the quotation submitted and on receipt of sponsor's approval.

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A2.6 Unscheduled Visit Due to Worsening MG Symptoms (Including 25% IOH) INR 21,118.00 +18% GST

Payable with final payment. An unscheduled visit should be performed if a patient complains of worsening MG symptoms and use of rescue therapy is being considered. This should be performed before the rescue therapy is initiated. This Unscheduled visit should follow the procedures as outlined in the protocol. If an Unscheduled Visit is performed for a different reason, then it is only necessary to perform those specific procedures. Unscheduled Visit must be entered into EDC prior to database lock and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit.

Total includes Adverse Events Assessment, Patient Daily Reimbursement, Study Coordinator Fee, and Physician's Fee. All other procedures should be invoiced at cost if completed

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Additional Procedures

Payment will be made for procedures listed below if required by the protocol and not considered as standard of care.

Table 5 - Unitized Procedures

FEES	COST	COST INCLUDING 18% GST
Optional B-cell Repertoire Profiling Substudy	INR 800	INR 944
Optional DNA Sample	INR 800	INR 944

A3.2 OLE - Day 1 Visit INR 70,848 + 18% GST, if applicable

Payable if the OLE - Day 1 visit occurs on a separate date from the Day 365 visit.

A3.3 Rescue Medication

Rescue Medications to be paid at actual cost upon receipt of invoice and supporting documentation, if not covered by a third party as standard of care and costs are reasonable and customary.

A3.4 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Medpace/Sponsor.

A3.5 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Medpace/Sponsor.

A4 MEDPACE RIGHTS

Medpace reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Medpace within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

A5 MEDPACE INVOICING

All payment inquiries and invoices submitted shall include the Protocol number and Principal Investigator name and be sent to the following:

Email: siteinvoices@medpace.com
Phone: 513-579-9911

Medpace Clinical Research, LLC
Attn: Clinical Operations Site Payments
5375 Medpace Way
Cincinnati, Ohio 45227

All invoices must be submitted to Medpace within ninety (90) days of occurrence or up to thirty (30) days after receipt of the final payment.

A6 PAYEE INFORMATION

All payments made by Medpace as set forth herein shall be payable solely to Payee at the address set forth below. Any such payments which are due to any other party performing services in connection with the Study shall be a matter solely between Payee and such party.

Table A - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name	Director SGPGIMS Research Scheme
Payee Mailing Address	Administrative Building, SGPGIMS, Raebareli Road, Lucknow
Contact Name	Dr. Jayantee Kalita
Email Address	jayanteek@yahoo.com
Bank	State Bank of India
Account №	10095237491
IBAN №	N/A
BIC Code/Swift Code	SBININBB500
IFSC Code (India)	SBIN0007789
Tax ID#**	AAAJS3913N

**Requested for Medpace Accounting tracking purposes only

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MUTUAL CONFIDENTIALITY AGREEMENT – Protocol no.: 64407564MMY3009 dated 28 April 2023 ("Effective date")

By and Between

1. **Johnson & Johnson Private Limited**, a company with CIN U33110MH1957PTC010928through its pharmaceutical division Janssen, having its corporate office at Arena Space, Behind Majas Bus Depot, Off J.V. Link Road, Jogeshwari (E) Mumbai 400060 (**"J&J"**), and

2. **Dr. Sanjeev** (**"Investigator"**), adult Indian, with professional registration no DLH20160000110KTK residing at Lucknow and presently engaged by Sanjay Gandhi Post Graduate Institute of Medical Sciences, 226014, as a Associate Professor, and

3. **Sanjay Gandhi Post Graduate Institute of Medical Sciences**("Institution"), a registered trust/foundation, operating from SGPGIMS, Raebareli Road Lucknow-226014, India

Referred to jointly as **"Parties"** and separately as **"Party"**.

Background - Each Party wishes to disclose to the other Parties, Confidential Information in relation to the Study to explore and evaluate the possibility and scope of collaboration and engagement in context of the Study (**"Study Purposes"**), but ensure that the other Parties maintains the confidentiality of its **Confidential Information**.

Now, therefore, in consideration of the premises and the mutual promises and covenants expressed herein, each Party agree as follows:

1. *(a) Confidential Information* shall mean all information (however recorded, preserved or disclosed) disclosed by a Party (hereinafter referred to as **"Disclosing Party"**) or its employees, officers, affiliates, representatives or advisers (together, its **"Representatives"**) to the other Party or Parties (hereinafter individually referred to as **"Receiving Party"** and jointly referred to as **"Receiving Parties"**) and such Receiving Party's Representatives in relation to the Study in any manner. Confidential Information shall include, but not be limited to, scientific, commercial, business, financial, technical data including, drawings, films, documents, analyses, compilations, studies, medical information related to medicinal products, dossiers, product know-how and the like, either orally or in written or electronic format or by demonstration or computer readable media otherwise, irrespective of it being marked or otherwise designated to show expressly or by necessary implication that it is proprietary to the Disclosing Party or that it is prepared by the Disclosing Party or that it belongs to the Disclosing Party, and such confidential information shall include developed intellectual property results and specifications and contents relating to the Study as received by the Receiving Parties and their Representatives.

1. (b) *"Study"* means a clinical trial with respect to Protocol no.:64407564MMY3009 with Protocol Titled: " A Phase 3 Randomized Study Comparing Talquetamab in Combination with Pomalidomide (TalPom), Talquetamab in Combination with Teclistamab (TalTec), and Elotuzumab (IV), Pomalidomide, and Dexamethasone (EPd) or Pomalidomide, Bortezomib (SC), and Dexamethasone (PVd) in Participants with Relapsed or Refractory Myeloma who Have Received at Least 1 Prior Line of Therapy"

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Executive Registrar
SGPGIMS,Lucknow

2. *Duty of Receiving Party*. Each Receiving Party here by agrees to keep the Confidential Information received by it in confidence and strictly not to disclose it to any third party or use it for any purpose other than for Study Purposes. However, nothing herein shall prevent a Receiving Party from disclosing the Confidential Information to its Representatives, if such persons need to know such information for Study Purposes, provided that the Receiving Party shall ensure that such Representatives are subject to a confidentiality obligations with respect to such Confidential Information of at least the same level as envisaged under this Agreement. Each Receiving Party agrees that it will be fully responsible, for any breach by its Representatives of their confidentiality obligations with respect to such Confidential Information under this Agreement.

3. *Structure Information*. Unless otherwise mutually agreed in writing between the Parties, the Investigator or Institution shall not identify the chemical structure or molecular composition of J&J's proprietary compound(s) or molecular entity/entities or any data from which J&J's proprietary compound's or molecular entity's chemical structure or molecular composition may be readily determined or elucidated, except if authorized by J&J and shall be disclosed only to those Representatives of Receiving Party who are identified and authorized in writing by J&J to receive such structure, composition or data. For the avoidance of doubt, such structure, composition or data that might be disclosed directly by Principal Investigator to J&J shall not be considered "Confidential Information" of Investigator or Institution or both for any purpose hereunder.

4. *Exceptions*. Each Receiving Party shall not be obligated to maintain in confidence or to refrain from disclosing or using the Confidential Information if such information:

a) was known to the Receiving Party prior to being received from the disclosing party or its Representatives as evidenced by the Receiving Party's written records; or
b) is or without the fault of the Receiving Party (or any of its Representatives) becomes part of the public domain; or
c) is received by the Receiving Party from a third party having to the knowledge of the recipient no obligation of confidence to the other parties hereto; or
d) is independently developed by or on behalf of the Receiving Party without reliance on the information received hereunder as evidenced by the Receiving Party's written records or other competent evidence.

5. *Non–Disclosure/Publicity*. No Party will disclose, and each Party will direct its Representatives, who are aware of the contemplated discussions, not to disclose, publish or disseminate, at any time to any person the identity of the other Parties and the fact that Confidential Information has been made available or that discussions are taking place for Study Purposes or any of the terms, conditions or other facts with respect to Study or Study Purposes, including the status thereof.

6. *Business Acknowledgement*. The Investigator and Institution hereby acknowledge that J&J or its group companies or affiliates may presently have internal development programs relating to the Study, or without recourse to the Confidential Information disclosed hereunder may undertake such development programs, or may receive information on the same or related subject matter from third parties, and may develop and commercialize products and/or services relating to such subject matter independently or in cooperation with such third parties.

7. *Compelled Disclosures*. In the event a Receiving Party or Receiving Parties (or any person to whom it has transmitted the Confidential Information received hereunder) is required by law or legal process to disclose any of such Confidential Information, then the concerned Receiving Party(ies)will (i) provide the Disclosing Party with prompt notice of such event so that the Disclosing Party may intervene to protect the confidentiality of the

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Confidential Information and (ii) at the Disclosing Party's request and expense, use reasonable efforts to obtain assurance that confidential treatment will be accorded to the Confidential Information to be disclosed.

8. *Return of Confidential Information.* All written and electronic documents containing Confidential Information and other confidential material in tangible form including copies thereof in any form irrespective of storage or presentation medium, received by a Receiving Party under this Agreement shall remain the property of the Disclosing Party. Upon request of the Disclosing Party and solely at the expense of the concerned Receiving Party, all such documents (together with any copies or excerpts thereof) and such other material received hereunder shall promptly be either returned to the Disclosing Party or destroyed and the destruction confirmed to the Disclosing Party in writing. Notwithstanding the return or destruction of the documents and materials, each Receiving Party will continue to be bound by its obligations under this Agreement.

9. *No Right or License.* No right or license to use any Confidential Information disclosed hereunder, either express or implied, is granted to the Receiving Parties.

10. *Accuracy of Confidential Information.* Each Receiving Party understands that although the Disclosing Party and its Representatives have endeavored to include in the Confidential Information, information that it believes to be relevant for the purpose of the recipient's evaluation, neither the Disclosing Party nor any of its Representatives have made or make any representation or warranty as to the accuracy or completeness of the Confidential Information.

11. *No Obligation to Pursue Proposed Transaction.* Unless and until a definitive agreement between the parties with respect to Study Purposes has been executed and delivered, no Party will be under any legal obligation of any kind whatsoever with respect to such a transaction by virtue of this or any written or oral expression by any of its representatives, except for the matters specifically agreed to herein.

12. *Survival.* The obligations of Section 2 shall continue for forty-eight months from the Effective Date of this Agreement and for Section 3 shall be in perpetuity or as long as permitted by law.

13. *Governing Law.* Any disputes that may arise from this Agreement or in relation thereto shall be governed under Indian laws and the parties hereby agree to submit themselves to the exclusive jurisdiction of the competent courts in Lucknow. This clause shall survive the expiration or termination of the Agreement

14. *Entire Agreement & Modifications; Severability; Construction.* This Agreement contains the entire agreement between the parties and supersedes all pre-existing agreements, whether oral or written, between the parties respecting its subject matter. Modifications or waivers of this Agreement shall only be effective if made in writing and signed by all the parties hereto. The invalidity of any provision of this Agreement will not affect the enforceability of any other provision hereof. The Parties have jointly negotiated and drafted this Agreement and this Agreement shall be interpreted without presumption favoring or disfavoring any Party by virtue of authorship of any provision of this Agreement. This Agreement shall not be assignable, in whole or in part, by any Party without the prior written consent of the other Parties, and any such assignment without prior written consent shall be considered void.

[SIGNATURE PAGE FOLLOWS]

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This Agreement is executed in three counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

For Johnson & Johnson Private Limited

By: Manik Prabhu Nanna

Print Name: Dr. Manik Prabhu Nanna
Print Title: Manager-Global Clinical Operation, India
Date:

For Institution

By:

Director 30/5/23
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Print Name: Dr. R K Dhiman
Print Title: Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Date:
Institution Seal:

Principal Investigator

By:

Print Name: Dr. Sanjeev
Print Title: Associate Professor

Date: 03/05/2023
Physician Seal:

Dr. SANJEEV
Associate Professor
Department of Hematology
S.G.P.G.I.M.S., Lucknow
U.P.-226014

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ BW 522341

उप कोषागार अधिकारी
कल्याण

20 NOV 2023

NOVARTIS HEALTHCARE PRIVATE LIMITED (FIRST PART)

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SECOND PART)

AND

Dr. Dharmendra Bhadauria (THIRD PART)

NOVARTIS HEALTHCARE MUMBAI

Lt Col Varun Baipai VSM
Executive Registrar
SGPGIMS,Lucknow

FIRST AMENDMENT TO CLINICAL TRIAL AGREEMENT

This first Amendment is made at Mumbai and entered into on 20 day of Dec, 2023 by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at Inspire BKC, 7th Floor, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**", which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the First Part;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Dharmendra Bhadauria as clinical practitioner in the field of ***Nephrology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

(Novartis, Principal Investigator, and Institution may hereinafter be individually referred to as '**Party**' and are collectively referred as '**Parties**').

WHEREAS

A. By a Clinical Trial Agreement dated 25 Feb 2022 entered into between the Parties hereto ("**Agreement**"), the Principal Investigator and the Institution have agreed to provide certain Clinical Trial related services to Novartis on the terms and conditions contained in the Agreement.

B. Now by this first Amendment, the Parties are desirous of modifying and restating the sub-clause on 'Use of Trial Drug', and 'PUBLICATION' and 'TRANSPARENCY/DISCLOSURE , Modifying Annex-1 (Update in Payment Schedule for Corrected cost) 'clause to amend the Agreement on the terms and conditions herein after appearing.

NOW THIS AMENDMENT WITNESSETH AND IT IS HERE BY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. Clause 5.2 (Use of Trial Drug) of the Agreement is modified, and the revised clause 5.2 is as set forth below:

Lt Col Varun Baijpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOVARTIS HEALTHCARE PRIVATE LIMITED MUMBAI

5.2 Novartis shall provide the Trial Drugs (as defined hereunder) in sufficient quantity to conduct the Trial, unless specified in Protocol that one or more drugs is supplied locally. If the Drugs are supplied locally, Novartis Shall reimburse the Institution. Trial Drugs shall be defined as any investigational drug referred in the Protocol, which can include active ingredient, comparator, or placebo. For purposes of this Agreement only, the Trial Drugs shall be free of charge to the Institution. In all events, the Trial Drug shall remain the sole property of Novartis.

2. Clause 13.1, 13.3, 13.5 and 13.9 are added to the Agreement and the additional clauses are set forth as below:

13.1 The term 'publications' is used interchangeably to refer to peer-reviewed scientific manuscripts (e.g. primary and secondary manuscripts, submitted to scientific or medical journals), scientific congress abstracts, and corresponding posters and oral presentations.
13.3 Novartis follows the ICMJE authorship guidelines (www.icmje.org). All authors must therefore fulfill all four ICMJE authorship criteria during publication development to be included as authors on the publication, as follows:

(a) Substantial contributions to conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND

(b) Drafting the work or revising it critically for important intellectual content; AND

(c) Final approval of the version to be published; AND

(d) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

13.5 Authors will not receive remuneration for their writing of a publication, either directly from Novartis or through a professional medical writing agency.
13.9 Novartis and its agents may list participating investigators and their institutional affiliations in the acknowledgement section of the manuscript or abstract submitted for publication according to the journal or congress guidelines.

3. Clause 13.4 of the Agreement is modified, and revised clause is set forth as below:

13.4 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement prior to drafting the publication.

4. Clause 13.7 of the Agreement is modified and the revised clause 13.7 is as set forth below:

13.7 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis. Publication of partial data sets shall not be made until the full data is released.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOVARTIS HEALTHCARE MUMBAI

5. Clause 24.3 is modified and revised clause is as set forth below:

   24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy

6. This amendment shall be effective from 10 Jul 2023 and shall be coterminous with the agreement read with the prior addendums/amendments for all intents and purposes.

7. Save and except to the extent aforesaid, all other terms and conditions of the Agreement shall continue to remain unaltered, valid and binding upon the Parties. This Amendment shall hereafter be incorporated into and deemed part of the Agreement and any future reference to the Agreement shall include the terms and conditions of this Amendment.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOVAGITIS HEALTHCARE PVT. LIMITED * MUMBAI

IN WITNESS WHEREOF, the Parties to this Amendment have caused their duly authorized representatives to enter into and execute this Amendment.

Novartis Healthcare Private Limited

By: _____

Name: **Murugahanthan K.**

Title: SSO Country Head

Date: 26, Dec 2023

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

Name: Prof. R K Dhiman

Title: Director

Acting Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow - 226014, INDIA

Date: 20.1.24

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Dharmendra Singh Bhadauria

Title: Professor, Department of Nephrology

Date: _____

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOVARTIS HEALTHCARE MUMBAI

Annex1: Payment (and Equipment) Schedule

Financial Break-up

STUDY NUMBER: CLNP023F12301

STUDY NAME: A MULTICENTER, SINGLE-ARM, OPEN LABEL TRIAL TO EVALUATE EFFICACY AND SAFETY OF ORAL, TWICE DAILY LNP023 (IPTACOPAN) IN ADULT ATYPICAL HEMOLYTIC UREMIC SYNDROME (AHUS) PATIENTS WHO ARE NAIVE TO COMPLEMENT INHIBITOR THERAPY

Investigator's Name: Dr. Dharmendra Bhaduria

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Payee Name: Director, SGPGIMS Research Scheme Account

Pan Card Number: AAAJS3913N

GSTIN: 09AAAJS3913N2ZN

Committed Number of Study Subjects: 2

Payment Schedule:

Visits		*Investigator fees*	*HOI (25%)*	*Total per visit cost*
Screening	**SCR**	40547	10137	50684
Core Treatment Period	**W1D1**	9645	2411	12056
	W1D7	7299	1825	9124
	W2	7033	1758	8791
	W3	4157	1039	5196
	W4	9378	2345	11723
	W6	4157	1039	5196
	W8	7832	1958	9790
	W10	4157	1039	5196
	W12	7672	1918	9590
	W14	4157	1039	5196
	W16	6234	1559	7793
	W18	4157	1039	5196
	W20	6234	1559	7793
	W22	4157	1039	5196
	W24	4157	1039	5196
	W26 (EOT/EOS)	11243	2811	14054
Extension Treatment Up To Month 12	**W28**	6234	1559	7793
	W32	6234	1559	7793
	W36	6234	1559	7793
	W40	6234	1559	7793
	W44	6234	1559	7793
	W48	6234	1559	7793
	EOT/EOS	8099	2025	10124
Follow Up	**D7FU**	1332	333	1665
Total Per Patient cost		236314		

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOVARTIS HEALTHCARE MUMBAI

To,
Dr. Sudeep Kumar
Professor
Department of Cardiology
SGPGI, Lucknow

Subject: Invitation for being a faculty in CCMH cycle 4

Dear Sir,

On behalf of Public Health Foundation of India (PHFI), Center for Chronic Disease Control (CCDC) and knowledge partners International Society of Hypertension (ISH) and British Hypertension Society (BHS), **a very warm welcome to the** Certificate Course in Management of Hypertension **(CCHQ) Cycle IV.** We would like to invite you to be a faculty to deliver this course and we thank you for agreeing to spare your valuable time to ensure its success. Your leadership, support and vision is of utmost importance to make this new initiative unique in the field of healthcare quality.

Brief overview of the course:

Certificate Course in Management of Hypertension (CCMH) is a joint certification program designed, implemented and delivered by Public Health Foundation of India in collaboration with academic partners Center for Chronic Disease Control (CCDC) and knowledge partners International Society of Hypertension (ISH) and British Hypertension Society (BHS). The educational grant for the same has been provided by ISH. This is an 8 modular course with the following objectives:

Primary objective
- To enhance knowledge, skills and core competencies of practicing Primary Care Physicians in management of Hypertension and its complications.

Secondary objectives
- To develop a standard teaching protocol and module for evidence-based learning on Management of Hypertension.
- To build a network of Primary Care Physicians and specialists in the field of Hypertension.
- To update practicing/primary care physicians with the latest advancements in the field of Hypertension.

Journey So far:
The CCMH initiative has been widely successful and over 2000 primary care physicians have been trained/enrolled till date. The first cycle of the course was launched on 24th of July 2016 across 25 centres in India in which 612 primary care physicians were trained. The second cycle of the course (Oct 2017 – July 2018) was implemented across 40 centres in India and a total of 658 primary care physicians were enrolled. A total of 175 primary care physicians were trained in the third cycle of the program (May-Dec 2019) across 10 centres in India.

State Government and Industry adoption
The state governments of Madhya Pradesh, Meghalaya, Manipur, Odisha and Tripura, and the Municipal Corporation of Kolkata to adopt the program for the capacity building of over 600 government medical officers. CCMH initiative implemented in Madhya Pradesh was selected as an innovative model at the

- 1 : 15 Class Ratio (Faculty and Participants)
- The candidate completing the certificate course successfully shall be awarded the certificate jointly issued by PHFI, ISH, BHS, CCDC and respective Regional Faculty.

The Minimum Eligibility for admission in course would be:
Medical graduate (MBBS) with minimum 3 years of clinical experience.
OR MD/DNB (Medicine or Internal Medicine or Family Medicine)
The course curriculum for the CCMH cycle-IV has been designed with inputs from the national expert members of the academic partners who are all eminent cardiologist and medicine specialists from across the world. Even though all efforts have been made to ensure that the information provided is accurate and up-to-date, you may occasionally come across instances where this is not so. We request you to point these errors and omissions to us so that we may rectify them in time for the next cycle.

Any curriculum is only good as the faculty that delivers it. We are fortunate to have the services of a panel of esteemed and experienced faculty, who represent the league of eminent cardiologists of this country. We feel that in your hands, the success of this course is assured.

With warm regards,

Dr. Arun P. Jose
Sr. Program Manager
Public Health Foundation of India

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Certificate No.	:	IN-UP82270697794813T
Certificate Issued Date	:	10-Jun-2021 12:14 PM
Account Reference	:	NEWIMPACC (SV)/ up14238304/ MOHANLALGANJ/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14238304523605231547237
Purchased by	:	DR UJJALA GHOSHAL WIFE OF DR UDAY CHAND GHOSHAL
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	DR UJJALA GHOSHAL WIFE OF DR UDAY CHAND GHOSHAL
Second Party	:	Not Applicable
Stamp Duty Paid By	:	DR UJJALA GHOSHAL WIFE OF DR UDAY CHAND GHOSHAL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

Between

JPN APEX TRAUMA CENTRE,
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NEW DELHI
(JPNATC, AIIMS)
And
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
UTTAR PRADESH

T s is the Memorandum of Understanding (MoU) entered **by JPN Apex Trauma Centre, AIIMS, New Delhi** (Prime Recipient) and **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Uttar Pradesh** ,Sub Recipient) **on 01-05-2021**, to specify the terms and conditions for the BMGF, USA funded project, titled ***"Infection Prevention and Control (IPC)- Capacity Building- Orientation Training for COVID-19 Preparedness and IPC for Healthcare Facilities"***, conducted by the JPN Apex Trauma Centre, AIIMS, New Delhi.

The terms of the Agreement are applicable to the project identified below conducted by the JPN Apex Trauma Centre, AIIMS, New Delhi.

Project covered under this Agreement

Name of the Project	**Infection Prevention and Control (IPC)- Capacity Building- Orientation Training for COVID-19 Preparedness and IPC for Healthcare Facilities**
Principal Investigator	Dr. Purva Mathur, Professor, Department of Laboratory Medicine, JPN Apex Trauma Centre, AIIMS, New Delhi.
ICMR Co-Ordinator	Dr. Kamini Walia, Scientist F, Division of Epidemiology and communicable Diseases, Indian Council of Medical Research, New Delhi
Collaborating Centre Principal Investigator	Dr. Ujjala Ghoshal, Professor, Depart nt of Microbiology, Sanjay Gandhi Postgraduate institute of Medical Sciences, Uttar Pradesh.
Funding Agency	Bill and Melinda Gates Foundation, [BMGF], USA.
Duration	2 years (1st of May 2021 to 30th of April 2023)

Background of the Project

COVID-19 caused by the novel coronavirus now known as SARS-CoV-2 (severe acute respiratory syndrome coronavirus-2), has spread worldwide with its first reported case in late December 2019 in Wuhan city of China. This rapidly growing pandemic has also affected many the healthcare workers. Presently, the clinical spectrum of disease is being defined including the potential for asymptomatic spread. So far, no specific treatment and prevention strategies like targeted antiviral drugs and vaccines, are available for COVID-19. Thus, we can only depend on the traditional public health outbreak response practices—isolation, quarantine, social distancing, and community containment.

On 30 January 2020, WHO declared the outbreak of COVID-19 as Public Health Emergency of International Concern and recommended that all countries should be prepared for containment, including active surveillance, early detection, isolation and case management, contact tracing and prevention of

On 30 January 2020, WHO declared the outbreak of COVID-19 as Public Health Emergency of International Concern and recommended that all countries should be prepared for containment, including active surveillance, early detection, isolation and case management, contact tracing and prevention of onward spread of COVID-19. On 28 February 2020, WHO raised the risk assessment for the COVID-19 outbreak internationally from "high" to "very high."

In order to protect our healthcare work force, such times call for appropriate training among healthcare workers, especially in populous countries like India. The World Health Organization (WHO) has defined four transmission scenarios for COVID-19:

1. Countries with no cases (No cases).
2. Countries with 1 or more cases, imported or locally detected (Sporadic cases).
3. Countries experiencing cases clusters in time, geographic location and/or common exposure (Clusters of cases).
4. Countries experiencing larger outbreaks of local transmission (Community transmission).

Technical guidance for government authorities, health workers, and other key stakeholders to guide response to community spread has been given by the WHO. Since, the number of cases in India as on 15th May 2021, has reached over 163 million, it becomes even more important to provide adequate training to the healthcare workers to deal with and contain the spread in case of future waves.

Thus, this project on COVID-19 preparedness and l. ' capacity building has been proposed. The aim of ti proposed activities is to strengthen COVID-19 prevention across Indian health care facilities (HCF), with a focus on triage of symptomatic individuals, surveillance, infection prevention and control, and risk communication and community engagement, targeting high risk health care workers working directly with suspect and infected patients, many of whom will be severely ill, in healthcare facilities. These materials can also inform the general public. These efforts will support the maintenance of safe essential healthcare services by preventing healthcare-associated transmission of COVID-19 among healthcare workers (HCW) and patients.

All India Institute of Medical Sciences, New Delhi (AIIMS) will work with the ICMR, United States Centre for Disease Control (USCDC) and other AIIMS designated partners to develop and deliver these trainings. This work leverages the ICMR AMR network, and the AIIMS/USCDC supported IPC work within the AIIMS hospital acquired infection surveillance network and expands it to ensure appropriate IPC for COVID-19.

Responsibilities of Recipient (Sanjay Gandhi Postgraduate Institute of Medical Sciences, Uttar Pradesh)

- Nominate one person to liaise with AIIMS, New Delhi for workshop/training/review meetings related to the project and for feedbacks, reporting and troubleshooting as well as for financial matters.
- Should ensure trainings to maintain safe essential healthcare services by preventing healthcare associated transmission of COVID-19 among healthcare workers and patients.
- Identification and coordination of key leaders will be prioritized to optimize the use of all resources.
- Train staff of hospital to ensure that all they get prepared and ready to do fresher trainings in your region, in the future
- Provide sufficient IPC materials to training centers (in your region) tailored to COVID-19.
- Identify key staff needed to implement work and strengthen capacity and skills of key healthcare professionals.
- Would try to generate, apply and report accurate data of HAI and AMR to strengthen and expand the ability of healthcare systems.
- Recruitment of staff would be done as per the rules of Govt. of India. The positions and salaries would be as per ICMR guidelines.
- Provide technical and other assistance as and when required to the staff of hospital.
- Presentation of data in the annual/biannual meetings between various centres.
- The expenditure in each category (personnel salary/consumables) will not exceed the limit mentioned in the allotted budget.
- Ensure all procurements are done as per government of India's rules and regulations.
- All reports to be submitted to AIIMS in a timely manner.
- Financial audit as per requirement of BMGF will be conducted. Sites need to comply to audit requirements.

Responsibilities of JPN Apex Trauma Centre, AIIMS, New Delhi

- AIIMS will be responsible to work, implement and train for project related activities for staff of other networking sites.
- AIIMS will be responsible for development of training modules and SOPs as well as for conducting meetings.
- AIIMS would be responsible for data compilation, FAQ's and logs of the trainings conducted.
- AIIMS will be responsible to provide all IPC material tailored to COVID- 19.

- The existing HAI network will further receive the proposed orientation training for COVID -19 preparedness and IPC in two overlapping stages.
- Ensure the coordination of key leaders and partners to maximize the use of human resources and material resources.
- Primarily training in Bihar and U.P (7 to 8 Regional Trainers through TOT)
- Will identify additional centers for next phase as the network will expand and work closely with all centers.
- Targeted in person training as well as virtual IPC trainings will be conducted by AIIMS for regional hospitals focusing on triage and IPC
- The actual implementation of the training would be monitored through site-visits whenever possible. Till then, videoconferencing would be used at AIIMS for long distance trainings between site investigators and trainers.
- AIIMS would ensure timely collation of reports.
- AIIMS would be responsible for writing of manuscripts.
- AIIMS will provide all required technical and other assistance as and when required.

Financial responsibilities, Disbursement and Management of the Grant

Budget allocated to Sanjay Gandhi Postgraduate Institute of Medical Sciences, Uttar Pradesh

Budget Summary

Tentative Budget for two years:

Budget Statement
01.05.2021 to 30.04.2023

Head	Per Month	24 Months
Staff	**In INR**	**In INR**
JRF (31,000 + 24% HRA)	38,440.00	9,22,560.00
Junior Nurse	18,000.00	4,32,000.00
For Training Program/Stationary	50,000.00	
Overhead Charge (3%)	42,137.00	
Total Budget	**14,46,697.00/-**	

*(House Rent Allowance (HRA): JRF may be provided hostel accommodation wherever available and those residing in accommodation provided by the institute will not be eligible for drawing HRA. Wherever provision of hostel accommodation is not possible, HRA may be allowed as per Central Government norms applicable in the city/ location where they are working. The fellowship amount may be taken as basic for calculating the HRA)

Govt. of India Pay scales and Qualifications/ eligibility rules will apply. Each selected staff will work 100% of time for this project only.

Term and Termination

The initial term of this agreement has commenced on the 1st of May 2021 and shall continue till 30th April 2023, unless otherwise terminated in writing by either party as provided herein.

1. Either party may terminate the agreement upon 90 days written notice to the other party.
2. In the event of a material breach of any terms of this agreement, any party may terminate the agreement upon 15 days written notice of any material breach of its terms with the other party and affording the breaching party 15 working days to rectify the breach to the noticing party's satisfaction.

Amendments

This agreement may be modified, cancelled, or renegotiated upon mutual consent, at any time, through an amendment signed by authorized representatives of the organizations.

This Agreement Document contains a total number of 9 pages.

In WITNESS WHEREOF, the parties have duly executed this Agreement, which shall become effective from May .

Authorized Signatories

Recipient Centre: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Uttar Pradesh	
Signature of PI Dr. Ujjala Ghoshal Professor & Head Dept. of Microbiology SGPGIMS, Lucknow-14	Signature of the Head of the Institute
Name: **Dr Ujjala Ghoshal** Designation: Professor & Head Address: Department of Microbiology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014 Uttar Pradesh Phone No: +91-7706997492 Email: ujjalaghoshal@yahoo.co.in	Name: **Prof. R.K. Dhiman** Designation: Director Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014, Uttar Pradesh Phone No: 91-522-668004-8, 668700, 668800, 668900 Ext: 2469/2009 Email: director@sgpgi.ac.in

Two Witnesses

Signature Dr. Chinmoy Sahu Associate Professor Dept of Microbiology SGPGIMS, Lucknow-14	Signature
Name: **Dr. Chinmoy Sahu** Designation: Associate Professor Address: Department of Microbiology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014 Uttar Pradesh Phone No: +91-8004904515 Email: sahu.chinmoy@gmail.com	Name: **Dr. Sangram Singh Patel** Designation: Assistant Professor Address: Department of Microbiology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014 Uttar Pradesh Phone No:+91-8005381619 Email: sangramsgpgi@gmail.com

उत्तर प्रदेश UTTAR PRADESH

EN 023759
5 JAN 2019

Memorandum of Understanding

Joint Research Project Agreement

This Joint Research Project Agreement ("Agreement") is made and entered on the date that appears on the signature page hereof ('Effective Date') between:

Sanjay Gandhi Postgraduate Institute of Medical Sciences, **Lucknow,** having its registered office at Raebareli Rd, Lucknow, Uttar Pradesh 226014 (herein after referred as SGPGIMS), which expression unless repugnant to the context or meaning hereof shall include its successors, administrators or permitted assignees.

and

Indian Institute Of Technology, Kharagpur ("IIT-KGP"), having its address at Kharagpur- 721302, India, which expression unless repugnant to the context or meaning hereof shall include its successors, administrators or permitted assignees.

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and IIT-KGP may be referred to herein individually as a "Party" and collectively as "Parties".

WHEREAS Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and

IIT-KGP had joined hands with each other by entering into a MoU dated 14th day of January 2020, to promote interaction and collaboration and carry out joint academic and research programme and also collaborative research projects.

AND WHEREAS Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and IIT-KGP now propose to collaborate to form a nucleus for promoting research & development and creation of human capital in the fields of biomedical and clinical engineering and allied areas by exploiting the unique expertise, intellectual and infrastructural capabilities of both the parties, under the supervision of Dr. Sudipta Mukhopadhyay, Professor, Department of Electronics & Electrical Communication Engineering, Indian Institute of Technology Kharagpur, and project funded by external agencies. Dr. Sunil Kumar, Professor and HOD, Department of Radiodiagnosis, will be the contact person at SGPGIMS for this project and all other project initiated by him.

The project "Clinical Trial of the Content-based Image Retrieval-based Computer Aided Diagnosis (CBIR-CAD) for lung nodules and ILD patterns" was executed under the supervision of Dr. Sudipta Mukhopadhyay of Electronics & Electrical Communication Engineering Department, Indian Institute of Technology Kharagpur. This project was funded by DeitY. PGIMER was helping with critical data for the successful implementation of this project. In this project AIIMS Delhi has served as independent site to evaluate the tools developed in this project.

A new project proposal is under preparation and will be sent by Dr. Sudipta Mukhopadhyay on the continuation of the previous projects "Clinical Trial of the Content-based Image Retrieval-based Computer Aided Diagnosis (CBIR-CAD) for lung nodules and ILD patterns " to MeitY for funding. The project has been conceived with the expressed understanding that the medical data and interpretation of data, a critical inputs to the project, will be provided by experts of SGPGIMS who will also help the research in this area. This MOU will facilitate mutual cooperation and help us to make meaningful research and project proposals for funding.

1. **OBJECT OF THIS AGREEMENT.**

WHEREAS, SGPGIMS, and IITKGP are, now

- Recognizing the importance of research and development in the areas of biomedical science, engineering and technology,

- Appreciating the need for integrating the reservoir of highly qualified manpower in the fields of medical science and technology,

- Desiring to amalgamate their efforts by pooling their expertise and resources,

Now agree upon, to form a nucleus for promoting research & development and creation of human capital in the fields of biomedical and clinical engineering and allied areas by exploiting the unique expertise, intellectual and infrastructural capabilities of both the parties. General terms and activities are given as follows:

1. Exchange of research documents/findings on a case to case basis.

2. Visits of Faculty, Staff and Students to each other's campus (During visits, Faculty/ Staff/ Students would be provided appropriate accommodation in hostel/ guest houses).

3. Submission of joint projects seeking external support for collaboration in research & consultancy.

4. Sharing of laboratory, library and such other resources for the research teams on availability for bilateral applications without any financial burden on either party.

5. Agreement will be made for specific projects and activities separately.

6. Joint research project initiations and execution.

7. Any other activity may be included with mutual consent. Each organization will nominate one coordinator to oversee the functioning facilities under MOU.

2. **CONFIDENTIALITY AND PUBLICITY.**

a) During the TERM of the MOU, either party may provide to the other proprietary and confidential information that it considers essential for the conduct of any PROJECT at their sole discretion.

b) PROPRIETARY INFORMATION for the purposes of this AGREEMENT shall include all data, samples, discoveries, inventions, technical information, reports, know-how and other information related to and disclosed by either party to the other in any form of written materials and it shall be the duty of the receiving party to maintain its confidentiality.

c) The SGPGIMS and IITKGP agree to hold PROPRIETARY INFORMATION in confidence and to protect it against disclosure to the public and third parties. Accordingly SGPGIMS, and IITKGP shall employ protective measures fully commensurate with those used by them to protect their own trade secrets and other

confidential information from disclosure to the public and to third parties, but in no event less than the ordinary degree of care required by law to preserve the secrecy of information that under such law is deemed confidential. By way of example, such efforts will include the act of obtaining the execution of suitable confidentiality agreements from other parties and from other persons to whom such information is disclosed in the course of execution of the PROJECT and to retrieve the connected documents on completion of the project where given for the same.

d) The SGPGIMS, and IITKGP agree to use PROPRIETARY INFORMATION only for the specific project during the term of such project.

e) The SGPGIMS, and IITKGP agree not to copy, reproduce or otherwise reduce to writing any Part of PROPRIETARY INFORMATION except and only as may be reasonably necessary for the PROJECT.

f) INFORMATION disclosed by either party to the other in the form of results of the study / research originating from the projects under this agreement shall be treated as confidential and should not be shared with any third party, including any country, without the expressed permission of giving party.

g) Both SGPGIMS, and IITKGP will be free to publish research results out of projects under this agreement that does not contain proprietary information. In case it contains proprietary information decision to publish will be on a mutual consent basis so as to ensure protection of the related intellectual property.

h) The non-disclosure clause will survive three years from the date of expiry of this MOU.

3.**NON EXCLUSIVITY**: Nothing in this Agreement shall mean or shall be construed to mean that any of the Party is at any time precluded from having similar arrangements with any other person or third party, subject always to maintaining confidentiality obligations stated herein.

4.**LIMITATION OF LIABILITY**: IN NO EVENT SHALL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER PARTY, END USERS OR ANY OTHER THIRD PARTY, FOR ANY INDIRECT, SPECULATIVE, SPECIAL OR CONSEQUENTIAL DAMAGES. NEITHER PARTY SHALL HAVE ANY LIABILITY UNDER THIS AGREEMENT BASED ON FAILURE TO ULTIMATELY COMPLETE THE ACTIVITIES ENVISIONED HEREIN. IN NO EVENT SHALL EITHER PARTY'S LIABILITY FOR MAINTAINING CONFIDENTIALITY UNDER THIS AGREEMENT EXCEED 70% OF THE TOTAL AMOUNT ACTUALLY PAID TO EITHER PARTY. The Parties also agree that this limitation of liability will only be in respect of this Agreement and will not in any event be applicable to any other specific agreement that may be executed between the Parties pursuant to this Agreement.

5.**INTELLECTUAL PROPERTY**: The Parties agree that all Intellectual Property, including but not limited to trade secret(s), copyrights, know how, or patents, owned or

possessed by either Party on the Date of signing of this Agreement shall remain the property of the said party. Intellectual Property, including but not limited to trade secret(s), copyrights, know how, or patents, created by either Party solely after the Date of signing of this agreement, as part of the performance under this Agreement shall remain the property of the said party exclusively. However, ownership and license rights in respect of joint intellectual property that may be developed or created jointly by the parties after signing of this Agreement as part of the delivery of services or performance under this Agreement, shall be jointly owned by the parties unless the sponsor suggest otherwise. The terms to exploit the joint intellectual property will be in accordance to the agreement with the sponsor.

The filing and maintenance of Joint IP generated shall be done jointly in the name of both the parties and the cost for the same shall also be borne jointly.

No license or any other right is granted or conferred under any Intellectual Property rights now or hereafter owned or controlled by either Party by implication, statute, inducement estoppel or otherwise, except of the basis of such agreements that may be specifically executed between the Parties.

6. **COSTS**:

There is no direct financial obligation on either Institute unless specifically agreed to. The financial requirement of individual institutions for joint project proposals will be separately mentioned in joint projects while submitting to funding agencies.

7.**DURATION**

This agreement shall come into effect on the day of the approval by both institutes with an initial duration of five years.

8.TERM, TERMINATION AND SURVIVAL: This Agreement shall commence on the Effective Date (the date of signing of this Agreement) and continue in full force and effect unless terminated by the Parties in writing. Either Party may terminate this Agreement at any time, with or without cause, by giving the other Party Thirty (30) days prior written notice. In such an event both Parties agree to fulfill their respective obligations which have accrued or arisen under the Annexure up to date of such termination. Within thirty (30) days after the termination of this Agreement, each Party shall prepare all items of the other Party in its possession for shipment and shall promptly deliver such material/ items to the other Party and shall erase all electronic copies of this or any other confidential information of the other Party. Effective upon the termination of this Agreement any permission as may have been granted to use the other Parties name, trademarks or trade names shall lapse. Termination of this Agreement by

either Party for any reason shall not affect the rights and obligations of the Parties accrued prior to the effective date of the termination.

9.CHOICE OF LAW: This Agreement shall be governed by and construed in accordance with the laws of India without reference to principles of conflict of laws and the parties irrevocably submit to the exclusive jurisdiction of the Courts in New Delhi for any action or proceeding regarding this Agreement.

10.**RELATIONSHIP**: The Parties agree that nothing in this Agreement should be construed as creating a partnership, employer-employee relationship, agency, franchise or joint venture, of any kind, between the Parties, and that neither Party will have the right power or authority to obligate or bind the other in any manner whatsoever, nor make any representations or warranties on behalf of the other, without the other Party's prior written consent in a separate writing.

11.**ENTIRE UNDERSTANDING, AMENDMENT ASSIGNMENT**: This Agreement sets forth the entire and final understanding of the Parties, and supersedes any and all oral or written agreements or understandings between the Parties, as to the subject matter hereof. No amendments or modifications shall be effective unless in writing and signed by authorized representatives of all the Parties. No right, duty or obligation under this Agreement may be assigned, delegated, factored or subcontracted in any manner by either Party without the prior written consent from the other Party.

12. **NOTICES:** All notices shall be directed in writing to the address aforesaid of the Parties.

The signature of the Parties below indicates their acceptance with the foregoing Agreement

.

SIGNED FOR AND ON
BEHALF OF IIT KHARAGPUR

SIGNED FOR AND ON
BEHALF OF SGPGIMS Lucknow

Name:

Designation: Dean (SRIC)

(Authorized Signatory)

Name: 05/02/21
Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Designation: Director

(Authorized Signatory)

WITNESSES

1) Signature

Name: Dr Sudipta Mukhopadhyay

Address: Dept. of E&ECE,
IIT Kharagpur

1) Signature

Name: Dr. Sunil Kumar

Address: Department of Radiodiagnosis
SGPGIMS Lucknow

2) Signature

Name: Dr. Debashis Sen

Address: Dept. of E&ECE,
IIT Kharagpur

2) Signature

Name. Dr. Neeraj Jain

Address: Department of Radiodiagnosis
SGPGIMS Lucknow

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THE ASCO FOUNDATION

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571.483.1700
F: 571.366.9552
CONQUER.ORG

April 30, 2021

Sushma Agrawal, MD
Sanjay Ghandi Post Graduate Institute of Medical Sciences
SGPGIMS CAMPUS
Rae Bareily Road
Lucknow, 226014, India

Dear Dr. Agrawal:

On behalf of the Conquer Cancer Foundation of the American Society of Clinical Oncology ("Conquer Cancer") and the American Society of Clinical Oncology (ASCO), we congratulate you and your institution on being selected to receive a 2021 Conquer Cancer International Innovation Grant in the amount of $20,000 for your research titled, "A Randomized Study of Chemotherapy (CT) vs CT followed by Consolidation CTRT in Locally Advanced Gall bladder Cancers (LA-GBC) (RACE-GB Study)". The grant period commences July 1, 2021 and concludes June 30, 2022. Sanjay Ghandi Post Graduate Institute of Medical Sciences will receive the first year installment of the grant funds on or about July 1, 2021 by wire transfer.

Conquer Cancer will be distributing nationally a press release announcing all 2021 Conquer Cancer award recipients on May 28, 2021. We request that you and your institution refrain from making any public announcements regarding this honor until after this date so as to not precede Conquer Cancer's national announcement. Please share the release with the public affairs office at your institution to let them know you have received a grant from Conquer Cancer, and encourage them to share the release with local press and promote it in your institutional newsletter, website, and social media channels. We also request that your institution coordinate its own announcement with Vicki Kilpatrick at Vicki.Kilpatrick@asco.org

Please read and submit the attached Terms and Conditions with appropriate signatures by **May 17, 2021** through your account at Conquer Cancer's application portal (http://awards.asco.org) to confirm your acceptance of this award. If you are unable to accept this award for any reason, please contact Conquer Cancer as soon as possible at (571) 483-1700 or grants@conquer.org.

Congratulations again for being selected to receive this award. Best of luck in your research!

Sincerely,

Nancy R. Daly, MS, MPH
Chief Executive Officer, Conquer Cancer

Howard A. Burris, III, MD, FACP, FASCO
Chair, Conquer Cancer

Clifford A. Hudis, MD, FACP, FASCO
Executive Vice Chair, Conquer Cancer
Chief Executive Officer, ASCO

Lori J. Pierce, MD, FASTRO, FASCO
President, ASCO

(25)

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Terms and Conditions of the
2021 Conquer Cancer International Innovation Grant

The lead Principal Investigator set forth on the signature line below ("**Principal Investigator**") and the Grantee Organization ("**Recipient**") set forth on the signature line below agree to comply with these terms and conditions applicable to the 2021 Conquer Cancer International Innovation Grant (the "**Award**") as set forth herein ("**Terms and Conditions**"). These Terms and Conditions include the 2021 Conquer Cancer International Innovation Grant Request for Proposals dated September 9, 2020 and all forms and instructions of the Conquer Cancer Foundation of the American Society of Clinical Oncology ("**Conquer Cancer**") relating to the Award, which are incorporated into these Terms and Conditions by reference. Principal Investigator and Recipient agree to comply with these Terms and Conditions throughout the Award Period.

Definitions

A. The "**Research Project**" is the clinical research project described in the Recipient's grant proposal and approved by Conquer Cancer: A Randomized Study of Chemotherapy (CT) vs CT followed by Consolidation CTRT in Locally Advanced Gall bladder Cancers (LA-GBC) (RACE-GB Study).

B. The "**Award Period**" starts on July 1, 2021 and ends on June 30, 2022.

C. The "**Award Total**" shall be up to 20,000 United States Dollars, paid in two installments of up to $10,000, on or about July 1 2021 and January 1, 2022, subject to compliance by Principal Investigator and Recipient with these Terms and Conditions. Payment of the second installment is dependent on Recipient's satisfactory submission of the six-month progress report and financial report, and satisfactory research progress during the first reporting period.

D. The "**Announcement Date**" is May 28, 2021, the date on which Conquer Cancer will announce the Award and other recipients of Conquer Cancer awards.

E. The "**Required Acknowledgement**", to be used as described in paragraph 52 of these Terms and Conditions, is "This work was funded by a Conquer Cancer International Innovation Grant. Any opinions, findings, and conclusions expressed in this material are those of the author(s) and do not necessarily reflect those of the American Society of Clinical Oncology® or Conquer Cancer®."

Certifications, Representations, Warranties, and Covenants

(1) Recipient and Principal Investigator each certify that to the best of their or its knowledge, the information provided in its Award grant proposal (including the Letter of Intent) is complete and true. Recipient and Principal Investigator each agree to promptly notify Conquer Cancer of any changes to the information provided in the grant proposal.

(2) Recipient and Principal Investigator agree to comply with all applicable laws and regulations, including human subjects research, privacy, tax, humane care and use of laboratory animals, and laboratory safety laws. Award funds must be expended in accordance with United States laws and regulations addressing foreign corrupt practices and economic and trade sanctions, including those administered by the U.S. Treasury Department's Office of Foreign Assets Control (OFAC). By way of illustration but not of limitation, Recipient and Principal Investigator shall ensure that no Award funds are paid to any person included on the OFAC list of Specially Designated Nationals and Blocked Persons (available on the OFAC web site at http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx). Award funds will be expended in accordance with all applicable anti-terrorist laws and executive orders, including financing and asset control laws.

(3) The Recipient and Principal Investigator agree that the Award is for scientific and educational purposes. Award funds will not be used for lobbying or political activities and will be used consistent with the purpose of the Award as stated in 2021 Conquer Cancer International Innovation Grant Request for Proposals.

General Requirements

(4) The Principal Investigator will be an active-status member of the American Society of Clinical Oncology (ASCO) throughout the Award period.

(5) The Principal Investigator will be a citizen or permanent resident of a country defined by the World Bank as low-income or middle-income, and currently residing in that country.

(6) The Principal Investigator will be affiliated with the Recipient.

(7) The Award will fund only the Research Project.

(8) The Recipient will be an organization with a charitable purpose registered as a not-for-profit with the relevant national authority or is a government agency. The Recipient will administer the grant funds for the sole purpose of the Research Project.

(9) The Recipient will be located in a country categorized by the World Bank as Low-Income, Lower-Middle Income or Upper-Middle Income.

(10) The Recipient has been operating for at least one full year, has an acceptable management structure and processes in place, and will be solvent with or without the support of the Award.

(11) The Recipient has experience in carrying out activities with tangible outcomes.

(12) The Principal Investigator and Recipient will require and ensure that all members of the research team relating to the Research Project will comply with these Terms and Conditions.

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Award Period

(13)The Principal Investigator will not be absent from participation in the Research Project or from the Recipient for extended periods of time during the Award Period, such as for a sabbatical leave or leave of absence, without prior written approval from Conquer Cancer. The Principal Investigator may request that the Award Period be delayed with a start date that begins up to six months after the published start date indicated in the Request for Proposals, which request will be approved or disapproved by Conquer Cancer in its sole discretion.

Responsible Conduct of Research

(14)The Research Project will be conducted according to the highest scientific and ethical standards and in compliance with all applicable laws and regulations and with the policies of the Recipient, including with respect to Recipient's conflict of interest policies and procedures. To the extent policies of the Recipient conflict with these Terms and Conditions, these Terms and Conditions will prevail.

(15)The Principal Investigator will provide evidence of permission to conduct human subjects research in the host country to Conquer Cancer prior to commencing research on human subjects, if applicable.

(16)The Principal Investigator will provide evidence of approval for the use animals in research in the host country to Conquer Cancer prior to commencing research on animal subjects, if applicable.

Funds: Payment and Use

(17)The Award funds will be paid to the Recipient in United States Dollars by wire transfer.

(18) The Award will be used solely as detailed in the Research Project (including the grant proposal and budget).

(19) Award funds must be maintained in a separate fund dedicated to the charitable purpose of the Award. Such a separate fund may be either 1) a physically separate bank account restricted to the described charitable purpose, or 2) a separate bookkeeping account (limited to the described charitable purpose) maintained as part of Recipient's financial records.

(20) No more than 5% of total costs will be applied to overhead or indirect costs of the Recipient in administering the Research Project.

(21) Award funds may not be used to pay for: ASCO Membership Fees; fees for courses or classes; costs for proposal development for additional funding; travel to the ASCO Annual Meeting or other international congresses or conferences; political campaigns; direct donations, grants, or scholarships to individuals; lobbying; bribery; illegal activity; or any costs that are not directly

related to the Research Project. No funds should be allocated to travel unless it is directly related to the Research Project itself.

(22) Award funds will not be used for expenditures incurred prior to the first day of the Award Period or after the last day of the Award Period. No additional expenses may be paid from Award funds after Conquer Cancer has received the Principal Investigator's final expenditure report or after any unexpended funds have been returned to Conquer Cancer, which must be provided in accordance with paragraphs 56 and 57.

(23) At the end of the Award Period, any unexpended funds and any funds expended inconsistent with the Research Project will be returned to Conquer Cancer.

(24) If the Research Project included budgeted subcontracts to other institutions, Principal Investigator will be responsible for obtaining expenditure reports and progress information annually, in concordance with the reporting schedule set forth herein. All consortium and contractual agreements must be pre-approved by Conquer Cancer and will be subject to and will comply with these Terms and Conditions. Principal Investigator will ensure that the Research Project is conducted in compliance with these Terms and Conditions.

(25) Principal Investigator may not subcontract with a new third party without written approval from Conquer Cancer. A request to reallocate the budget will be submitted to Conquer Cancer through its application portal (see Submission of Change Requests) for approval and will include a description of the work to be performed by the third party, reason for contracting with the third party, and a complete budget for the third party including revisions to the original budget categories. All contractual agreements will be subject to and will comply with these Terms and Conditions.

Submission of Change Requests

(26) All change requests related to the Award must be made through Conquer Cancer's application portal (awards.asco.org).

Requests for Budget Changes or Extensions

(27) The Principal Investigator may not move funds between budget categories or into new budget categories without prior written approval of Conquer Cancer. Budget changes must be consistent with the budget guidelines. The budget limit on indirect costs will be strictly followed and cannot be adjusted.

(28) Budget changes will be approved in writing by Conquer Cancer before expenditure of funds. The Principal Investigator will submit a re-budget request with a detailed justification of the proposed change through the application portal. The re-budget request must be made during the Award Period.

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(29)Any request for a no-cost extension must be made through the application portal at least 90 days prior to the expiration of the Award Period. Requests received after the last day of the Award Period will not be accepted and will automatically be disapproved. No cost-extensions of up to six months may be approved by Conquer Cancer in its sole discretion. Conquer Cancer may approve up to a maximum of three no-cost extensions.

(30)Requests for a six month no-cost extension require a no-cost-extension request submission through the application portal, an updated expenditure report and progress report, and a detailed explanation of why the request is being made. Requests will only be approved if they pertain to the Research Project. Conquer Cancer will approve or disapprove the request at its discretion.

(31)If a no-cost extension is granted by Conquer Cancer, the Principal Investigator will submit additional progress reports and financial expenditure reports every six months during the extension term.

Change of Personnel

(32)If the Principal Investigator desires to take a leave of absence from the Research Project for any reason during the Award Period, the Principal Investigator will submit a request in writing to Conquer Cancer to allow one of the co-investigators on the Research Project, who must be affiliated with the Recipient, to lead the Research Project. Subject to Conquer Cancer's written approval and in Conquer Cancer's sole discretion, the Award may be transferred to a co-investigator of the Research Project provided arrangements satisfactory to Conquer Cancer are implemented to continue the Research Project. Among other things, the co-investigator will be an active-status ASCO member throughout the remaining Award Period and will agree to comply with these Terms and Conditions. Conquer Cancer will approve or disapprove the request at its discretion.

(33) If the Principal Investigator is unable or not permitted to transfer the Award to a co-investigator, the Principal Investigator and the Recipient will relinquish the Award and any unexpended funds and funds expended inconsistent with the Research Project will immediately be returned to Conquer Cancer.

(34) Changes in co-investigators listed on the Research Project require prior written approval from Conquer Cancer. A written request, including justification for the change and the biosketch of the proposed new co-investigator, must be submitted prior to the investigator joining the Research Project team.

Changes in Research Focus

(35)Changes in the specific aims of the Research Project will not be allowed without prior written consent from Conquer Cancer. Any request for changes in the specific aims of the Research Project must be made through the application portal prior to performing any changes to the Research Project. Conquer Cancer will approve or disapprove the request at its discretion.

(36) Major changes in research design require prior written approval from Conquer Cancer. A request must be submitted by the Principal Investigator through the application portal prior to performing any aspects of any newly designed study. Examples of a major change include, but are not limited to, studying a different patient population than originally proposed or studying a different therapeutic than originally proposed.

(37) Minor changes in research methodology are not subject to prior approval by Conquer Cancer, but must be explained and justified by the Principal Investigator in the progress report.

Change in Recipient

(38) If the Principal Investigator accepts an appointment or new employment at another institution or organization during the Award Period, the Principal Investigator is not permitted to transfer the Award to a new Recipient. If the Principal Investigator and the Recipient are unable to fulfill the requirements of the Award, they must relinquish the Award and any unexpended funds and funds expended inconsistent with the Research Project will be returned to Conquer Cancer.

Program Reporting

(39) Throughout the Award Period, the Principal Investigator will submit expenditure reports and progress reports, including information about all subcontractors, regarding the Research Project through the application portal as directed in Exhibit A. It is the responsibility of the Principal Investigator to submit the reports in a timely manner. Conquer Cancer may contact appropriate persons connected to the Research Project to ensure the progress reports and expenditure reports are received as required. Principal Investigator and Recipient will comply with the then-current procedures of Conquer Cancer regarding submission of progress and expenditure reports.

(40) Noncompliance with any of these Terms and Conditions, including failure to submit progress or expenditure reports, may result in the withholding of payment on this Award or other awards of Conquer Cancer in effect at the Recipient, or on Conquer Cancer awards that may be awarded in the future, or such other action deemed appropriate by Conquer Cancer.

(41) Any unobligated balance remaining at the end of the Award Period or any extension term must be returned in full to Conquer Cancer along with the Final Expenditure Report by wire transfer. Wire transfer details are as follows:

Conquer Cancer, the ASCO Foundation
Bank – BB & T
ABA / Routing Number (WIRES) – 051404260
Swift Code: BRBTUS33
Account Number – 0000159760723
Reference Information: (Principal Investigator Name, 2021 International Innovation Grant)
BANK ADDRESS:

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THE ASCO FOUNDATION

BB & T
8200 GREENSBORO DR
MCLEAN, VA 22102
TEL: 703-442-5562

Post-Award Reporting Obligation

(42) The Principal Investigator is required to submit a post-Award report through the application portal one year after the Award end date as directed in Exhibit A. It is the responsibility of the Principal Investigator to submit the report in a timely manner.

(43) The Principal Investigator will respond to Conquer Cancer's requests for information following the Award Period and may be requested to update their information on the application portal. The Principal Investigator understands that this obligation survives the Award Period and that they have an ongoing obligation to provide this information.

(44) Conquer Cancer reserves the right to include information relating to the Award in its periodic reports, annual reports, awardee directory, publicly accessible databases of privately funded grant awards, or in any other materials issued by or on behalf of Conquer Cancer or Conquer Cancer's affiliates.

Recordkeeping and Audit

(45) The Recipient will record receipt of the Award funds and any Award Research Project expenditures in such a form as to enable Conquer Cancer to verify that the Award funds were expended for the stated purpose of the Award. All pertinent records, including invoices, purchase orders, worksheets supporting allocations, and copies of reports submitted to Conquer Cancer will be retained by Recipient for at least three (3) years after either the end of the Award Period or the expenditure of all Award funds, whichever is later.

(46) Conquer Cancer or its designated agent will have the right to request and receive from the Recipient or Principal Investigator copies of any and all documents, files, or records related to the Award at any time during or after the Award Period. This right includes, but is not limited to the right to audit such documents, files, and records or have them audited during or after the Award Period. If as a result of an audit, Conquer Cancer reasonably concludes that Award funds were utilized for purposes other than the Research Project, Conquer Cancer will be entitled to a refund of such funds.

Publications and Other Public Release of Results

(47) Conquer Cancer strongly encourages Principal Investigator to submit the results of Research Project for publication or other public release. In the event the Principal Investigator's results are published or otherwise publicly released either during or after the Award Period, the

Principal Investigator will provide Conquer Cancer with a copy of such publication or public release. All publications and public releases will include an acknowledgment of Conquer Cancer (see Public Announcements and Acknowledgments).

(48) Conquer Cancer supports the widest possible dissemination of funded research results. Principal Investigator is highly encouraged to publish in scientific journals that will provide public access to the research findings no later than twelve months after the date of publication.

Fee Waivers for ASCO Journals

(49) Principal Investigator will receive a full waiver of the flat submission fee to the *Journal of Clinical Oncology* (JCO) for submission of an article on the results of the Research Project for publication in the JCO. Principal Investigator shall clearly state, in the cover letter and on the title page, that the Research Project was supported by the Award and funded by Conquer Cancer. Any submission from Principal Investigator to the JCO shall be reviewed using the JCO's then-current established review process. Principal Investigator and Recipient acknowledge and understand that there is no guarantee that any submission will be accepted for publication in the JCO. Principal Investigator is not eligible for waiver of submission fees for submission of an article that does not directly focus on the results of the Research Project.

(50) Principal Investigator will receive a full waiver of the Open Access Article Publishing Charge to the *Journal of Global Oncology* (JGO) if the manuscript is accepted for publication in the JGO. Principal Investigator shall clearly state, in the cover letter and on the title page, that the Research Project was supported by the Award and funded by Conquer Cancer. Any manuscript submitted by Principal Investigator will be reviewed using the JGO's then-current established review process. Principal Investigator and Recipient acknowledge and understand that there is no guarantee that any submission will be accepted for publication in the JGO. Principal Investigator is not eligible for waiver of the Open Access Article Publishing Charge for submission of an article that does not directly focus on the results of the Research Project.

Public Announcements and Acknowledgments

(51) Conquer Cancer anticipates that the Recipient may wish to make a public announcement of this Award. The Recipient will submit to Conquer Cancer any proposed announcement, press release, or other public statement by the Recipient relating to the Award, prior to release, and will coordinate the release of such public announcement, press release, or statement with Conquer Cancer. A copy of any press release, announcement, or public statement must be provided to Conquer Cancer.

(52) The Principal Investigator and the Recipient will acknowledge the support of Conquer Cancer in all publications and presentations of the research funded by the Award. The Principal Investigator understands that all abstracts, publications, and presentations resulting from research supported by the Award will contain the Required Acknowledgment.

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(53)The Principal Investigator is encouraged to use an emblem for the Conquer Cancer International Innovation Grant on posters, presentations, and similar items produced for scientific meetings and conferences. The emblem may be used with the acknowledgment language. The Principal Investigator can request this emblem by sending an email to grants@conquer.org

Intellectual Property Rights

(54) Conquer Cancer will have no intellectual property rights or other rights in or to data collected or scientific discoveries made through the Research Project funded by the Award. Conquer Cancer encourages its principal investigators and their grantee organizations to report to Conquer Cancer any inventions, discoveries, or intellectual properties that result from the support of the research.

Award Conclusion and Termination

(55) The Principal Investigator and Recipient will communicate immediately in writing to Conquer Cancer any intent to terminate the Award.

(56) Upon the earlier of the conclusion of the Award Term or the termination of the Award, all unexpended funds and any funds expended inconsistent with the Research Project will be returned to Conquer Cancer within 30 days. A final progress report and final expenditure report are also due within 30 days of the earlier of the conclusion of Award Term or the Award termination.

(57) Conquer Cancer reserves the right to terminate the Award, and these Terms and Conditions, if the Principal Investigator or Recipient: (i) does not comply with these Terms and Conditions (including the submission of progress and financial reports, as described under "Program Reporting"); (ii) does not make satisfactory progress towards the aims of the Research Project; (iii) requests a change to the Award as set forth in these Terms and Conditions and such request is not approved by Conquer Cancer; (iv) engages in gross negligence or willful misconduct in connection with the Research Project; or (v) in Conquer Cancer's sole judgment, becomes unable to carry out the purposes of the Research Project. If Conquer Cancer terminates the Award, the Recipient will repay Conquer Cancer within 30 days all grants funds unexpended as of the effective date of termination and all grant funds expended inconsistent with the Research Project.

Liability and Insurance

(58)Neither Conquer Cancer nor any of its affiliates assumes responsibility for activities supported by the Award. Principal Investigator and Recipient acknowledge complete responsibility for all aspects of the research, investigation, funding, and administration of and in connection with the Research Project. To the extent permitted by law, the Recipient will indemnify and hold

Conquer Cancer and its affiliates and all of their respective officers, directors, employees, contractors, members, and assigns harmless from and against any and all costs, losses, or expenses, including reasonable attorneys' fees, that the indemnified parties may incur by reason of the negligence or misconduct of the Recipient, the Principal Investigator, or any part of the research team related to the Research Project or any third party claim arising out of or in connection with the Research Project. If this indemnification is prohibited by the laws that govern the Recipient, then this provision will be deemed to be unenforceable and will have no force and effect.

(59) Recipient will maintain adequate liability and other insurance comparable to coverage held by institutions of similar size and nature, covering the Principal Investigator, employees, officers, and agents of Recipient during the Award Period. Upon request, Recipient will provide certificates evidencing its insurance coverage to Conquer Cancer.

Miscellaneous

(60) The provisions of these Terms and Conditions that, by their sense and context, are intended to survive the termination of this Award shall survive termination, including sections on Post-Award Reporting, Publications and Other Public Release of Results, Recordkeeping and Audit, Public Announcements and Acknowledgments, Intellectual Property Rights, and Liability.

(61) Recipient and Principal Investigator each agree that any personal data provided by them to Conquer Cancer pursuant to these Terms and Conditions will be provided in compliance with all applicable laws. With respect to any reports and other information provided to Conquer Cancer, Recipient and Principal Investigator each agree to seek consent or other lawful basis to provide such information to Conquer Cancer.

(62) No delay or omission by a party to exercise any right or remedy under these Terms and Conditions will be construed to be either acquiescence or the waiver of the ability to exercise any right or remedy in the future. Any waiver of any terms and conditions hereof must be in writing, and signed by the parties hereto. A waiver of any term or condition hereof shall not be construed as a future waiver of the same or any other term or condition hereof. In the event any part or provision of these Terms and Conditions is deemed unenforceable, void, or voidable, the remainder of the Terms and Conditions will remain in effect.

(63) These Terms and Conditions, including all exhibits and all materials incorporated by reference into these Terms and Conditions, constitute the entire agreement between the parties concerning the subject matter hereof, and supersede any prior oral or written agreements concerning the subject matter hereof. This Agreement may only be amended by a written agreement signed by the parties hereto. E-mail communication from Conquer Cancer, with or without a name and/or signature block, shall be considered a "written agreement" and shall constitute an amendment of this Agreement, except as specifically provided for in this Agreement.

(15)

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Remainder of Page Intentionally Left Blank

(19)

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IN WITNESS WHEREOF, each party, by their signature or by signature of its duly authorized officer, has agreed to and accepted these Terms and Conditions.

Agreed and accepted by
Principal Investigator:

Signature

SUSHMA AGRAWAL
Principal Investigator
(Printed Name)

3/5/21
Date:

Agreed and accepted by
Recipient[1]:

Signature

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Recipient Authorized Signing Official
(Printed Name and Title)
Sanjay Ghandi Post Graduate Institute of Medical Sciences

16/07/21
Date:

[1] *Must be signed by the Director or member of the Board of Trustees of the Grantee Organization*

Upload signed Terms and Conditions to your account at awards.asco.org by May 17, 2021.

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Exhibit A.
Reporting Deadlines and Requirements for the
2021 Conquer Cancer International Innovation Grant

Report Covers the Period of:	Required Report	Report Due Date
July 1, 2021 – November 30, 2021	Mid-Year Progress Update	December 15, 2021
	Mid-Year Expenditure Report	
July 1, 2021 – June 30, 2022	Final Progress Report	July 31, 2022
	Final Expenditure Report	August 31, 2022
July 1, 2022 – June 30, 2023	Post-award Progress Report	July 31, 2023

The Oriental Insurance Company Limited

This Document is Digitally Signed
Signer: arti mathur
[illegible] 21 4:32 AM

PROFFESSIONAL INDEMNITY -DOCTORS POLICY SCHEDULE

Policy No.	: 221113/48/2022/1074	Prev. Policy No.	: -
Cover Note No.	: -	Cover Note Date	: -
Insured's Code	: 131998106	Issue Office Code	: 221113
Insured's Name	: Dr. Sushma Agrawal (GSTIN:)	Issue Office Name	: CBO 4 LUCKNOW (GSTIN: 09AAACT0627R4ZU)
Address	: Type V/B-1, SGPGIMS Campus, Rae Bareilly Road, Lucknow	Address	: 134/135, SAHU PLAZA ALAMBAGH
			LUCKNOW UTTAR PRADESH 226005
Tel. /Fax /Email	: LUCKNOW UTTAR PRADESH 226014 noreply@doclandservices.com	Tel ./Fax /Email	: 0522 2450167 2450114 / 0 / gspal@orientalinsurance.co.in

Agent/Broker Details

Dev.Off.Code :
Agent/Broker :
Address :
Tel/Fax/Email :

Period of Insurance : FROM 18:14 ON 29/05/2021 TO MIDNIGHT OF 28/05/2022
Collection No. & Dt. : CC 1024900449 - 29/05/2021 GST INVOICE NO :092062123 UIN :0
Gross Premium : 160 GST : 28 Stamp Duty : .5 Total : 188
Co-insurance Details : NIL

RISK DETAILS

Name of the Doctor : **Dr. Sushma Agrawal**
Description of Profession : **MBBS MD Cancer Physician**
Indemnity Limit : **ONCOLOGISTS**

Any One Accident Rs . 1,00,000
Aggregate during the policy period Rs . 2,00,000

Location ID	Location Description
1	Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Rae Bareilly Road, Lucknow

Retroactive Date :

Add on Covers :

Total Sum Insured in words : Indian Rupees Two Lakhs Only
Total Premium in words : Indian Rupees One Hundred Eighty-Eight Only

The Insurance under this policy is subject to Warranties & Clauses :

Territorial Limits : Any where in India

In the event of a claim under the policy exceeding Rs. 1 lac or a claim for refund of premium exceeding Rs. 1 lac,the

Place : LUCKNOW
Date : 29/05/2021

IRDA-REGNO-556

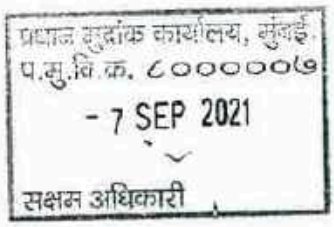
For and on behalf of
The Oriental Insurance Company Limited

This is an electronically generated document (Policy Schedule).The Policy document duly stamped will be sent by post.

In case of any query regarding the Policy please call Toll Free No. 1800 11 8485 and 011 33208485.

Authorised Signatory

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ ZB 052583



CLINICAL STUDY AGREEMENT

This clinical study agreement ("Agreement"), effective as of 22-Sep-2021 (the "Effective Date"), is entered into by and among Medpace Clinical Research, LLC, with its principal office and place of business at 5375 Medpace Way, Cincinnati, Ohio 45227 and Medpace Clinical Research India Private Limited, 8th floor,office no.817,Rupa solitaire building, Millennium business park, Maharashtra, Thane-400710, India ("Medpace") , and Sanjay Gandhi Postgraduate Institute of Medical Sciences, a clinical research site with its principal office and place of business at Department of Medical Genetics, Main Hospital, Raebareli Road, Uttar Pradesh, Lucknow, 226014, India., ("Institution") and Dr. Shubha Phadke, having an address at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Department of Medical Genetics, Main Hospital, Raebareli Road, Uttar Pradesh, Lucknow, 226014, India ("Principal Investigator"). Medpace, Institution and Principal Investigator are sometimes collectively referred to herein as parties (the "Parties").

WHEREAS, Catalyst Biosciences, Inc., 611 Gateway Blvd., Suite 710, South San Francisco, CA 94080 ("Sponsor") is sponsoring a clinical study on the compound Factor VIIa, marzeptacog alfa (activated) [MarzAA] (the "Study Drug"), in accordance with Protocol No. MAA-304, titled "Phase 3 Study to Evaluate the Efficacy and Safety of Subcutaneous Marzeptacog Alfa (Activated) For On demand Treatment and Control of Bleeding Episodes in Subjects with Hemophilia A or Hemophilia B, with Inhibitors: The Crimson 1 Study" (the "Protocol"), and Institution possesses expertise in the conduct and performance of clinical studies. The performance of the Protocol shall be referred to herein as the "Study"; and

WHEREAS, Medpace is a contract research organization which has been contracted by Sponsor to manage and administer the Study; and

WHEREAS, Medpace desires that Institution and Principal Investigator participate in the conduct of the Study in accordance with the Protocol and the terms and conditions of this Agreement, and Institution and Principal Investigator desire to participate in the conduct of the Study in accordance with the Protocol and the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the foregoing and the mutual covenants and promises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1 SCOPE OF WORK AND COMPLIANCE WITH APPLICABLE LAWS.

Institution and Principal Investigator (as defined in the Principal Investigator section) shall perform the Study in strict compliance with the terms and conditions of this Agreement, any written instructions from Sponsor and/or Medpace, all generally accepted standards of Good Clinical Practice ("GCP"), the Protocol, and with all applicable local laws, Indian GCP and regulations governing the performance of clinical investigations. A copy of the Protocol has been provided to Institution and Principal Investigator and is hereby incorporated by reference, together with any and all amendments thereto, into this Agreement.

2 PRINCIPAL INVESTIGATOR

Principal Investigator will be responsible for the direction of the Study in accordance with applicable Institution policies, which Institution warrants and represents are not inconsistent with the terms of this Agreement and the Protocol. If, for any reason, he/she is unable to continue to serve as Principal Investigator and a successor acceptable to Institution, Medpace, and Sponsor is not available, this Agreement shall be terminated as provided in the Term and Termination section. Institution and Principal Investigator warrant and represent that Principal Investigator is fully qualified to conduct the Study and to serve in the capacity of Principal Investigator. Principal Investigator and all persons or entities who perform any portion of the Study ("Study Personnel") shall be employees or subcontractors of Institution and Institution shall be responsible for their compliance with the terms of this Agreement. Institution and Principal Investigator represent that neither Principal Investigator nor Institution are a citizen or resident of the United States, or a corporation or partnership that is and has been treated as a U.S. corporation or U.S. partnership, and that all payments received under this Agreement will be for services rendered outside the United States.

3 CONFIDENTIAL INFORMATION

3.1 "Confidential Information" means all information that is (a) provided by or on behalf of Sponsor or Medpace to Institution or Principal Investigator in connection with this Agreement or the Study, or (b) developed, obtained, or generated by Institution, Principal Investigator, or Study Personnel as a result of performing the Study under this Agreement (except for a Study subject's medical records), including, but not limited to, the Protocol, Study data, results, and reports from all sites conducting the Study. Confidential Information and all tangible expressions, in any media, of Confidential Information are the sole property of Sponsor or Medpace, as applicable.

3.2 Institution and Principal Investigator agree not to use Confidential Information for any purposes other than to conduct the Study. Institution and Principal Investigator agree not to disclose Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this section. Institution and Principal Investigator shall safeguard Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

3.3 The term Confidential Information shall not be deemed to include information that:

3.3.1 Is or becomes publicly available through no fault of Institution or Principal Investigator;

3.3.2 Institution and Principal Investigator can demonstrate they possessed prior to, or developed independently from, disclosure or development under this Agreement;

3.3.3 Institution or Principal Investigator receives from a third party which is not legally prohibited from disclosing such information;

3.3.4 Is appropriate to include in a publication pursuant to the Publications and Publicity section.

3.4 Unless Sponsor provides prior written consent, Institution and Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Institution or Principal Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by Applicable Law. Required disclosure of Confidential Information to the independent ethics committee ("IEC") and/or regulatory authority ("RA") is specifically authorized.

If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Institution and Principal Investigator notify Medpace and/or Sponsor in writing as far as possible in advance of the disclosure so as to allow Sponsor to take legal action to protect its Confidential Information, discloses only that Confidential Information required to comply with the legal requirement, and continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

3.5 Is appropriate to include in a publication pursuant to the Publications and Publicity section.

Institution and Principal Investigator agree that Medpace may compile a database of information from Principal Investigator, Institution and Institution's personnel, for use in connection with the Study (including but not limited to feasibility questionnaires, CVs,

licenses, medical specialties, participation in clinical trials, financial disclosure forms) and/or may use this information for purposes related to its business. Institution shall have secured any necessary consents from its personnel to allow for this sharing of information and Principal Investigator hereby consents to such sharing of his/her information. Such information is used solely in connection with the initiation of studies and feasibility studies and is accessible only to the Sponsor of the respective study and personnel assigned to study management and for whom the information is needed in the performance of their duties (further described as "Authorized Personnel"). As some Medpace studies are being conducted worldwide, the personal information collected is available to Authorized Personnel who may be located in countries outside the country of origin. In order to provide for the protection of personal data, Medpace has established policies and procedures governing the security of and limited access to this data that are uniform throughout Medpace and its affiliates and comply with the applicable standards of personal data protection. When applicable, Medpace enters into data processing agreements with Sponsors in line with applicable data protection laws. The individuals' whose data is collected have a right to access, to modify, to rectify and to suppress their personal data, simply by requesting it to the attention of the Medpace Privacy Officer at privacy@Medpace.com, or to the following address: Medpace Privacy Officer, Medpace, Inc., 5375 Medpace Way, Cincinnati, Ohio 45227.

4 RECORDKEEPING

4.1 Instititution and/or Principal Investigator shall maintain all records, data, documents or information related to the performance of the Study until the later of:

4.1.1 Two (2) years following the date a New Drug Application is approved for the Study Drug that is the subject of the Study;

4.1.2 Two (2) years after the Investigational New Drug Application for such Study Drug is terminated or withdrawn; or

4.1.3 As defined by local laws and regulations.

4.2 At the end of such required retention period, neither Institution nor Principal Investigator shall destroy any such records until they have obtained Medpace's prior written permission to do so. Medpace will respond promptly to Institution's or Principal Investigator's requests to dispose of records.

4.3 Subject to the requirements of the Confidential Information section, following the end of the required retention period, Institution may retain in its possession an archival copy of Confidential Information that consists of any and all data, documents or information related to the performance of this Agreement solely as required for regulatory, legal, or insurance purposes.

5 ACCESS TO RECORDS AND AUDITS

5.1 Medpace and/or Sponsor shall have the right to inspect progress of the Study on the premises of Institution at reasonable times during the term of this Agreement. Medpace and/or Sponsor will notify Institution prior to any inspection of the date and time of the inspection. The representatives of Medpace and/or Sponsor may review and/or request copies of data derived from the Study, and Principal Investigator or Institution shall promptly provide such data. Principal Investigator and/or Institution will notify Medpace and/or Sponsor by telephone and

subsequently in written form, of any significant changes, including, but not limited to, changes in Study Personnel, Principal Investigator, or physical location, that occur during the Study.

5.1.1 Within twenty-four (24) hours after learning of any FDA, Drug Controller General Of India (DCGI) or other governmental or regulatory body (e.g., Institutional Review Board, Drug Enforcement Agency), regulatory inspections of which they become aware relating to the Study, Principal Investigator and/or Institution shall provide written notification to Medpace and Sponsor. Principal Investigator and/or Institution shall also provide a copy of any communications with the RA during and after inspection. Medpace and Sponsor shall have the right to be present at any such inspections and shall have the opportunity to provide, review, and comment on any responses that may be required. Further, Principal Investigator and/or Institution will provide in writing to Medpace and Sponsor copies of all materials, correspondence, statements, forms and records which Principal Investigator or Institution receives or obtains pursuant to this inspection.

6 COSTS AND PAYMENT SCHEDULE

In consideration of the proper performance of the Study by the Institution and the Principal Investigator under the terms of this Agreement and upon approval of Sponsor, payment will be made by Medpace or its designee to the payee ("Payee") designated in Schedule A appended hereto and incorporated herein by reference. Institution and Principal Investigator will accept payment from Medpace, or its designee, to the Payee as full consideration for services rendered. Once the designated Payees have been paid for the performance of the Study, neither Medpace nor Sponsor shall have any further obligation or liability whatsoever to pay Principal Investigator or Institution. All costs outlined on Schedule A shall remain firm for the duration of the Study, unless otherwise agreed to in writing by the Institution and Medpace. It is understood and agreed that no reimbursement will be provided by Medpace or Sponsor for subjects who are randomized into the Study in violation of the Protocol, or who do not conform to the Protocol's inclusion and exclusion criteria or for whom serious deviations from the Protocol are made. The budget contained in Schedule A is inclusive of all applicable taxes. Should any tax laws require withholding, the party legally responsible shall be liable for withholdings. Medpace, as Sponsor's payment agent, shall make payment to Payee under this Agreement from funds provided by Sponsor. Notwithstanding the foregoing, Medpace may issue a written amendment, signed only by Medpace, for the purpose of increasing the Study costs as described in the Schedule A.

7 TERM AND TERMINATION

7.1 This Agreement shall commence as of the Effective Date and, unless terminated earlier as provided for in this section, shall continue until the completion of the Study.

7.2 Institution and Principal Investigator may terminate this Agreement if Medpace materially breaches this Agreement and Medpace fails to cure the breach within thirty (30) days after receipt of written notice from a Party specifying in detail the nature of the breach. Medpace may terminate this Agreement at any time upon giving thirty (30) days' advance written notice to Institution and Principal Investigator. The Parties agree that in the event of a breach of this Agreement, the non-breaching Party shall be entitled to seek its expenses and attorney fees.

7.3 Medpace shall be obligated to pay Payee solely for those items set forth in the Schedule A that have been incurred prior to the date of notice of termination. Institution shall promptly refund

to Medpace or shall cause Payee to promptly refund all unearned advance payments made by Medpace under the Schedule A.

7.4 Upon completion or termination of this Agreement, in no event shall Medpace be obligated to pay any invoices submitted after the time period for submitting final invoices set forth in Schedule A has expired.

7.5 Upon completion or termination of this Agreement, Institution and Principal Investigator shall, upon Medpace's request, return or destroy all documents, information, and/or supplies, including, but not limited to, Study drug(s) and related devices, equipment, and any biological samples or other materials provided by Medpace or Sponsor for the conduct of the Study, to Sponsor or Medpace within thirty (30) days. If Medpace requests that such documents, information or supplies be destroyed, Institution or Principal Investigator, as applicable, agrees to destroy same and provide Medpace with written certification of such destruction. The Principal Investigator, Confidential Information, Recordkeeping, Access to Records, Costs and Payment Schedule, Term and Termination, Intellectual Property, Publications and Publicity, Indemnification and Insurance, Anti-Bribery/Anti-Corruption and Miscellaneous sections shall survive the termination or expiration of this Agreement.

8 INTELLECTUAL PROPERTY

8.1 It is agreed that none of Sponsor, Medpace, Principal Investigator, or Institution transfers to any other by operation of this Agreement any patent right, copyright, trademark right, or other proprietary right of Sponsor, Medpace, Principal Investigator, or Institution, except as expressly set forth herein.

8.1.1 "Invention" means any discovery, invention, technology, result, data, material, improvement, or idea, whether or not patentable, resulting from or reduced to practice as a result of conducting the Study, or made using the Study Drug or Confidential Information.

8.2 Institution and Principal Investigator will notify Sponsor, promptly and in writing, of any Invention made by Institution, Principal Investigator, and Study Personnel.

8.3 Sponsor shall own all right, title, and interest in and to any Invention and shall have the sole and exclusive right to obtain, at its option, patent protection in the United States and other countries on any such Invention. If Sponsor requests, Principal Investigator and Institution will execute and will cause Study Personnel to execute any application, assignment, or instrument or to testify as Sponsor deems necessary for Sponsor to obtain patents or otherwise to protect Sponsor's interest in an Invention. Sponsor will reasonably compensate Institution or its designated Payee for the time devoted to such activities and will reimburse Institution, Principal Investigator or their designated Payee for reasonable and necessary expenses incurred.

9 PUBLICATIONS AND PUBLICITY

9.1 It is understood that the Study is part of a multicenter trial, and Institution and Principal Investigator may publish the results of their part of the Study in collaboration with the other investigators, but in complete compliance with this section and with the Confidential Information section. After the multicenter publication or twenty-four (24) months after

completion of the Study, whichever occurs first, Institution and/or Principal Investigator may publish the results of their data from the Study. Institution and Principal Investigator shall provide Sponsor and Medpace with an advance copy of any proposed publication or oral presentation at least sixty (60) days prior to the planned date of submission or presentation and Sponsor shall have sixty (60) days to review the proposed publication for the purposes described below. Sponsor and Medpace may request in writing, and Institution and Principal Investigator shall agree to, (a) the deletion of any Confidential Information, (b) any reasonable changes requested by Sponsor or Medpace, or (c) a delay of such proposed submission for an additional period, not to exceed ninety (90) days, in order to protect the potential patentability of any technology described therein. Sponsor, at its election, shall be entitled to receive in any such publication an acknowledgement of its sponsorship of the Study.

9.2 None of the Parties shall use another Party's name or Sponsor's name, or issue any public statement about this Agreement, or publish any information about the Study, without the prior written permission of the Party to be named except as required by law. Such prior permission shall not be unreasonably withheld. The Parties agree that in order for Institution and Principal Investigator to satisfy their reporting obligations, they may identify Medpace or Sponsor and the amount of funding received from Medpace for the Study, but will not include in such report any information which identifies the name of the Study Drug or the therapeutic areas of the Study.

9.3 Notwithstanding the foregoing, nothing contained in this Agreement shall prevent the Study from being registered with www.clinicaltrials.gov, or any equivalent registry, including all information required by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors in effect as of the date of initiation of the Study (see www.icmje.org).

10 NOTICES

Any notice required or permitted under this Agreement shall be in writing and shall be deemed made and given three (3) days after sending, if mailed by registered or certified mail, postage prepaid, return receipt requested, or one (1) day after sending, if sent by express courier service or facsimile/electronic transmission. In addition, the Institution and Principal Investigator will communicate to Medpace in writing (email is considered a writing for the purposes of this section), any changes to the Payee name, Payee address, tax identification number, corporate address, or corporate name. Any such notification shall originate from an Institution official having the same or greater authority as the Institution official who signs this Agreement on behalf of the Institution or in the case of changes to Principal Investigator Payee information, the notification shall originate from Principal Investigator. All notices must be addressed to the contact set forth below:

IF TO MEDPACE:

Medpace Clinical Research, LLC
Attention General Counsel
5375 Medpace Way
Cincinnati, OH 45227

IF TO INSTITUTION:

Sanjay Gandhi Postgraduate Institute of Medical Sciences
Department of Medical Genetics,
Main Hospital, Raebareli Road, Uttar Pradesh, Lucknow, 226014
India.

IF TO SPONSOR:

Catalyst Biosciences, Inc.,
611 Gateway Blvd., Suite 710,
South San Francisco, CA 94080

WITH A COPY TO
Medpace Clinical Research India Pvt. Ltd.
Office No. 817, 8th Floor
Rupa Solitaire
Building No. A-1, Sector-1
Millenium Business Park
, Mahape
Navi Mumbai 400710, India

IF TO PRINCIPAL INVESTIGATOR:
Dr. Shubha Phadke
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Department of Medical Genetics,
Main Hospital, Raebareli Road, Uttar
Pradesh, Lucknow, 226014
India.

11 ELECTRONIC SIGNATURES

Institution and Principal Investigator consent to electronic communication and electronic signatures being equal to signatures inked on paper. Institution and Principal Investigator acknowledge and agree that electronic communication is an acceptable method of communicating information from Medpace to Institution and Principal Investigator without having to communicate the same subject matter on paper. Therefore, any communication and subsequent electronic signature that has been sent or signed in the past, present, or future between the Parties will hold the same force and effect as a document signed and inked on paper. Electronic signature includes without limitation a scanned copy of a signature, a typed signature, or the click of a mouse on an "I agree" icon or button. All communications that Medpace provides to Institution and Principal Investigator in electronic form will be provided either: (1) via e-mail by requesting Institution or Principal Investigator download a PDF or DOC file containing the communication; or (2) in the case of the License Agreement, will be provided immediately prior to the log-in screen for ClinTrak. Institution and Principal Investigator can obtain a paper copy of an electronic communication by printing it or by requesting that Medpace mail a paper copy, provided that such request is made within a reasonable time after Medpace first provided the electronic communication.

12 INDEMNIFICATION AND INSURANCE

12.1 Sponsor shall indemnify Institution and Principal Investigator pursuant to the terms and conditions of a separate letter of indemnification between Sponsor, Institution and Principal Investigator, as requested. Medpace shall not have any obligation to indemnify Principal Investigator(s), Institution and/or their agents, employees and representatives.

12.2 Medpace and Sponsor shall not be liable for incidental, special, indirect or consequential damages to persons or property including but not limited to the right to be paid for loss of time, loss of services, loss of production, lost profits, lost business, lost savings or other economic or business loss or claims of any kind whatsoever, arising out of or as a consequence of the services performed or otherwise under this Agreement, even if advised of the possibility of such damages.

12.3 Institution and Principal Investigator shall maintain insurance as required by applicable law, with limits consistent with statutory minimum amounts. Institution and Principal Investigator shall maintain such coverage for the duration of this Agreement and for two years thereafter. Proof of said insurance shall be supplied to Medpace upon request.

13 DEBARMENT

Each of Institution and Principal Investigator represents that neither of them, nor any of their management or any other employees or independent contractors or agents who will have any involvement in the Study, have been debarred by any regulatory authority. Institution and/or

Principal Investigator shall immediately notify Medpace in writing upon becoming aware of any such debarment, threat of debarment, or conviction or other matter that could result in any such debarment. Medpace may, upon its receipt of such notice or otherwise becoming aware of any debarment, threat of debarment or other matter that could result in any such debarment, terminate this Agreement in accordance with the Term and Termination Section.

14 ANTI-BRIBERY/ANTI-CORRUPTION

In carrying out its responsibilities under this Agreement, neither Party nor it nor any of its respective representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof corruptly for the purpose of improperly (i) influencing any act or decision of that person in his official capacity, including a decision to fail to perform his functions with such governmental agency or instrumentality or such public international organization or such political party, (ii) inducing such person to use his influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof or (iii) securing any improper advantage; provided however, the foregoing representation shall not apply to any facilitating or expediting payment to a foreign official, political party, or party official, the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official, political party, or party official.

15 ASSIGNMENT AND DELEGATION

This Agreement shall be binding upon and for the benefit of the Parties hereto, and their successors and permitted assigns. This Agreement, and all rights, duties and obligations hereunder, may not be assigned or delegated by Institution or Principal Investigator without the prior express written consent of Medpace. Any attempt made by Institution or Principal Investigator to assign or delegate this Agreement in violation of this section shall be of no force or effect. Institution and Principal Investigator acknowledge that Medpace shall have the right to assign or delegate this Agreement or any portion thereof without the consent of Institution or Principal Investigator.

In the event where Institution and/or Principal Investigator are responsible for use of a subcontractor or affiliate for performing study obligations under this Agreement. Institution and Principal Investigator shall remain responsible for the proper performance of such services, in accordance with this Agreement. In case of change in subcontractors of Institution, Institution and/or Principal Investigator will inform Sponsor and Medpace in writing.

16 INDEPENDENT CONTRACTOR

The relationship of the Parties is that of independent contractors, and no employment or agency relationship shall be construed to exist between the Parties. Neither Medpace nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding or employment-related taxes relating to Institution, Principal Investigator or Study Personnel.

17 CHANGES TO THE PROTOCOL

The Protocol may be amended only at the direction of Sponsor, subject to subsequent approval of the Ethics Committee. No financial adjustments shall be made because of such modifications unless the Parties hereto amend this Agreement accordingly.

18 MISCELLANEOUS

18.1 This Agreement represents the entire understanding of the Parties and supersedes all prior negotiations, understandings or agreements (oral or written) between the Parties concerning the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. If a provision of this Agreement is or becomes (i) illegal under any applicable law or regulation, (ii) invalid or (iii) otherwise unenforceable, such illegality, invalidity or unenforceability shall not affect the validity or enforceability of any other term or provision of this Agreement. All waivers of the terms of this Agreement shall be in writing. Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, but the same shall remain at all times in full force and effect.

18.2 This Agreement shall be governed by and construed in accordance with the laws of India. For any legal action arising from or related to this Agreement, the Parties hereby consent and submit solely to the jurisdiction and venue of the courts located at Lucknow and agree that such courts shall be the sole courts utilized and hereby waive any jurisdictional or venue objections to such court.18.3 This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement and shall become binding when any one or more counterparts hereof, individually or taken together, bears the signature of each of the Parties hereto. A facsimile or PDF electronic submission of this Agreement or any subsequent amendment(s) signed by a Party's duly authorized representative shall be legal and binding on all Parties.

19 SPONSOR AS THIRD-PARTY BENEFICIARY

The Parties to this Agreement recognize and agree that Sponsor takes the benefit of this Agreement as a third-party beneficiary and agree that Sponsor may enforce such rights either directly itself or indirectly through Medpace.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by proper persons thereunto duly authorized and that this Agreement shall be effective as of the Effective Date.

For Medpace, on its own behalf and as payment agent of Sponsor	Institution	Principal Investigator
Meghana Subramanian	22/X/25. Prof. R. K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA	
By (signature)	By (signature)	By (signature)
Meghana Subramanian		Dr Shubha Phadke
Name (print or type)	Name (print or type)	Name (print or type)
Sr. CRA Manager		Professor, Department of Medical Genetics, SGPGIMS.
Title	Title	Title
	o/c ucGul	

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

CATALYST BIOSCIENCES, INC.

PROTOCOL ID: MAA-304

// DR. SHUBHA PHADKE//

SITE: // 35601//

SCHEDULE A VERSION: 1.0

COUNTRY: INDIA

PROTOCOL VERSION: AMENDMENT 1 02JUN2020

SCHEDULE A

A1 STUDY BUDGET

Medpace, as Sponsor's payment agent, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. All fees listed include overhead. 18% GST is applicable on all the invoices generated. Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject

1.1.1	*Non-pediatric*	*INR 153,626.00*
1.1.2	*Pediatric*	*INR 175,501.00*

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit Month 1 (MarzAA Month 1 or SOC Month 1, based on Sequence A or Sequence B Patient Assignment).

A2 SETUP FEES & VISIT PAYMENTS

☒ Please check box if Payee must submit an invoice to Medpace prior to receiving payment. Payment will be made within forty-five (45) days of receipt of invoice.

A2.1 Setup Fees

2.1.1	*Non-refundable Administrative Set-up Fee*	*INR 35,000.00*

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation;
- IRB/EC approval; and
- Medpace's receipt of the fully executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. It is expected that all visits are completed per protocol requirements and will be paid based on EDC entry of visit. With prior notice to Payee and in exceptional circumstances, visit fees may require an adjustment if routine review of data identifies a significant concern with incomplete procedures or visits. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

Table 1 - Fees for Completed Clinical Visits for Randomized Subjects (Sequence A or Sequence B)

VISIT	Non-Pediatric Fee (including 25% overhead)		Pediatric Fee (Including 25% overhead)	
Screening (-30 to -1 Day)	INR	17,913.00	INR	22,288.00
MarzAA Treatment Period Month 1	INR	10,538.00	INR	11,788.00
MarzAA Treatment Period Month 2	INR	9,475.00	INR	10,725.00
MarzAA Treatment Period Month 3	INR	9,475.00	INR	10,725.00
MarzAA Treatment Period Month 4	INR	9,475.00	INR	10,725.00
MarzAA Treatment Period Month 5	INR	9,475.00	INR	10,725.00
MarzAA Treatment Period Month 6	INR	9,475.00	INR	10,725.00
IAP	INR	10,475.00	INR	11,725.00
SOC Treatment Period Month 1	INR	9,475.00	INR	10,725.00
SOC Treatment Period Month 2	INR	9,475.00	INR	10,725.00
SOC Treatment Period Month 3	INR	9,475.00	INR	10,725.00
SOC Treatment Period Month 4	INR	9,475.00	INR	10,725.00
SOC Treatment Period Month 5	INR	9,475.00	INR	10,725.00
SOC Treatment Period Month 6	INR	9,475.00	INR	10,725.00
EOS	INR	10,475.00	INR	11,725.00
TOTAL PER PATIENT	**INR**	**153,626.00**	**INR**	**175,501.00**
MarzAA Treatment Period Month >6	INR	9,475.00	INR	10,725.00
SOC Treatment Period Month >6	INR	9,475.00	INR	10,725.00

Sequence A: MarzAA Treatment Period monthly visits will occur prior to SOC Treatment Period monthly visits.
Sequence B: SOC Treatment Period monthly visits will occur prior to MarzAA Treatment Period monthly visits.

A2.3 Screen Failures

Table 2 - Screen Failures

VISIT OF FAILURE	FEE (NON-PEDIATRIC)	FEE (PEDIATRIC)
Screening (-30 to -1 Day)	INR 11,643.45	INR 14,487.20

Payment for up to three (3) screen failures will be made and thereafter, once the required number of subject(s) have been randomized per ratio (1 failures:3 randomized) for screen failures for whom Medpace has received all appropriate documentation of procedures/visits completed with the next scheduled payment owed to the Payee. Eligible screen failure payment will be based on the order (by date) of when the subject is consented.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Medpace after:

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor;
- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Ancillary Supplies Reimbursement Advanced Payment — INR 10,000.00

Payee will receive a one-time advanced payment for purchase of ancillary supplies required Study conduct, specifically [10ml sWFI, 3ml syringe, 18 gauge- 1' needle, 30 gauge- ½ " needle], paid with start-up payment. Payee is responsible for maintaining records of funds utilized for ancillary supplies purchases (vendor invoice, receipts, etc), as well as subject dispensing records of ancillary supplies purchased for Study. Records will be accessible during monitoring visits for CRA's review. Subsequent advanced payments may be available upon pre-approval by Sponsor based on enrollment needs and after CRA verification of sufficient records of funds utilized. Subsequent advanced payments will be paid within forty-five (45) days of Medpace's receipt of invoice, Sponsor approval, and CRA's verification of first advance depletion. At Study closure, if excessive funds remain and will not be utilized for Study purposes, Payee may be required to return remaining funds or amount may be deducted from Institution's final payment, at discretion of Sponsor. Medpace will notify Payee in writing of the amount of any refund due and Payee shall return within thirty (30) days after receipt of Medpace's notification.

A3.2 Additional Procedures

Payment will be made for procedures listed below if required by the protocol and not considered as standard of care.

Table 3 – Unitized Procedures (including 25% overhead)

FEES	COST
Pregnancy Test - Serum	INR 687.50
Pregnancy Test – Urine	INR 62.50
Accountability Applicable during MarzAA Treatment Month 1 to Month6, ECS and Unscheduled visit.	INR 531.25 per occurrence
Central Laboratory Specimen Draw and Processing (Immunogenicity Assays, Coagulation Assays, Thrombogenicity Markers, and MarzAA PK sampling nonbleeding/bleeding state) Applicable for scheduled protocol and unscheduled visits	INR 1,000 / per time point
Overnight Bed Fee charges	INR 1,375/ day

A3.3 Unscheduled Visit

3.3.1 ***Non-pediatric*** — ***UP TO INR 9,475.00***

3.3.2 ***Pediatric*** — ***UP TO INR 10,725.00***

Unscheduled Visit must be entered into EDC and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit. Itemized invoice included subject ID, unscheduled visit date, and list of completed procedures required.

A3.4 Subject travel fee — up to INR 1,000/ visit

A subject travel fee shall be reimbursed on actuals.

Additional funds may be available for travel costs exceeding INR 1,000/ per visit with prior written approval from the Sponsor.

A3.5 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Medpace/Sponsor.

A3.6 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Medpace/Sponsor.

A4 MEDPACE RIGHTS

Medpace reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Medpace within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.

A5 MEDPACE INVOICING

All payment inquiries and invoices submitted shall include the Protocol number and Principal Investigator name and be sent to the following:

Email: siteinvoices@medpace.com
Phone: 513-579-9911

Medpace Clinical Research, LLC
Attn: Clinical Operations Site Payments
5375 Medpace Way
Cincinnati, Ohio 45227

All invoices must be submitted to Medpace within ninety (90) days of occurrence or up to thirty (30) days after receipt of the final payment.

A6 PAYEE INFORMATION

All payments made by Medpace as set forth herein shall be payable solely to Payee at the address set forth below. Any such payments which are due to any other party performing services in connection with the Study shall be a matter solely between Payee and such party.

Table 4 - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name*	Director S.G.P.G.I.M.S Research Account
Payee Mailing Address	Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli road, Lucknow-226014, Uttar Pradesh, India.
Contact Name	Dr. Shubha Phadke
Email Address	//director@sgpgi.ac.in//
Bank	State Bank of India
Account №	10095237491
IBAN №	NA
BIC Code/Swift Code	SBININBB500
IFSC Code (India)	SBIN0007789
Tax ID #**	AAAJS3913N
GST ID#:	09AAAJS3913N2ZN

**Requested for Medpace Accounting tracking purposes only

MEDPACE
THE ADVANTAGE OF FOCUS

CLINICAL STUDY AGREEMENT

PROTOCOL: MAA-304

SITE: //35601//

//DR. SHUBHA PHADKE//

CATALYST BIOSCIENCES, INC.

//DD-MON-YYYY//

VERSION: //VERSION #1//

COUNTRY: INDIA

सत्यमेव जयते

INDIA NON JUDICIAL

105

Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	**IN-DL57763653645520T**
Certificate Issued Date	:	01-Dec-2021 01:24 PM
Account Reference	:	IMPACC (IV)/ dl777003/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL77700308009774628554T
Purchased by	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Second Party	:	Not Applicable
Stamp Duty Paid By	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter the "**Agreement**") is executed at New Delhi on _____, (hereinafter referred to as the "**Effective Date**") between;

GIGH Representative Initials

Institution Representative Initials

PI Initials

Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014

PACE in COPD_CTA,V 1.0, 30-Oct-2020
Dr.Alok Nath,SGPGI, Lucknow _CTA,V 1.0, 06-Jul-2021

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GEORGE INSTITUTE FOR GLOBAL HEALTH (CIN U74900TG2007NPL055085), a company registered under section 25 the Companies Act, 1956 (India), having its Registered office at 308, Third Floor, Elegance Tower Plot No. 8, Jasola District Centre, New Delhi 110025 (hereinafter referred to as "**GIGH**", which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the First Part;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences , with PAN AAAJS3913N, having its registered office at New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh- 226014, (hereinafter referred to as the "**Institution,**" which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the Second Part;

AND

Dr. Alok Nath, the principal investigator at the Institution, with office at Department of Pulmonary Medicine , Department of Pulmonary Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014 , (hereinafter referred to as the "**Investigator,**" which expression shall, unless repugnant to the meaning or context thereof, be deemed to mean and include his/her heirs, representatives and assigns) of the Third Part;

(Each of GIGH, the Institution, and the Investigator may hereinafter be referred individually as a "**Party**" and collectively as the "**Parties.**")

WHEREAS GIGH, as a sponsor is conducting a study, known as the "Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD): PACE in COPD (hereinafter referred to as the "**Study**")";

AND WHEREAS GIGH wishes the Study to be conducted in terms of the protocol, which includes the objectives, design, methodology, statistical considerations and organization of the Study attached hereto as Exhibit A including amendments made thereto from time to time (hereinafter referred to as the "**Protocol**");

AND WHEREAS GIGH may also conduct sub-studies from time to time (hereinafter referred to as each "**Sub-Study**") in conjunction with the Study, and upon written notification of a Sub-Study, all applicable references in this Agreement to 'Study' shall include such Sub-Study and

GIGH **Representative** Initials | Institution Representative Initials | PI Initials

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Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014

all references in this Agreement to 'Protocol' shall include the protocol related to such Sub-Study;

AND WHEREAS the continuance in force of this Agreement shall be related to the continuance of the provision of research funding and other support to GIGH;

AND WHEREAS in order to generally meet with international regulatory and other standards as also requirements as to the design and conduct of a clinical trial, and to better ensure the robustness and broader applicability of the results of the Study, it is necessary for GIGH to carry out the Study in collaboration with centers that are located in numerous cities across India;

AND WHEREAS Investigator and Institution possess the resources and expertise to carry out the Study at the various sites of the Institution (hereinafter individually referred to, for the purposes of this Agreement, as the "**Study Site**"), and wish to assist GIGH in conducting the Study;

AND WHEREAS the Parties wish to enter into this Agreement to record their understanding in this regard and other related understandings between the Parties.

NOW THIS AGREEMENT HEREBY RECORD THE RIGHTS AND OBLIGATIONS AGREED UPON IN CONNECTION WITH THE PERFORMANCE OF THE STUDY BY AND BETWEEN THE UNDERSIGNED PARTIES AS FOLLOWS:

1. PERFORMANCE OF THE STUDY

1.1. Institution and Investigator shall carry out and conduct the Study at the Study Site in strict conformance with:

(i) the terms of this Agreement, the Protocol and the written instructions or advice issued by GIGH;

(ii) generally accepted standards of good clinical practice, including the *Guidance for Good Clinical Practice of the International Conference on Harmonisation* (hereinafter referred to as the "**ICH-GCP**");

(iii) revised Schedule Y of the *Indian Drugs and Cosmetic Rules 1945* (as amended from time to time (hereinafter referred to as **"New Drugs and Clinical Trials Rules, 2019"**);

(iv) all applicable Study documents which are duly approved by the governing Institutional Review Board/Independent Ethics Committee Board (hereinafter referred to as the **"IRB/ IEC"**);

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(v) all Applicable Laws, applicable procedures, rules, regulations and guidelines established by law, or otherwise applicable within the Institution, governing the performance of clinical research involving human participants in the jurisdiction of the Study; and

(vi) all applicable rules, orders, regulations and guidelines Health Ministry Screening Committee (hereinafter referred to as the "**Regulatory Authority**", and all references to regulatory authority within this Agreement shall include Regulatory Authority).

Applicable Laws shall mean and include all statutes, enactments, acts of legislature or parliament, laws, ordinances, rules, bye-laws, regulations, notifications, guidelines, policies, directions, determinations, directives, writs, decrees, injunctions, judgments, awards or orders of any government authority, statutory authority, tribunal, board, court, and if applicable, international treaties and regulations, as amended from time to time and including but not limited to:

(i) Applicable provisions of the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945 (including Schedule Y);

(ii) International Conference on Harmonization - Good Clinical Practice (ICH-GCP) Guidelines;

(iii) WHO Guidelines for Good Clinical Practice (GCP);

(iv) Indian Council of Medical Research (ICMR) Guidelines;

(v) Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002;

(vi) Indian Good Clinical Practice of the Central Drugs Standard Control Organization;

(vii) WMA Declaration of Helsinki;

1.2. Institution and Investigator represent and agree that:

(i) they have, and at all times during the course of the Study shall have, personnel with appropriate training, information, licenses, approvals, and certifications as are necessary to safely, adequately and lawfully perform, conduct and coordinate the Study in accordance with generally accepted standards of good clinical practice, including ICH-GCP and Applicable Laws;

(ii) Investigator is currently, and shall throughout the performance of the Study, be authorised to perform his/her duties under this Agreement; and

(iii) Investigator has received, read and understood the Protocol, and confirms and acknowledges that he/she shall strictly adhere to all conditions set out therein and a written confirmation of which is attached hereto as Exhibit B.

1.3. Investigator shall obtain written approval from the IRB/IEC for the Protocol and for the patient information sheet and informed consent form, to be used (hereinafter referred to as the "**Consent Form**") and patient material (if any) prior to initiation of the Study and

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during the conduct of the Study, if required, and shall immediately provide copies of all such documentation to GIGH. GIGH shall provide Investigator with a sample Consent Form along with the protocol and other study documents for IEC review and approval. Investigator may add additional information to the sample Consent Form, if required by the IRB/IEC and Institution; however, such changes should not be material and should not change GIGH's intent concerning the minimum level of information provided to each human subject (hereinafter referred to as the "**Participant**") in order to obtain Participant's consent, and must not modify the compensation provision without GIGH's consent.

1.4. The Investigator shall obtain a written consent from each Participant or from their legally acceptable representative participating in the Study as specified in the Protocol and as required by the Applicable Laws prior to enrolling a Participant into the Study and shall further ensure that all Participants or their legally acceptable representative understand the latest information sheet and consent form approved by the IRB. The Institution /Investigator shall maintain each Participant's Consent Form in the Participant's permanent record. The Investigator will be responsible to obtain an audio-visual informed consent process for all vulnerable participants in addition to the written consent. Such audio-visual recording and related documentation must be preserved adhering to the principles of confidentiality by the Investigator.

1.5. It is anticipated that 300 to 500 Participants will be recruited from approximately 06 centres in India. The Investigator shall start recruiting Participants only after he/she has received written authorisation from GIGH to start recruitment, such authorization to be provided after receipt of all relevant documentation at GIGH. GIGH reserves the right to limit the recruitment of further Participants or cease the recruitment at the Study Site, notably if the overall recruitment target for the Study has been reached. Upon receipt of written notice from GIGH to cease recruitment, the Investigator shall immediately cease further recruitment of Participants.

1.6. Institution and Investigator undertake, represent and agree that they are not, and shall not at any time during the performance of the Study be, under any obligation to a third party, or subject to any other legal impediments, which would create conflict with their duties set out herein, or that might otherwise impair the acceptance by a regulatory authority of the data collected by the Study Site.

1.7. Institution and Investigator agree to provide to GIGH, any documentation required by regulatory authorities and/or under Applicable Laws, including but not limited to Investigator's curriculum vitae, each signed by Investigator, or any other documentation or information that relates to disclosure of Institution and Investigator's

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interests, including any financial interests of Institution and/or Investigator, in the Study.

1.8. Institution and Investigator warrant and represents that: (i) Investigator has not been debarred pursuant to any Applicable Laws or by any regulatory authority; and (ii) neither the Institution nor the Investigator have been disqualified from participating in a clinical study by any regulatory authority. Additionally, Institution and Investigator agree not to use any person for the services provided hereunder who has been: (i) debarred, disqualified or is under investigation by the FDA/MHRA/DCGI for debarment action or disqualification; or (ii) found by any regulatory authority to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations (all of the foregoing in items (i) and (ii) hereinafter referred to as "**Disqualified**"). Furthermore, Institution agrees that they shall promptly notify GIGH in the event of such debarment, conviction, threat, disqualification or indictment of Investigator or any person who has provided services under this Agreement, during the term of this Agreement or three (3) years following its expiration or earlier termination.

1.9. Investigator may appoint other individuals as may be deemed appropriate and approved by the Institution (hereinafter referred to as the "**Study Team**") to assist in the conduct of the Study in accordance with the Protocol, provided that Investigator shall be required to act in accordance with proper professional judgment in making all such appointments. Investigator shall be solely responsible for the Study and for leading the Study Team, who in all respects shall be bound by the same obligations as Investigator under this Agreement, and Investigator shall inform and keep informed in detail the Study Team about all such obligations as they may exist from time to time. Further, Investigator shall be responsible for ensuring that all members of the Study Team are appropriately qualified to conduct the Study and have read and understood the Protocol.

1.10. During the course of the Study, should the Institution and/or Investigator receive any correspondence from a regulatory authority or the IRB/IEC in relation to the Study, such receiving Party shall immediately provide to GIGH a copy of any such correspondence and take appropriate action in this regard as may be appropriate including actions in accordance with the lawful instructions and advice of GIGH.

1.11. Institution and Investigator shall prepare and maintain complete and up to date accurate medical records, accounts, medical notes, reports, and data including all supportive documentation for each Participant (hereinafter referred to as the "**Source Documents**") in accordance with the operating procedures required by GIGH and the Applicable Laws. The Institution and/or the Investigator shall ensure that information collected for the Study is recorded into the database via the corresponding electronic Case Report Forms (eCRFs) found in the web-based management system for each Participant, if and as required by the Protocol. Investigator shall ensure that any data

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or supportive documentation provided to GIGH does not include any information that would personally identify a Participant.

1.12. The Investigator shall immediately inform GIGH of any Serious Adverse Events (hereinafter referred to as "**SAE**"), as defined in the Protocol provided by GIGH. The Institution and the Investigator shall comply with and shall ensure compliance with all the requirements of New Drugs and Clinical Trials Rules, 2019 in terms of safety reporting including notifying GIGH in writing of any SAE as defined in the Protocol and Site Manual of Procedures. During the period of the Study, Investigator and/or the Institution shall submit periodic reports to GIGH regarding progress of the Study, in form and manner as may be acceptable to GIGH or as recommended by GIGH, to enable GIGH to assess the progress of the Study being carried out at the Study Site.

1.13. Institution and/or Investigator shall maintain a copy of all documents, including the Source Documents, relating to this Study for longer of: (i) fifteen (15) years after the Study is completed or discontinued by GIGH; or (ii) a period as may be required by the applicable laws. GIGH will be consulted before the destruction of the documents. Further details are in clause 3.2 (xvii).

1.14. Institution and Investigator shall cooperate and permit, upon the request of GIGH or an official of any regulatory authority, such party to examine and inspect Institution's facilities and equipment required for performance of the Study and inspect and copy all data, reports, work products and results relating to the Study. GIGH's access to records for monitoring or audit does not entitle them to copy any Participant's personal identifiable information. If the Institution or the Investigator is notified of an inspection by a regulatory authority, the Party so notified shall immediately inform GIGH about the pending inspection and shall ensure and authorize GIGH, or any person designated by them, to participate in such inspection, to the extent permitted under Applicable Laws. The Institution or the Investigator shall immediately communicate to GIGH the information that arises from such inspections by a regulatory authority, to the extent permitted under Applicable Laws. It is expressly agreed that GIGH shall not compensate the Institution and/or the Investigator for the cost and/or expense incurred by the Institution and/or the Investigator in relation with any audits and/or inspections and that the assistance and availability of the Institution and/or the Investigator for the audits and inspections is included as part of their obligations to be performed in consideration of payment of the amount mentioned in clause 6 of this Agreement.

1.15. GIGH's monitor shall ensure to send monitoring follow up report promptly.

1.16. GIGH to send the DSMB report (if applicable) and its timely submission to EC.

1.17. GIGH to notify, up to two years post study closure, relevant safety findings from the study data.

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1.18. In the event that Investigator leaves Institution or otherwise becomes unavailable during the term of this Agreement, Institution shall make reasonable efforts to find a replacement investigator of similar expertise and qualifications who is acceptable to both Institution and GIGH. Institution shall ensure that any replacement investigator agrees to be bound by all the terms and conditions hereunder and, where required by GIGH, a new agreement will be executed between Institution, the replacement investigator and GIGH.

1.19. Notwithstanding the foregoing, GIGH, in its sole and absolute discretion, may elect not to approve a person proposed as a replacement investigator, in which event GIGH shall have the right to terminate the Agreement in accordance with clause 10.1 of this Agreement.

1.20. From time to time, GIGH may modify the Protocol by written notice to Institution and Investigator. Except where the modification is necessary to eliminate an immediate hazard to Participants, or involves only logistical or administrative aspects of the trial, any modification may not be implemented before approval by the IRM/IEC.

1.21. During the term of this Agreement, neither Institution nor Investigator shall conduct any other study, investigation or trial on the Participants recruited for the Study which might in any way hinder the results of the Study.

1.22. GIGH represents and warrants that:

i. It has the absolute right and authority to provide any or all material and information ("**Materials**") provided by GIGH for the purpose of the Agreement.

ii. The signatory to the present Agreement is having the right and full authority to enter into this Agreement and the Agreement so executed is binding in nature.

iii. It is not subject to/party to, any covenants, agreements or restrictions including without limitation any covenants, agreement or restrictions arising out of its prior engagements or independent contractor relationships, which would be breached or violated by it because of execution of this Agreement or by performance of its duties hereunder.

2. PERFORMANCE PERIOD

2.1 This Agreement commences from the date specified on the first page of this Agreement, or if such date is not included on the date this Agreement is last signed by either Party. Unless terminated early, in the ordinary course of events this Agreement terminates on Study Completion.

2.2 Investigator and Institution understand and acknowledge that Participant enrolment will commence only after all approvals (IEC/IRB etc.) have been obtained.

Dr. Alok Nath
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Lucknow-226014

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3. DUTIES AND RESPONSIBILITIES OF THE PARTIES

2.3 In addition to applicable provisions of clause 1 of this Agreement, GIGH shall be responsible for:

(i) obtaining the necessary approvals or authorisations for the conduct of the Study in India, and coordinate the Study in India;

(ii) making timely payments to the Institution (in accordance with clause 6 of this Agreement), subject always to approvals mentioned in clause 3.1(i) above;

(iii) supplying Institution and Investigator with appropriate Study documents necessary to conduct the Study;

(iv) providing all necessary information as per Protocol, and related Study material, and study drug, to assist the Institution and Investigator to comply with its obligations under this Agreement;

(v) overall conduct of the study including monitoring and evaluation of study sites in India; and

(vi) Advise and provide information to the Institution and to the IRB/IEC as and when necessary and update the appropriate Regulatory Authorities of:

a) Any SAEs, adverse events or risk information; or

b) The cessation elsewhere of any relevant trial of the Study drug (or closely related products); or

c) The withdrawal of the Study drug (or closely related products) from any other market for safety reasons; or

d) Any other information available to justify any variations to the Study Protocol and the nature, scope and duration of the Study.

3.2 In addition to applicable provisions of clause 1 of this Agreement, Institution and Investigator shall be responsible for:

(i) obtaining the necessary consents, approvals or authorisations for the conduct of the Study at the Study Site;

(ii) obtaining and maintaining approvals or communications from the IRB/IEC;

(iii) understanding and strictly adhering to all requirements of the Protocol and this Agreement;

(iv) ensuring the protection of the rights, safety and well-being of Participants, and the scientific integrity of the Study;

(v) appointing and monitoring of research staff and other appropriately trained and qualified personnel with clinical knowledge necessary to conduct the Study at the Study Site;

(vi) evaluating and keeping GIGH informed of any outcomes, and adverse events identified during the conduct of the Study;

(vii) maintaining updated and accurate records pertaining to the Study;

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(viii) submitting the requisite documentation to the relevant regulatory authorities from time to time during and after the conclusion of the Study;

(ix) providing Investigator with materials, access to personnel, facilities and information as may be reasonably required to satisfactorily perform the Study;

(x) complying with all Applicable Laws, rules and regulations governing the Study and any conditions imposed by relevant regulatory authorities from time to time;

(xi) permitting the representatives of GIGH access to the Study Site as and when required; during normal duty hours;

(xii) exercising due care and skill and work in a competent and professional manner in carrying out their obligations under this Agreement;

(xiii) ensure that the equipment used by the Institution and/or the Investigator for conduct of the Study are properly maintained;

(xiv) having and continuing to have all licences, authorisations, consents, approval and permits required by all Applicable Laws and regulations in order to perform their obligations under this Agreement;

(xv) monitoring to ensure that no unlawful or unethical activity arises during the conduct of the Study at the Study Site; and

(xvi) ensure that any agreement concluded, or arrangement reached by them with any and all agents or personnel or members of the Study Team appointed by them, if any, in connection with the Study shall be subject to and not inconsistent with the provisions of this Agreement.

(xvii) Institutions would be responsible for maintaining the Master list of identifiable data which could be linked to the stored data for any future reference. Storage of hard copy is responsibility of the participating institutions.

4. OWNERSHIP OF DATA, RESULTS, INTELLECTUAL PROPERTY

4.1 The Parties acknowledge and agree that GIGH shall have all right, title and interest in and to all data and results of the Study, including without limitation all inventions, patents, tests, applications, creations, research data and Confidential Information that may be developed, produced, created, furnished or disclosed by any Party made during the conduct of the Study, or arising from the performance of the Study, including:

(i) any discovery, concept, or idea, whether or not patentable, including but not limited to processes, methods, software, tangible research products, formulas and techniques, improvements thereto, and know-how related thereto;

(ii) any patents and designs; and

(iii) any other material in which any intellectual property rights subsist or may subsist (hereinafter referred to as **"Intellectual Property"**).

4.2 The ownership of any or all intellectual properties owned by the Institution before the execution date of this Agreement and used under this Agreement by the Institution

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("**Background IP**") for the purpose of the Study shall remain with the Institution. GIGH agrees not to claim the ownership of the Background IP, in any whatsoever manner, either directly or indirectly.

4.3 Institution and Investigator hereby specifically disclaim any right, title or interest of any kind whatsoever to the Intellectual Property or to any information received by Institution or Investigator as a result of or in the course of performing the Study, including ownership rights thereof, except to the extent that such rights are specifically granted hereunder for the purposes of the Study.

4.4 In the event of any discovery or invention made by Institution, Investigator, Study Team or any agents or employees of Institution or Investigator in the course of or in connection with the performance of the Study, such discovery or invention shall be communicated immediately to GIGH. All right, title and interest in and to any such discovery and invention shall belong to GIGH and/or its assignee (in its sole and absolute discretion). Institution and Investigator shall have no right, title or interest in or to such discovery or invention, and consequently shall refrain from, and shall cause Study Team and other employees or agents to refrain from filing any application on their discovery or invention with any patent or other relevant authority.

4.5 If GIGH and/or its assignee desires to file patent applications on such discovery or invention, whether in its name or in the name of any assignee, it will do so at its own expense, and those persons participating in the discovery or invention hereby assign all right, title and interests to such discovery or invention to GIGH (or to such third party as GIGH may instruct/ identify) without any additional compensation, and, if requested by GIGH to do so, assist in the preparation of such patent applications. It is expressly agreed by the Investigator that GIGH be under no obligation to patent, develop, market or otherwise utilise the results of the work done by Investigator, Study Team or other agents or employees of Institution or Investigator in connection with this Agreement.

4.6 Investigator and Institution shall ensure that all employees, Study Team or other agents hired to perform services hereunder shall agree to fulfill the obligations herein, especially in relation to the assignment of rights in discoveries and inventions to GIGH as applicable.

4.7 This Agreement does not grant either party any license grant or assignment, whether expressed or implied, with regard to such Intellectual Property that belongs to the other party. This Agreement also does not grant, transfer or assign to the party/ies any legal right or beneficial ownership in any Intellectual Property Rights of the other party/ies.

4.8 Each party will not use the other party's/ies' Intellectual Property in any publicity, advertising or news release without the prior written consent of the other party/ies. For the avoidance of doubt, this restriction does not apply to the inclusion in documents of

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or use of Intellectual Property for the proper performance of the services under this Agreement.

4.9 The parties will not infringe the Intellectual Property Rights of a third party or misappropriate any Know How or Intellectual Property Rights of a third party.

4.10 The Investigator shall have a right to use the Study results for non-commercial research and teaching purposes and for publications.

4.11 Nothing in this Section shall restrict the Institution from using the Intellectual Property and Know How generated from the Study for their normal hospital activities.

5. PUBLICATION

5.1 The Parties acknowledge that the Study is a multi-centre study that is overseen and supervised by a committee known as the 'Steering Committee' to be appointed GIGH (hereinafter referred to as "Steering Committee").

5.2 Institution and Investigator each acknowledge and agree that:

(i) there shall be no publication, report, release, disclosure or likewise of any preliminary or final Study findings or results prior to release of the multi-centre publication approved by the Steering Committee (hereinafter referred to as "**Multi-Centre Publication**"); and

(ii) the first publication of Study findings or results shall be made as part of the Multi-Center Publication, which will involve all participating investigators and institutions, including Institution and Investigator. Attribution and authorship shall be given in accordance with academic standards.

5.3 Notwithstanding the foregoing, the Steering Committee and GIGH may at any time disclose or publish all information as they may reasonably decide where such disclosure or publication relates to the safety of the Participants, patients in general, or the general public.

5.4 Proposals for all publications, abstracts, and other presentations arising from the Study will be submitted for approval to the Steering Committee. Each paper or abstract must be submitted to the Steering Committee, through GIGH, for approval at least four (4) weeks prior to the date it is intended to be submitted for publication. The Steering Committee or a subcommittee thereof, may recommend changes prior to approval.

5.5 All publications must comply with the Protocol and Consolidated Standards of Reporting Trials (CONSORT) statement. Authorship of publications will be granted according to the guidelines from the International Committee for Medical Journal Editors (ICMJE).

5.6 No Party shall use the name of any other Party in any advertising or promotional material without having received the prior written consent of such other Party, provided however that:

(i) a Party may acknowledge, in general terms, the existence of this Agreement;

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(ii) GIGH (or its affiliates) may state on its website or in any Study material that Institution is a participating site of the Study and Investigator is the investigator of the Study at the Study Site; and

(iii) Institution may acknowledge receipt of financial support from GIGH for the Study at the Study Site.

6. PAYMENTS

6.1 As consideration for performance of the Study under the terms of this Agreement, upon receipt of necessary regulatory approval , GIGH shall pay to Institution the amounts as set forth in the Payment Schedule and Payment Rule Form that is attached hereto as Exhibit C (hereinafter referred to as the "**PRF**"). Payments shall be made in the manner and on the terms set forth in the PRF. All fees set out in the PRF shall be full and final and shall remain unchanged for the duration of the Study, unless otherwise agreed in writing by all Parties. All fees set out in the PRF shall be deemed to be inclusive of all applicable taxes. Institution and Investigator each agree and undertake not to seek any payment from any third party or Participant for any services provided to a Participant in connection with such Participant's participation in the Study or the costs incurred in connection therewith.

6.2 Institution shall be responsible for the payment of any or all taxes that may apply to any payment received pursuant to this Agreement, including, without limitation, for paying any GST or similar tax imposed by the taxation authorities in any jurisdiction.

6.3 Institution and Investigator shall review the payment details generated by GIGH that shall accompany each payment and shall inform GIGH in writing in accordance with the instructions provided in the payment details of any discrepancies that may exist in the payment(s) received and the payment(s) expected. After each payment, Institution and Investigator shall ensure that any such discrepancies that may exist, if any, are brought to the attention of GIGH no later than one (1) month after the payment is received. The Parties shall work diligently and in good faith to resolve any such discrepancies. In the event GIGH does not receive written notice of any final discrepancies within such one (1) month period, then all payments required to be made hereunder shall be deemed to have been made in full, and Institution and Investigator shall be deemed to have, and each hereby waives, all rights to receive further compensation in connection with the Study.

6.4 The Parties agree that, other than as described herein, GIGH will not be liable to contribute and/or make any other payment to Institution or Investigator for undertaking the Study.

6.5 Institution warrants that the Payee as per Exhibit C, wherever different from the Institution name, is part of or an affiliate of the Institution and that the Institution shall remain responsible for all obligations under this Agreement.

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7. CONFIDENTIALITY & PRIVACY

7.1 The Institution and the Investigator acknowledge and agree that they shall not disclose or publish Confidential Information to any third party, other than in accordance with this clause 7. For the purpose of this Agreement, **"Confidential Information"** shall mean any confidential or proprietary information, including without limitation, any derivatives thereof, which is confidential and proprietary in nature, including, but not limited to, past, present and future disclosing Party: business and financial records; business and marketing plans; contracts; sales; reports; billings; insurance filings; employees; customers; vendors; proof of concepts; products and/or services, in preliminary and final production form; pricing; intellectual property; source codes; object codes; technical knowledge; trade secrets; internal practices and procedures; feedback relating to any results of the Participant, Participant or Confidential Information; deliverables information; other information relating to disclosing Party's business, including, without limitation, the terms and conditions of this Agreement; and any third-party confidential information which disclosing party may be authorized, from time to time, to review, have access to and/or use and are provided by disclosing Party to any receiving Party (in any form) in connection with this Agreement which by its nature the other Party knows, or reasonably ought to know, is confidential, and in the case of GIGH (and/or its affiliates), Confidential Information shall include (but shall not be limited to): (i) all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere; (ii) the Protocol, and information related to the Protocol and Study materials; (iii) know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques owned by GIGH (and/or its affiliates); (iv) know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study; and (v) information concerning the business affairs of GIGH (and/or its affiliates); and in the case of Institution, Confidential Information shall include (but shall not be limited to) information relating to the Institution's business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors.

The preceding obligations shall not apply to Confidential Information, Data or information that falls under Confidentiality:

a) which the Disclosing Party agrees in writing, may be used or disclosed,

b) which is published in accordance with the Publication Section of this Agreement,

c) which a Receiving Party can demonstrate through contemporaneous written records was in its possession prior to disclosure by the Disclosing Party,

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d) which is in the public domain or which later becomes part of the public domain other than by breach of this Agreement by a Receiving Party,

e) which is lawfully disclosed to a Receiving Party by a third party not obligated to the Disclosing Party to keep the information confidential, and

f) which is required to be disclosed by law, or by order of a court of competent jurisdiction.

7.2 A Party must not, and must ensure that its employees, agents and other authorised representatives do not use or disclose any Confidential Information of another Party, other than where and only to the extent that such use or disclosure is absolutely necessary for the performance of the Study, or the exercise of the first mentioned Party's rights or the performance of the first mentioned Party's obligations under this Agreement, or as otherwise permitted by clause 7.3.

7.3 A Party may disclose Confidential Information of another Party:

(i) as directed by the written consent of the Party whose Confidential Information is to be disclosed, provided that the recipient is subject to similar confidentiality obligations as set out in this Agreement; and

(ii) when required to do so by law, by court order or by order of a regulatory authority having jurisdiction to so direct, provided that prior to such disclosure the Party whose Confidential Information is to be disclosed is promptly advised and given reasonable opportunity to protect its Confidential Information, and then provided only to the extent that such Confidential Information is required to be disclosed to satisfy the particular law or order.

7.4 The obligations of confidentiality under this clause 7 shall be binding for the term of this Agreement and shall survive for a period of ten (10) years after expiry or termination of this Agreement.

7.5 Each Party agrees to comply with all applicable privacy laws and regulations regarding the collection, use, disclosure, holding and protection of personal and/or health information.

7.6 In the event that GIGH shall come into contact with Participants' medical records, GIGH shall hold in confidence the identity of the Participants and shall comply with Applicable Laws regarding the confidentiality of such records.

8. RELATIONSHIP OF PARTIES

8.1 This Agreement does not create, and no provision of this Agreement shall be interpreted to create, a relationship of employer and employee, principal and agent, joint venture or partnership between: (i) Institution and GIGH (or its affiliates); or (ii) Investigator and GIGH (or its affiliates). Neither Party (including any employee, agent or authorised representative thereof) shall have the power to bind or designate the other Party or any persons affiliated with GIGH in any manner whatsoever.

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8.2 No employee, agent or authorised representative of the Institution and/or Investigator or any other person undertaking or performing work for the Study at the Study Site (hereinafter referred to as "**Study Site Personnel**") shall be considered or deemed to be, at any time during the term of this Agreement, an employee of GIGH. Study Site Personnel shall, at all times, be under the direct supervision and responsibility of Institution and/or Investigator. Institution shall be solely responsible for the disbursement of all wages/salaries to Study Site Personnel, and shall comply with all applicable labour laws and legislation. Institution shall indemnify and hold harmless GIGH (and its affiliates) against all claims and demands that may be made by any Study Site Personnel against GIGH for non-compliance by Institution and/or Investigator with this clause 8.2.

9. NOTICES

9.1 Any notice, consent, approval or other communication (each a "**notice**") under this Agreement shall be in writing and shall be delivered to the recipient Party by hand or by sending to the address or email specified below (or as subsequently varied by notice):

(i) If to GIGH:
Amit Khanna
George Institute for Global Health
308, Elegance Tower
Plot No. 8, Jasola District Centre
New Delhi 110025 , India
Email- akhanna@georgeinstitute.org.in

(ii) If to Institute:
Director SGPGI
Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
Email- director@sgpgi.ac.in

(iii) If to Investigator:
Name: Dr.Alok Nath
Department of Pulmonary Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
Email: draloknath@gmail.com

9.2 A notice given in accordance with clause 9.1 is taken to be received: (i) if hand delivered to a Party's address, on the day of delivery; (ii) if sent by courier to a Party's address, upon the day of the courier's delivery (as verified by the courier's records); (iii) if sent

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by certified or registered mail, upon the day of the postal service's delivery (as verified by the postal service's records); or (iv) if sent by email, upon confirmed successful transmission at the sender's location; but if delivery or receipt is not on a business day or is after 5:00 P.M. on a business day, notice is taken to be received in the next business day.

10. TERMINATION

10.1 GIGH may terminate this Agreement forthwith by written notice (hereinafter referred to as the "**Termination Notice**") to Institution and Investigator if:

(i) any regulatory authority requires the Study to be discontinued or materially altered;

(ii) Investigator or Institution is Disqualified (as defined by clause 1.8 of this Agreement);

(iii) Institution proposes a replacement investigator and GIGH does not approve of the proposed replacement;

(iv) GIGH fails or ceases to receive research funding for the Study;

(v) Institution and Investigator do not randomize at least four (4) Participant within one (1) months of receiving an authorisation letter from GIGH to commence recruitment (as provided by clause 1.5 of this Agreement);

(vi) Institution or Investigator, or Study Site Personnel, fail to perform, or performs improperly, any obligation of it under this Agreement (hereinafter referred to as the "**Default**"), provided that GIGH shall first have: (i) notified Institution and Investigator of such Default; and (ii) permitted the Party in Default a period of three working days (hereinafter referred to as the "**Cure Period**"), to cure the Default, which Cure Period shall be stated in the notice from GIGH,; or

(vii) it comes to the attention of GIGH that Institution or Investigator has fabricated, falsified or plagiarised data pertaining to the Study or has otherwise breached or compromised the scientific integrity of the Study or caused harm to Participants.

10.2 GIGH may terminate this Agreement for whatever reason by giving thirty (30) days' prior written notice to the other Party.

10.3 Institution and Investigator may terminate this Agreement by written notice to GIGH, which notice and termination shall, subject to the ongoing obligations of each of the Parties pursuant to paragraph 10.4 below, be effective immediately upon receipt of written notice by GIGH if:

(i) the IRB/IEC or any regulatory authority requires that Institution and/or Investigator cease a material part or all of their activities in connection with the Study; or

(ii) GIGH fails to perform, or performs improperly, any of its material obligations under this Agreement (hereinafter referred to as "**GIGH Default**"), provided that

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the Institution and/or Investigator shall first have: (i) notified GIGH of such GIGH Default; and (ii) permitted GIGH a period of thirty (30) days to cure the GIGH Default, which Cure Period shall be stated in the notice from the Institution and/or Investigator.

10.4 In the event of termination, the Parties shall promptly do all that is reasonably necessary to close-out the Study and shall cooperate to ensure the continued safety of the Participants. Each Party will, upon request of otherParty, return or destroy any Confidential Information of that Party.

10.5 If this Agreement is terminated under clause 10.1, GIGH shall pay Institution work completed by Institution and Investigator up to the date of Termination and for closing-out activities in accordance with generally accepted standards of good clinical practice, including ICH-GCP. Investigator and Institution acknowledge that they shall not be entitled to any further or additional payments from GIGH (or its affiliates).

10.6 Clauses 1 (Performance of the Study), 4 (Ownership of Data, Results, Intellectual Property), 5 (Publication), 7 (Confidentiality & Privacy), 10.4 (Termination), 11 (Indemnities, Limitation of Liability & Insurance) and 14.4 (Arbitration) of this Agreement, and any other clauses or provisions giving operational effect thereto, and any other clause or provision that should by its nature, shall survive expiry or termination of this Agreement.

11. INDEMNITIES, LIMITATION OF LIABILITY & INSURANCE

11.1 GIGH shall hold harmless the Institution and the Investigator and their respective officers, directors and employees (hereinafter individually referred to as an "**Indemnified Party**" and collectively referred to as the "**Indemnified Parties**"), as applicable, from and all claims made by third parties and against any and all liabilities, losses, damages and expenses (hereinafter collectively referred to as "**Losses**") that one or more of the Indemnified Parties may sustain or incur in connection with any injury, (including death), suffered by any Participant participating in the Study resulting only from the administration of the Study drug described in the Protocol, when used in the Study in accordance with the approved labelling, the Protocol and any written instructions of GIGH provided that the Indemnified Party has (i) used reasonable medical judgment in the conduct of the Study, (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and (iii) duly complied with all Applicable Laws and regulations and all ethical and professional standards relating to the protection of human Participants, including with respect to ensuring appropriate IRB approval and oversight, obtaining effective informed consent and maintaining patient privacy in accordance with the Protocol and the instructions/guidance/advice issued by GIGH, from time to time.

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11.2 Each Party ("**Indemnifying Party**") agrees and undertakes to indemnify, hold harmless and defend the other Party ("**Indemnified Party**") from and against any and all Losses arising as a result of or arising directly out of (a) breach by the Indemnifying Party of any provision of this Agreement or (b) the Indemnifying Party's negligence or wilful default in relation to performance or non-performance of any of its obligations under this Agreement.

11.3 Each Party's obligation to indemnify the other as set forth above is conditional on the Indemnified Party: (a) providing written notice to the Indemnifying Party of any Losses for which it is seeking an indemnity hereunder within ten (10) business days after the Indemnified Party having knowledge of such Losses; (b) permitting the Indemnifying Party to assume full responsibility to investigate, prepare for and defend any such Losses; (c) assisting the Indemnifying Party, at the Indemnifying Party's reasonable expense, in the investigation and defence of any such Losses; and (d) not compromising or settling such Losses without the Indemnifying Party's prior written approval. In turn, the Indemnifying Party will not make any settlement which adversely affects in a material manner the reputation of an Indemnified Party without such Indemnified Party's prior approval, which approval shall not be unreasonably withheld.

11.4 Notwithstanding the above or anything contained to the contrary in this Agreement:

(i) neither Party shall be liable to the other for any punitive or consequential loss, including, without limitation, any loss of business, revenue, profit, reputation or goodwill;

(ii) the Parties shall take all reasonable steps to mitigate any loss, damage, claim, action or expense (including legal expense) they may suffer in terms of this Agreement; and

(iii) GIGH's liability whether in terms of this Agreement, tort (including gross negligence), strict liability, indemnity or otherwise and for any and all claims arising out of or in connection with this Agreement shall be limited in aggregate, whether in relation to a single event or a series of events, and whether each event is related or not, to a maximum of the fees paid to the Institution and/or the Investigator under this Agreement till the date such liability arose or the per subject and aggregate limit of GIGH's Clinical Trials Liability insurance cover, whichever is lower.

11.5 GIGH has made an arrangement of Clinical Trials Liability insurance cover adequate to cover the risks as specified under the aforementioned provisions of this Article. However, it is understood and agreed that the maintenance of such insurance cover will not relieve either Party of its other obligations under this Agreement.

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11.6 Institution and Investigator may secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:
(i) medical professional and/or medical malpractice liability; and
(ii) general liability; and
(iii) employee's compensation,
each such insurance coverage in amounts appropriate to the conduct of Institution's business activities and the services contemplated by the Study and in compliance with minimum amounts of insurance required by Applicable Laws or regulations.

12. ENTIRE AGREEMENT, AMENDMENT

12.1 All exhibits, schedules attached hereto, including the Protocol referenced herein, shall be incorporated by reference and will form part of this Agreement. This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter herein and, other than expressly provided herein, no part of this Agreement may be modified except where agreed to in writing by the Parties. All previous negotiations, understandings, representations, warranties, memoranda or commitments concerning the subject matter of this Agreement are merged in and superseded by this Agreement and are of no effect. No oral explanation or information provided by any Party to any other Party affects the meaning or interpretation of this Agreement, or constitutes any collateral agreement, warranty or understanding between the Parties.

12.2 In the event of any inconsistency between the terms of this Agreement and the Protocol, the terms of this Agreement will prevail.

13. ASSIGNMENT& SUBCONTRACTING

13.1 The parties shall not assign or transfer any of its rights or obligations under this Agreement or any part thereof without the prior written consent of the other party. Further, the parties shall not sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other party, such consent not to be unreasonably withheld or delayed.

14. CONCLUDING PROVISIONS

14.1 Any clause or provision of this Agreement which is prohibited or unenforceable is ineffective to the extent of the prohibition or unenforceability, but the validity or enforceability of the remaining clauses of this Agreement will not be affected.

14.2 The obligations of a Party under this Agreement are suspended during the period and to the extent that such Party is prevented or hindered from complying by causes or circumstances: (i) beyond its reasonable control not due to its own fault or negligence;

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(ii) which are not reasonably forseeable; and (iii) which the Party is by exercise of reasonable diligence, unable to prevent, including (a) act of God; (b) industrial dispute of any kind; (c) act of public enemy, war (whether declared or undeclared), blockade, revolution, riot, insurrection, malicious damage, civil commotion; (d) natural disaster/ pandemic/epidemic, medical emergency; (e) order of any court or authority, restraint, restriction, requirements, prevention, frustration or hindrance by or of any person, government or competent authority; and (f) embargo, unavailability or shortage of essential equipment, chemicals or other materials, goods, labour or services, lack of transportation or communication, breakage of facilities or machinery (each hereinafter a "**Force Majeure Event**"). A Party relying on this clause 14.2 must promptly provide notice to the other Parties of the occurrence or cessation of any Force Majeure Event. Where such Majeure Event continues for more than three (3) calendar months, the other Parties have the right to promptly terminate the Agreement by written notice to the affected Party, and clauses 10.4 and 10.6 of this Agreement will apply.

14.3 This Agreement shall be construed, interpreted and applied in accordance with, and shall be governed by, the laws applicable in India within the jurisdiction of Lucknow.

14.4 The Parties agree to first attempt to negotiate in good faith to resolve any dispute or difference arising out of or in connection with this Agreement or in respect of any defined legal relationship associated therewith or derived therefrom (hereinafter referred to as the "**Dispute**"). However, if the Parties are unable to resolve the Dispute within fourteen (14) days after first commencing good faith negotiations, the Parties agree to submit such Dispute for arbitration before a sole arbitrator to be appointed by mutual agreement of the Parties under the Arbitration and Conciliation Act, 1996 having jurisdiction in Luckow, India. Each Party to the Dispute will be responsible for its own costs and expenses, and arbitration fees will be shared equally between the Parties to the Dispute. The decision of the arbiter shall be final and binding between the Parties subject to legal remedies under the Arbitration and Conciliation Act, 1996.. The Parties agree to continue to perform this Agreement despite the existence of a Dispute or any proceedings under this clause 14.4. Nothing in this clause prevents a Party from obtaining urgent injunctive relief from any court, including with respect to the protection of its confidential or proprietary information.

14.5 No right under this Agreement is waived or deemed to be waived except by notice in writing signed by the Party waiving the right. A failure or delay to exercise any right, power or remedy under this Agreement will not operate as a waiver. Likewise, a single or partial exercise of any right, power or remedy will not preclude any other or further exercise of that or any other right, power or remedy.

14.6 This Agreement may be executed in any number of counterparts, and all counterparts together shall be taken to constitute one instrument.

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed, as of the day and year first above written.

On Behalf of GIGH:

Signature

Date: 01st December, 2021

Name: Mr. Amit Khanna
Designation: Director, Finance & Operations

Signature

Date: 01st December, 2021

Name: Dr. Pallab Maulik
Designation: Deputy Director & Director of Research

INSTITUTION:

Signature

Date: _____

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Name: Prof. RK Dhiman
Designation: Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow. 226014

INVESTIGATOR:

Signature

Date: 9/12/21

Name: Dr.Alok Nath
Designation: Additional Professor & Head, Department of Pulmonary Medicine

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Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
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EXHIBIT A

Enclosed: Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD) study protocol
STUDY PROTOCOL- PACE in COPD, V6.0, 24 February 2021

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EXHIBIT B
INVESTIGATOR CONFIRMATION

Study Name: Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD)

Investigator: Dr.Alok Nath

I, the Investigator, confirm that I have received the PACE in COPD trial Protocol. I represent that I have read and fully understand the Protocol and other study related obligations. I will provide copies of the Protocol, and all information furnished by GIGH, to the Study Team and to discuss this material with them and ensure they are fully informed and understand the Protocol.

I agree and undertake to abide by the contents of the latest IRB/IEC approved Protocol and any amendments there to that are communicated to me.

Signature

Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014

Date: 9/12/21

Name: Dr.Alok Nath

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EXHIBIT C

PAYMENT SCHEDULE, AND PAYMENT RULE FORM

STUDY: Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD)

COUNTRY: INDIA

Target Recruitment at the site (randomized patients): 50 - 100

Payment distribution will be as shown below. Payments will be made as per the below schedule if all study visit data has been entered and queries resolved. Payments will be processed on a quarterly basis with the payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued and sent out within 25 days from the processing/run date (i.e. Payment for run date Mar 31st will be mailed on or prior to April 25th.)

All payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws and GIGH will deduct the tax at the time of making payments unless a valid certificate for Tax Exemption is made available from the tax authority in a timely manner.

Payments will be made as per the below schedule if all study visit data has been entered and queries resolved adequately.

ITEM	Per Month/Visit (INR)	No. of months/ visits
Study Coordinator/Nurse	30,000	36
Site Investigator	13,000	36
Participant travel	700	8
Overheads @ 25%		

Institutional Ethics Committee Fees: Institutional Ethics Committee (IEC) fees shall be reimbursed for initial review, annual reviews, ICF reviews and amendments only if applicable as per the IEC SOP. Processing of payment will begin upon receipt of original invoice/disbursement request.

Fee for Study Coordinator and Site Investigator + 25% overheads shall be paid quarterly in advance, except for the last quarter of third year which will be retained until all data has been entered and all outstanding data queries have been responded to.

Fee to cover participant travel + 25% overheads will be paid quarterly in arrears for all visits attended within the previous quarter.

Fee for Study Coordinator and Site Investigator is based on the assumption that a minimum of 50 participants will be randomised within the first year of recruitment. Institution will be paid

as per the above schedule so long as the Study Site randomises a minimum of 50 participants within the first year of recruitment. If the site fails to recruit 50 participants, fee for Study Coordinator and Site Investigator (plus overheads) shall stand reduced proportionate to the number of participants randomised in the first year, and will be adjusted from payments in subsequent quarters .

All payments will be based on completion of visits and collection of all required data for each visit completed and includes ALL costs (including but not limited to investigator & study team salary, patient recruitment and follow-up, events reporting, overheads, laboratory costs, monitoring visits, patient travel expenses, any applicable taxes, etc.)

Disbursement of travel cost for participants (as per table above) will be at the discretion of the Investigator.

Payments will be made to the following party:

(ALL INFORMATION BELOW MUST BE PRINTED)

Payable to:Director, SGPGIMS, Research a/c

PAN No. of Institution: AAAJS3913N

Account Number: 10095237491

Bank Name & Address: State bank of India, SGPGI Branch, Lucknow, U.P

IFSC Code: SBIN0007789

Mailing Address: Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014

Signature of the authorized signatory of the Institution: _____ 27/12/21.

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW (U.P.) INDIA

Name of authorized signatory:. Prof. RK Dhiman

Phone: 05222492668112

Email address: director@sgpgi.ac.in

Date:_____

GIGH Representative Initials

Institution Representative Initials

PI Initials

(34)

Bond

Indian-Non Judicial Stamp
Haryana Government

Date :20/10/2020

Certificate No. G0T2020J2691

GRN No. 68423865

Stamp Duty Paid : ₹ 101

Penalty :₹ 0

Deponent

Name: Eli Lilly and company India Pvt ltd

H.No/Floor : 92 Sector/Ward : 32 Landmark : Na

City/Village : Gurugram District : Gurugram State : Haryana

Phone : 98******18

Purpose : AGREEMENT to be submitted at Others

OUS Templates
OUS LOA
Revised: 01 2018

Date:06-Aug-2019

Dr. Amita Agarwal
Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI),
RaeBareli Road,
Lucknow – 226014, UP,
India

Dear Dr. Agarwal,

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd ("Lilly") **Dr. Amita Agarwal** as the principal investigator ("Investigator"), and **Sanjay Gandhi Post Graduate Institute of Medical Sciences, RaeBareli Road, Lucknow – 226014, UP, India.** ("Institution") for the performance of the study ("Study) entitled **"A Randomized, Double-Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less Than 18 Years Old with Systemic Juvenile Idiopathic Arthritis "** protocol **I4V-MC-JAHU** ("Protocol"), which Protocol is incorporated herein by

reference. Investigator is an employee of Institution. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. INVESTIGATOR AND INSTITUTION OBLIGATIONS

Investigator and Institution agree to assume the following obligations in executing this Agreement:

A. Conduct of the Study

Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites (collectively "Study Sites"), if applicable. Investigator and Institution agree that Investigator and Institution will not use sub-sites or satellite sites in the conduct of the Study unless Lilly has given written approval for use of the sub-sites and satellite sites. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Investigator and/or Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Investigator and Institution (and colleagues, including sub investigators) agree to comply with the following: all conditions specified in the Protocol and Protocol amendments and/or addenda; Good Clinical Practice Guidelines; the approval of Ethical Review Board ("ERB"); data privacy laws and all other applicable national, state and local laws regulations and standards. Investigator and Institution shall ensure that all of sub investigators , associates, colleagues and employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

In carrying out Investigator and Institution's responsibilities under this Agreement, Investigator and Institution agree to comply with all applicable anti-bribery laws in the countries where Investigator and Institution have Institution's principal place of business and where Investigator and Institution conduct activities under this Agreement. Additionally, Investigator and Institution understand and agree to comply with the U.S. Foreign Corrupt Practices Act, as revised, which generally prohibits the offer, promise, payment or giving of anything of value either directly or indirectly to any government official for the purpose of obtaining or retaining business or any improper advantage. For purposes of this section, "government official" means any official, officer, representative, or employee of, including any doctor employed by, any non-U.S. government department, agency or instrumentality (including any government-owned or controlled commercial enterprise), or any official of a public international organization or political party or candidate for political office. Additionally, if Investigator and Institution or any of Institution's owners, directors, employees, agents, and consultants are government officials, Investigator and Institution agree that Lilly's payment of Investigator and Institution in connection with this Agreement is not intended to influence any decision that any individual may make in their capacity as a government official. Investigator and Institution further represent that neither Investigator and Institution nor any of Institution's owners, directors, employees, agents, or consultants will directly or indirectly offer to pay, promise to pay or give anything of value to any government official for purposes of (i) influencing any act or decision of such government official in his official capacity; (ii) inducing such government official to do or omit to do any act in violation of the lawful duty of such official; (iii) securing any improper advantage; or (iv) inducing such government official to use his influence with the government or instrumentality thereof to affect or influence any act or decision of the government or such instrumentality with respect to any activities undertaken relating to this Agreement. Additionally, Investigator and Institution will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to enable Lilly to ensure compliance with applicable anti-bribery laws. Investigator and Institution agree that Lilly's payment to Investigator and Institution in connection with the services to be provided under this Agreement is not

intended to influence any decision Investigator and Institution may make regarding the prescription of Lilly medicines or to otherwise influence any pending or future Lilly business.

Investigator and Institution shall also ensure that each investigator and sub-investigator at Institution's Study Site (s) provides Lilly with the appropriate financial information for compliance with all applicable laws and regulations and Lilly policy, and Investigator and Institution understand and shall ensure that each investigator and sub-investigator understands that laws, regulations and Lilly policy may require certain financial information to be submitted to regulatory authorities.

If Investigator is not a licensed physician, Investigator and/or Institution shall ensure that a licensed physician is an investigator or sub-investigator at Study Site (s) and will be responsible for patient care and other appropriate aspects of this Study.

Investigator acknowledges that Investigator has read and understands all information in the investigator's brochure provided to Investigator by Lilly, including the potential risks and side effects of the Study drug.

Investigator and Institution agree not to pay fees to another physician for the referral of patients.

Investigator and Institution agree that if Investigator and/or Institution collect any biological samples for independent research from Study subjects, such samples will only be collected prior to the administration of the Study drug(s) or device(s). Additionally, Investigator and Institution agree to obtain separate informed consent documents, as well as distinct ERB approval for such research, and to comply with all applicable privacy laws related to such samples.
Investigator and Institution agree to only use an informed consent document which has been reviewed and approved by Lilly.

Investigator and Institution agree that Lilly, Lilly-designated representatives and domestic or foreign regulatory agencies may inspect procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent Study Site (s) used in conducting the Study. Investigator and Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit or inspection of of the facility or processes related to the Study Lilly shall be given the opportunity to provide assistance to Investigator and Institution in responding to any such review, audit or inspection. Investigator and Institution shall provide Lilly with the results of any such review, audit or inspection. When data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug and end Investigator and/or Institution's participation in the Study.

B. Clinical Trial Materials and Record Retention

Drugs furnished for the Study will be used solely under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly's instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at Study Site(s). All Study records must be retained for fifteen (15) years after completion or termination of the Study, provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two

(2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated, or if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly will notify Investigator and Institution regarding any additional length of time that records must be retained to meet such requirements. The Investigator and/or Institution shall use their best efforts to prevent premature destruction of Study records.

If there is a change of responsibility/ownership of Study records (ex. Investigator retires or hospital closes), Investigator and Institution must notify Lilly.

C. Confidentiality and Non-Use

All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study, will be kept in confidence and not used for any purpose not expressly provided for in this Agreement for at least five (5) years after the termination or conclusion of the Study, except to the extent that Lilly gives Investigator and/or Institution written permission or particular information is required by laws or regulations to be disclosed to the ERB, the patient or local regulatory agencies. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and/or Institution will reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation or judicial or governmental order. Investigator and Institution shall be responsible for ensuring that their employees, sub investigators, contractors and agents are obligated to these same terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered confidential information and may be disclosed only to the extent required by law or necessary for approval of this Study.

Additionally, in the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution agree that they will hold all new information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

The foregoing obligations of confidentiality and non-use will not apply to information that:

(1) is or later becomes part of the public domain other than through Investigator or Institution's act or omission;

(2) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source or third party under no obligation to Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or

(3) is independently developed, as shown by written documentation, by Investigator or Institution or their personnel who have not had access to confidential information provided by Lilly.

D. Data

Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, , raw source data, original medical records, "Source Documents" and "Source Data" as defined in ICH guidelines, other personal record and the Investigators personal notes shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth above. Institution and/or Investigator shall have the right to use the data for their own internal non-commercial educational, research, quality assurance, and/or patient care purposes.

E. Information Security

Institution and Investigator represent and certify that they have documented information security policies, standards and/or procedures in place to protect the confidentiality and integrity of confidential information, as well as certain protected health information as that term is defined under local privacy laws. Institution and Investigator further represent and certify that they have procedures and/or processes for identifying threats and vulnerabilities to their information system(s), and will train their personnel accordingly. The Institution agrees that all personal data transferred to or stored on any mobile device, including but not limited to smart phones, laptop computers, compact discs, PDAs, thumb drives, backup tapes, and/or zip drives, shall utilize encryption.

F. Publications

Notwithstanding the obligations of Confidentiality and Non-Use set forth above, Investigator and Institution will be free to publish and present the results of the Study subject to the following conditions: Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in Indianapolis, Indiana. At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution will remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Investigator and/or Institution will assist Lilly in obtaining reprints of Investigator or Institution's publication(s) resulting from the Study.

Notwithstanding the foregoing, scientific conclusions and professional judgments regarding the results of a Study in any publication submitted by Investigator shall be determined solely by Investigator and will adhere to the policies and principles of the International Committee of Medical Journal Editors and other major medical journals and will not be subject to censor or unreasonable control or delay by Lilly.

G. Inventions

If during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g. but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Investigator and/or Institution shall promptly notify Lilly. The new invention or use shall be the sole property of Lilly. As such, Institution and Investigator hereby assign the exclusive ownership of any such Invention to Lilly.

H. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth above Investigator and/or Institution agree to the following:

(1) Solicitation of patients. Lilly and the ERB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

(2) Press releases. Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) before the statements are released.

(3) Inquiries from media and financial analysts. During and after the Study Investigator and Institution may receive inquiries from reporters or financial analysts. Investigator and Institution agree to confer with Lilly's Research Physician or Medical Director at +91-124-4753000 or Lilly's Corporate Communications Department in the United States at (001-317-276-3402) to discuss such inquiries before responding to them.

(4) Use of name. Neither Lilly nor Investigator and Institution will use the name or names of the other party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator and Institution agree to the use of their names in Study publications and communications, including clinical trial web sites and Study newsletters and Lilly may disclose Investigator and Institution's name, business contact information and the names of any sub-investigators, the type of services performed by Investigator and Institution and and/or any sub-investigator for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for Investigator and Institution's services or the services of any sub-investigator, in order to comply with applicable laws and regulations. Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

I. Debarment Certification (Generic Drug Enforcement Act of 1992)

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that they will not use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution or any person or organization they use or involve

in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution agree to promptly notify Lilly in writing.

J. Contract Research Organization Involvement
Lilly shall be entitled to authorize a contract research organization to perform certain sponsor obligations for this Study. Investigator and Institution agree to cooperate with any Lilly-authorized contract research organization in performing this Study.

K. Equipment
Lilly is providing Investigator and/or Institution with equipment ("Equipment") for use in the Study. Investigator and Institution agree to comply with all manuals and instructions from Lilly regarding the use and care of the Equipment. Investigator and Institution agree that the Equipment shall remain in the same condition, ordinary wear and tear excepted, and that Investigator and Institution shall be responsible for the Equipment including the maintenance (and recalibration) or any risk of loss in connection with the Equipment during the term of the Study. Investigator and Institution will follow Lilly's instructions for disposition of the Equipment at the completion or termination of the Study.

II. LILLY SUPPORT

Lilly will provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study. In addition, Lilly will provide financial support for the Study as follows:

A. Payee
Payment in connection with the Study will be made to the name and address listed below:

Payee name: SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES
Address: Raebareli Road, Lucknow, Uttar Pradesh - 226014
PAN Number: AAAJS3913N
GST Number: 09AAAJS3913N2ZN
(Identification Number for Tax Purposes)

B. Payment Schedule
In connection with the Study, Institution will be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. For those amounts designated for patient services, Institution will receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study by Close-Out4, unless Lilly gives Investigator or Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional patients. Other than the final payment, Lilly shall not issue any payment for a total amount less than INR 1,000 (Rupees One Thousand Only). In the event the amount due in any given period is less than INR 1,000 (Rupees One Thousand Only), such amount shall carry over without payment to the next payment period. In addition to the payments set forth above, Lilly will also reimburse Payee for reimbursable expenses as set forth in the Budget.

To be eligible for payment, all procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an ERB-approved consent document, and all procedures designated in the

Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. Final payment will be made by Lilly to the Payee when all patients at the Site have completed the Study and upon final acceptance by Lilly of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Lilly, the return of all unused supplies to Lilly, and upon satisfaction of all other applicable conditions set forth in this Agreement. It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation. Institution will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Matters in dispute shall be payable upon mutual resolution of such dispute.

When Investigator and/or Institution data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Lilly reserves the right to refuse payment for data not received by Lilly within ten (10) days after the representative's review.

In addition, if Lilly requests Investigator and/ or Institution attendance at a Study startup meeting or other meeting necessary to provide Investigator and/or Institution information regarding the Study or Study drug, Lilly shall reimburse Institution for reasonable and necessary travel and lodging expenses (including meals) that are incurred to attend such meeting(s) that have been specifically approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred.

C. Subject Injury Reimbursement
Lilly agrees to reimburse Institution for the following additional costs:

(1) All reasonable and customary costs incurred and associated with the diagnosis of an adverse event involving the Study drug or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigator that the adverse event was reasonably related to administration of the Study drug or Protocol; provided, however, that:

(a) such costs are not covered by the subject's medical or hospital insurance or other governmental program providing such coverage;

(b) the adverse event is not attributable to Investigator and/or Institution or any of their agents' or employees' negligence or misconduct;

(c) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(d) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study provided that deviations from the Protocol and recommendations resulting from

an imminent threat to the health or safety of a Subject that do not cause the injury to the Subject will not disqualify Institution and/or Investigator from reimbursement under this provision .

Lilly shall have the option of paying the additional costs directly to the provider of the service or to Institution .

D. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Investigator, Institution or any patient's participation in the Study or the Study itself at any time for any reason. Investigator and/or Institution may terminate the Study upon thirty (30) days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death or disability and Institution and Lilly are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by any local regulatory authority, any United States regulatory authority or by the ERB. In the event Investigator and/or Institution's participation in the Study or the Study itself is terminated, Investigator and/or Institution agree to return, retain or dispose of all Study drug(s) in accordance with instructions to be provided by Lilly and regulatory requirements.

In the event of termination, payments will be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget. If any payments exceed the amount owed for work performed under the Protocol, Investigator and/or Institution agree to return the excess balance to Lilly.

III. Data Privacy and Security

(1) Site Personnel Data

Lilly may collect personal information from Investigator and Institution personnel including but not limited to names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study to fulfill Lilly's business purposes, including:

(1) Compliance with laws and regulations regarding possible financial conflicts of interest;
(2) Assessment of personnel qualifications to conduct the Study;
(3) Quality control and Study management; and
(4) Disclosures to ERBs, Ethics Committees or national or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists.

Investigator and Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate.

Investigator and Institution agree to obtain the permission of their personnel for the transfer and use of Site Personnel Data for the purposes described in this section

Investigator and Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data. Lilly agrees to comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data.

IV. INDEMNIFICATION and INSURANCE

In consideration of the performance by Investigator, Institution and their staff, officers, agents and employees ("Indemnitees") of the Study, Lilly agrees to indemnify, defend and hold harmless the Indemnitees from and against loss, damage, cost and expense of claims and suits (including reasonable legal fees) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol, including the cost and expense of handling such claims and defending such suits; provided, however, (1) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (2) that Lilly is promptly notified of any such claim or suit; (3) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (4) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain counsel of its choice; and (5) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's obligation of indemnification shall not extend to any loss, damage or expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Agreement. Lilly hereby agrees that any deviations from or failures to adhere to the terms of the Protocol that are mutually agreed upon in writing by all parties to the Study (including the ERB) or any deviations from the Protocol that are necessary to eliminate an immediate safety hazard to the Study participants are not considered violations of the Protocol or failures to adhere to the terms of the Protocol pursuant to this provision.

Lilly warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the obligations of indemnification provided above. Upon written request, Lilly will provide evidence of its insurance, or if self-insured, its most recent audited financial statement to Institution.

V. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, PRIVACY DATA AND SECURITY, SUBJECT INJURY REIMBURSEMENT and INDEMNIFICATION shall survive the expiration, termination or cancellation of this Agreement. Investigator and/or Institution shall promptly notify Lilly in the event Investigator and/or Institution breach any of the terms and/or obligations contained in this Agreement or become aware of such breach.

VI. ASSIGNMENT

Institution shall not assign, transfer or otherwise delegate any of its obligations under this Agreement without Lilly's prior written consent in each instance. Institution and Investigator acknowledge that Lilly will have the right to assign this Agreement to any of its affiliates, to a contract research organization in connection

with the transfer of sponsor obligations, or in connection with a merger or other corporate reorganization, or otherwise in connection with the transfer of all or substantially all of Lilly's assets that bear on the Study drug(s) or device(s)

VII. AMENDMENTS

This Agreement may be amended by an instrument in writing signed by the parties to this Agreement, pursuant to the terms of Payment Schedule or as otherwise agreed by the parties. Amendments may be required or requested in order to document changes or modifications to the Protocol, the Study Budget and/or Institution or Investigator information. Institution and Investigator shall use their best efforts to review any amendments to this Agreement in good faith and in a timely manner and, if applicable, to facilitate the timely execution of said amendments.

VIII. INDEPENDENT CONTRACTOR

Investigator, Institution and Lilly will be acting as independent contractors and not as agents, partners or employees of any other party. No party has the authority to make agreements with third parties that are binding on any other party.

By signing this Agreement, Investigator and Institution represent and warrant that they have the authority and ability to or will otherwise contractually bind any individual or entity who performs services for Investigator and Institution in connection with the Study hereunder to the terms and conditions of this Agreement. This Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile or email copies of this Agreement are considered to be a legal original and signatures thereon shall be legal and binding agreement.
This Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against either party. This Agreement shall be interpreted in accordance with the laws of India (Lucknow Jurisdiction).

If the foregoing is acceptable, please sign the enclosed Agreement and return it to Lilly by: (1) forwarding the scanned or electronically signed document to **sharma_roopesh@lilly.com**; (2) by facsimile transmission to **91-124-4753036**; or (3) by mail/courier service to **Roopesh Sharma, Eli Lilly and Company, Plot No. 92, Sector**

– 32, Gurugram, Haryana - 122001. If You have any questions, please call **Roopesh Sharma** at 91-8826462220.

Sincerely,

ELI LILLY AND COMPANY (INDIA) PVT. LTD.

(Signature of Authorized Official)

Dr. Rajeev Sharan Shrivastava
Associate Director – Regulatory Affairs and Pharmacovigilance
(Typed or Printed Name and Title)

15-Dec-2020.
(Date)

AGREED AND ACCEPTED:
Investigator

Dr. Amita Agarwal

21-Dec-2020
(Date)

AGREED AND ACCEPTED:
Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI)

(Signature of Authorized Official)

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

(Typed or Printed Name and Title)

(Date) 05/01/21

Exhibit-A

The following table outlines cost and frequency of grant heads that will be paid for in the trial I4V-MC-JAHU:

S. No.	Investigations	Visit Frequency (X)	Cost/frequency INR (Y)	Total Amount (X*Y*Z)
1.	**Principal Investigator Fee:** @Rs. 5500/- per patient clinic visit x 22 visits for 05 enrolled patients (Z)	V1 – V21 & V801/ET	5500	6,05,000
2.	**Co-Investigator Fee:** @ Rs. 3300/- patient clinic visit x 22 visits for 05 enrolled patients	V1 – V21 & V801/ET	3300	3,63,000
3.	**Phlebotomist Fees** @ Rs. 1000/- per patient clinic visit x 22 visits for 05 enrolled patients	V1 – V21 & V801/ET	1000	1,10,000
4.	**Patient & Parents Reimbursement** including TDS @ Rs. 2222/- per patient x 22 visits x 05 enrolled patients	V1 – V21 & V801/ET	2222	2,44,420
5.	**Archival Fees (payable after site close-out)**	One time	50,000	50,000
6.	**Start-up Fee** Includes communication expenses for telephone & fax, Courier, stationary, storage, high speed internet etc.	Initial Start-Up Fee after SIV	60000	60,000
7.	**Study Close-Out Fee** payable at the time of study close-out	NA	30000	30,000
8.	**Study Cordinator Fee** @ INR 18000 per month effective after SIV for 36 months or until LPV whichever comes earlier	NA	18000	6,48,000
9.	**Institutional Grant**	25% of total grant of Sr. No. 1, 2, 3		2,69,500
	TOTAL			**23,79,920**

Exhibit B Payment Schedule

The payments will be made per patient visit entered into the data management system (based on the investigation schedule and cost outlined in the table number 1, unless indicated otherwise, as per the following table:

S. No.	Particulars	Cost INR
	Total Payment for each visit inclusive of 25% institutional Grant on PI, Co-I, & Phlebotomist per visit	
1.	Visit 1	14472
2.	Visit 2	14472
3.	Visit 3	14472
4.	Visit 4	14472
5.	Visit 5	14472
6.	Visit 6	14472
7.	Visit 7	14472
8.	Visit 8	14472
9.	Visit 9	14472
10.	Visit 10	14472
11.	Visit 11	14472
12.	Visit 12	14472
13.	Visit 13	14472
14.	Visit 14	14472
15.	Visit 15	14472
16.	Visit 16	14472
17.	Visit 17	14472
18.	Visit 18	14472
19.	Visit 19	14472
20.	Visit 20	14472
21.	Visit 21	14472
22.	Visit 801	14472
23.	Early termination visit (If applicable)	14472

Exhibit C: Procedural Payment

S. No.	Investigations/Frequecy	Name of Test/Procedure	Cost in INR/Procedure	Estimated No. of Procedures/Patients	Estimated Total Cost
1.	As Applicable	Urine Pregnancy Test (Assuming 5 patients)	500	20/Patient	50,000
2.	As Applicable	TB test (Assuming 5 patients)	1000	1/Patient	5,000
3.	As Applicable	ECG (Assuming 5 patients)	500	1/Patient	2,500
4.	As Applicable	X-ray (Assuming 5 patients)	700	1/Patient	3,500
5.	As Applicable	Uveitis evaluation (Assuming 5 patients)	1500	1/Patient	7,500

Exhibit D: COVID-19 Related Expenses

Sr. No.	Particulars	Amount (INR)
1.	**Ancillary Supplies (PPE) and Study Site Cleaning** - Costs that are a study-specific expense incurred as part of continued protocol compliance. *(e.g., gloves, masks, PPE Kit etc.)* ***Notes: These expenses can be reimbursed by invoice that indicates the dates of completed clinic visits for each patient during the period of heightened coronavirus protections/restrictions. If the site completes multiple clinic visits for the patient on different dates of service, each visit's costs could be included on the invoice.***	INR 1000 per visit
2.	**Patient Travel Reimbursement (Local Transportation by Taxi/Cab etc..) for Clinical Trial Site Visit** - This local transportation reimbursement is NOT applicable for any travel by flight/Air fare - Reimbursement to be based on actual expenses supported by third-party receipts - Investigator site will need to provide Tax Invoice after deducting the Patient Inconvenience/Patient Travel cost as mentioned in Exhibit A. which will be paid along with standard patient visit payment.	Maximum of INR 20000 per visit

Additional details for the COVID-19 related expense reimbursement

- The investigator site will be responsible to provide valid invoices with requested detail as mentioned in the Table above for reimbursement.
- Institutional overhead will NOT be applicable for the COVID-19 expenses.

Descriptions:

- Total budget for one patient: **Rs. 4,79,684**
- The site enrollment target (Z): 05 patients
- Total Budget for site for 05 patients including screen failure cost, Procedural cost & admin grant: **Rs. 25,93,140**

Payment Cycle and Procedure:

- Payments will be made on a monthly basis, based on invoices received **on or before 5th working day of every month**
- All the visits and procedures included in the invoice must be entered into eCRF (Case Report Form) for the payment to be processed

Goods & Services Tax:

- The above mentioned calculation of visit payment does not include goods & services tax. Goods & Services Tax will be paid as applicable based on the invoices received.

Screen Failure & Early Discontinuation Patients:

- The Payment of screen failure patients would be paid on the basis of patients who have signed the ICF and the eCRF data entry for the same has been completed in Electronic Data Management System (INFORM) and as per amount specified for screen failure in Exhibit A (Visit 1).
- Early discontinuation visit will be paid at Rs. 14472, as applicable.

Patient Reimbursement:

- Patient reimbursement amount is inclusive of the TDS amount.
- This LOA is valid for a maximum of 10 Screen-failure & 05 Randomized patients.
- Screen failure visit cost i.e. Rs. 14472 will be paid as applicable.

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA89629265139670T
Certificate Issued Date	:	30-Aug-2021 03:20 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ PADMANABHANAGAR3/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08390604997279 78T
Purchased by	:	SHIRE HUMAN GENETIC THERAPIES INC
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	SHIRE HUMAN GENETIC THERAPIES INC
Second Party	:	SGPGIMS
Stamp Duty Paid By	:	SHIRE HUMAN GENETIC THERAPIES INC
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

AMARAJYOTI CO-OPERATIVE SOCIETY LTD
DRB-3/REG/02/ 42156/2017-18
BANGALORE

Please write or type below this line

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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Sponsored Observational Study Agreement
(Non-Interventional)

[A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India]

Clinical Protocol No. SHP669-406

THIS SPONSORED OBSERVATIONAL STUDY AGREEMENT (the "**Agreement**") is made as of 01 Sept 2021 (the "**Effective Date**"), by and among **[Shire Human Genetic Therapies, Inc**], a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, having a place of business at 300 Shire Way, Lexington, MA 02421, United States ("**Sponsor**"), **IQVIA RDS (India) Private Limited** (formerly Quintiles Research (India) Private Limited) , a corporation organized under the laws of India having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road, Bangalore – 560103, Karnataka, India ("**CRO**"), Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPIMS) organized under the laws of India with its principal place of business at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow- 226014, Uttar Pradesh, India ("**Institution**") and Dr. Shubha R Phadke, (the "**Investigator**" and together with the Institution, the "**Site**"). . For purposes of this Agreement, each of Sponsor, CRO, and Institution may be referred to as a "**Party**" and together as the "**Parties.**"

RECITALS

WHEREAS, Sponsor is interested in collecting safety and/or efficacy data on a product and during routine application and desires to obtain the services of Institution and the Investigator to conduct a non-interventional clinical study;

WHEREAS, the Investigator is an employee of Institution, experienced in the conduct of clinical research studies in humans, who shall serve as the principal investigator for the Study (defined below);

WHEREAS, the Investigator and Institution have reviewed sufficient information regarding the Protocol (defined below) to evaluate his/her/its interest in participating in the Study, and the Investigator and Institution both are equipped to undertake the Study and desire to perform the Study on the terms and conditions set forth herein;

WHEREAS, Sponsor has entered into a separate agreement with CRO to provide support services to facilitate Sponsor's oversight, monitoring, and administration of the Study in

accordance with 21 CFR Part 312.52 and with this Agreement; Sponsor has authorized CRO to handle Sponsor communications with Institution and Investigator with respect to the Study and this Agreement; and, upon written notice to Institution and Investigator, Sponsor may designate other such organizations to replace or work with CRO in the performance of such services for Sponsor, and Institution and Investigator shall permit such other organizations to perform any or all of Sponsor's obligations under this Agreement;

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein, the Parties, intending to be legally bound, have entered into this Agreement to conduct a non-interventional study and do specifically agree as follows:

1. Study Protocol.

The Site will conduct the study entitled "[A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India]" (the "**Study**") at Institution in accordance with the Protocol, incorporated herein by reference, as may be further amended pursuant to the terms of this Agreement (the "**Protocol**"). The Protocol sets forth the Study activities and responsibilities to be undertaken by the Parties. The Protocol shall be considered final after it is signed by Sponsor and the Investigator and approved by the relevant institutional review board ("**IRB**") or Ethics Committee ("**EC**"). Thereafter, the Protocol may be amended only by prior written consent of Sponsor and subsequent approval by the IRB/EC. The Parties agree that in the event of a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement shall govern, except in the case of matters relating directly to clinical procedures or patient safety, with respect to which the terms of the Protocol shall prevail.

2. Conduct of Study.

A. The Site shall, and shall ensure that its employees and agents shall, conduct the Study in strict compliance with any and all applicable federal, national, state, local or other jurisdictional laws, rules, regulations, policies, guidelines, guidances, governmental requirements, as may be applicable to the Parties, Study Personnel, and/or the Study, DCGI New Drugs and Clinical Trials Rules, 2019, NMC Regulations [National Medical Commission], 2019 as may be amended from time to time or any replacement regulations], and state and local tax and finance regulations ("**Applicable Law**"), including without limitation:

i. the U.S. Code of Federal Regulations, 21 C.F.R. Parts 50, 54, 56 and 312; the requirements of the Federal Food, Drug and Cosmetic Act ("**FDCA**") and any similar or successor legislation; any policies or guidance issued by the FDA;

ii. all applicable rules, policies, or guidance issued by the European Medicines Agency ("**EMA**"); all applicable requirements of the U.S. Federal Controlled Substances Act, as enforced by the U.S. Drug Enforcement Administration ("**DEA**");

iii. the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**") Guidelines for Good Clinical Practices as adopted or issued by any governmental or other regulatory authority, including FDA and EMA (collectively, "**GCP**" or "**GCP Guidelines**"),

iv. all applicable local, state, federal, and national laws and regulations regarding the protection of privacy, personal data, and medical data, including the Health Insurance Portability and Accountability Act of 1996 and any regulations and official

guidance promulgated thereunder ("**HIPAA**"), and the General Data Protection Regulation ("**GDPR**") (collectively, the "**Privacy Regulations**");

v. all applicable state HIV testing laws;

vi. all applicable local, state, federal, and national laws and regulations regarding the reporting of any fees and other expenditures paid to healthcare professionals, including without limitation, the Physician Payment Sunshine Provision set forth in Section 1128G(e)(6) of the Social Security Act, added in by Section 6002 of the Affordable Care Act (the "**US Federal Sunshine Act**");

vii. all applicable anti-bribery legislation, including without limitation, the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq., and the UK Bribery Act, and the rules and regulations promulgated thereto; all applicable requirements of the U.S. Federal Anti-Kickback law; and

viii. all generally accepted professional standards.

B. The Site further agrees to conduct the Study in accordance with all conditions imposed by the FDA and the IRB/EC, and all requirements of the Institution.

C. For the avoidance of doubt, Sponsor also shall be subject to Applicable Law.

D. Upon the prior written consent of Sponsor, Institution and/or Investigator may use sub-investigators, other employees of Institution, and contractors to perform Study-related services under this Agreement (together with Investigator, "**Study Personnel**"). Institution shall ensure that:

i. Adequate numbers of qualified Study Personnel are assigned to the Study to meet its obligations under this Agreement;

ii. All Study Personnel perform their Study responsibilities and fulfill their obligations under this Agreement, including strict adherence to the Protocol and the Investigator's instructions;

iii. All Study Personnel have the necessary licenses and certifications as may be required to perform their Study responsibilities, and shall, upon request of Sponsor, provide such documented evidence of any such licenses and certifications;

iv. All Study Personnel receive the necessary information, education, and training in any applicable regulatory requirements, proper performance of the Protocol, GCP Guidelines, and any other applicable guidelines relevant to the Study and performance of the Protocol, and shall, upon request of Sponsor, provide such documented evidence of any such education and training; and

v. Any Study Personnel not employed by Institution shall comply with the same terms that bind Investigator hereunder.

E. Without limitation of the foregoing, the Site further agrees that, in the performance of the Study, the Site and the Site's employees and agents shall:

i. provide to each potential subject verbal and written information about the risks, benefits, and requirements associated with Study participation and obtain in advance

from each Study subject a signed and dated written consent form that has received prior approval from the IRB/EC and Sponsor and that is consistent with the Protocol, this Agreement, and complies with 21 C.F.R. Parts 50 and 56, HIPAA or other Privacy Regulations, the GCP Guidelines, and other Applicable Law;

ii. require that no subject in the Study may participate concurrently in any other clinical study in which a study drug is given. Should Site become aware of any such concurrent study participation, it shall notify Sponsor promptly;

iii. maintain and prepare records relating to the Study and subjects participating in the Study as specified in the Protocol and consistent with the requirements of 21 C.F.R. Part 312, GCP Guidelines, and other Applicable Law;

iv. complete all subject case report forms (**"CRFs"**) using the form(s) provided by or on behalf of Sponsor, whether recorded on paper or in digital format, review the CRFs to assure their accuracy and completeness, assist the representatives and clinical monitors of Sponsor in promptly resolving any discrepancies or errors on CRFs, and, provided subject confidentiality is maintained, assist in performing audits of original subject records, laboratory reports, or other raw data sources for the purpose of verifying data recorded on the CRFs;

v. submit all data and all requested information to Sponsor or its designee, and undertake all activities hereunder in a timely, efficient, and competent manner so that the time schedules set forth in the Protocol and this Agreement are strictly met;

vi. ensure that all clinical data are accurate, complete, and legible, and that such data are promptly and fully disclosed to and produced for the inspection and use of Sponsor or its designee at any time upon reasonable request during normal business hours;

vii. cooperate with Sponsor and its designee in all of their efforts to support and monitor the Study, including without limitation, allowing Sponsor and/or its designee on-site access to the facilities where the Study is being conducted and any and all records and other documents associated with the conduct of the Study as reasonably requested by Sponsor or its designee, providing all requested documentation in a timely and organized manner, and keeping Sponsor fully apprised of the progress of the Study;

viii. record all adverse events on the Adverse Events page(s) of the CRFs and report all adverse events and serious adverse events in accordance with 21 C.F.R. Part 312, GCP Guidelines, and the Protocol and cooperate with Sponsor in identifying and resolving unexpected occurrences involving the Protocol;

ix. retain all records relating to the Study, including without limitation, all records that the FDA requires to be maintained under 21 C.F.R. Part 312, for the period required by Applicable Law, and prior to the Site's disposition of any Study records, the Site shall provide prior written notice to Sponsor, and upon Sponsor's request and at Sponsor's reasonable expense, the Site shall either retain such Study records for the period specified by Sponsor or send such records to Sponsor, as designated by Sponsor;

x. cooperate with and support the Sponsor with regard to the relevant applications or communications with the relevant IRB/EC; and

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xi. conduct the Study solely at the Site's facilities; the location for the conduct of the Study may not be changed without Sponsor's prior written consent.

F. Institution further represents and warrants to Sponsor that:

i. neither the Site, nor any of the Site's employees or agents performing the Study, (1) are under any contractual or other obligations or restrictions that are inconsistent with the Site's obligations under this Agreement, or (2) have a financial or other interest in Sponsor or the outcome of the Study that might interfere with their independent judgment, or (3) are under investigation by any regulatory authority, including the FDA, for debarment or any action in relation to clinical research, or (4) are presently debarred, disqualified, or deemed ineligible to conduct clinical research or to receive investigational drugs or devices as a clinical investigator under any Applicable Law. The Site will notify Sponsor immediately (a) if Institution, Investigator, or any of their employees or agents become debarred, disqualified, or deemed ineligible by any court or regulatory agency, or (b) upon any inquiry concerning or the commencement of any such proceeding regarding any such person, the Investigator, or Institution, together with any other information known to Site that is relevant to such debarment or disqualification proceedings or actions;

ii. Institution shall properly supervise all persons performing the Study under its direction and shall ensure that such persons comply with the terms of this Agreement;

iii. Institution has the capability in-house to perform the Study and will not engage any external sub-investigators or third parties to participate in the conduct of the Study without obtaining Sponsor's prior written consent to do so subject to the terms of this Agreement; and

iv. The Institution has obtained and will maintain all licenses, authorizations, and permits required by law for the Institution to conduct the Study under this Agreement and in compliance with the Protocol.

3. **Investigator; Replacement.**

A. In the event that the Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Institution shall promptly notify Sponsor of such event, and shall cooperate, in good faith and expeditiously, to find a replacement investigator acceptable to Sponsor (a "**Replacement Investigator**"); provided, however, that the Site and/or Investigator shall continue to be bound by all obligations and conditions stipulated in this Agreement until a Replacement Investigator acceptable to the Sponsor is found. In the event an acceptable Replacement Investigator is not found within thirty (30) days of Sponsor's receipt of such notice (or such longer period as mutually agreed upon by the Parties), Sponsor may terminate this Agreement in accordance with the terms of this Agreement. The Site's cooperation in finding a Replacement Investigator does not negate its obligation to perform its obligations under this Agreement up to Completion (defined below) or the effective date of any termination of this Agreement. The Parties hereto agree, in the event that a Replacement Investigator is designated pursuant to this article, that such Replacement Investigator shall be bound by all terms of this Agreement that are applicable to the Investigator, and the Parties shall amend this Agreement accordingly.

B. Investigator shall provide Sponsor with a copy of the Investigator's current curriculum vitae, which shall include a description of the Investigator's relevant experience.

C. Investigator shall provide CRO and Sponsor with sufficient accurate financial disclosure information to permit Sponsor to submit a complete and accurate certification or disclosure statement as required by 21 C.F.R. Part 54, and will promptly update the information if any relevant changes occur during the course of the Study and for one (1) year following completion or termination of the Study.

4. Term; Study Initiation.

A. This Agreement shall commence as of the Effective Date and shall continue until completion of all obligations herein, including without limitation receipt by Sponsor or its designee of all Study data and resolution of all corresponding queries in a form acceptable to Sponsor ("**Completion**"), unless otherwise terminated in accordance with this Agreement.

B. The Study shall be initiated on the date that Sponsor or its designee notifies the Investigator to begin enrollment, which notification will occur only after: (i) the Investigator obtains IRB/EC approval to conduct the Study; and (ii) the Site has received sufficient materials from Sponsor to initiate the Study. The Investigator shall deliver a copy of the IRB/EC approval letter to Sponsor or its designee, and Sponsor shall not deliver Study materials to the Site until it has received a copy of such approval letter. If IRB/EC approval is not obtained, this Agreement shall be null and void. No subject may be enrolled and no Study procedures may be performed unless the subject has given all necessary permissions to participate in the Study consistent with the Protocol and the terms of this Agreement. The Site shall not request informed consent from any subject or allow any subject to participate in the Study prior to the initiation of the Study in accordance with the Protocol and the terms of this Agreement. The Site shall immediately notify Sponsor by telephone promptly followed by written notification if IRB or EC approval for the Study is lapsed, suspended, or withdrawn in whole or in part.

5. Payment Terms and Budget.

A. In consideration for performance of the Study, Sponsor or its designee will compensate Institution in accordance with the payment terms and budget set forth in Schedule A attached hereto and made a part hereof (the "**Budget**"). No other benefits or compensation, beyond those expressly included in the Budget, or as otherwise approved by Sponsor in advance in writing, will be provided by Sponsor to Institution. Absent a good faith dispute, payments shall be made by Sponsor within thirty (30) days of receipt of a detailed invoice from Institution, which invoice shall be consistent with the provisions set forth in the Budget. All invoices will be itemized as set forth in the Budget. Any expenses, including travel expenses, for which reimbursement is sought, shall be paid only if (i) the request for reimbursement for such expenses is accompanied by original receipts and (ii) Sponsor has expressly agreed to reimburse such expenses in the Budget, or as otherwise approved in advance by Sponsor in writing. Such expenses may include, if identified in the Budget or as otherwise approved in advance by Sponsor in writing, Investigator's reasonable travel-related expenses and registration fees incurred in presenting Study Results (defined in Article 9 - Ownership of Data; Publication, below) at medical conferences, in accordance with and subject to the terms of Article 9. The last payment due pursuant to the Study will be made by Sponsor after the Site completes all of its obligations hereunder, and Sponsor has received all completed CRFs, all deliverables defined in the Protocol, and all other data and rights to which Sponsor is entitled under this Agreement. Reports comparing actual costs incurred by Institution to costs paid by Sponsor will be provided by Institution to Sponsor within thirty (30) business days of any written request. The terms of the Budget may be modified only upon the prior written consent of the Parties.

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B. Non-emergency additional tests or services (i.e., those tests or services not required by the Protocol or performed in excess of Protocol requirements) shall not be compensable hereunder without the prior written consent of the Sponsor.

C. The Parties to this Agreement specifically intend to comply with all applicable laws, rules, and regulations, including (i) the federal anti-kickback statute (42 U.S.C. 1320a-7(b)) and the related safe harbor regulations; and (ii) the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395 (n)). Accordingly, the Parties acknowledge and agree that the amounts payable by Sponsor under this Agreement represent the fair market value of the covered costs associated with the Study and no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.

D. If applicable, any equipment supplied by Sponsor or its designee for use in the Study will be used solely in connection with the Study and will be returned to Sponsor or its designee promptly upon completion or termination of the Study, unless otherwise agreed in writing by Sponsor.

E. Pursuant to Applicable Law, the Site understands and acknowledges that Sponsor may be required to disclose to relevant governmental authorities the payments made by or on behalf of Sponsor to the Site under this Agreement, as well as the purpose and nature of such payments.

6. Confidentiality.

A. All information (including, but not limited to, verbal, written, and electronically stored or transmitted information), materials, and documents provided to the Site by or on behalf of Sponsor in connection with the Study, including but not limited to preclinical data and case report forms, and all information, data, reports and knowledge developed by Site as a result of work in connection with the Study shall be considered "**Confidential Information.**" Confidential Information includes, without limitation, the Protocol, the Investigators' Drug Brochure, Study correspondence, and Study Results; provided, however, that Institution and Investigator may use and/or publish Study Results in accordance with the terms of this Agreement. During and after the term of this Agreement, the Site hereby agrees that it: (i) shall maintain in strict confidence all of the Confidential Information, (ii) shall not disclose or disseminate Confidential Information to any third party, (iii) shall not use the Confidential Information for any purpose other than the performance of the Study, and (iv) shall safeguard the Confidential Information using the same degree of care, but no less than a reasonable degree of care, as the Site uses to protect its own confidential information. Such Confidential Information shall remain the exclusive confidential and proprietary property of Sponsor, and shall be disclosed only on a need-to-know basis and only to the Site and the Site's employees and agents. The Site agrees to ensure that each of the Site's employees and agents rendering services hereunder are obligated to treat, and do treat, the Confidential Information as confidential consistent with the terms hereof.

B. The foregoing obligations shall not apply to Confidential Information that:

i. is or becomes publicly available through no fault of the Site;

ii. is lawfully disclosed to the Site by a third party entitled to disclose such information not subject to any obligation of confidence;

iii. is already known to the Site prior to disclosure hereunder, as shown by the Site's prior written records; or

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iv. was developed by the Site without the use of any Confidential Information, as evidenced by Site's prior written records.

C. In the event that Confidential Information is required to be disclosed by law or regulation, (i) Site shall immediately notify Sponsor and provide Sponsor an opportunity to object to such disclosure, prior to making any such disclosure, and (ii) in no event shall Site disclose more than the minimum amount of Confidential Information required to be disclosed to comply with such law or regulation. Site shall reasonably cooperate, at Sponsor's expense, with Sponsor to enable Sponsor to challenge or limit such disclosure.

D. Upon demand by Sponsor, the Site shall return all Confidential Information, including all copies thereof, to Sponsor; provided, however, that one (1) copy of such Confidential Information may be retained by Institution in its confidential files for compliance purposes only.

E. Institution and Investigator acknowledge and agree that any violation of the terms of this Agreement relating to the disclosure or use of Confidential Information may result in irreparable injury and damage to Sponsor not adequately compensable in monetary damages, and for which Sponsor may have no adequate remedy at law. Institution and Investigator acknowledge and agree, therefore, that if the disclosure and non-use terms herein are violated, Sponsor may need to seek injunctions, orders, or decrees in order to protect the Confidential Information and will be entitled to do so without having to post a bond.

7. **Data Protection.** The Parties agree to the terms and conditions set forth in Schedule B.

8. **Use of Study Results.**

The Site shall maintain the security of Study subject data and shall obtain all authorizations or other necessary documentation from Study subjects to allow disclosures of Study subjects' data to Sponsor and its agents and contractors, and, if this is a multi-site Study, with researchers at other Study sites, to the extent necessary for them to comply with this Agreement, the Privacy Regulations, and other Applicable Law, and for purposes related to the Study (including, without limitation, Study monitoring, analysis of Study data, and preparing applications and other reports to be submitted to regulatory authorities). The Institution and the Investigator agree to transfer to Sponsor only those data, including but not limited to clinical data regarding patients, which are made anonymous. This means that the data could be transferred by the Sponsor to any country in the world for processing including countries which do not have data protection laws as strict as those in force in the European Union (including, without limitation, the United States of America).

9. **Ownership of Data; Publication.**

A. All data, information, and results generated during the course of conducting the Study, including, without limitation, the completed CRFs and any reports prepared by the Site (collectively the "**Study Results**") shall be provided promptly to Sponsor or its designee and shall be the sole property of Sponsor. The Site shall have the right to publish or otherwise publicly disclose the Study Results for its own internal, bona-fide, academic, non-commercial purposes, in accordance with the terms of this article. The medical records or other Source Documents, as defined by current ICH Guidelines, that support the Study Results shall remain the property of Institution.

B. For purposes of this Agreement, "Publication" shall mean any paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video,

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instructional material, presentation (in the form of a written summary), or other public disclosure of the Study Results, in printed, electronic, oral, or other form. The Parties understand and agree that participation in the Study may involve a commitment to publish the data from all sites participating in the Study in a cooperative publication with other investigators prior to publication or oral presentations of the Study Results on an individual basis. The Site agrees not to publish or present the Site's Study Results until such time as either the aggregate multi-site Study results are published in a cooperative Publication or for a period of one (1) year after termination or Completion of the Study at all participating sites, whichever shall first occur. After that time, the Site may publish the Site's Study Results in scientific journals or present the Study Results at symposia or other professional meetings in accordance with the following provisions:

At least ninety (90) days prior to submitting an abstract, manuscript, or other document for publication, a copy of the proposed Publication will be provided to Sponsor by the Site for review. Upon Sponsor's request, the Site agrees to remove any and all Confidential Information (expressly excluding Study Results) identified in the Publication and to delay such submission or presentation for an additional ninety (90) day period in order to allow Sponsor time to file any patent application(s). All Publications of the Study Results shall appropriately reference the multi-site study Publication, if any, or the fact that the Study Results are a subset of data resulting from a larger multi-site study.

D. The Parties agree that all related research Publication, as defined below, will be submitted to journals that offer public availability via Open Access (including publisher platforms/repositories and self-archiving). Open Access refers to the free at point of entry, online availability of published research output with, where available, rights of re-use according to an End User License. Unless otherwise required by the journal in which the publication appears, or the forum in which it is made, authorship will comply with the International Committee of Medical Journal Editors (**ICMJE**) Recommendation for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical journals. Participation as an investigator, in and of itself, does not confer any rights to authorship of publications.

E. Site warrants the compliance of all Study Personnel with the provisions of this article.

10. Release of Information; Use of Name. Sponsor may use, refer to, and disseminate reprints of scientific, medical, and other published articles relating to the Study that disclose the name of the Investigator and/or Institution, consistent with U.S. copyright laws. Sponsor also may disclose the name of Investigator and Institution and shall provide a description of this Study on public websites (e.g., www.clinicaltrials.gov) consistent with and as required by Applicable Law. No Party shall use the name of any other Party or such other Party's affiliate's name(s) in connection with any advertising or promotion of any product or service without the prior written permission of such other Party or such other Party's affiliate, as applicable; provided, however, that the limitations contained in this article shall not apply to any documents that may be necessary or appropriate for Sponsor or the Site to provide to a federal, state, or local governmental agency or in scientific publications and grant applications. The Site and its employees, agents, and representatives shall not communicate with or provide any information to any media representative (including, but not limited to, traditional and alternative press outlets such as newspapers, magazines, television, radio and Internet) regarding Sponsor, Sponsor's products or the Study without the prior express written approval of Sponsor.

11. **Independent Contractors**. The Site shall act as an independent contractor and shall not be construed for any purpose as the partner, agent, employee, servant, or representative of the Sponsor or CRO. Accordingly, the employee(s) and agent(s) of the Site shall not be considered to be employee(s) and agent(s) of the Sponsor or CRO, and the Site shall not enter into any contract or agreement with a third party that purports to obligate or bind the Sponsor or CRO. Site personnel performing the Study hereunder shall at all times be under the exclusive direction and control and shall be employees or agents of the Site and shall not be employees, agents, or representatives of the Sponsor or CRO.

12. **[RESERVED]**

13. **[RESERVED]**

14. **Inspections, Audits, and Study Monitoring.**

A. **Regulatory Inspection.** The Site shall notify Sponsor and its designee immediately by telephone promptly followed by written notification of any inquiries, correspondence, or communications with or from the FDA or any other governmental or regulatory authority relating to the Study. If a regulatory authority, including without limitation the FDA, requests permission to or does inspect the Site's facilities or research records relating to the Study, the Site will cooperate with the regulatory authority's representative(s) and permit such inspection, and will make all reasonable efforts to permit Sponsor to review the records before the inspection and be present and available during such inspections. The Institution shall provide sufficient and appropriate space as deemed needed by the Investigator and/or Sponsor for such inspections without delay at no additional cost to Sponsor. Investigator and appropriate Study personnel will be available during such inspection to comply with the legitimate requirements of the inspection and to explain and discuss records and documentation related to the Study. The Site shall provide to Sponsor or its designees, in writing and in an organized manner, copies of all materials, correspondence, statements, forms, and records that the Site receives, obtains, or generates in connection with any such inspection or in connection with any inquiries, communications, or correspondence from the FDA or any other governmental or regulatory authorities. The Site will make reasonable efforts to segregate, and not disclose, all documents and materials that are not required to be disclosed during such an inspection, including financial data and pricing information.

B. **Sponsor Inspection/Audit.**

i. Site agrees to permit representatives of Sponsor (including monitors, auditors, and inspectors), upon reasonable notice and during normal business hours, to examine (i) the facilities where the Study is being conducted, (ii) raw Study Results including original Source Documents (as defined by current ICH Guidelines), regardless of media, if allowed under the terms of the Informed Consent, (iii) Electronic Data Capture ("**EDC**") equipment and/or EDC documentation system, and (d) any other relevant information (and to make copies) necessary for Sponsor to confirm that the Study is being conducted in conformance with the Protocol and in compliance with Applicable Law.

ii The Site agrees to take reasonable actions requested by Sponsor to cure deficiencies noted during an audit or inspection. The Site will have five (5) days to cure a breach of the requirements of Schedule B. If the breach is not cured within five (5) days or is incapable of cure, Sponsor has the

right to immediately terminate the Agreement, including any applicable Statements of Work hereunder, without penalty.

C. Each Party shall bear their own expenses in relation to audits conducted pursuant to this article.

15. Termination.

A. This Agreement may be terminated in whole or in part prior to Completion upon written notice as follows:

i. by any Party, effective immediately upon written notice, if (1) the authorization and approval to conduct the Study in the United States is permanently and irrevocably withdrawn by the FDA; or (2) the emergence of any adverse reaction or side effect related to the Study is of such magnitude or occurs with such frequency that either the Investigator, in his or her reasonable medical judgment, or Sponsor, determines that subject safety requires such termination;

ii. by Sponsor, effective immediately upon written notice, if (1) the Investigator is unwilling or unable to serve as the principal investigator and the Parties are not able to agree on a substitute pursuant to the terms of this Agreement; (2) the Site fails to perform the Study in accordance with the terms of the Protocol (excluding permitted deviations pursuant to the Study Protocol and under the terms of this Agreement), this Agreement, or Applicable Law; or (3) Sponsor deems enrollment to be insufficient to reasonably complete the Study in the time frame necessary to meet Sponsor requirements;

iii. by Sponsor or CRO, upon thirty (30) days written notice; or

iv. by the Site, upon forty-five (45) days written notice, in the event of a material breach of this Agreement by Sponsor and Sponsor's failure to remedy such breach within such forty-five (45) day period.

B. In the event of termination of this Agreement prior to Completion, the Site shall, upon receipt or delivery of notice of termination, make all reasonable efforts to minimize incurring further costs. In the event of such early termination, Sponsor shall make a final payment to the Site for outstanding amounts due for services performed in accordance herewith and for reasonable, actual, direct costs incurred as set forth in the Budget through the date of notice of termination. Sponsor also shall reimburse Institution for any reasonable, non-cancelable commitments properly incurred (i) prior to the date of notice of termination and (ii) after the date of notice of termination but reasonably necessary to ensure the safety of enrolled subjects. Upon reasonable request by Sponsor, Institution shall provide Sponsor with documentation of any such committed and non-cancellable costs.

C. Immediately upon receipt or delivery of notice of termination, the Site shall (i) comply with post-termination procedures included in the Protocol, if any, and (ii) unless otherwise directed by Sponsor, cease enrolling subjects into the Study and cease the Study-related treatment of subjects already enrolled in the Study, except if the safety of such enrolled subjects could be compromised. Notwithstanding the foregoing, the Site shall continue to provide follow-up care to subjects as long as necessary to ensure the safety of such enrolled subjects.

D. [RESERVED]

E. Promptly upon Completion or termination of this Agreement for any reason, the Site will furnish to Sponsor or its designee all CRFs, whether complete or incomplete, up to the effective date of termination, as well as all devices, equipment, and Sponsor materials that were furnished to the Site in connection with the performance of the Study, whether the same are in the Site's actual possession or under its control. Confidential Information and materials will be returned, at Sponsor's instruction, to Sponsor, except for record copies or samples which the Site is required by law to retain. Within thirty (30) days of termination of this Agreement or completion of the Study (whichever comes first), Investigator will submit a final written report of the Study to Sponsor.

16. Patent Rights and Inventions.

A. It is recognized and understood that certain existing intellectual property, inventions, and technologies of Sponsor and the Institution are the separate property of each Party and are not affected by this Agreement, and neither shall have any claims to or rights in such separate existing intellectual property, inventions, and technologies of the other Party.

B. Any new invention, development, improvement, or discovery made or conceived by the Site, whether or not patentable, resulting from the Study or Confidential Information ("**Invention**") shall be promptly disclosed by the Site, in writing, to Sponsor. Except as otherwise expressly stated herein, and except as prohibited by federal or state law, any and all Inventions are the sole and exclusive property of Sponsor regardless of the inventor or discoverer. The Site shall, at Sponsor's expense, execute any and all applications, assignments, or other instruments and give testimony which Sponsor shall deem necessary to apply for and obtain letters of patent of the United States or of any foreign country or otherwise to protect Sponsor's interest therein. The Site shall not take any action that is inconsistent with Sponsor's ownership of such Inventions.

C. Title to any Inventions arising from the Site's proper conduct of the Study and conceived and reduced to practice solely by the Site and not arising from any Confidential Information shall be owned solely and exclusively by the Site. The Institution will offer Sponsor a first right of refusal to enter into an exclusive license for the Institution's rights in any such Invention. Such license shall be perpetual, exclusive, and worldwide to the maximum extent permitted by law, shall be on commercially reasonable terms, and shall provide Sponsor with an exclusive right to make, have made, use, sell, have sold, and offer to sell such Invention. If Sponsor declines to enter into such a license, and Institution then offers such license to a third party on terms more favorable than those offered to Sponsor, Sponsor shall have the right to enter into negotiations for said license on terms at least as favorable as those offered to such third party.

D. The Site represents that it has no present obligations to assign or exclusively license to any person or entity other than Institution or Sponsor any Inventions or other intellectual property covered by this article. The Site represents and warrants that all Study Personnel, consultants, or other parties engaged by the Site to conduct work under this Agreement shall be, prior to undertaking such work and for the entire duration of such work, contractually obligated to assign their rights in any Inventions to the Institution.

E. The obligations set forth in this article shall continue beyond Completion or any termination of this Agreement and shall be binding upon the Site and the Site's employees and agents.

17. Indemnification; Insurance.

A. Sponsor Indemnification. Sponsor agrees to indemnify, defend and hold harmless Institution, its trustees, officers, employees, staff, subcontractors, and agents ("**Institution Indemnitees**") against any independent third party claim (each, a "**Claim**") arising out of (i) any side-effect or adverse reaction, illness, or injury directly resulting from procedures performed pursuant to the Protocol. The foregoing indemnity will not apply to the extent a Claim arises out of (1) the negligence, omission, or willful misconduct of any Institution Indemnitee or (2) the failure of any Institution Indemnitee to adhere to the terms of this Agreement, the Protocol, or any written instructions from Sponsor or its designee, or to comply with any Applicable Law or governmental requirements.

B. Institution Indemnification. Institution agrees to indemnify, defend, and hold harmless the Sponsor, its directors, officers, employees, staff, and agents (the "**Sponsor Indemnitees**") against any Claim arising out of (i) the negligence, omission, or willful misconduct of any Institution Indemnitee or (ii) the failure of any Institution Indemnitee to adhere to the terms of this Agreement, the Protocol, or any written instructions from the Sponsor or its designee, or to comply with any Applicable Law or governmental requirements.

C. Indemnification Procedure. The Party or Parties seeking indemnification under this article shall (i) give written notice to the indemnifying Party within five (5) business days after (1) receiving any Claim or (2) learning of any potential Claim; (ii) permit the indemnifying Party to assume the defense and/or disposition of any such Claim or related litigation, provided that counsel selected by such indemnifying Party is reasonably acceptable to the Party or Parties seeking indemnification; and (iii) cooperate with the indemnifying Party in all reasonable respects with regard to the defense of such Claim, with reasonable out-of-pocket costs of the Party or Parties seeking indemnification to be reimbursed by the indemnifying Party. The indemnifying Party under this article shall not enter into any settlement agreement with a claimant without the prior written permission of the Party or Parties seeking indemnification, which permission shall not be unreasonably withheld.

D. Sponsor Insurance. Sponsor agrees to maintain a policy or program of insurance or self-insurance at levels sufficient to support its obligations assumed herein. Sponsor shall provide a certificate of insurance evidencing such coverage upon written request by the Institution.

E. Institution Insurance. The Site represents and warrants that it has and will maintain appropriate insurance, including malpractice insurance, in amounts sufficient to pay all claims arising from its activities or obligations under this Agreement. Sponsor represents that it has and will maintain appropriate insurance and/or self-insurance in amounts sufficient to respond to events that may occur in the conduct of the Study.

18. [RESERVED]

19. **Consequential Damages.** Neither CRO nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to CRO or Sponsor for any lost profits, lost opportunities, or other consequential damages.

20. **Anti-kickback and Anti-Fraud.** Institution and Investigator agree that their judgment with respect to the advice and care of each Study subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or CRO provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation pursuant to this Agreement, or which are not part of the ordinary care they would normally provide for the Study subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

21. **Anti-bribery.** Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or items of value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a government official or otherwise, in order to assist Sponsor to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any items of value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, CRO or Sponsor may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if CRO or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

22. **CRO DISCLAIMER**

CRO expressly disclaims any liability in connection with the Study, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by CRO.

This Section 22 "CRO Disclaimer" shall survive termination or expiration of this Agreement.

23. **Complete Agreement; Amendment; Notice.** This Agreement together with all attachments hereto constitutes the entire agreement among the Parties with respect to the subject matter hereof and all prior negotiations, representations, agreements, and understandings with respect to the subject matter hereof are superseded hereby. No agreements amending, altering, or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of each of the Parties. Any notice to be given hereunder shall be given by personal delivery, by recognized express courier, or by registered or certified mail, return receipt requested. Such notice shall be addressed to a Party at the address set forth below, except as set forth in Schedule A. Any Party may change its address for notice by giving written notice of such change to the other Parties.

To Sponsor:	**Shire Human Genetic Therapies, Inc** **[300 Shire Way, Lexington, MA 02421, United States]** **Attn: Project Manager – Protocol # [*SHP669-406*]**
With a copy to:	Attn: Legal Department (same Sponsor address)
To Institution:	Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow-226014, Uttar Pradesh, India Attn: Dr.R K Dhiman (Director)
To Investigator:	Dept. of Medical Genetics, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow-226014, Uttar Pradesh, India

24. **Binding Effect; Survival of Terms.** This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. The rights and obligations of the Parties which by intent or meaning have validity beyond termination of this Agreement (including, but not limited to, rights with respect to ownership, patents, confidentiality, and indemnification) shall survive Completion or any termination of this Agreement.

25. **Governing Law.** This Agreement and all matters arising out of or relating to this Agreement shall be governed by, and construed and enforced in accordance with, the laws of the country in which Institution is located without regard to the conflicts of law provisions thereof. Any dispute arising hereunder shall be tried exclusively by the courts where Institution is located i.e. Lucknow, India and each Party hereby consents to the jurisdiction of such courts and waives any objections thereto.

26. **Waiver.** Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect. All waivers must be set forth in writing and executed by duly authorized representatives of the Parties.

27. **Severability.** If a judicial determination is made that any of the provisions contained in this Agreement constitute an unreasonable restriction against any Party or are otherwise unenforceable, such provision or provisions shall be rendered void or invalid only to the extent that such judicial determination finds such provision or provisions to be unreasonable or otherwise unenforceable, and the remainder of this Agreement shall remain operative and in full force and effect.

B. Data Protection Schedule

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as the Effective Date defined above.

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS)

By: _____ 22/X/21
(Signature)
Name: Dr. R K Dhiman
Title: Director

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Dr. Shubha R Phadke (Principal Investigator)

_____
(Signature)
Name: Dr Shubha P Phadke

Shire Human Genetic Therapies, Inc

By: _____
(Signature)
Name:
Title:

IQVIA RDS (India) Private Limited

By: _____ 3 Sep 2021
(Signature)
Name: Shweta Pradhan
Title: Director and Head Site Management

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as the Effective Date defined above.

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS)

By: _____
(Signature)
Name: Dr. R K Dhiman
Title: Director

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Dr. Shubha R Phadke (Principal Investigator)

_____
(Signature)
Name: Dr Shubha Phadke

Shire Human Genetic Therapies, Inc

By: _____
(Signature)
Name:
Title:

IQVIA RDS (India) Private Limited

By: Pradhan
(Signature) 3/Sep/2024
Name: Shweta Pradhan
Title: Director and Head Site Management

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Schedule A

BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAIL

Site agrees that the payee designated below is the proper payee for this Agreement, and that payment under this Agreement to the payee designated below will not violate any rules or policies of the Site, will not violate applicable national, state, or local laws or regulations, and that payment under this Agreement will be made only to the following payee (the "**Payee**"):

PAYEE NAME:	Director SGPGIMS Research Account
PAYEE ADDRESS:	Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, lucknow-226014, Uttar Pradesh, India
PAYEE EMAIL ADDRESS	director@sgpgi.ac.in
BANK NAME	State bank of India
BANK ADDRESS	SGPGIMS, Raebareli Road, Lucknow
BANK ACCOUNT NUMBER	10095237491
IFSC	SBIN0007789
IBAN NUMBER	NA
SWIFT CODE / BRANCH CODE	SWIFT CODE: SBININBB500
VAT/GST/TAX ID NUMBER	GST Number: 09AAAJS3913N2ZN

In case of changes in the Payee's bank details above, Payee is obliged to inform Company in writing. The parties agree that in case of any such changes, a formal amendment to this Agreement shall not be required, and that Payee shall inform Company of the change in bank details by written notice provided to the Company.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, shall be determined by a separate agreement between the Investigator and the Payee, which may involve different payment amounts and different payment intervals than the payments made by Company to the Payee. The Investigator acknowledges that if the Investigator is not the Payee, Company will not pay Investigator even if the Payee fails to reimburse the Investigator.

B. PAYMENT TERMS

Company, or a Company affiliate on behalf of Company, will reimburse the Payee Quarterly, in accordance with this Agreement and attached budget. Compensation will be based upon completed Case Report Forms ("**CRFs**").

Services performed that result in disqualified data due to major, disqualifying Protocol violations are not payable under this Agreement.

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by Company or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Company will pay the Payee *quarterly*, based on a completed months per subject basis in accordance with this Compensation Schedule. Payment will be made upon verification of actual subject visits, and will be paid by Company to the Payee. The compensation will be made based upon prior month enrollment data confirmed by subject CRFs received from the Site supporting subject visitation.

Site shall be responsible to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to the Investigator, the Site and its employees and/or collaborators.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Goods and Services Tax ("**GST**") in India, and that it is required to charge GST for the services rendered to Company at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide Company with an invoice, to be sent to Company at the address mentioned in Section E of this Exhibit B, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

C. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

D. DISCONTINUED OR EARLY TERMINATION PAYMENTS

Reimbursement for discontinued or early termination of Subjects will be prorated based on the number of completed CRFs/Month for those Subjects in accordance with the Protocol.

E. INVOICE

Original invoices pertaining to this Study of the following items must be issued for reimbursement to:

IQVIA RDS (India) Private Limited
(formerly **Quintiles Research (India) Private Limited**)
Attn: Accounts Payable
Address: III Floor, Etamin Block, Prestige Technology Park, Sarjapur- Marathahalli Outer Ring Road, Bangalore– 560103, Karnataka, India

Invoices will not be processed unless they reference the Sponsor name, Study name, Protocol number, Investigator name, Site name and Payee GST registration number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for Study activity.

F. Institutional Review Boards ("IRB")/Ethics Committee ("EC") Payments

IRB/EC costs will be reimbursed on a pass-through basis and are not included in the budget above. Any subsequent re-submissions or renewals, upon approval by Company and Sponsor, will be reimbursed upon receipt of appropriate documentation.

H. BUDGET

The Budget is as follows:

Payment Milestone Table(s):

MILESTONES	Investigator Grant Per Subject		Institutional Over heads 25% (IOH)	Investigator Grant Per Subject (Inclusive of Institutional Over Heads 25%)
	Consumables & Contingency	Manpower for source and Data entry		
Month 1: Screening & Enrollment	28000	5000	11000	44000
Month 2	6550	5000	3850	15400
Month 3	6550	5000	3850	15400
Month 4	6550	5000	3850	15400
Month 5	6550	5000	3850	15400
Month 6	6550	5000	3850	15400
Month 7	6550	5000	3850	15400
Month 8	6550	5000	3850	15400
Month 9	6550	5000	3850	15400
Month 10	6550	5000	3850	15400
Month 11	6550	5000	3850	15400
Month 12/End of Study / Early Withdrawal	11500	5000	5500	22000
Total (INR)	105000	60000	55000	220000

*All amounts are inclusive of any overhead.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED.

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Schedule B

DATA PROTECTION SCHEDULE

Where Institution jointly Controls the Processing of Personal Data (defined below) created, collected, or received pursuant to the Services under the Agreement, the Parties agree that the terms of this Schedule B shall apply to the Agreement. In the event of a conflict between this Schedule B and the Agreement with respect to the Processing of Personal Data, the terms and definitions of this Schedule B shall control and govern.

A. **Definitions.** Capitalized terms used herein shall have the meanings set forth in this Section A or in the Agreement.

1. **"Affiliate"** means an entity related to Institution or Sponsor, respectively, through common ownership or control.

2. **"Data Controller"** shall mean the entity which alone or jointly with others determines the purposes and means of the Processing of Personal Data.

3. **"Data Processor"** shall mean an entity which Processes Personal Data on behalf of the Data Controller.

4. **"Data Security Breach"** means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored, or otherwise processed.

5. **"Encryption"** or **"Encrypted"** means the transformation of data through the use of an algorithmic process, or an alternative method at least as secure, into a form in which meaning cannot be assigned without the use of a confidential process or key. For the purposes of this agreement, any encryption mechanism used must accord with industry best practices for data encryption. "Unencrypted" means data that is not encrypted or is encrypted using an encryption method of insufficient strength.

6. **"Government Authority"** means a legislative, executive, administrative, or regulatory entity, judicial body, or other public agency or authority of any country, state, territory, or political subdivision of a country, state, or territory, or a person or entity acting under a grant of authority from or under contract with such public agency or authority, that is authorized by law to enforce individual rights with respect to Personal Data, or to oversee or monitor compliance with privacy, data protection, or data security laws, rules regulations, or other Applicable Law.

7. **"Joint Controllers"** shall mean two or more entities, each a Data Controller, which jointly determine the purposes and means of the Processing of Personal Data.

8. **"Personal Data"** shall mean all individually identifiable information created, collected or received pursuant to the Agreement. Personal Data includes, without limitation, individually identifiable information created, collected or received concerning research subjects, patients, consumers, caregivers, and health care professionals.

9. **"Process"** or **"Processing"** shall mean any operation or set of operations which is performed upon Personal Data, whether or not by automatic means, such as collection, recording,

organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

10. **"Security Incident"** shall mean:
    a. any of the following:
        i. a Data Security Breach;
        ii. a security vulnerability that carries a material risk of compromising the confidentiality, integrity, or security of Personal Data; or
        iii. a violation of Applicable Law relating to the Processing of Personal Data under this Agreement;
    b. but shall exclude:
        i. any unintentional acquisition, access, or use of Personal Data by an employee or agent of Institution if such acquisition, access, or use was made in good faith and does not result in further unauthorized or inappropriate Processing of Personal Data;
        ii. any inadvertent disclosure by a person who is authorized to access Personal Data on behalf of Institution to another person authorized to access Personal Data on behalf of Institution, provided the information received as a result of such disclosure is not further used or disclosed in an unauthorized or inappropriate manner; or
        iii. any loss or unauthorized acquisition of or access to Encrypted Personal Data, provided the confidential process or key that is capable of compromising the security, confidentiality, or integrity of the Encrypted Personal Data is not also subject to loss or unauthorized acquisition or access.
    c. Notwithstanding paragraph (b), a "Security Incident" shall include any loss or unauthorized acquisition, access, or use of Personal Data that triggers a breach notification requirement under Applicable Law.

11. **"Technical, and Organizational Security Measures"** means those administrative, technical, and physical safeguards designed to protect the confidentiality, security, integrity and confidentiality of Personal Data, including measures aimed at protecting Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the Processing involves the transmission of data over a network, and against all other unlawful forms of Processing.

B. Identification of Parties. The Parties agree that:

1. Institution and Sponsor both may Process Personal Data for their own, independent purposes. When Processing Personal Data for their own, independent purposes, each Party acts as a separate Data Controller.

2. When Processing Personal Data for purposes of fulfilling an obligation under the Agreement, Institution and Sponsor are jointly determining the purposes and means for the Processing of Personal Data and the Parties are acting as Joint Controllers.

3. Nothing in this Section B shall be interpreted to alter Institution's obligation to conduct the Study pursuant to the terms of the Agreement.

C. Joint Controllers. The Parties agree that with respect to Processing of Personal Data for purposes of fulfilling an obligation under the Agreement:

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1. *Use and Disclosure of Personal Data.*
   a. The Parties' Processing of Personal Data shall be governed by the Agreement, which sets out the subject matter, duration, nature, and purpose of the Processing, type of Personal Data and categories of data subjects, and obligations and rights of the Parties.
   b. Institution shall Process Personal Data in accordance with the Study Protocol. Institution agrees to obtain from each data subject, prior to that individual's participation in the Study, a signed informed consent approved in writing by Sponsor and any applicable ethics committee. Such consent shall authorize Sponsor and its representatives to Process Personal Data for the following purposes:
      i. conduct the research and to confirm research results;
      ii. report the research results to Government Authorities;
      iii. evaluate and improve the treatment, diagnostic, or preventative therapy being investigated;
      iv. assure the safety, effectiveness and quality of the research and the treatment, diagnostic, or preventative therapy being investigated;
      v. comply with Applicable Law;
      vi. conduct new research related to the disease or condition being investigated, or related to the treatment, diagnostic, or preventative therapy being investigated;
      vii. develop proposals for new research protocols; and
      viii. improve the design and efficiency of future research studies.
   c. Sponsor shall not attempt to re-identify data subjects except as necessary:
      i. To comply with Applicable Law.
      ii. For purposes of monitoring the conduct of the Study.
      iii. For purposes of monitoring, investigating, and responding to adverse events.
      iv. In order to respond to a claim or proceeding brought by a data subject in connection with the Study.

2. *Compliance with Applicable Law.*
   Both Parties agree to comply with all Applicable Law throughout the term of the Agreement.
   a. Both Parties understand that they have a duty to stay informed of possible changes to such laws throughout the course of this Agreement.
   b. Both Parties mutually covenant not to place the other in violation of Applicable Law.

3. *Registration of Data Processing.*
   It is the responsibility of each Party to effect and maintain all registrations for the Processing of Personal Data as required under Applicable Law.

4. *Data Protection Assistance.*
   a. *Data Protection Impact Assessment.* The Parties shall cooperate and assist each other with respect to any data protection impact assessments and/or prior consultations with Government Authorities that may be required in respect of Processing carried out under the Agreement.

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b. The Parties shall promptly make available to each other all information necessary to demonstrate compliance with this Schedule B and Applicable Law, and shall cooperate with relevant Government Authorities.

5. *Privacy and Security Programs.*
During the term of this Agreement, the Parties will each maintain a comprehensive privacy and security program designed to ensure that Personal Data will only be Processed in accordance with this Schedule B (a "Privacy Program"), including the appointment of a data protection officer as required by Applicable Law.
   a. *Security Measures.* The Parties will implement appropriate Technical and Organizational Measures to protect Personal Data and ensure a level of security appropriate to the risk as required by Applicable Law. The Parties agree to regularly test, assess and evaluate the effectiveness of the measures for ensuring the security of Processing.
   b. *Encryption.* The Parties agree that all Personal Data transferred to or stored on any mobile device, including but not limited to smart phones, laptop computers, compact discs, PDAs, thumb drives, backup tapes, and/or zip drives, shall utilize Encryption.

6. *Oversight of Personnel.*
   a. *Confidentiality.* The Parties shall ensure that their personnel engaged in the Processing of Personal Data are informed of the confidential nature of the Personal Data, have received appropriate training on their responsibilities, and have executed written confidentiality agreements. Institution shall ensure that such confidentiality obligations survive the termination of the personnel engagement.
   b. *Limitation of Access.* The Parties shall ensure that access to Personal Data is limited to those personnel performing services in accordance with the Agreement.

7. *Security Incidents.*
   a. *Notification of Security Incidents.* The Parties agree to notify each other within thirty-six (36) hours of discovery of a Security Incident.
   b. In the course of notification to each other, the Parties will provide, as feasible, sufficient information for the Parties to jointly assess the Security Incident and make any required notification to any Government Authority within the timeline required by Applicable Law. Such information may include, but is not necessarily limited to:
      i. The nature of the Security Incident, the categories and approximate number of data subjects and Personal Data records;
      ii. The likely consequences of the Security Incident, in so far as consequences are able to be determined; and
      iii. Any measures taken to address or mitigate the incident.
   c. The Parties will jointly decide on the basis of all available information and Applicable Law if the Security Incident will be considered a Data Security Breach and arrange for notification to data subjects and/or Government Authorities if required by law. Where the Parties decide that notification is required by law, Institution shall be responsible for providing such notification.
   d. *Assistance in Event of Security Incident.* In the event of a Security Incident relating to the Personal Data collected or received by Institution under this Agreement, Institution agrees to assist and fully cooperate as instructed by Sponsor with any internal investigation or external investigation by third parties, such as law enforcement, through the provision of information, employees, interviews,

materials, databases, or any and all other items required to fully investigate and resolve any such incidents and provide information necessary to provide required notifications. Institution agrees to take such remedial actions as the Parties mutually agree is warranted, such agreement not to be unreasonably withheld by Institution.

e. Institution shall not disclose, without Sponsor 's prior written approval, any information related to the suspected Security Incident to any third party other than a vendor hired to investigate/mitigate such Security Incident and bound by confidentiality obligations, except as required by Applicable Law.

f. Institution agrees to indemnify Sponsor for all losses resulting from any Security Incident due to negligence or willful misconduct by Institution, its agents, its affiliates, or any Processor retained by Institution, including but not limited to legal damages, government penalties, and/or mitigation expenses.

8. *Rights of Data Subjects.*

a. The Parties agree that, as between them, Institution is best able to manage requests from data subjects for access, amendment, transfer, blocking, or deletion of Personal Data. In the event Sponsor receives a request from a data subject for such access, amendment, transfer, blocking, or deletion, Sponsor shall forward the request to Institution.

b. Institution shall respond to data subjects' requests for access, amendment, transfer, blocking, or deletion of Personal Data in accordance with Applicable Law and the Agreement. Institution acknowledges that in order to maintain the integrity of Study results, the ability to amend, block, or delete Personal Data may be limited, in accordance with Applicable Law.

c. Sponsor acknowledges that data subjects may withdraw their informed consent to Study participation and consent to Processing of Personal Data at any time. Institution shall promptly notify Sponsor of any such withdrawal that may affect the use of the Personal Data under the Agreement.

9. *Notification of Inspection.*

Institution agrees to promptly notify Sponsor of any inspection or audit by a Government Authority concerning compliance with Applicable Law to the extent related to the services provided under the Agreement.

10. *Cross-Border Data Transfers.*

a. The Parties agree to only transfer Personal Data outside of the European Economic Area or Switzerland as allowed pursuant to Applicable Law.

11. *Records.*

Each Party shall maintain a written record of all Processing activities carried out under the Agreement. Such record shall contain, at a minimum:

a. The name and contact details of any Processors;

b. The name and contact details of the Processors' data protection officers;

c. The categories of Processing carried out;

d. Transfers to third countries or international organizations and documentation of the suitable safeguards employed;

e. A general description of the Technical and Organizational Measures taken to safeguard the Personal Data.

Institution shall provide such written record to Sponsor promptly upon request and agrees that such written record may be submitted by Sponsor to any third- party data controller (where applicable) and to relevant Government Authorities.

12. *Processors.*
    a. The Parties agree that all Processing agreements shall be in writing and that Processors shall be required to comply with the terms of this Schedule B.
    b. Each Party shall be responsible for any noncompliance with the terms of this Schedule B by a Processor it has engaged, which noncompliance will constitute a breach as if committed directly by that Party.

13. *Delegation.*
    Sponsor may delegate its rights and obligations under this Schedule B to an Affiliate of Sponsor.

14. *Effect of Violation.*
    Failure to comply with any provision of this Schedule B shall constitute a material breach of the Agreement.

15. *Survival.*
    The obligations of confidentiality and data privacy under this Schedule B will survive the termination and/or expiration of this Agreement.

D. **Personal Data of Study Staff.** Institution shall be responsible for obtaining any necessary consents from Principal Investigator and all other Study Staff to the Processing of their Personal Data, as required under applicable laws Such consent shall inform Principal Investigator and Study Staff of, and obtain their agreement to, the following:

1. That their Personal Data, including name, contact details, government identification number, and financial information relating to, among other matters, compensation and reimbursement payments for Study conduct, will be Processed by Sponsor and Sponsor's Affiliates and agents in order to:
    a. Comply with Sponsor's and its Affiliate's obligations under Applicable Law,
    b. Assess the suitability of the Investigator and Study Staff for the Study,
    c. Prepare and submit regulatory filings, correspondence, and communications to Government Authorities concerning the Study,
    d. Conduct safety reporting and pharmacovigilance relating to the Study,
    e. Disclose payments and other transfers of value to Institution and Investigator in order to comply with transparency reporting laws, including but not limited to the US Physician Payments Sunshine Act and implementing regulations, as well as industry codes of practice or standards to which Sponsor and/or Sponsor's Affiliates are subject, and
    f. Consider from time to time potential sites and investigators for future studies.

2. That their Personal Data may be made available to Government Authorities and ethics committees in jurisdictions around the world.

3. That their Personal Data may be transmitted to countries around the world, including to countries whose data protection laws do not provide the same level of protection as that where they are located.

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4. That they may request access, amendment, blocking, or deletion of their Personal Data by Sponsor and Sponsor's Affiliates under Applicable Law.

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA53015018441773R
Certificate Issued Date	:	04-Dec-2019 01:19 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ K R PURAM/ KA-BN
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Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
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Second Party	:	Dr NARAYAN PRASAD SANJAY GANDHI P G I OF M SCIENCE
Stamp Duty Paid By	:	NOVO NORDISK INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Karnataka SDDM-Co Society Ltd # 30010, K.R. Puram, Bangalore 36 — Sign.

Please write or type below this line

This non-judicial stamp of INR 200 forms an integral part of the **INVESTIGATOR AGREEMENT** (Novo Nordisk Sponsored Clinical Trial) executed between the following three parties, for the trial ID: NN9535-4321.

05 FEB 2020

1) Novo Nordisk India Private Limited ____________

2) Dr. Narayan Prasad ____________ 10.02.20

3) Sanjay Gandhi Post Graduate Institute of Medical Sciences ____________

INVESTIGATOR AGREEMENT
NOVO NORDISK SPONSORED CLINICAL TRIAL
Trial ID: NN9535-4321

This Investigator Agreement (hereinafter referred to as the "**Agreement**"), is entered into and executed at Bangalore, India and shall become effective as of on the last date of execution by the Parties to this Agreement (the "**Effective Date**")

By and between

NOVO NORDISK INDIA PRIVATE LIMITED

a Company registered under the Companies Act, 1956, having its registered office at Plot No. 32, 47-50, EPIP Area, Whitefield, Bangalore - 560 066
CIN: U24111KA1994PTC015194

(hereinafter referred to as "**Sponsor**")

And

Dr. Narayan Prasad

a healthcare professional, having address at Department of Nephrology, C block Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebarli Road Lucknow

PAN: AAAJS3913N
(hereinafter referred to as the "**Principal Investigator**")

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences

a healthcare organization, located at Department of Nephrology, C block Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebarli Road Lucknow

PAN: AAAJS3913N
(hereinafter referred to as "**Institution**")

In the following, Sponsor, Principal Investigator and Institution are also referred to individually as "Party" and collectively as "Parties".

PREAMBLE

WHEREAS Sponsor wishes to conduct the following clinical trial in India: FLOW - Effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease; **Protocol ID:** NN9535-4321 (hereinafter referred to as the '**Trial**'). The nature of the Trial is further elaborated upon in this Agreement;

WHEREAS Sponsor wishes to conduct the Trial in cooperation with Investigator at the Institution;

WHEREAS The Investigator has the expertise and the Institution has the necessary resources relating to clinical trial design, conduct, evaluation and analysis. The Institution has agreed to assist Sponsor in the conduct of the Trial at the Institution under the supervision of its employee the Principal Investigator, under the terms and conditions of this Agreement.

1. DEFINITIONS

1.1 "Adverse Event" shall be defined as in APPENDIX 1.

1.2 "Confidential Information" shall mean all information, whether written, oral, or in any other form, pertaining to either Party's business, whether developed or acquired hereunder and whether kept in its original form.

1.3 "CRF" shall mean Case Report Form.

1.4 "FPFV" shall mean First Patient First Visit.

1.5 "Healthcare Organisation (HCO)" shall mean any legal person (i) that is a healthcare, medical or scientific association or organisation (*irrespective of the legal or organisational form, whether it is a Company, Sole Proprietorship, Partnership, Trust or otherwise*) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA Patient Organisation Code) or (ii) through which one or more HCPs provide services.

1.6 "Healthcare Professional (HCP)" shall mean any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and, (ii) any person whose primary occupation is that of a practising HCP irrespectively of any other employment

1.7 "Intellectual Property" shall mean any and all know-how, inventions, improvements and discoveries, whether patentable or not, arising from or related to the clinical trial covered by this Investigator Agreement.

1.8 "LPFV" shall mean Last Patient First Visit.

1.9 "LPLV" shall mean Last Patient Last Visit.

1.10 "Personal Data" shall mean the personal data as stipulated in APPENDIX 3.

1.11 "Protocol" shall mean protocol number [NN9535-4321]: [FLOW - Effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease], attached herein as APPENDIX 1.

1.12 "Serious Adverse Event" shall be defined as in the Protocol.

1.13 "SPC" shall mean Summary of Product Characteristics.

1.14 "SUSARs" shall mean Suspected Unexpected Serious Adverse Reactions.

1.15 "Termination Date" shall mean [24] weeks after LPLV unless this Agreement is terminated pursuant to Clause 12.4.

1.16 "Trial Materials" shall mean the materials used to conduct the Trial, including but not limited to CRF and auxiliary supplies.

1.17 "Trial Product" shall be defined as in the Protocol.

1.18 "Trial Subject" shall mean any subject participating in the Trial.

2. INTRODUCTION

2.1 The Parties hereby agree that the Principal Investigator shall carry out the Trial in accordance with the Protocol, as amended over time, and this Agreement. All appendices and amendments to the Protocol and the Agreement shall be deemed to be an integral part of this Agreement and may be updated from time to time by mutual agreement.

3. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

3.1 Prior to the Trial the Principal Investigator must:

a) assist the Sponsor to obtain all necessary approvals from the Institutional Ethics Committee (IEC) and relevant regulatory bodies, from the relevant departmental head of the Institution and from any other authority that is responsible for the administration of the Institution;

b) be fully informed of the Trial Protocol and the Trial Product and attend, or ensure a delegate attends, all Investigator's meetings for the Trial from time to time as required by Sponsor;

c) ensure all the Institution's employees and collaborators who are involved in the Trial fully understand and adhere to the Trial Protocol and the obligations of both the Institution and the Principal Investigator;

d) obtain prior written approval from Sponsor and the Institutional Ethics Committee (IEC) for any proposed recruitment material to be used for the purpose of Subject recruitment in the Trial;

e) resolve any revenue issues in respect of the Trial with the Institution and keep Sponsor informed of such issues and the progress of resolution of such issues;

3.2 During the Trial each of the Institution and Principal Investigator must:

a) conduct the Trial in accordance with the terms of this Agreement and:

i. all applicable laws and regulations in India including any guidelines governing the conduct of clinical studies, including but not limited to the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines

ii. the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP),

iii. the Declaration of Helsinki as referenced in the Protocol,

iv. the Protocol, any amendments, separate manuals and specific procedures provided by Sponsor applicable for conducting the Trial, depending on which of the stated options ensures the greatest protection for the patient;

b) ensure that all Trial Materials are handled correctly and stored securely for the duration of the Trial and any period thereafter as required by law or this Agreement, whichever is later, in accordance with Article 7 Treatment of the Protocol;

c) ensure that Trial Product is used only for the conduct of the Trial in accordance with Article 7 Treatment of the Protocol;

d) do all possible efforts to ensure that the target number of 15 eligible subjects are recruited for the Trial and that data from all eligible subjects are available on or before the Termination Date. Any over-recruitment of Subjects not authorised by Sponsor will not be financially compensated;

e) have all available data entered in the CRF [5] days after each visit. Principal Investigator shall ensure that the patient record is updated with final information and signed as applicable as soon as possible after each visit;

f) maintain accurate data collection and up-to-date records of all Trial Materials and Trial related correspondences by the Principal Investigator, the Institution's employees, Sponsor and any other person involved in the Trial, during the Trial;

g) submit written reports, in accordance with all laws, regulations and guidelines including the Ethics Committee standards, to Sponsor and the Ethics Committee regarding the Trial being conducted at the Institution on request.

h) record and evaluate all Adverse Events experienced by the Trial Subjects in accordance with Article 9.3 Adverse events of the Protocol;

i) retain Trial Records in accordance with the Protocol, Article Appendix 3, point 11, and under storage conditions conducive to their stability and protection. The Principal Investigator and the Institution further agree to permit Sponsor to ensure that the records are retained for a longer period if necessary, at Sponsor's expense, under an arrangement that protects the confidentiality of the records (e.g. secure off-site storage);

j) provide to Sponsor timely updates of their contact data; and

3.3 Principal Investigator shall comply with the requirements of Appendix 3: Data Protection.

3.4 In the cooperation with Sponsor the following shall apply:

a) The Institution and Principal Investigator must allow any person nominated by the Sponsor during regular business hours and with one Business Day notice in advance access to the following:

i. subject records relating to the Trial;

ii. the Institution and facilities where the Trial is being conducted; and

iii. any Trial Materials.

Regulatory or other authorities shall be allowed direct and immediate access to the same information.

b) Subject to Clause 8 of this Agreement the Institution and the Principal Investigator must not, without the prior written approval of Sponsor, disclose any Confidential Information to any third person other than for the proper conduct of the Trial and in accordance with this Agreement provided that such recipients are bound by obligations of confidentiality and non-use to Sponsor which are equal to the terms of this Agreement. Principal Investigator shall ensure that said recipients be fully aware of the obligations of confidentiality of this Agreement and shall be responsible for any breach of these provisions by such recipient.

c) Institution and Principal Investigator acknowledge and agree that in accordance with Protocol, Article 5, Trial Design,

i. the Trial is being conducted as part of a multi-centre clinical trial,

ii. that the number of clinical trial sites will be decided solely by Sponsor,

iii. that these sites may enroll Trial Subjects in mutual competition, and

iv. that Sponsor reserves the right to end Trial Subject enrolment under this Agreement when the desired number of Trial Subjects for all clinical trial sites has been reached. Institution and Principal Investigator agree that further screening or randomisation of subjects must not take place after Trial Subject enrolment has been sended by Sponsor.

d) If electronic systems are used in the Trial, it may be required to file these site specific data at the Trial site. If the Sponsor provided media is found not readable during the retention period, a new copy can be provided by Sponsor.

4. OBLIGATIONS OF SPONSOR

4.1 Sponsor shall obtain all necessary approvals from the Institutional Ethics Committee (IEC) and relevant regulatory bodies, from the relevant departmental head of the Institution and from any other authority that is responsible for the administration of the Institution;

4.2 Sponsor must:

a) conduct the Trial in accordance with the terms of this Agreement and:

i. all applicable laws and regulations in India including any guidelines governing the conduct of clinical studies,

ii. the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP),

iii. the Declaration of Helsinki as referenced in the Protocol.

iv. the Protocol, any amendments, separate manuals and specific procedures provided by Sponsor applicable for conducting the Trial, depending on which of the stated options ensures the greatest protection for the patient.

4.3 Sponsor agrees to provide:

a) all Trial Materials necessary for the conduct of the Trial;

b) all relevant clinical pharmacology and toxicology information and advice to the Principal Investigator and the Institution which are required for the proper planning and conduct of the Trial throughout the Trial period. Such information will include the Investigator's Brochure and information on SUSARs for unlicensed products or the SPC for licensed products; and

c) reasonable supervision, training and monitoring during the conduct of the Trial.

4.4 The Parties agree to adhere to all applicable laws and regulations pertaining to medical confidentiality of the subjects. The Principal Investigator shall not disclose to Sponsor the identity of the subjects or information from which the identity of the subject can be deduced without prior written consent of the subject.

4.5 Any amendment to the Protocol must be agreed upon by both the Principal Investigator and Sponsor and be documented in writing. Implementation of amendments cannot take place until approval by health authorities, as applicable, and IEC/IRB's has been obtained unless required for the safety of the Trial Subjects or for administrative reasons in accordance with ICH/GCP.

5. DISCLOSURE REQUIREMENTS

5.1 The Principal Investigator shall ensure that he/she provide the appropriate financial disclosures required for compliance with DCGI, and under any other applicable law, rules or codes.

5.2 The Principal Investigator and the Institution represent and warrants that neither he/she nor the Institution involved in conducting the Trial nor any member of the staff of the Institution, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct. The Investigator shall immediately notify the Sponsor should he/she be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Agreement.

6. PAYMENT

6.1 Each payment under this Agreement shall be made on the basis of an invoice stating all relevant details regarding number of Trial Subjects and number of

visits. Furthermore, each invoice shall include full details regarding the bank account to which the payment shall take place. Any payment payable by sponsor is due forty-five (45) days after receipt of a correct and proper invoice prepared in accordance with the sponsor invoicing instructions set out in Appendix 2. The parties acknowledge that this payment deadline has been actively negotiated and agreed between the parties as fair and reasonable. For the avoidance of doubt, all bank fees related to receipt of interbank transfers must be borne by the recipient.

7. TRIAL TIME SCHEDULE

7.1 For the whole project the following dates are in force:

FPFV: 23 Sep 2019
LPFV: 01 Feb 2021

LPLV: 19 Aug 2024

The date of the FPFV can be delayed locally; however, in such case date of LPFV shall still be valid.

7.2 If the Principal Investigator has not screened 03 Trial Subjects after 12 weeks from FPFV, it may be decided by Sponsor to re-allocate Trial Subjects to other sites and the site may be closed.

8. CONFIDENTIAL INFORMATION

8.1 The information obtained during the conduct of this trial is considered Confidential Information and will be used by Sponsor for registration purposes and for the general development of the drug.

8.2 All information supplied by Sponsor in connection with this Trial shall at all times during the term of this Agreement and thereafter remain the sole property of Sponsor and is to be considered Confidential Information. The Parties shall take all reasonable steps to ensure that any Confidential Information shall not be disclosed, whether directly or indirectly, to third (3rd) parties without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except:

a) for the purpose contemplated, pursuant to and in accordance with the terms of this Agreement;

b) with the consent of the other Party and then only to the extent specified in such consent; and

c) to the extent as may be required by law or in accordance with the order of a court of competent jurisdiction, regulation, effective government policy or by any regulatory authority arising out of this Agreement or relating to or in connection with the other Party, provided that the Party so required must give the other Party prompt written notice and make a reasonable effort to obtain a protective order.

8.3 The restrictions on disclosure of Confidential Information described above shall not extend to information which:

a) is, at the time of the disclosure hereunder in the public domain, or subsequently enters the public domain through no breach of this Agreement,

b) can be shown by the receiving Party to have been in its possession at the time of disclosure hereunder,

c) is lawfully acquired by the receiving Party from a third party under no obligation of confidentiality to the disclosing Party,

d) is independently developed by an employee of the receiving Party or its Subsidiaries without reference to or reliance upon Confidential Information disclosed by the other Party, or

e) is required to be disclosed by law, or by order of a court of competent jurisdiction; provided, however, that the receiving Party shall provide the disclosing Party with notice as soon as possible enabling the disclosing Party to contest such potential use or disclosure.

9. INTELLECTUAL PROPERTY

9.1 All Intellectual Property provided by Sponsor shall remain the sole property of the Sponsor.

9.2 The Principal Investigator shall promptly disclose and assign to Sponsor all inventions and discoveries made by the Principal Investigator related to the Trial.

9.3 The Principal Investigator/ Institute shall have a royalty-free right to use the results for non-commercial research and teaching purposes.

10. REPORTS AND PUBLICATIONS

10.1 Preparation and publication of information obtained during the conduct of the Trial shall be carried out in accordance with Article 12 Appendices - Appendix 3 Trial governance considerations of the Protocol.

11. INSURANCE & INDEMNIFICATION

11.1 Principal Investigator and Institution hereby confirm that they have adequate insurance coverage for employers' liability and professional liability for all its activities under this Agreement. Principal Investigator and Institution shall provide Sponsor with proof of the existence of such insurances. Such proof, to be received by Sponsor before the proposed starting date, shall include the duration and cover of the insured and the insured amounts.

11.2 Sponsor will indemnify and defend the Principal Investigator and personnel working under his/her direct supervision against any claim or suit brought against any of them by or on behalf of Trial Subjects taking part in the Trial and based on a bodily injury directly resulting from the use of any product submitted by Sponsor for clinical investigation or any procedure provided for or required by the Protocol to which the Trial Subjects would not have been exposed but for the participation in the Trial.

11.3 For this indemnification under Clause 11.2 to apply, use of the product and the conduct of the investigation must be in accordance with the relevant laws and regulations and the approved Protocol for clinical investigation and any other

information, instructions, or warning furnished by Sponsor. Also, Institutional Review Board or other Ethics Committee approval must be obtained and the Subject Informed Consent Form must comply with all relevant regulations and a copy must be received by Sponsor at commencement of the investigation.

11.4 In addition, for this indemnification under Clause 11.2 to apply, Principal Investigator must immediately notify Sponsor, upon receipt of notice of any claim or lawsuit and must permit Sponsor authorised attorneys and personnel (at Sponsor's discretion and cost) to handle and control the defence to such claims or suits. Principal Investigator cannot settle any such claims or suits without the prior written consent of Sponsor. By signing this Agreement, Principal Investigator agrees to fully cooperate and aid in such defence. Principal Investigator understands that the sole liability of Sponsor to the Principal Investigator and those employees engaged in conducting the approved clinical investigation at the request of Sponsor will be the indemnification described above.

11.5 Sponsor does not agree to indemnify, defend or hold harmless any person or Institution against any claim or suit in which it is determined that the individual or Institution was negligent, committed malpractice or breached a representation or warranty given by any of them; such a person or Institution will repay to Sponsor any defence costs incurred by the Sponsor on its behalf.

11.6 The Principal Investigator and Institution will indemnify, defend and hold harmless Sponsor and any Sponsor Affiliate, staff and subcontractors against any claim or suit brought against any of them by or on behalf of Trial Subjects taking part in the Trial and based on an injury caused by the Institution's or Principal's Investigators or staff working under their supervision negligence, wilful misconduct, mal practice, breach of Protocol, Sponsor's instructions, applicable laws and regulations or otherwise breach of this Agreement.

12. TERM AND TERMINATION

12.1 This Agreement shall commence on the date set forth at the beginning of the Agreement and shall terminate without further notice upon completion of the Trial in accordance with the Protocol. Clauses 3.2b), c), h), i), j), 8 and 12 shall survive the termination of this Agreement.

12.2 The anticipated FPFV date for the Trial is 23 Sep 2019, provided applicable approvals have been obtained, and provided that all Trial Materials except Trial Products have been received from Sponsor 5 (five) working days before the FPFV date.

12.3 Sponsor shall be entitled to have FPFV date delayed by up to 3 (three) weeks for ethical reasons. However, in case Sponsor notifies Investigator of the delay later than 1 (one) week before the FPFV date Sponsor may upon negotiation between the Parties compensate Investigator for his/her direct and fully documented costs caused by such delay.

12.4 Sponsor may terminate this Agreement as follows:

a) if Principal Investigator negligently fails to perform or performs negligently any material work in accordance with this Agreement and such failure continues for thirty (30) days after receipt of written notice of Sponsor;

b) if Investigator for administrative or other reasons becomes unable to recruit Trial Subjects for the Trial;

c) with immediate effect, if Sponsor and/or regulatory authority recognise that any safety concerns necessitate discontinuation of the Trial;

d) if continuation of the Trial becomes unfeasible for Sponsor for efficacy reasons, by giving Principal Investigator one (1) month's prior written notice;

e) if Sponsor licenses the Trial product to a third party who wishes to conduct the remaining part of the Trial themselves, by giving Investigator one (1) month's prior written notice.

f) forthwith upon written notice in the event of either Principal Investigator's or Institution's voluntary or compulsory liquidation, dissolution, insolvency, suspension of its payments, bankruptcy or any statutory or private composition or agreement with its creditors in order to escape a bankruptcy, or if either of the Principal Investigator or the Institution discontinues substantial parts of its established business or its business is placed in the hands of a receiver, assignee or trustee in bankruptcy, whether voluntarily or otherwise.

In the event of termination of this Investigator Agreement by Sponsor pursuant to Clause 12.4b), c), d), e) or f) above, Sponsor shall pay Principal Investigator for all services properly performed in accordance with this Investigator Agreement until the point in time of the expiry of the notice of termination, if relevant. Upon receipt of a termination notice Investigator shall cease any work not deemed necessary by Sponsor for the orderly close out of Trial or for the fulfilment of regulatory requirements.

12.5 The Principal Investigator may terminate this Agreement as follows:

a) if Sponsor negligently fails to perform or performs negligently any material work in accordance with this Agreement and such failure continues for thirty (30) days after receipt of written notice of the Principal Investigator;

b) if the Principal Investigator becomes incapacitated or terminates his/her relationship with the Institution and a replacement suitable and agreeable to Sponsor cannot, after reasonable efforts by the Institution, be found.

13. GOVERNING LAW AND DISPUTE RESOLUTION

13.1 Both Parties will use commercially reasonable efforts to settle all matters in dispute amicably. All disputes arising out of or in connection with this Agreement must be settled under Rules under the Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Rules. The arbitration shall take place in Lucknow, India and shall be conducted in the English language. The award of the Arbitrator shall be final and binding on both Parties. The Parties bind themselves to carry out the awards of the Arbitrator.

13.2 This contract shall be construed and interpreted pursuant to the Laws of India and shall be subject to the exclusive jurisdiction of the Courts at Lucknow.

14. GENERAL

14.1 Any notice, report, request, approval, consent, invoice, payment or other communication required or permitted to be given under this Agreement shall be in writing and shall for all purposes be deemed to be fully given and received if

delivered in person or sent by registered mail, or by facsimile transmission (with an appropriate transmission receipt) to the respective Parties at the following addresses:

If to the Sponsor:

Novo Nordisk India Private Limited
Plot No. 32, 47-50
EPIP Area, Whitefield
Bangalore - 560 066

Att: Director - CMRQ

If to the Principal Investigator: Dr. Narayan Prasad
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow- 226014

If to the Institution:

Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow- 226014
Att:

15. ASSIGNMENT

15.1 This Agreement shall not be assigned by either Party, in whole or in part, without the prior written consent of the Parties hereto.

15.2 Sponsor shall have the right at any time to assign or transfer any or all of its rights and obligations under this Agreement to any of its Affiliates. For the purpose of this Agreement "Affiliate" means any corporation, company, partnership, joint venture or other entity which controls, is Controlled by, or is under common Control with a person or entity. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the party in question. For the avoidance of doubt, none of Novo Holdings A/S, Novozymes A/S, NNIT A/S, NNE Pharmaplan A/S nor any entity, which Controls, is Controlled by, or is under common Control with such entities, other than entities within the Novo Nordisk group of companies, will be deemed to be an "Affiliate" of Novo Nordisk. This shall bind the Parties, their successors and permitted assigns.

16. INDEPENDENT CONTRACTOR

16.1 In the performance of the Trial hereunder:

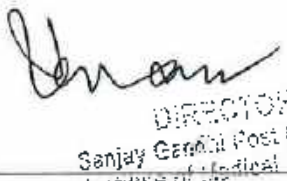
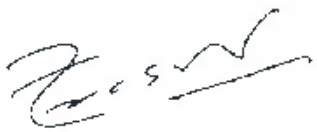
a) Principal Investigator shall be deemed to be and shall be an independent contractor and, as such, Principal Investigator shall not be entitled to any benefits applicable to employees of Sponsor.

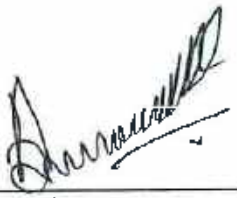
b) Principal Investigator and Institution on one side, and Sponsor on the other side acknowledge that the relationship between them is that of independent contractors, and not that of employer and employee, or principal and agent, or partners in a joint venture, nor any similar relationship whatsoever. Neither Party shall exercise control over the business of the other Party, nor is neither Party granted any right or authority to assume or to create any obligation or responsibility, express

or implied, on behalf of, or in the name of the other Party, or in any other way to act on behalf of, or to bind, the other Party.

16.2 IN WITNESS HEREOF, the Parties have executed and delivered this Agreement,

(SIGNATURE PAGE FOLLOWS)

Signed and Delivered by the within named **Novo Nordisk India Private Limited**	Signed and Delivered by the within named **Institution**
	 DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
Name: Vikrant Shrotriya Title: Managing Director Date: 05 FEB 2020	Name: Title: Director Date:
	Signed and Delivered by the within named **Principal Investigator** 
Name: Dr. Anil N Shinde Title: Director - Clinical, Medical, Regulatory Affairs & Quality (CMRQ) Date: 05 FEB 2020	Name: Dr. Narayan Prasad Title: Principal Investigator Date: 10.02.20

Signed and Delivered by the within named **Novo Nordisk India Private Limited**	Signed and Delivered by the within named **Institution**
	
Name: Vikrant Shrotriya Title: Managing Director Date: 05 FEB 2020	Name: Title: Director Date:
	Signed and Delivered by the within named **Principal Investigator** 
Name: Dr. Anil N Shinde Title: Director - Clinical, Medical, Regulatory Affairs & Quality (CMRQ) Date: 05 FEB 2020	Name: Dr. Narayan Prasad Title: Principal Investigator Date: 10.02.20

APPENDIX 1: (THE PROTOCOL)

Attached herewith is a link to the soft copy/electronic copy of the Protocol. The Sponsor, through its Authorized Signatory, and the Principal Investigator have already agreed upon in writing to conduct the trial as outlined in the Protocol. The Parties hereby agree that for the sake of convenience, the hard copies of the Protocol are not annexed to this Agreement. The updated, as amended from time to time, electronic copy of the Protocol shall be made available at all times to the Institution and the Principal Investigator by the Sponsor, upon request, or as a standard procedure, whichever applies. The Protocol shall at all times be considered to be an integral part of this Agreement and reference to this Agreement includes reference thereto to the Protocol.

Link -

4321 protocol versi
on 2.pdf

APPENDIX 2: PAYMENT

a) Following the screening phase, payment shall only cover eligible Trial Subjects. Payment for screening and randomization and for each fully performed visit per Trial Subject shall be as follows:

	Amount in INR (Rs.)
Visit 1	17740
Visit 2	17690
Visit 3	4100
Visit 4	4100
Visit 5	14600
Visit 6	13600
Visit 7	15500
Visit 8	14600
Visit 9	4100
Visit 10	17100
Visit 11	4100
Visit 12	14600
Visit 13	4100
Visit 14	17100
Visit 15	4100
Visit 16	14600
Visit 17	4100
Visit 18	17100
Visit 19	4100
Visit 20	14600
Visit 21	4100
Visit 22	17100
Visit 23	4100
Visit 24	14600
Visit 25	4100
Visit 26	17100
Visit 27 (V-EOT)	16250
Visit 28 (V-FU)	15350
Total Cost per Trial Subject: (The payment will be made on pro-rata basis depending upon the Subjects recruitment. The Institution is allowed to recruit additional Subjects for this Trial based on the confirmation from the Sponsor. The Invoice shall be raised on pro-rata basis and accordingly payment will be made)	314330

The travel allowance for the Subjects is included in the above cost up to INR 600.

In addition, a start-up fee of INR 50000 shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission and approval activities. The

payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

b) If Trial Subjects drop-out of the Trial, payment will be calculated on the basis of the visits performed.

c) Full fee will only be paid for patients fulfilling all inclusion and exclusion requirements as defined in the Protocol (eligible Trial Subjects). Patients that do not fulfil all inclusion and exclusion requirements will only be reimbursed the screening and randomization fee set above.

d) Patients that do not fulfil all inclusion and exclusion requirements must be withdrawn from the study, unless exception to allow the specific patient continuing in the study is granted by Sponsor and the Ethics Committee/Institutional Review Board according to local regulations;

e) Payment will be made every 06 months. Payment for the last 06 month visits for all subjects will be paid as soon as all queries have been solved and data are clean.

f) The Institution will be paid 25 % overhead to cover administrative costs which is included in the per patient cost mentioned in Appendix-2.

g) All payments shall be made by Sponsor to the Institution in the following bank account:

Bank details of Institution:

Recipient:	Sanjay Gandhi Post Graduate Institute of Medical Sciences
Bank name:	State Bank of India
Bank address:	SANJAY GANDHI PGIMS, LUCKNOW, RAEBARELI ROAD, LUCKNOW- 226014
IFSC Code:	SBIN0007789
Account Holder:	Director SGPGIMS Research A/C
Account Number:	10095237491
Transfer Purpose:	Conduct of Clinical Trial

h) All invoices shall be sent to Sponsor as follows:

Novo Nordisk India Private Limited
Plot No. 32, 47 - 50,
EPIP Area, Whitefield,
Bengaluru - 560 066

APPENDIX 3: DATA PROTECTION APPENDIX

1. **Scope.** This Data Protection Appendix sets out the requirements and obligations applicable to the Supplier and/or its sub-processors processing of Personal Data on behalf of Novo Nordisk.

2. **Parties**. For the purpose of this Data Protection Appendix:

    a. "Novo Nordisk" means Novo Nordisk India Private Limited and any Novo Nordisk subsidiary or other group company that in accordance with the Data Protection Requirements is data controller in respect of the Personal Data;

    b. "Supplier" means [Dr. Narayan Prasad, Department of Nephrology, C Block, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014] who will act as a data processor in respect of Personal Data processed under the Agreement.

3. **Precedence**. This Appendix shall govern the processing of Personal Data by the Supplier, notwithstanding any other obligations made by the Parties under the Agreement or otherwise agreed by the Parties.

4. **Terms used in this Appendix.** Capitalised terms used in this Data Protection Appendix, unless defined in this Appendix or in the Agreement, will have the meaning given in the Data Protection Requirements, which include any requirements under the EU Directive 95/46/EC and the General Data Protection Regulation (EU) 2016/679 as well as any applicable laws implementing or amending the same.

5. **Purpose of processing Personal Data**. The Supplier will, during the term of the Agreement, be processing Personal Data on behalf of Novo Nordisk for the purpose of performing its obligations under the Agreement.

6. **Type of Personal Data**. The Supplier will be processing the following types of Personal Data under the Agreement:

    a. ***Categories of (non-sensitive) Personal Data***:

        i. Contact information, including name, address, phone number, email etc.;
        ii. Job related information, including title, position, work tasks, department, performance; and

    b. ***Special (sensitive) categories of Personal Data***:

        i. Genetic data, biometric data for the purpose uniquely identifying a natural person;
        ii. Clinical data originating from clinical trials, studies and other research work;
        iii. Other data concerning health; and
        iv. Data concerning a natural person's sex life or sexual orientation.

7. **Categories of data subjects**. The Personal Data regards the following categories of data subjects: employees, customers, healthcare professionals, patients, trial subjects etc.

8. **Obligation to comply with Data Protection Requirements**. The Supplier represents and warrants that:

   a. It will comply with and ensure that all sub-processors will comply with all of applicable obligations under the Data Protection Requirements that arise in connection with the Agreement;

   b. It will perform its obligations under the Agreement and ensure that all sub-processors perform their obligations in such a manner that allows Novo Nordisk to comply with the Data Protection Requirements;

   c. Unless otherwise requested by Novo Nordisk, process Personal Data only to the extent necessary for the performance of the Agreement; and

   d. Subject to any other notification requirements set out in this Data Protection Appendix, notify Novo Nordisk of any unauthorised or unlawful processing or any accidental loss, destruction, damage, alteration or disclosure of the Personal Data as soon as it becomes aware and keep Novo Nordisk informed of any related developments.

9. **Reliance on Supplier's skills**. Novo Nordisk is relying upon the Supplier's skill and knowledge to assess what is "appropriate" to protect Personal Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure.

10. **Requirements to Supplier personnel**. The Supplier will ensure that all its employees and sub-processor personnel perform their duties strictly in compliance with the confidentially obligations imposed under the Agreement by treating such Personal Data as confidential information and are informed of the security procedures applicable to the processing of or access to the Personal.

11. **Compliance with the processing instruction**. The Supplier will and will procure that it's sub-processors Process the Personal Data only to the extent strictly required in order for the Supplier to perform its obligations in accordance with the Agreement or as instructed by Novo Nordisk, from time to time.

12. **Access to information and assistance.** Upon request by Novo Nordisk and without undue delay, the Supplier will and will cause its sub-processor to:

   a. Make available to Novo Nordisk and/or any Data Protection Authority having jurisdiction over Novo Nordisk, documentation and any and all other information that is reasonably necessary for Novo Nordisk to comply with its obligations under the Data Protection Requirements

   b. Provide Novo Nordisk with full cooperation and assistance in relation to any complaint or request from Data Subjects or a Data Protection Authority;

   c. Permit Novo Nordisk, or any third party appointed by Novo Nordisk (subject to reasonable and appropriate confidentiality undertakings), to inspect and audit the Supplier's data processing activities (and/or those of its group entities, agents, subsidiaries and sub-contractors)

   d. Comply with all reasonable requests or directions by Novo Nordisk to enable Novo Nordisk to verify and/or procure that the Supplier and/or sub-processors are in full compliance with their obligations under the

Agreement, including by providing an account of the technical and organisational security measures implemented by the Supplier or its sub-processor to comply with applicable security controls; and

e. Provide Novo Nordisk with detailed information on the current location of any Personal Data being Processed or stored by the Supplier and/or any of its sub-processors.

13. Use of sub-processors.

a. The Supplier will be entitled to assign processing of Personal Data under the Agreement to a designated sub-processor subject to the following requirements:

   i. Novo Nordisk pre-approves the sub-processor in writing; or

   ii. The Supplier gives Novo Nordisk at least six (6) months written notice before engaging the sub-processor and Novo Nordisk has the right to object to the engagement such that (i) Supplier refrains from engaging the sub-processor; (ii) Supplier amends the sub-processor engagement so that it becomes acceptable to Novo Nordisk; or (iii) Supplier allows Novo Nordisk to terminate the Agreement without incurring any liability to pay compensation or termination fees.

b. The Supplier's agreement with sub-processor(s) must be in accordance with the Data Protection Requirements and may not contain terms that are less restrictive than those agreed between Novo Nordisk and the Supplier.

c. The Supplier must ensure that its sub-processors do not engage any further sub-processors without prior written approval by Novo Nordisk.

d. Supplier will remain responsible for all acts and omissions of its sub-processors and the acts and omissions of those employed or engaged by the sub-processors as if they were its own.

14. Technical and organisational security measures. The Supplier will implement and maintain throughout the term of the Agreement and will procure that its sub-processors implement and maintain throughout the term, appropriate technical and organisational security measures to protect the Personal Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure. These measures will be appropriate to prevent the harm which might result from any unauthorised or unlawful processing, accidental loss, destruction or damage to the Personal Data and having regard to the nature of the Personal Data which is to be protected.

15. Notification of a Personal Data breach. Supplier will, in writing, notify Novo Nordisk of a Personal Data breach (including any security breach affecting Personal Data or any breach as defined under applicable law) immediately after becoming aware of such breach. Such notice must be provided in accordance with the provisions of the Agreement.

16. Documentation of Personal Data breaches. The Supplier will, upon request, submit to Novo Nordisk documentation on any breaches of Personal Data. The documentation should include information sufficient to enable a Data Protection Authority to verify compliance with the Data Protection Requirements.

17. **Other notifications**. The Supplier will:

    a. Notify Novo Nordisk in writing immediately if it receives (i) a request from a data subject to have access to that person's Personal Data; or (ii) a complaint or request relating to Novo Nordisk's obligations under the Data Protection Requirements; and

    b. Notify Novo Nordisk immediately in writing if it receives a request from any Data Protection Authority or other governmental body requiring the Supplier or any of its sub-processors to grant the Data Protection Authority or other governmental body access to inspect or provide information regarding the Supplier's and/or the sub-processor's processing of Personal Data covered by the Agreement.

18. **Liability**. The Supplier shall hold Novo Nordisk, fully and effectively indemnified against any and all claims, expenses, losses and damages or liabilities suffered due to the Supplier or sub-processors not fulfilling the data protection obligations under this Schedule.

19. **Transfer of Personal Data**. The Supplier will process or permit processing of Personal Data outside the European Economic Area (EEA), Switzerland, or any country determined officially by the relevant Data Protection Authority to have adequate data protection measures in place, only pursuant to a signed agreement between on the Supplier and Novo Nordisk using the European Commission's Standard Contract Clauses.

    a. With respect to any sub-processors, the Supplier will either (i) enter into the above mentioned agreement on behalf of the sub-processors or (ii) cause the sub-processors to enter into the agreement with Novo Nordisk.

    b. The Supplier will provide Novo Nordisk with a copy of all such signed agreements in advance of permitting the transfer or processing.

APPENDIX 4: NOTICE OF PERSONAL DATA PROCESSING

NOTICE OF PERSONAL DATA PROCESSING

Novo Nordisk India Private Limited is required by law to protect your Personal Data. This Notice explains how we process (e.g. collect, use, store, and share) your Personal Data. We will process any Personal Data about you in accordance with this Notice and with applicable law.

1. WHO ARE WE?

The company responsible for processing your Personal Data is:

Novo Nordisk India Private Limited
CIN: U24111KA1994PTC015194
Plot No.32, 47-50,
EPIP Area, Whitefield,
Bangalore - 560 066

Toll-free number: 18001039527
Switchboard: +91 80 4030 3200
Fax No.: +91 80 4112 3518
prindia@novonordisk.com

You can always contact Novo Nordisk India Private Limited or the Novo Nordisk Data Privacy Officer at privacy@novonordisk.com with questions or concerns about how we process your Personal Data.

2. HOW DO WE COLLECT PERSONAL DATA ABOUT YOU?

We get your Personal Data from the following sources:

- From you directly
- From publicly available publications, websites, or social media
- From a previous employer
- From other Novo Nordisk entities
- From vendors or consultants

3. WHY DO WE PROCESS YOUR PERSONAL DATA?

We process Personal Data about you for the following purposes:

- To analyse data for compliance
- To meet transparency obligations
- To investigate compliance/fraud
- To coordinate a conference or event
- To reimburse you
- To conduct interviews as part of a research project
- To respond to your questions or request for information

You are not required to provide us with your Personal Data. If you do not want Novo Nordisk to use your Personal Data, we will not be able to enforce this Agreement.

4. WHAT PERSONAL DATA DO WE PROCESS ABOUT YOU?

For the purposes described above in Section 2, we may process the following types of Personal Data:

- Contact information (name, address, telephone number, email address)

- Financial information (bank account number, amounts paid to you for services rendered)
- Emergency contact (e.g., name and telephone of family members)
- Data concerning health;
- Data on trade union membership;
- Genetic data, biometric data for the purpose uniquely identifying a natural person;
- Data concerning sex life or sexual orientation.
- Data relating to criminal convictions and offences

5. WHY ARE WE ALLOWED BY LAW TO PROCESS YOUR PERSONAL DATA?

Our processing of your Personal Data requires a legal basis. By law, we are allowed to process your Personal Data described above in Section 1 based on the following legal bases:

- You gave consent for us to process your Personal Data;
- The processing is necessary to fulfil a contract with you;
- The processing is necessary for our compliance with a legal obligation;
- The processing is necessary to protect your vital interests or the interests of another person;
- The processing is necessary for our legitimate interests.

6. HOW DO WE SHARE YOUR PERSONAL DATA?

We may share your Personal Data with:

- Suppliers or vendors that assist our company (e.g., consultants, IT service providers, financial institutions, law firms)
- Other Novo Nordisk entities (e.g., Novo Nordisk affiliates in other countries)
- Public authorities

7. WHEN DO WE TRANSFER YOUR PERSONAL DATA OUTSIDE INDIA?

For the purposes described above in Section 2, we transfer your Personal Data to countries outside India. We therefore use the following safeguards, as required by law, to protect your Personal Data in case of such transfers:

- The transfer is to a Novo Nordisk entity covered by Novo Nordisk's Binding Corporate Rules, available at https://www.novonordisk.com/about-novo-nordisk/corporate-governance/personal-data-protection.html.

8. HOW LONG WILL WE KEEP YOUR PERSONAL DATA?

We will keep your Personal Data for the following period of time:

- For as long as needed to provide you with the services requested by you
- For as long as required by applicable law.

9. WHAT ARE YOUR RIGHTS?

In general, you have the following rights:

- You can get an overview of what Personal Data we have about you
- You can get a copy of your Personal Data in a structured, commonly used and machine-readable format

- You can get an update or correction to your Personal Data
- You can have your Personal Data deleted or destroyed
- You can have us stop or limit processing of your Personal Data
- If you have given consent for us to process your Personal Data (see Section 5), you can withdraw your consent at any time. Your withdrawal will not affect the lawfulness of the processing carried out before you withdrew your consent
- You can submit a complaint about how we process your Personal Data to a Data Protection Authority.

Under applicable law, there may be limits on these rights depending on the specific circumstances of the processing activity. Contact us as described in Section 1 with questions or requests relating to these rights.

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CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("Agreement") is made as of ..... (the "Effective Date") by and among

Medclin Research Pvt. Ltd. Having its registered office at Acropolis, unit 10/5 , 10th floor 1858/1, Rajdanga Main Road, Kol-107("CRO")

And

Sanjay Gandhi Postgraduate Institute of Medical Science, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh, 226014.

Prof. Uday C Ghoshal, Department of Gastroenterology to be the signatory for this agreement and he will perform this research work.

WHEREAS,

Sponsor (Zydus Healthcare Limited, CTS No. 460/6, I. B. Patel Road, Village Pahadi, Goregaon (East), Mumbai 400063, Maharashtra) based on the representation and warranties given by the CRO, desires to engage CRO on non-exclusive basis to initiate study of "Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess effectiveness and safety of Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12® in the treatment of Non-Constipated Irritable Bowel Syndrome in adults aged 18 years to 65 years" (hereinafter referred to as the "Study")

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a. The CRO has approached the Institution and Principal Investigators to perform the study in accordance with the corresponding Protocol, and all applicable rules and regulations. The Institution and PI agree to conduct the study in accordance with the same.

b. The Institution is equipped to undertake the Study and the Institution, CRO and Principal Investigator have agreed to perform the Study according to the terms and conditions hereinafter set forth.

1. REPRESENTATIONS AND WARRANTEES:

a. Each party represents and warrants to and covenants with the other that:

i. It has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this agreement; wherever applicable,

ii. It has the corporate power and authority to enter into and perform its obligations under this Agreement, whenever applicable,

iii. This Agreement has been duly authorized, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

iv. Neither the execution and delivery of this Agreement by either party, nor the performance by such party of its obligations here under nor compliance by such party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any indenture, mortgage, lease, agreement, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such party;

b. CRO represents and warrants that

It has the facilities, professional, technical and clerical staff, experience, and expertise sufficient in quality and quantity to perform the Services and the Clinical Study pursuant to the Protocol within the time frame set forth herein and all appropriate permits and authorizations necessary to provide and perform, to the highest of professional standards, the services for the conduct of the clinical study in accordance with this agreement, the Protocol. ICH - GCP and all applicable standard operating procedures and has capability to perform or arrange for the performance of all services required by Sponsor.

c. Institution represent that

i. It is entitled to procure the services of Principal investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.

ii. The Institution shall notify Medelin if the Principal Investigator ceases to be employed by or associated with the Institution and shall use its best endeavors to find a replacement acceptable to both The Sponsor and CRO. In order to ensure high

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standard of clinical trials, if no mutually acceptable replacement can be found, The CRO may terminate this agreement pursuant to clause 22(d).

d. Principal Investigator represents :

i. A competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub investigators and research staff and the Institution.

ii. Free participation in Clinical Studies and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.

iii. Non-involvement in any regulatory or misconduct litigation or investigation by the Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Evaluation Agency (EMEA), The Drug Controller general of India (DCGI) or other regulatory authorities. No data produced in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

iv. That facilities appropriate to the Clinical Trial are available at the Trial Site and that there is support of medical and other staff of sufficient number and experience to perform the Clinical Trial efficiently and in accordance with the provisions of this Agreement.

2. OBLIGATIONS/RESPONSIBILITIES:

a. Principal Investigator:

i. Will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub investigators or research staff. The duties and responsibilities delegated will be only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.

ii. Will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is accountable for the compliance of Investigators to the terms of this Agreement.

iii. Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from Sponsor and CRO.

iv. Will comply with the policies and procedures of the organization / institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify CRO promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

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v. Shall be responsible for obtaining and maintaining all approvals from the relevant local research ethics committee/other Authorities for the conduct of the Clinical Trial keeping The CRO fully apprised of the progress of ethics committee submissions. The written evidence of review shall be provided prior to initiation. All other communications, upon request be made available to Medclin. The Principal investigator shall not consent to any change in the Protocol requested by the relevant ethics committee without the proper written consent of The Sponsor and CRO, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study. Investigator will notify The CRO and the responsible Institutional Review Board as soon as possible. Any emergency change to the Protocol must be followed by a written Amendment.

vi. Agrees to use best efforts to provide Sponsor's with the data called for in the Protocol, including copies of each research subject's signed informed consent form, a signed authorization as required under any applicable India regulations/policies and properly completed case report forms, in a timely manner. The PI and Institution will provide for (i) access to the research subject's medical records by Sponsor/CRO and other appropriate regulatory agencies and (ii) the facilities where the Study is being conducted (iii) Raw data (iv) the use of Study data by Sponsor/CRO for any purpose that it deems appropriate provided that the research subject's personal identifying information has been removed. In the event of a conflict between terms of the Protocol and this Agreement, the terms of this Agreement shall govern (v) any other relevant information necessary for Sponsor, other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. The Principal Investigator shall notify Sponsor immediately if another regulatory authority schedules or, without scheduling, begins such an inspection.

vii. Agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

viii. Shall promptly report to CRO any significant developments that may occur during the Study, including but not limited to adverse clinical events as described in the Protocol.

ix. Agrees to maintain records and data related to the Study in compliance with all applicable regulations, and in any event, for the period as per Indian GCP after the completion/termination of the study.

x. In the event that during the term of this Agreement, either the Institution or Principal Investigator becomes debarred or receives notice of an action or threat of an action with respect to its debarment, the Institution or Principal Investigator, as the case may be, shall notify Sponsor immediately.

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b. Institution:

i. The Institution shall ensure that all employees and agents of Institution who are assigned to perform services under the Agreement are made aware of the obligations contained in the Agreement and the Protocol and are bound by such obligations.

ii. The Institution and Principal Investigator shall all the time comply with all types of License, permission or certificates as required under laws, rules and regulations.

iii. The Institution shall bear all costs related to the performance of the Study except as expressly set forth in section 23.1 and attached budget.

iv. Institution shall apply its best efforts to retain the services of the Principal Investigator.

v. In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform The CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, who shall have a similar background and also knowledge of the Clinical Trial.

vi. Any successor to the Principal Investigator must be approved, in writing, by The Sponsor and CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this agreement and to sign each such document as evidence of such agreement (although failure to sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

vii. The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India, and agrees to immediately inform The Sponsor/CRO if such cases arise.

viii. The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with the Protocol and all other terms of this Agreement; Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs; Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP; All applicable laws and regulations.

c. Sponsor /CRO:

i. Medelin agrees to provide to the PI all information concerning the Study Material that is necessary for safe and proper handling and storage of the Study Material and for performance of the Study which is in accordance to the Protocol.

ii. Medelin shall be held responsible and therefore train all personnel involved in the clinical trial at site to ensure compliance to GCP and Protocol.

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iii. The CRO in collaboration with the Sponsor may make any changes, amendments, addendum or supplements to the Protocol from time to time, as it may think fit and shall inform PI by giving a written notice to abide by the same.

iv. The CRO in consultation with the Sponsor may designate a different investigator or other supporting personnel.

v. May visit Site with a prior written notice at reasonable times and with reasonable frequency during normal business hours to obtain information regarding the progress of Study.

3. PAYMENT:

i. Institution / Investigator fees for the services shall be made in the amounts and upon the terms specified in the Study Budget attached to and made a part of this agreement.

ii. Institution / Investigator shall not revise its prices for any reason unless mutually agreed in writing by all parties during the term of this Agreement. In any case, Institution / Investigator shall endure that the overall budget shall not exceed the total study budget as specified which shall form the part of this Agreement unless agreed by Sponsor / CRO.

iii. Institution / Investigator will not charge any amount to Sponsor / CRO for their services which were not provided to the Sponsor / CRO or agreed upon by and between the parties.

iv. Any income tax, withholding tax or similar taxes deductible from the payment will be deducted by CRO.

4. NO ADDITIONAL RESEARCH: No Additional Research. The Institution & PI Investigator ensures that no additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol.

5. SUBJECT ENROLMENT: Investigator has agreed to enroll in Study approximately 52 subjects within approximately three to four months. The same can be extended with an intimation from the CRO. If Investigator fails to enroll subjects at a rate adequate to meet the enrolment requirement, Sponsor/CRO shall be free to terminate the Study early (see Section 22(d) Termination).

6. ETHICS COMMITTEE ("EC"): Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct

7. STUDY DISAPPROVAL: Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with

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all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct.

8. DATA PROTECTION: The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. The Sponsor / CRO will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any other requirements. Such data may be disclosed or transferred to other members of sponsor team, to representatives and contractors working on behalf of The Sponsor. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause (13).

9. INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION: Investigator will obtain written informed consent from each study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow Sponsor/ CRO to inspect signed informed consent forms or photocopies there during monitoring visits or audits (see Monitoring and Audits, Section 15).

10. CONFIDENTIAL INFORMATION: During the course of the Study, Investigator may receive or generate information that is confidential to The Sponsor. Any information marked by The Sponsor as confidential and provided to the investigator before the execution of this agreement will also be treated as confidential information

11. OBLIGATIONS OF CONFIDENTIALITY: Unless The Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the EC or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 17, Publications, of this Agreement.

11.1 Disclosure Required by Law: If disclosure of Confidential Information to any party other than the EC is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator :

a) Notifies the sponsor in writing in 15 working days advance of the disclosure so as to allow The Sponsor to take legal action to protect its Confidential Information,

b) Discloses only that Confidential Information required to comply with the legal requirement, and

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c) Continues to maintain the confidentiality of this Confidential Information with respect to all other parties.

11.2 Individually Identifiable Health Information: If, in connection with this Study or performance of this Agreement, the Sponsor comes into contact with individually identifiable health information relating to subjects, the Sponsor agrees to maintain the confidentiality of such information and not to use it for any purpose.

11.3 Survival of Obligations: These obligations of confidentiality survive termination of this Agreement and continue for a period as required after completion of the studies.

11.4 Return of Confidential Information: If requested by The Sponsor in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

12. Study Product and Document:

a) All the trial product and document necessary to conduct this study, as described in the Protocol, shall be supplied free of charge to the PI/Institution. In certain circumstances the Sponsor/CRO may request the PI/Institution to purchase the control product and/or concomitant product. In such cases, the PI/Institute will be reimbursed on actuals.

b) All trial product/ documents and all other material being provided shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to this agreement. It is understood that the trial product is provided by the Sponsor for the sole purpose of conducting the clinical trial.

c) The sponsor makes no warranties, express or implied, concerning the trial product or its merchantability or fitness for a particular use or purpose, other than for its use in this clinical study.

d) Upon delivery, the PI and Institution shall be responsible for the Dispensing, administration, storage and handling of the trial product.

e) All used and unused products provided by the Sponsor shall be returned to the Sponsor/CRO or destroyed by the site as instructed by the Sponsor/CRO. The site shall conform with all laws and regulations pertaining to the destruction and provide the Sponsor and CRO with a destruction certificate of the same.

13. STUDY DATA AND STUDY RECORDS:

13.1 Study Data: During the course of the Study, Investigator will collect and submit certain data to The Sponsor/CRO, as specified in the Protocol. This may include case report forms or their equivalent, or other types of medical reports, subject diary, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data within the time periods.

a) **Ownership of Study Data**. Subject to Investigator's right to publish the results of the Study (see Section 17, Publications), The Sponsor is the exclusive owner of all Study Data.

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b) **Non-exclusive License.** The Sponsor grants Investigator no right to use study data for any purpose including research and/or education purpose.

13.2 Data Management and statistical Analysis: The CRO shall carry out the data management and statistical analysis. The CRO may consult and / or provide The Principal Investigator for interpretation during report writing.

13.3 Study Records: Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a) **Retention.** Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period as per Indian GCP after the completion/termination of the study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify The Sponsor and CRO before destroying any Study Records after the required retention period. Investigator further agrees to permit The Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

14. MONITORING AND AUDITS:

14.1 Monitoring and Audits: The Sponsor / CRO shall be entitled at its absolute discretion (and in such form as the Sponsor / CRO sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit The Sponsor's / CRO's representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by Sponsor / CRO will relieve the Investigator of any of its obligations hereunder.

a) **Cooperation.** Investigator will cooperate with the Sponsor / CRO in the conduct of audits and will ensure that Study Records are maintained in a way that facilitates such activities.

b) **Resolution of Discrepancies.** Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

c) **Data Clarification Form:** The CRO may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the PI or his/her nominee shall clarify within a specified time.

d) **Study Conduct Evaluations.** The Sponsor / CRO may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor / CRO or its representative will use these evaluations solely for internal purposes

15. INVENTIONS:

15.1 Notification. If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the Sponsor and CRO.

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15.2 Assignment. Investigator will assign all interest in any such Invention to the Sponsor, or its representative free of any obligation or consideration beyond that provided for in this Agreement.

15.3 Assistance. Investigator will provide reasonable assistance to the Sponsor or its representative in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

16. PUBLICATIONS: The findings of this study may be published in a scientific journal or presented at a scientific meeting with prior permission from Sponsor and CRO. The Sponsor reserves the right to review all manuscripts prior to submission for publication or any paper before it is presented. In accordance with standard editorial and ethical practice, the Sponsor will generally support publication of multicentric trials only in their entirety and not as individual center data. Authorship will be determined by mutual agreement between The Sponsor in conjunction with the CRO and the Principal investigator(s).

17. DEBARMENT AND EXCLUSION: Investigators certify that s/he is not debarred and that s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and after its termination, Investigator will notify the Sponsor/CRO promptly if either of these certifications needs to be amended in light of new information.

18. USE OF NAME: Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify The PI and Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

18.1 Assignment and Delegation: The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the CRO, any attempt to assign, delegate, or subcontract is invalid. The Sponsor / CRO will authorize delegation or subcontracting any duties.

18.2 Affiliates: As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with The Sponsor / CRO.

18.3 Successors and Assigns: This Agreement will bind and inure to the benefit of the successors and permitted assigns of each party.

19. CONFLICT WITH ATTACHMENTS: If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

20. Liability and Indemnification:
The PI/CRO shall indemnify, defend and hold harmless the indemnity, from and against any demands, claims, actions, which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from participation in this Clinical Trial.

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a) Sponsor shall maintain with the CRO, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this section and shall also provide the clinical trial liability coverage.

b) CRO shall maintain the aforementioned insurance during and after the subsistence of the Clinical Trial. The CRO shall provide the Institution with written evidence of such insurance upon the written request of the Indemnity. This obligation to maintain insurance shall survive the termination of this Agreement.

c) In the event a claim is made or an action is brought against the Sponsor and/or Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the CRO's representative and shall assist the CRO's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses.

d) Violation of the Protocol, scientific misconduct or negligence by CRO or the Institution/Principal Investigator, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the Principal Investigator, then the Institution/Principal Investigator will be liable to reimburse to the Sponsor the expenses on such medical management and financial compensation that The Sponsor has paid;

e) The Sponsor's representative shall indemnify, defend and hold harmless the indemnity, from and against any demands, claims, actions, which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from participation in this Clinical Trial. Notwithstanding anything contained herein, the liability of The Sponsor will be limited to The Sponsorship amount paid to CRO.

f) In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its additional personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to The Sponsor's / CRO's representative and shall assist The Sponsor's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses.

g) Notwithstanding the foregoing, The Sponsor's representative shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless The Sponsor, officers, directors, agents and employees for loss or damage resulting from:

I. Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

II. Failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

III. Any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

21. TERM: The term of this Agreement shall commence on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol unless sooner terminated as provided herein.
Termination Conditions. This Agreement terminates upon the earlier of any of, the following events:

a) **Disapproval by EC**. If, through no fault of Investigator. the Study is never initiated because of EC disapproval, this Agreement will terminate immediately.

b) **Study Completion.** For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by The Sponsor / CRO of all Protocol-required data; and receipt of all payments due to either party.

c) **Termination upon Notice**: CRO reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

d) **Immediate Termination by The CRO**: The CRO further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the CRO's opinion pose risks to the health or all being of Study subjects

e) **Termination upon Notice by Investigator**: The Principal Investigator may terminate the study, if The Sponsor / CRO does not comply with the agreement related to finance and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to The Sponsor / CRO fifteen days prior to termination and The Sponsor / CRO shall have fifteen days to cure its default.

f) **Immediate Termination by Investigator**. Investigator reserves the right to terminate the Study immediately upon notification to The Sponsor / CRO if requested to do so by the responsible EC or if such termination is required to protect the health of Study subjects.

g) **Payment upon Termination.** If the Study is terminated early in accordance with Section 22 Termination Conditions, above, The Sponsor / CRO will provide a termination payment equal to the amount owed for work already performed, in accordance with Exhibit A, less' payments already made. If the Study was never initiated because of disapproval by the EC (see Section 22b, Disapproval by EC , above), The Sponsor / CRO will reimburse Investigator for EC fees and for any other expenses that were prospectively approved, in writing, by The Sponsor or its representative.

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h) **Return of Materials.** Unless The Sponsor / CRO instructs otherwise in writing, Investigator will promptly return all materials supplied by The Sponsor / CRO for Study conduct, unused Case Report Forms, other study related material and any The Sponsor / CRO - supplied Equipment.

i) **Survival of Obligations.** Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification, and Debarment and Exclusion survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

22. FORCE MAJEURE: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance cause a delay or failure in performance ("a Delay") and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator / Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to Sponsor / CRO. Sponsor / CRO shall have the right to terminate an agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

23. NOTICE: Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to CRO:

Dr Monjori Mitra (Research Director, Medelin Research Pvt. Ltd); Phone: 9831075734

If to Institution:

Prof. R. K. Dhiman, The Director of SGPGIMS, Lucknow
Phone: 05222494001/2/3
OR

If to Principal Investigator:

Dr.Uday Chand Ghoshal
Phone: 9628842456

24. ENTIRE AGREEMENT: This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial will be retained for a period as per required Regulations after the completion/termination of the study whichever is later. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform The Sponsor, the Parties shall discuss in good faith in order to find an alternative solution

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for the proper archiving of these elements in. Subjects' files should be retained as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of The Sponsor

25. GOVERNING LAW: This agreement shall be interpreted and enforced under the laws of India and courts of India shall have exclusive jurisdiction to resolve any dispute under this Agreement. Any dispute or difference which may at any time arise between the parties hereto as to the construction, meaning or effect hereof or as to any clause, matter or thing herein contained or as to the rights or liabilities of the parties hereunder then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within 90 days, then such a question or dispute shall be referred to the arbitration of a sole arbitrator to be mutually appointed by both the parties, under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996 and the rules thereunder, as amended from time to time. The venue of such Arbitration shall be in Lucknow and the arbitration proceedings shall be conducted in English. The decision of such arbitrator shall be final, binding and conclusive on the Parties. The parties hereto agree that the Courts in Lucknow, India alone shall have exclusive jurisdiction in respect of any matters pertaining to, arising out of or in connection with Agreement.

Prof. Uday C Ghoshal will do this research work and He will be the signatory in this document in addition to authority of SGPGIMS.
Executed by the parties
PI, CONTRACT RESEARCH ORGANIZATION and INSTITUTION

CRO: Medclin Research Pvt. Ltd., Kolkata	**The Principal Investigator**	**The Institution**
Signature:	Signature: U C Ghoshal	Signature:
Name: Dr.Monjori Mitra	Name: Prof. Uday C Ghoshal	Name: Prof. R. K. Dhiman U C Ghoshal
Designation: Research Director	Designation: Principal Investigator	Designation: Director of SGPGI, Lucknow
Date: 07/OCT/2020	Date: 12/10/2020	Date: 16/10/2020
Stamp: MEDCLIN RESEARCH PVT. LTD.	Stamp:	Stamp: Director SGPGIMS, Lko.

EXHIBIT A

Budget		
Study Name	Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess efficacy and safety of Providac (Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12®) in the treatment of Irritable Bowel Syndrome in adults aged 18 years to 65 years.	
CRO Name :	Medclin Research Pvt Ltd, Kolkata	
Cost Head	**Details**	
Research Grant Including Manpower And Travel Allowances	**52 Subjects**	**338000**
Institutional overhead charges	25%	65000
Gut Microbiota	Analysis	500000
EC Fees	On actuals	25000
Total Study Fees		928000

a) The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess effectiveness and safety of Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12® in the treatment of Non-Constipated Irritable Bowel Syndrome in adults aged 18 years to 65 years.

b) The investigator agrees to the protocol of this trial and will perform the study in accordance with ICMR Good Clinical Practice, and applicable laws, rules and regulations.

EXHIBIT B

SL. No	Milestone	Amount
1	Study Start up(At the time of SIV)	240000
2	30 subject Enrolled	98000
3	last subject Last Visit(Institutional Overhead)	65000

For Gut Microbiota			
SL. No	**Milestone**	**Percentage**	**Amount**
1	Before Analysis	60%	300000
2	Completion of Analysis	40%	200000

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प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क. ८०००७१
15 DEC 2020
सक्षम अधिकारी

Novartis Healthcare Private Limited, (FIRST PART);

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, (SECOND PART);

AND

Dr. Jayantee Kalita (THIRD PART);

(84)

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of [18th DECEMBER 2020] ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Jayantee Kalita as clinical practitioner in the field of ***Neurology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: AMG334 (hereafter the "Trial Drug") in accordance with a protocol entitled "***A 12-week phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of once monthly subcutaneous erenumab 70 mg in adult chronic migraine patients, CAMG334A2304***" and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by

Novartis. all, as amended from time to

time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments, unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Trial is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 5.3 (d) provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon signature by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

4.2 The following provisions shall survive the termination or expiry of this Agreement: Section 11 (Intellectual Property), Section 13 (Publication), Section 14 (Confidentiality) and Section 15 (Data Privacy), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not shall make payments for new Trial Subjects.

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During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drug in sufficient quantity to conduct the Trial. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

(c) not permit Trial Drug to be used for any purpose other than the conduct of the Trial in compliance with the Protocol;

(d) shall not make the Trial Drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(e) keep full and accurate records of who dispenses the Trial Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor entrusted with the oversight of the Trial ("Novartis Monitor") at any scheduled monitoring visit;

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

(g) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Trial Drugs to Novartis.

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the qualification of each prospective Trial Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Trial Subject's suitability for participation in the Trial, and abide by Novartis's decision as to whether or not to enrol that Trial Subject;

(c) ensure that, before their participation in the Trial, the Trial Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Trial that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Trial; and
(ii) the collection, processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF") in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Trial Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with; and

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (1 Subjects per month) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

Novartis will review the Trial Subjects recruitment on an on-going basis to ensure that the enrolment continues at an acceptable rate. Novartis is empowered to discontinue the Trial at Institution medical facilities in case of no or poor enrolment.

In a multicentre trial, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrolment of Trial Subjects prior to enrolment of the targeted number of Trial Subjects. Institution and Principal Investigator undertake to cease such enrolment upon request of Novartis and further undertake not to seek any compensation thereof.

5.5 Recordkeeping

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(a) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Trial Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial; and obtain Novartis approval prior to disposing of any Records that would not be owned by the patient under Applicable Laws. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

(f) Make available all Records to Novartis, its nominee or Health Authorities promptly upon request for monitoring and/or auditing purposes;

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Trial; and

(b) Make the hospital notes and Case Report Forms for each Trial Subject available for source data verification or auditing purposes by representatives of Novartis and the officers of any competent regulatory authority.

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

The Institution and the Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given whether or not notification was initially given by telephone. This Section shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis.

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Trial Subject or which could result in a re-assessment of the risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per current ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the Protocol) in accordance with the trial Protocol, applicable trial procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

These reporting obligations shall survive expiration or earlier termination of the Agreement.

During the Trial Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Trial and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Trial procedures.

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annexure 1) and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto (but in any case within ten (10) days after the Indemnitee shall have received notice thereof);

(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

The PI of Institution warrants that it has appropriate and adequate professional indemnity insurance cover claims or damages for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred

in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

6 & 7 floor, Inspire

BKC, G Block, BKC

Main Road,

Bandra Kurla Complex ,

Bandra (East), Mumbai –

400051

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

9. EQUIPMENT

9.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution, the Investigator and/or the designated Trial Staff. The Equipment shall only be used for the conduct of the Trial in accordance with the Protocol, Novartis instructions and until the Trial is completed or discontinued.

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall

remain in the same condition during the Trial, with the exception of ordinary depreciation.

9.3 During the term of the Trial, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

9.4 Following completion of the Trial or upon discontinuation of the Trial for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

10. TERMINATION

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution accordingly. Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations (as set out in Annex 3), or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis

all documents, Trial results and material used, generated or referred to in the course of the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution and/or Principal Investigator by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Trial or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion to any of its Affiliate or such third parties with no further payment or other obligation to the Institution and/or Principal Investigator. The Institution and/or Principal Investigator shall have no rights whatsoever therein

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1 shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those, which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

13. PUBLICATION

13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement,

and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary or confidential information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.2 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement.

13.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Trial are made available to Novartis, whichever is later.

13.4 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis.

13.5 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.6 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.7 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.8 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

14. CONFIDENTIALITY

14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Trial (collectively "**Information**") shall be treated as confidential. The Institution agrees not to disclose to any third parties or to use any Information for any purpose other than the performance of the Trial. The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

14.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said Information, its collection or creation did not occur during or in connection with the Trial;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning any Trial Subjects) shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for obtaining appropriate consent to the extent it is required by the Applicable Laws.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual competent authorities or Applicable Laws, for example to report serious adverse events and comply with drug safety laws and regulations.

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15.5 Retention of data. Personal data will be kept only for the period necessary to fulfil the purposes of the collection unless a longer retention period is required or permitted by Applicable Laws.

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution of its obligations hereunder.

Whenever a subcontractor is appointed and approved by Novartis, the Principal Investigator shall be responsible for the oversight of the subcontractor's personnel as part of the Trial Staff.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the Parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT OF INSTITUTION/PRINCIPAL INVESTIGATOR OR OTHER RESTRICTIONS FROM THE COMPETENT AUTHORITIES

(a) **Debarment**. The Institution and the Principal Investigator certify that they are not debarred or more generally under a prohibition under the relevant Applicable Laws to perform their activities. They certify that they will not use in any capacity the services of any person debarred (or otherwise under a prohibition to perform their activity) with respect to services to be performed under this Agreement. During the term of this Agreement and for three (3) years after its termination, the Institution and the Principal Investigator will notify Novartis promptly if this certification needs to be amended in light of new information. Principal Investigator also certifies that he/she does not have a revoked or suspended medical license or applicable certification.

(b) **Investigations, Inquiries, Warnings or Enforcement Actions Related to Conduct of Clinical Research**. The Institution and the Principal Investigator certify that they are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Competent Authority Action**") related to its conduct of clinical research that has not been disclosed to Novartis. The Institution and the Principal Investigator will notify Novartis promptly if it receives notice of or becomes the subject of any Competent Authority Action regarding its compliance with ethical, scientific, or regulatory standards for the conduct of clinical research, if the Competent Authority Action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

23. CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

23.1 The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

23.2 As the case may be, the Institution and the Principal Investigator shall ensure that the Principal Investigator and all Sub-Investigators involved in the Trial provide Novartis or its designee with the appropriate financial disclosures required by the U.S. Food and Drug Administration under 21 CFR Part 54, on such forms as Novartis or its designee may supply or approve. During the term of this Agreement and one (1) year following its expiration or earlier termination, the Institution and the Principal Investigator agree to assist the Sponsor or its designee in obtaining updated forms.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Trial; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services. In addition, disclosures of transfers of value in accordance with national pharmaceutical industry association codes to which Novartis is a party shall also apply.

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy. This term is mandatory for clinical studies that have sites in China as they have to be registered in the "Drug Clinical Trial Registry", and this registration includes investigator's personal data. Please inform clinicaltrial.cn@novartis.com if this term could not be included due to Local Regulations on Data Privacy so that individual consent request could be administered.

The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws or pharmaceutical industry codes applicable to Novartis. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Trial Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Trial Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. AUDITS AND INSPECTIONS

(a) Audit by Novartis and Records. The Institution shall grant access to its premises periodically as frequently as required for the proper performance and oversight of the Trial site in order to proceed with any and all monitoring activities required for the Trial. In addition, the Institution shall permit Novartis and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the Institution and the Principal Investigator in the course of conducting the Trial and to inspect the facilities at which the Trial is conducted to verify compliance with this Agreement, the Protocol, Applicable Laws and the accuracy of information provided in connection with the Trial. The Institution shall ensure that the Principal Investigator and other relevant staff is available for Novartis and its agents during an audit in order to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Novartis or its agents, the Institution and the Principal Investigator shall immediately correct any errors or omissions in such records and reports.

(b) Cooperation during Audit by Novartis. The Institution shall cooperate, and shall cause the Principal Investigator and the staff to cooperate, with Novartis and its contractors and agents in the event of any internal audits, upon reasonable notice and during normal business hours. The Institution shall furthermore make available to Novartis and its contractors and agents (for examination and duplication) all documentation, data and information relating to the Trial. Trial Subject medical records will be made available where appropriate for the purpose of source document verification procedures as part of the audit. The Institution also shall make the Principal Investigator and staff available to Novartis and its contractors and agents to explain and discuss such documentation, data and information. For the avoidance of doubt audits shall be supported at no cost by the Principal Investigator and investigational staff.

(c) Inspection by Competent Authority. The Institution and the Principal Investigator acknowledge that the Trial is subject to inspections by regulatory agencies worldwide, and that such inspections may also occur after completion of the Trial. In the event the Institution or the Principal Investigator receives notice that the Institution shall be the subject of an investigation or audit by any competent authority or Ethics Committee, as applicable, in relation to the Trial, it shall notify Novartis immediately within twenty four (24) hours the latest and shall obtain approval for Novartis or its agents to be present at the inspection or otherwise keep Novartis timely and constantly informed of the progress. In the event the Institution or the Principal Investigator does not receive prior notice of said inspection, it shall notify Novartis as soon as practicable after receiving knowledge of said inspection. Institution shall provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response. The Institution will promptly forward to Novartis copies of any inspection findings that the Institution receives from a competent authority or Ethics Committee, as applicable, in relation to the Trial. The Institution will provide Novartis with an opportunity to prospectively review any Institution responses to competent authority inspections in regard to the Trial.

(d) The Institution, the Principal Investigator and the staff shall cooperate with the relevant competent authorities or Ethics Committee, as applicable and comply with the legitimate requirements of an inspection. This also includes the making available (for examination and duplication) of documentation, data and information relating to the Trial. Subject medical records shall be made available where required for source document verification procedures as part of the inspection. The Institution also shall make the Principal Investigator and other staff available to the relevant competent authority to explain and discuss such documentation, data and information.

26. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The Parties hereby submit to the exclusive jurisdiction of Lucknow, India, without restricting any right of appeal.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in relation with trial procedures.

(69)

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: SAUMYA MATHEW

Title: COUNTRY TRIAL OPERATIONS LEAD

Date: 18·DEC·2020

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____ Name: Prof. R. K. DHIMAN

Prof. R K Dhiman

Title: Director

Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA

Date: 07.01.2021

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Jayantee Kalita

Dr. J. KALITA
Prof.
Department of Neurology
S.G.P.G.I.M.S., LUCKNOW

Title: Professor, Department of Neurology

Date: 01/Jan/2021

(64)

Annex1: Payment (and Equipment)

Schedule STUDY NUMBER: CAMG334A2304

STUDY NAME: A 12-Week Phase 3, Randomized, Double-Blind, Placebo-Controlled Study To Evaluate The Efficacy And Safety Of Once Monthly Subcutaneous Erenumab 70 Mg In Adult Chronic Migraine Patients

Investigator's Name: Dr. Jayantee Kalita

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical

Sciences Payee Name: Director, SGPGIMS Research Scheme

Account

Pan Card Number:

AAAJS3913N GSTIN:

09AAAJS3913N2ZN

Committed Number of Study Subjects: 20

List of Equipments provided to Institution / Principal Investigator:

- Thermohygrometer- To be retrieved post DBL
- ECG Machine – To be retrieved post DBL
- Log Pads – To be retrieved post DBL

1. Payment shall be made directly by Novartis
2. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be any and all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial;
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved;
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will not receive remuneration in the amount of a screening visit cost.
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.

- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting receipts.

- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the Institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.
- Add provision of equipment terms E.g. leasing, Novartis own equipment lent or other ad hoc solution
- CRC salary of INR 35,000/- per month will be paid by sponsor from SIV till Close out visit.

The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Study Budget:

CAMG334A2304_ Master Budget Sheet			Treatment							Post study treatment	
Visit	Screening	Baseline	Day-1	Wk-4	Wk-8	EOT	WK-4 FU	WK-8 FU	WK-12 FU	FUP	
Week		0	6	12	18	24	30	36	42	96	
Protocol Procedures	4000	4000	4000	4000	4000	4000	4000	4000	4000	4000	
Investigator Fees	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	
Coordinator Fees	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	
Subject travel Expense	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	
Institutional Overhead @ 25% (Variable)	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	
TOTAL (INR)	12500	12500	12500	12500	12500	12500	12500	12500	12500	12500	125000

(61)

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.

You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

(4)

☑ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..

☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.

☑ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.

☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date: 01/Jan/2021

Name: Dr.

Jayantee Kalita

Principal

Investigator

ANNEX 3

59

Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti- corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:

(i) securing any improper advantage; or

(ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –

(i) transactions are executed in accordance with management's general or specific authorization;

(ii) transactions are recorded as necessary

(I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and

(II) to maintain accountability for assets;

(iii) access to assets is permitted only in accordance with management's general or specific authorization; and

(iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

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INDIA NON JUDICIAL

Government of Uttar Pradesh

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Purchased by	:	LUCKNOW SMART CITY
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Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	LUCKNOW SMART CITY
Second Party	:	SGPGI
Stamp Duty Paid By	:	LUCKNOW SMART CITY
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

Memorandum of Understanding

"Health Kiosk ATM"

Smart & Specialist Tele-Health

This Memorandum of Understanding, (hereinafter referred to as MOU) between School of Telemedicine & Biomedical Informatics (STBMI), Sanjay Gandhi Postgraduate Institute of

1.1.1 To act as Smart & Specialist Tele-Health Hub (*Health Kiosk ATM*) for digital health access to smart citizen residing in the Lucknow city

1.1.2 To facilitate Basic Tele-Health services from the Doctors appointed under the *Health Kiosk ATM* of LSCL

1.1.3 To facilitate the Specialist Tele-Health services from SGPGI existing resources

1.1.4 To act as domain expert for the Smart City project in the field of digital health technology intervention across platform

1.1.4.1 SGPGI will provide the qualifications and the details of the manpower to be deployed for the operations of the smart health kiosk.

1.1.4.2 SGPGI will provide the details and specifications of medical equipment that may be required to be provided at Kiosk.

1.1.5 To assist the Lucknow Smart City Ltd for rolling out the project execution, monitoring and supervision for effective delivery of the outcome digital health project

1.1.5.1 SGPGI shall be responsible for Overseeing, monitoring, attendance and performance management of manpower deployed at to operate and maintain the smart health Kiosk.

1.1.5.2 SGPGI shall be responsible for vetting the quality of the consumables, coordinating with the consumables suppliers for stocking and smooth operations of the kiosks, to place orders and rationalize the usage of the consumables as per medical requirements at the kiosks.

1.1.6 To monitor, manage and evaluate the project on regular basis. Preparation of report on weekly/ monthly/annual basis and submit to the competent authority as per requirement

1.1.7 To evaluative the performance of each node in terms of quantitative & qualitative and made recommendation for any modification / update into the system as per the approval of LSCL

1.1.8 A develop a tripartite agreement between SGPGI, LSCL and identified agency for operation & maintenance of system

1.1.8.1 SGPGI will propose and put in place protocols for emergencies and will coordinate with UP112 for their services wherever required.

1.1.9 Orientation training/ re-training of the personnel to be deployed at each node for operating the platform.

1.1.10 Any other responsibilities agreed on mutual agreement basis time to time

1.1.11 Project Manager Key Responsibilities - SGPGI will appoint a Project Manager at the Hub Level to liaison and coordinate with LSCL and supervise the project entirely in terms of management of the proposed hub and spokes. The Project Manager needs to coordinate and periodically conduct meetings with LSCL in order to update them about the Operational status, issues and challenges.

प्रबन्धक (परियोजना)
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3. Payment provisions

3.1 LSCL, shall provide funds in a manner it is already submitted by the STBMI, SGPGI, Lucknow for the identified activities within the scope of this MOU.

3.2 The proposal shall be examined and funds released on yearly advance basis based on the discretion of the LSCL.

4. Modification

The Memorandum of Understanding may be amended by mutual consent through an exchange of correspondences between the two Partners.

5. Conflict of Interest

SGPGI, Lucknow will not engage in consulting activities that conflict with the interest of the LSCL under this MoU and will provide professional, objective and impartial advice

6. Professional Liability

SGPGI, Lucknow will carry out the activities specified in this MoU with due diligence and in accordance with prevailing standards of the profession and highest standards of ethics shall be solely liable for any and all claims, losses, liabilities, and/or damages arising out of, or in connection with, the activities undertaken in relation, or pursuant to this MoU.

7. Applicable Law and Settlement of Disputes

In the event of any dispute relating to the interpretation or performance of this MoU arising between the Parties, both Parties will first do their utmost to settle their dispute amicably.

8. Seal of the Parties

In witness thereof the Parties hereto have signed this Agreement on the day, month and year mentioned hereinbefore of their free will and accord.

(Dr. [illegible])
[illegible]

Minutes of 7th meeting of Executive Working Committee for Mobile Tele-oncology project held on 22.01.2022

The seventh meeting of Executive Working Committee for the Mobile Tele-oncology project was held under the Chairmanship of Prof. Aneesh Srivastava, Dean, SGPGI on 22nd January 2022 at 12.00 PM in the e-tumor board room of School of Telemedicine & Biomedical Informatics, SGPGIMS, Lucknow to review the progress of Mobile Tele-oncology project.

Following members were present in the meeting;

1. Prof. S.K. Mishra, Advisor, SGPGI Telemedicine Program (over V.C.)
2. Mr. T.K. Dixit, Advisor, Dr. K.L. Garg Memorial Trust
3. Dr. Sushma Agarwal, Dept. of Radiotherapy, SGPGI
4. Dr. Zafar Niyaz, Dept. of Radio- diagnosis, SGPGI
5. Prof. P.K. Pradhan, Member-Secretary & Nodal Officer, TM

Mr. Piyush Gupta, Cancer Aid Society could not attend the meeting due to the pre-occupied schedule.

Chairman welcome all the members and Member-Secretary apprised the members about the activities under taken during the FY 2019-20.

At the outset, Prof. P.K. Pradhan & Prof. S.K. Mishra, gave a detailed background of the project and progress made till date. During the Covid-19 pandemic, the activity of the project was hampered. The detailed accounts report for the last year' was presented by the Nodal Officer. The committee members were satisfied with the details of the accounts presented by the Nodal officer.

The following new agenda were deliberated in detail and recommendation was made for onward action;

1. **Renaming the project name from outreach Mobile Tele-oncology care to Primary care:** Member Secretary apprised the committee members that the oncology care using the mobile unit could not be carried out in all dimensions as envisaged due to local logistics issue at the community and people did not coming forward for the cancer screening. Most of the patient comes for general health screening followed by consultation and ultimately free medicine for immediate health care, which is a primary care in nature. Therefore, the suggestion to change the project name proposed. The chairman suggested to modify the name as "Mobile Tele-oncology and Primary Care" in place of **Primary Care.** All the members agreed upon the suggestion.
2. **Renewal of Memorandum of Understanding (MOU)** A MOU was signed on 14th Sept. 2011 for execution of the project. Further, it was amended as per the recommendation of the third executive working committee with due approval of competent authority. As per the clause no. (11) of original MOU "*The duration of the period for three years initially and will be extendable as per the outcome of the Mobile Telemedicine Unit* ". Committee felt that outcome of the project is satisfactory and community are getting benefitted through this project, the project period is to be extended for three more years' **w.e.f. 14th Sept. 2020 to 13th Sept. 2023** on the same terms & conditions as had been extended in first & second renewal (i.e. from 14th Sept. 2014 to 13th Sept. 2017 & 14th Sept. 2017 to 13th Sept. 2020). Shri Dikshit, advisor of the funding agency agreed upon the recommendation of the committee.

5/2/22

(Dr. PK Pradhan)

3. **Account Management due to superannuation of Prof. S.K. Mishra**

Member Secretary apprised the members that the account, which is being operated by Prof. S.K. Mishra, will be handed over to the Prof. P.K. Pradhan, Nodal Officer, Telemedicine due to his superannuation. All the members were agreed and same procedure of budget utilization will be followed as laid down in the agreement.

4. **Revision of honorarium and salary of manpower laid down within allocated budget**

Member Secretary apprised the members that the honorarium & salary amount approved in the FY 2014-15 needs to be upgraded keeping escalation rate at the current scenario. Shri T.K. Dikshit, Advisor, Trust agreed upon the suggestion made by the committee with note that allocated annual budget should not be exceeded. As approved, the revised/upgraded as per followings;
Honorarium for personnel: Medical Doctor (MBBS/ BDS/ BHMS/BUMS)@Rs 2,500/- per camp, Paramedical Staff (Nurse/x-ray tech.) @ 1000/- per camp, Technical Staff@ 1000/- per camp. The stipend of Accounts handling personnel be increased from 3,000 to Rs. 5,000 . Manpower engaged in the project should be given annual increment @7% from FY20-21 & 2021-22 respectively.

5. **Table Agenda incorporating Prof. S.K. Mishra, outgoing Project In-charge as Advisor to this project from the funding agency side:** Mr. T.K. Dixit appreciated the contribution of Prof. S.K. Mishra from starting till execution of the project for the last several years. He suggested that Prof S.K. Mishra to be included in the Executive Working Committee as an Advisor from the side of funding agency. The committee had given the concurrence for the same.

Meeting ended with thanks to the chair.

(Prof. S.K. Mishra)
Member

(Dr. Sushma Agarwal)
Member 5/2/22

(Dr. Zafar Niyaz)
Member

(Prof. P.K. Pradhan)
Member-Secretary

(Mr. T.K. Dixit)
Member

(Prof. Aneesh Srivastava)
Chairman

उत्तर प्रदेश UTTAR PRADESH

BP 633418

SUPPLEMENTARY MEMORANDUM OF UNDERSTANDING

THIS SUPPLEMENTARY MEMORANDUM OF UNDERSTANDING, supplement to the original Memorandum of Understanding dated 14/09/2011, executed on dated 19/03/14 among the parties as under

(1) **Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS)**, Raibareli Road, Lucknow, (hereinafter referred to as "Institute") of the one part,

(2) **Cancer Aid Society**, a society registered under society Registration Act, 1860 and having office at 2A,1st Floor Regency Avadh, Complex, Chowk, Lucknow (hereinafter referred to as "Society") of the second part

And

(3) **Dr. K. L. Garg Memorial Charitable Trust**, a Trust under Indian Trust Act, 1882 and having office at second floor, Eldeco Corporate Chamber-1, Vibhuti Khand, Gomati Nagar, Lucknow (hereinafter referred to as "Trust") of the Third Part for implementing the Mobile Telemedicine Project programme under the title of "Martyr Dr. Garg – SGPGIMS – Mobile Tele- Oncology Programme".

This Supplementary M.O.U. is required to be formed because of the decision taken in the Third Review meeting of Executive Committee held under the Chairmanship of Prof. R.N. Misra, Dean SGPGI on 18th January 2014 at 12.30P.M. at the Board Room Of School Of Telemedicine & Biomedical Informatics, SGPGIMS, Lucknow.

Following members were present in the meeting;

1. Prof. P.K. Pradhan, Member
2. Mr. T.K. Dixit, Advisor, Dr. K.L. Garg Memorial Trust
3. Prof. S.K. Mishra, Member - Secretary

Meeting held and several decisions were taken for better implementation of the programme. Then was a discussion on one subject - UTILIZATION OF THE BUDGET.

Second Party

Sanjay Kumar

As per the M.O.U. dated 14.09.2011 point no. 7 the Trust was to provide annual grant of Rs.12,00,000/- (Rs.Twelve Lacs) per annum and the heads were also mentioned for the allocation of the Budget. Chairman informed the committee that the fixation of the budget under the different heads is causing problem to meet out the expenditure other than broad heads mentioned in the M.O.U.

Chairman felt that this project is non research project so the funding agency can directly operate this account as per their organizational rules and regulations. Members present at the meeting agreed with the view of the Chairman, for the solution, Committee decided that clause no.7 of the M.O.U. be replaced with the clause as under –

"TRUST MANAGES THE BUDGET DIRECTLY WITH SAME RECURRING GRANT AMOUNT i.e. (Rs.12.00 Lacs). P.I. WILL FOLLOW THE ADMINISTRATIVE NORMS OF THE TRUST IN MANAGING THE GRANT".

Besides the above, other terms and conditions of the MOU dated 14.09.2011 remain unchanged.

In witness whereof, the parties, named above, have signed this MOU on the day, month and year first above written.

1. For and on behalf of Institute

(Prof.S.K. Mishra)
Nodal Officer, Telemedicine, SGPGIMS

(Prof. R. K. Sharma)
Director, SGPGIMS,

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

2. For and on behalf of Society

(Mr. Piyush Gupta)
Principal Executive Officer
Cancer Aid Society, Lucknow.

3. For and on behalf of Trust

(Mr. S. K. Garg)
Chairman,
Dr. K. L. Garg Memorial Charitable Trust

Witness: 1. (O.K. DIKSHIT)
B-703, Mahanagar
Lucknow

Third ~~First~~ Party

2. Neha Tripathi Second Party
2A, Ist Floor
Regency Avadh Complex
Chowk, Lucknow

3. Third Party
(Prof. P.K. Pradhan
Dept. of Nuclear medicine
SGPGIMS
Lucknow - 226014)

Drafted by:

Typed by:

MEMORANDUM OF UNDERSTANDING

BETWEEN

AND

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उप कोषागार कार्यालय
उप कोषागार अधिकारी

11 JUL 2019

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is entered into, on the _____**day of**_____**2019** between **1) Dr. Amita Aggarwal, Professor, Department of Clinical Immunology at** Sanjay Gandhi Post Graduate Institute of Medical Sciences, having an address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India ("Investigator") and **2)** Sanjay Gandhi Post Graduate Institute of Medical Sciences **("Institution")** having its address at Raebareli Road, Lucknow-226014, Uttar Pradesh, India and **3) Reliance Life Sciences Pvt. Ltd.**, ("**Reliance**"), with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701.

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"Investigator", "Institution", and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	RLS/IMM/2014/01
PROTOCOL TITLE:	Prospective, multi-centric, single-arm, clinical study to evaluate the efficacy, safety, and pharmacokinetic properties of ImmunoRel® in patients with Primary Immunodeficiency Disease
STUDY PRODUCT:	ImmunoRel®
	Reliance Life Sciences Pvt. Ltd.
INVESTIGATOR:	Dr. Amita Aggarwal
INSTITUTION/SITE:	Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India

WHEREAS, Reliance Life Sciences is involved in clinical trials management and related clinical development activities.

WHEREAS, Reliance wishes to engage the Investigator to carry out Reliance's designated clinical study set out and described in protocol RLS/IMM/2014/01 and the Investigator is able and willing to conduct a clinical study (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator for conducting the Study at the Institution.

WHEREAS, the Investigator is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Study that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement. The Investigator and Institution agree to ensure that all associates, employees and contractors, assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein, (d) the International Council on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Indian GCP Guidelines, Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), New Drugs and Clinical Trials Rules, 2019 and all applicable laws and regulations and amendment to these

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that arise from time to time (hereinafter "Applicable Laws and Requirements", and the approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget attached as Appendix A to this Agreement, with the last payment being made after the Investigator and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed Case Report Forms (CRFs) have been completed and data queries have been resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Package Insert/ Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

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TERMS AND CONDITIONS

1. **Conduct of the Study.**

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and applicable laws, regulations, guidelines, and other requirements, hereinafter referred to as "Applicable Laws and Requirements", including:

a. Written approval or favourable opinion from all relevant ethics committees or institutional review boards (the "Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Ethics Committee by providing relevant information and documentation

b In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Table 4, covered under Third Schedule of GSR 227(E)of the New Drugs and Clinical Trials Rules, 2019, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution and Investigator shall cause any co-investigators or sub-investigators to submit such documentation to Reliance in a timely manner.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by the Ethics Committee, and (iii) any other documentation filed with and/or received from Ethics Committee or any Regulatory Authority related to the Study.

d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Package Insert/ Investigator's Brochure, and shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study subject are met. Investigator will complete a Case Report Form (CRF) for each Study subject in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRFs to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Ethics Committee and provide a summary of the Study report.

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1.2 Site Visits. The Institution and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study files and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product. (a) Upon the receipt by Reliance of the written approval of the Institution's Ethics Committee, Reliance shall provide the Investigator, at no charge, with such quantities of the Study Product as may be required for the Study. The Investigator and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Product. Upon completion or termination of the Study, Reliance may retrieve all unused Study Product and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator and Institution will keep full and accurate records of who dispenses the Study Product, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Product being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Product and Study materials provided by Reliance in a locked, secured area at all times.

(b) The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, identity of the person who dispenses the Study Product, the quantity dispensed, and the quantity returned to Reliance or disposed off.

(c) Institution and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from Reliance.

1.4 Adverse Events. The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Package Insert/ Investigator's Brochure on the Study Product is available for dissemination to the Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and Informed Consent Form template.

1.5 New findings. Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation, influence the conduct of the

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study, or alter the Ethics Committee's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. Recruitment. Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by Reliance from time to time. Investigator acknowledges that Reliance reserves the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Ethics Committee and Reliance to any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations

3. Enrolment; Notices; Informed Consent; Authorization:

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects, including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution and/or Investigator and their study team, (b) persons monitoring the Study or conducting an independent evaluation of the Study, (c) the representatives of the Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Reliance related to the Study.

3.3 The status of enrolment of the trial subjects shall be submitted by the Investigator/ Institution on a quarterly or more frequent basis as per the duration of treatment in accordance with the approved clinical trial protocol; such reports will be processed in accordance with Protocol and Applicable Laws and Requirements.

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4. Confidential and Proprietary Information. All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator and Institution by Reliance or Reliance's agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Reliance. The Investigator and Institution will undertake to keep in strict confidence and not, at any time, to use other than in the Study, or to disclose or permit to be disclosed to any third party, the data and results of the Study and any information provided directly or indirectly by Reliance or Reliance's Representatives under this Agreement. The Investigator and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of fifteen (15) years after disclosure of said Confidential Information to Investigator and /or Institution under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator and Institution; b) is disclosed to the Investigator by a third party not subject to any obligatron of confidence; c) must be disclosed to Ethics Committees or applicable Regulatory Authorities; d) must be included in any Study subjects Informed Consent Form; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. Intellectual Property Rights -All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain, by virtue of this Agreement, any rights in or ownership of, copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator and Institution hereby agree that Reliance shall own all intellectual property rights arising out of the Study and related to the Study Product, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator and Institution will, at Reliance's expense, execute any documents and give any testimony necessary for Reliance to effect the transfer of the title of such property, obtain patents in any country or to otherwise protect Reliance's interests in such inventions. The Investigator and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator and Institution during the course of the Study that are wholly unrelated to the Study Product and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer Reliance the right of first refusal as to any sales or licenses of such inventions. The Investigator and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

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6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number/ code assigned to the subjects rather than by the subjects' name(s), personal identification information and / or addresses. The Investigator shall retain the Records of the Study, including the original of all volunteer consent forms, for upto fifteen years from the date of the end of the study

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Reliance. Upon expiration of the applicable retention period, Reliance shall, upon Institution or Investigator's request, direct that such Records be delivered to Reliance or Reliance's representative, be destroyed, or be retained by Institution/Investigator, and Institution/Investigator shall comply with Reliance's directions.

7. **Publication.** The results of the Study including all obtained data will be the property of Reliance. The Investigator and Institution should not publish or communicate the data in public without written authorisation by Reliance, unpublished data should not be disclosed to any third party by the Investigator and Institution without the written approval of Reliance. The Investigator and /or Institution may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Reliance shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Reliance desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Reliance requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a

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delay in publication to allow the filing of patent applications before publication or release, Investigator shall take the requested action.

8. Subject Injury Reimbursement

8.1 Subject to Investigator, Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Reliance agrees to reimburse Institution and/or Principal Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Study Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 42 of New Drugs and Clinical Trial Rules [GSR 227(E), 19 March 2019 in case of Subject's injury and/or death. Institution and Principal Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Subject as a result of the Subject's participation in the Study. Institution and Principal Investigator further agree to promptly notify Reliance of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Study Product or procedures prescribed in the Protocol, which are different from the medical management the Subject would have received if he/ she had not participated in the Study.

9. Inspection and Debarment.

9.1 Investigator and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator and Institution agree to communicate with Reliance in writing or contact Reliance by telephone or fax prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator and Institution agree, upon reasonable notice, to disclose, from time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator and Institution shall permit Reliance to attend any such inspections. The Investigator and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study Subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the Subject in the signed Informed Consent Form.

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9.2 The Investigator and / or Institution shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator and Institution shall permit Reliance to inspect and audit the Institution. The Investigator and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, Applicable Laws and Requirements, and Reliance requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator and Institution shall promptly notify the same to Reliance

9.4 The Investigator and Institution represent and warrant that neither the Investigator nor the Institution or nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical studies or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to, any of the following occurrences:

i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or

ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

iii) If no subjects have been enrolled, or the Investigator recruits no subjects, or recruits such a low number (less than 04 in number) of subjects that it can be assumed that the agreed number of subjects will not be reached during the planned recruitment phase;

iv) Reliance terminates the Study, or the development of the Study Product or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A Regulatory Authority or other pertinent institution decides to terminate the Study in the Institution or as a whole;

vii) The Investigator/ Institution fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Applicable Laws and Requirements and the Study Protocol.

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b. Should the Investigator/Institution recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of Serious Adverse Events or (iii) perceived insufficient efficacy of the treatment with Study Product; then he/ she will promptly notify Reliance as well as the Ethics Committee in writing. Should Reliance, or the Ethics Committee agree that continuation is not justifiable, the Investigator/Institution may arrange termination of the Study in accordance with Applicable Laws and Requirements and the Study Protocol.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory Authorities as appropriate of early termination, except that the Investigator will notify the Ethics Committee.

10.2 Effect of Termination Upon receipt of notice of termination, the Investigator shall immediately cease any subject recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination, Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Reliance of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator or the Institution for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the Ethics Committee that approved the Study (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, and expenses to the extent that it relates to the death of a Subject caused by: a) the administration of Reliance Study Product (b) a properly-performed Protocol-required procedure, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or

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(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Reliance and/or generally accepted medical standards and the applicable SOPs; and/or

(iii) any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,

(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by Reliance for the use and administration of the Study Product and/or

(v) failure to have complied with all Applicable Laws and Requirements.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved, gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;

b. Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance is promptly notified in writing of any such claim or suit;.

c. Indemnified Parties reasonably cooperate with Reliance and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement, and

d. Indemnified Parties permit Reliance to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent Indemnified Parties and

e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of Reliance.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Product.

11.2 Investigator and Institution shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain a signed Informed Consent Form in

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compliance with the terms of this Agreement or otherwise fails to comply with Applicable Laws and Requirements provided:

a. Investigator and Institution are promptly notified in writing of any such claim or suit;

b. Reliance cooperates fully in the investigation and defense of any such claim or suit;

c. Investigator and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and

d. Investigator and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Reliance's behalf without Reliance's advance written permission.

11.3 The Investigator and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlement negotiations), and shall cooperate fully with Reliance in its handling of the claim.

11.4 Institution and Investigator acknowledge that the Study Product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation to damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. Financial Disclosure. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Reliance and their agents and Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reported to Reliance.

13. Insurance: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. Shipping of Dangerous Goods and Infectious Materials. The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. Publicity.

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15.1 Solicitation of subject: Reliance and Ethics Committee shall approve in writing, any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 Press Releases: Reliance shall approve, in writing, any and all press statements by Investigator and Institution regarding the Study or the Study Product before such statement is released. It is the Investigator's obligation to take such prior approval from Reliance.

15.3 Enquiries from media and financial analysts: During and after the Study, the Investigator and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution must confer with Reliance and Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no R-282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 Use of Name Investigator and /or Institution or any of the Investigator, Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. Reliance shall not use the name of the Investigator or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator and Institution. It is agreed that all Study Reports, Study Proposals, and notifications to Regulatory Agencies by Reliance may contain the name of the Investigator and Institution.

16.0 Additional Contractual Provisions.

16.1 In conducting the Study, the Investigator and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance, and the Investigator and /or Institution has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names).

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16.3 Amendments: No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution shall directly or indirectly conduct any study as set out in the protocol no. RLS/IMM/2014/01 and any subsequent amendments thereto or participate in the study, which is same or similar to Reliance designated study mentioned in this Agreement, without prior written approval of Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with his/her entering into this Agreement. Investigator and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Data Privacy. The Parties shall comply with all the Data Privacy related requirements prescribed by Applicable Laws and Requirements, and implement administrative, physical and technical safeguards to protect personal/sensitive personal information that are no less rigorous than accepted industry practices.

16.8 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.9 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.10 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof, shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties.

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The place of Arbitration shall be at Lucknow and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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Reliance
Life Sciences

A.2 Per Visit Payment schedule

Week	Screening within 21 days of W0	Week 0/ Day 1	4/3	8/6	12/9	16/12	20/15	24/18	28/21	32/24	36/27	40/30	44/33	48/36, 39,42, 45,48	52 or Early Withdrawal	
												40/30	44/33			
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14-18		Total
Written Informed Consent	1000															1000
Inclusion/ Exclusion Criteria	1000															1000
Demographics	200															200
Body Weight & Height	100	100	100	100	100	100	100	100	100	100	100	100	100	500		1800
Medical History	100															100
Prior Medications	100															100
Physical Examination	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Concomitant Medication review	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Adverse Event Recording	200	200	200	200	200	200	200	200	200	200	200	200	200	1000	200	3800
Patient diary details	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Vital signs	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Study Coordinator	700	700	700	700	700	700	700	700	700	700	700	700	700	3500	700	13300
Study Medication Administration		1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	7500		25500
Hospitalization cost		1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	7500		25500
12-Lead ECG	300	300	300			300	300		300		300	300		1500	300	4200
Chest X ray	500							500		500						1500
Patient travel reimbursement	500	500	500	500	500	500	500	500	500	500	500	500	500	2500	500	9500
Total (A)	5100	5200	5200	4900	4900	5200	5200	5400	5200	5400	5200	5200	4900	26000	2100	95100
25% Overhead (B)	1275	1300	1300	1225	1225	1300	1300	1350	1300	1350	1300	1300	1225	6500	525	23775
Per Visit Budget (A+B)	**6375**	**6500**	**6500**	**6125**	**6125**	**6500**	**6500**	**6750**	**6500**	**6750**	**6500**	**6500**	**6125**	**32500**	**2625**	**118875**
GST (18%)	1148	1170	1170	1103	1103	1170	1170	1215	1170	1215	1170	1170	1103	5850	473	21398
Per Visit Budget with 18% GST	**7523**	**7670**	**7670**	**7228**	**7228**	**7670**	**7670**	**7965**	**7670**	**7965**	**7670**	**7670**	**7228**	**38350**	**3098**	**140273**

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Note:

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

* In addition to the above Reliance shall make the following payments:

- The screen failure cost will be reimbursed on actual in the ratio of 2:1, i.e. for every 2 patients enrolled into the study. The laboratory and Investigation cost incurred for every screen failure would be reimbursed to the site. Additionally, Investigator Charges for Screen failure will be paid 50 % of the total screening of Investigator charges. However, site need to send prescreen report to Reliance before performing actual screening
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, Reliance's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- The per visit activity cost will be paid on the completion of the corresponding activity and the completion of the corresponding CRF.
- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment will be made for those evaluable subjects enrolled in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Forms. The Payee agrees to refund any excess amount previously paid, and Reliance agrees to promptly pay any amount owing based to the receipt of acceptable CRFs at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from Reliance. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to reallocate subjects budget to other sites originally reserved for the site if site is having difficulty in enrolling and qualifying subjects.
- Site and Investigator are responsible to archive all study documents including source data as per regulatory requirements. The archival activity is to be undertaken at a third-party location; the archival facility should comply with global standards of safety, security, temperature and humidity controls, and controlled access. Reliance will pay the third-party directly for this archival. However, the investigator and site will have full control to the documents archived at all times.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted at applicable rate.

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महाराष्ट्र MAHARASHTRA

15 FEB 2014

KL 705966

Amgen Technology Pvt. Ltd.
Dynasty Business Park
A Wing
Andheri - Kurla Road
Andheri (East)
Mumbai - 400059

मुख्य सुद्रांक कार्यालय, मुंबई
13 FEB 2014

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is made and entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India, and its parent or wholly owned subsidiaries of the parent ("**Company**") and Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Site**"). This Agreement shall be considered fully executed on the latest date that a party executes the same.

1. SCOPE OF SERVICES

1.1 Engagement. The execution of this Agreement alone, in the absence of any duly executed Order, as defined below, shall neither create any obligation of Site to perform hereunder nor create any obligation of Company to give Site any compensation. An "**Order**" is a document executed, at a minimum, by Company and Site, and issued pursuant to, and to be governed by, the terms of this Agreement. Unless otherwise specified, references to Agreement herein include all applicable Order(s).

1.2 Scope of Services. Company may engage Site through one or more Orders. An Order will be in a format similar to the document attached hereto and, among other things, shall set forth the particulars of the services to be performed ("**Study**"), including the clinical research and definition of the applicable Study drug ("**Study Drug**"). If engaged, Site agrees to and shall cause its employees, contractors, agents, representatives, including the principal investigator and sub-investigators (collectively, "**Site Representatives**") to perform the Study in accordance with this Agreement and Study protocol (as defined, including subsequent amendments) ("**Protocol**"). Site represents and warrants that it has the authority to require that Site Representatives comply with the applicable terms of this Agreement. Site shall notify Company of any material changes to Site Representatives, but in no event may Site change the principal investigator or any sub-investigator for a Study without Company's prior written consent. This Agreement,

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together with a duly executed Order, will be used by the parties for one Study only. Should the parties agree to use the Agreement for additional Study(ies), such agreement will be evidenced by an Order duly executed by all parties.

1.3 Biological Materials. All samples derived from Subjects enrolled in the Study, including blood, bone marrow, sera, platelets and other biological materials (the "**Biological Materials**") shall only be used in accordance with the Protocol and the EC approved informed consent.

1.4 Changes. In the event of a change to a Study that results in an increased cost, or if any increase in the compensation due for the conduct of a Study is necessary or appropriate, Company shall provide written notice in the form of a budget increase letter ("**Change**") to the Site to memorialize such increase in compensation. Unless the Site objects to such Change within ten (10) calendar days of the Change's date, said Change shall constitute an amendment to the applicable Order.

1.5 Protocol Deviations. If principles outlined in the ICH Harmonized Tripartite Guidelines for Good Clinical Practice ("**ICH GCP**") relating to the safety of Subjects (as defined herein) require a deviation from the Protocol, ICH GCP should be followed and the deviation shall immediately be reported to the other parties of this Agreement. Site shall also, within twenty-four (24) hours, notify Company of any Serious Breach of which Site becomes aware. For the purposes of this provision, a "**Serious Breach**" shall mean a breach of ICH GCP or Study Protocol, which is likely to affect (i) the safety of physical or mental integrity of the Subjects of any Study; or (ii) the scientific value of any Study. In addition, Site shall promptly inform the Institution Review Board or Independent Ethics Committee ("**IRB/IEC**") and any governmental authority as may be required by Applicable Law (as defined herein) of such deviation or breach.

2. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

2.1 Site shall use its best efforts to enroll evaluable subjects who meet all of the Protocol eligibility requirements ("**Subject(s)**").

3. COMPENSATION

3.1 Compensation. Compensation and payment terms for the applicable services shall be as set forth in the applicable Order. Site represents and warrants that the compensation provided under the terms of this Agreement as may be amended by subsequent Changes, represents fair market value and complies with Applicable Laws (as defined herein) and is consistent with fees charged for similar activities in Site's geographical area, has been negotiated at arms-length, and is unrelated to any procurement decision or promotion of Company's (or its affiliates') products, the volume or value of any referrals or other business otherwise generated between Company and Site.

3.2 Subject Withdrawal. Company shall have no obligation to compensate Site for a Subject who is determined to be ineligible for a Study, except for screen fails if provided for in the Schedule A, or for additional individuals who are enrolled in a Study without Company's prior written approval. In the event that a Subject (i) withdraws voluntarily; or (ii) is withdrawn from a Study for any reason other than the Subject failing to meet eligibility requirements, then Company shall compensate Site pursuant to the terms of the Schedule A for the procedures completed through the date of such withdrawal.

3.3 Payment Reconciliation. If, at the completion of a Study, Company has paid sums under the terms of this Agreement that exceed the total Study cost as provided in the Schedule A, Site shall, within 30 calendar days reimburse to Company any amount paid by Company that exceeds the adjusted Study cost. Site agrees to provide Company or its representative with all requests for payment under the terms set forth in the Schedule A within 30 calendar days after receipt of the adjusted Study/final payment. Where this is not possible, Site shall make all payment requests at the latest within 12 calendar months thereafter. Company shall not be obligated to make any payments after this period has expired.

3.4 Taxes, Customs, Fees, and Import/Export Duties. The pricing, fees, and compensation stated herein are inclusive of all applicable employment-related, consumer, use and other similar taxes (except Value Added Tax ("**VAT**")/sales tax), levies, duties, fees, and assessments which are legally enacted on or before the Effective Date (as defined herein), whether or not then in effect. VAT/sales tax, if applicable, will be paid by Company at the applicable rate and upon receipt of a valid VAT/sales tax invoice. Site, not Company, shall be responsible for any and all taxes on any and all income Site receives from Company under this Agreement.

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4. CONFIDENTIAL INFORMATION

4.1 Confidential Information. In view of Company's proprietary rights and interests, Site agrees to maintain as confidential all information received from or on behalf of Company or obtained as a result of the performance of this Agreement or developed under a Study ("**Confidential Information**"), and further agrees to limit access to any Confidential Information to only those persons who, under Site's direct control, will be engaged in employing such information for the purposes of fulfilling the obligations under this Agreement. At no time shall such information be employed for any purpose other than as described herein or disclosed to any third party without the prior written consent of Company.

4.2 Exclusions. The obligations set forth in this Article shall not apply to any portion of Confidential Information which (i) is or later becomes generally available to the public by use, publication or the like, through no act or omission of Site; (ii) Site possessed prior to the latest execution date of this Agreement without being subject to an obligation to keep such Confidential Information confidential; (iii) is lawfully obtained without restriction from a third party who had the legal right to disclose the same to Site; or (iv) is independently developed by the Site without the use or benefit of Confidential Information as evidenced by the Site's written records. In the event Site becomes legally compelled to disclose any Confidential Information, it shall immediately provide Company with notice thereof prior to any disclosure, shall use its best efforts to minimize the disclosure of any Confidential Information, and shall cooperate with Company should Company seek to obtain a protective order or other appropriate remedy.

4.3 Return of Company's Confidential Information. Site must return to Company all of Company's Confidential Information in tangible form, including without limitation all copies, translations, interpretations, derivative works and adaptations thereof, immediately upon request by Company. Notwithstanding the foregoing, if and to the extent required by Applicable Law (as defined herein), Site may retain 1 copy of applicable Confidential Information for record keeping purposes only.

5. PROPRIETARY RIGHTS

5.1 Ownership. Site agrees that all information, inventions, discoveries, know-how and improvements resulting from a Study conducted under this Agreement, including but not limited to material that may be subject to patent, trademark, or copyright protection ("**Intellectual Property**") shall promptly be made known to Company and shall be the sole property of Amgen Inc. Site represents and warrants that it has secured from principal investigator and Site Representatives any and all transferable rights to Intellectual Property. Site hereby transfers and assigns to Amgen Inc. Site's full right and title to all Intellectual Property and agrees to undertake such actions reasonably requested by Company to give effect to such ownership. Amgen Inc. and its subsidiaries or affiliates including the Company shall be free to use the Intellectual Property. For each Study, Site shall furnish to Company all Study data, results, case report forms and an acceptable investigator's report. Any copyright in any such data, results, case report forms and investigator's report shall be the sole property of Company. Neither Company nor Site transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of any party, except as described in this Agreement.

5.2 Use of Study Drug. Site agrees that use of a Study Drug provided under this Agreement for any purpose outside of a Study is prohibited. If Site uses a Study Drug provided under this Agreement for any purpose outside of a Study, all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Intellectual Property in accordance with this Agreement and shall be the sole property of Company.

6. PUBLICATIONS

6.1 Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or

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oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

6.2 Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7. COMPANY-PROVIDED MATERIALS

7.1 Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

8. REQUIRED EQUIPMENT AND SYSTEMS

8.1 Required Equipment. The parties acknowledge that certain equipment may be needed to properly conduct a Study. If Company and Site agree that Site does not have sufficient access to some or all of that certain equipment, then such equipment shall be identified in the Agreement and referred to as "Required Equipment." Unless otherwise specified, Company or its representative shall lend to Site for the duration of the Study such Required Equipment. As applicable, Company or its representative shall arrange for the delivery of such Required Equipment. At the completion or earlier termination of the Study, Company or its representative may retrieve any or all of the Required Equipment, title to which remains with Company or its representative.

8.2 Site's obligations. While the Required Equipment is on Site's premises, Required Equipment shall remain Company's or its representative's property at all times and shall be identified as such and can only be used to perform Studies. The Site shall ensure that the Required Equipment is stored, maintained and used properly. At all times after its delivery to Site and except for normal wear and tear, Required Equipment shall be at the sole risk of the Site as regards damage, loss, or destruction. While in Site's possession or control, Site shall be liable for the repair or replacement of any such Required Equipment that is damaged, destroyed, or lost.

8.3 Customized Required Equipment. If Company or its representative provides Site with Required Equipment that is specifically customized for use in a particular Study, then Site shall ensure that this Required Equipment is not used in any manner or for any purpose other than as set forth in the applicable Protocol. Additionally, at or before the conclusion of a Study, Company or its representative will provide instructions to Site regarding the destruction of or, at Company's expense, return to Company of such

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customized Required Equipment. Site agrees to destroy or return such Required Equipment pursuant to Company's or its representative's direction.

8.4 Required Systems. Site agrees to use any electronic system that Company may specify for use in the reporting and monitoring of clinical data and Study findings.

9. COMPLIANCE WITH APPLICABLE LAWS AND ACCEPTED PRACTICE

9.1 Accepted Practice. Site shall perform and shall cause Site Representatives to perform a Study in a professional and competent manner, using the degree of skill, diligence, prudence and foresight which would reasonably and ordinarily be expected from skilled and experienced professionals engaged in the provision of, and activities comprising, a Study.

9.2 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement before the Subject is allowed to participate in the Study. Site shall ensure that such consent permits Company's use of Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

9.3 Compliance with Applicable Laws. Site agrees to ensure that the Study is conducted in compliance with generally accepted standards of Good Clinical Practice, all laws, regulations, and guidance applicable to its performance hereunder, including the ICH GCP, Company's Protocol, written instructions and policies provided or referenced by Company and, applicable export control and economic sanctions regulations which prohibit the shipment of certain products and technology to certain restricted countries, entities and individuals, as well as applicable anti-bribery laws pertaining to interactions with government agents, officials and representatives ("**Applicable Law(s)**").

9.4 Data Protection. Site shall comply with the data protection provisions set forth by Applicable Law.

9.5 Records. Site shall maintain all records required under Applicable Law and the Protocol for 10 years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records.

9.6 Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors.

9.7 Governmental Contact by Site. Site shall not initiate any communications involving or relating to any Study with any governmental or regulatory authority (such as the United States Food and Drug Administration or the Drug Controller General of India) unless required by Applicable Law or requested to do so by Company and, then, only upon prior consultation with Company. However, if any governmental or regulatory authority initiates communications with, or gives notice to Site of its desire to meet with Site, conduct an inspection, or take any regulatory action regarding any subject matter relating to a Study, Site will promptly:

(i) Notify Company thereof;

(ii) Notify Company of any warning, violation or deficiency, including without limitation those noted by any governmental authority, with respect to a Study including without limitation facilities, equipment, or personnel supporting a Study;

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(iii) Provide Company with a copy of any correspondence or inspection reports issued with respect to a Study;

(iv) Provide Company with copies of and opportunities to comment on drafts of documents Site is required to submit to governmental authorities pursuant to its obligations hereunder; and

(v) Take action to correct any such violations or deficiencies or heed any such warnings.

Company acknowledges that it may not direct the manner in which Site fulfills its obligations to permit inspection by governmental authorities. Company representatives shall have the right to be on site during any such inspection by a governmental or regulatory authority, unless prohibited by Applicable Law.

9.8 For the purposes of this Agreement, Site shall ensure that the principal investigator for a Study and other Site Representative with applicable experience and knowledge are present during any inspections.

9.9 Debarment. Site represents and warrants that neither Site nor Site Representatives have been the subject of a debarment, disqualification or exclusion under any rules, in any jurisdiction where they have practiced, in particular in Europe or in the United States (where the main applicable texts are: Generic Drug Enforcement Act of 1992, Title 21 Code of Federal Regulations ("**C.F.R.**") Section 312.70 and 42 C.F.R. Part 1001 et seq.). Site shall notify Company immediately upon any inquiry concerning debarment, disqualification, or exclusion of Site or Site Representatives, or the commencement of any proceeding concerning the same. Notice of or failure to provide any such notice under this Section shall constitute a breach hereunder for which Company may terminate this Agreement immediately for default notwithstanding any right of Site to cure.

10. ANTI-CORRUPTION REPRESENTATION AND WARRANTY

10.1 Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site.

11. INDEMNIFICATION

11.1 Company's Indemnity. Company shall defend, indemnify, and hold harmless Site and Site Representatives (collectively, "**Site Indemnitees**") from any and all third party liabilities, claims, damages, losses, actions and suits ("**Claims**") for Personal injury or death arising out of, or in connection with the applicable Study. This includes medical management and financial compensation as may be required by Applicable Law.

11.2 Notwithstanding its obligations to the Subjects as defined per Applicable Law, Company's indemnification obligations towards the Indemnitees are contingent upon the following conditions:

(i) Site conducted the Study in accordance with, and otherwise complied with, this Agreement and Applicable Laws and such Claims do not arise out of or in connection with any of Site Indemnitees' failure to comply with the same;

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(ii) Such Claims do not arise out of the negligence or willful misconduct of any of the Site Indemnitees, or any other person on the Site Indemnitees' property who is not a Company employee;

(iii) Site timely provides written notice to Company of Claims such that Company is in no way prejudiced;

(iv) Site Indemnitees fully cooperate with Company and its legal representatives in the investigation and defense of Claims; and

(v) Company has sole control over the defense and settlement of Claims and Site Indemnitees do not settle or compromise Claims without Company's prior written consent (which consent shall not be unreasonably withheld).

11.3 Company's Indemnification Obligations. If Company is obligated pursuant to the terms of this Agreement to provide indemnity, Company shall do so diligently. Company shall not admit fault on behalf of any one or more of the Site Indemnitees without the relevant Site Indemnitees' written permission, such permission shall not be unreasonably withheld, conditioned, or delayed. Without limiting the Company's right to have sole control over the defense and settlement of Claims, Site Indemnitees shall have the right to retain separate legal counsel and representation at Site Indemnitees' sole cost.

11.4 Site's Insurance. Site shall maintain a policy or program of insurance at levels sufficient to support its obligations assumed under this Agreement and as required by Applicable Law, evidence of which shall be provided to Company upon written request, and Site shall provide prompt notice to Company of any cancellation in its coverage.

12. WAIVER OF CONSEQUENTIAL DAMAGES

12.1 IN NO CIRCUMSTANCES SHALL ANY PARTY BE LIABLE TO ANY OTHER PARTY IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR BREACH OF STATUTORY DUTY) OR OTHERWISE HOWSOEVER ARISING OR WHATEVER THE CAUSE THEREOF, FOR ANY LOSS OF PROFIT, BUSINESS, REPUTATION, CONTRACTS, REVENUES OR ANTICIPATED SAVINGS, OR FOR ANY OTHER SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGE OF ANY NATURE, WHICH ARISES DIRECTLY OR INDIRECTLY FROM ANY BREACH OF THIS AGREEMENT ON THE PART OF ANY OTHER PARTY. NOTHING IN THIS SECTION SHALL OPERATE SO AS TO RESTRICT OR EXCLUDE THE LIABILITY OF ANY PARTY IN RELATION TO DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OR INTENTIONAL MISCONDUCT OF SAID PARTY OR TO RESTRICT OR EXCLUDE ANY OTHER LIABILITY OF ANY PARTY THAT CANNOT BE SO RESTRICTED OR EXCLUDED BY APPLICABLE LAW.

13. SUBJECT INJURY

13.1 Subject Injury. In the event that a Subject suffers personal injury or death as a consequence of participation in the Study, Company shall bear such responsibilities as may apply to Company under Applicable Law. This does not prevent Company from filing an action against the Site or Site Representatives in case the adverse reactions described above are the result of the negligence or misconduct of the Investigator or any of the Site Representatives. Company does not authorize Site to offer compensation on behalf of Company, or to bind Company to any indemnity obligations in favor of any Subjects.

14. TERM AND TERMINATION

14.1 Effective Date. "**Effective Date**" shall be defined in each Order and such definition shall apply only to that Order.

14.2 Company's Right to Terminate. Company shall have the right, at any time, to suspend or terminate an Order, with or without cause and in whole or in part, by issuing a thirty (30) calendar day written notice to Site specifying the date and extent of termination. In the event of such termination, Site shall be entitled to compensation in accordance with the terms of the applicable Order up to the date of termination.

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Company shall also have the right to terminate immediately if it is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.3 Site's Right to Terminate. Site shall have the right to terminate any Order (i) if a principal investigator is identified in an Order and such principal investigator is unable to perform its obligations thereunder and a successor acceptable to Company is not available; (ii) if Company is in breach of any of its obligations hereunder and has failed to remedy such breach where it is capable of remedy within thirty (30) calendar days of a written notice from Site specifying the breach and requiring its remedy; or (iii) if Site is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.4 Obligations Upon Termination. Immediately upon receipt of notice of termination, Site shall stop enrolling Subjects into the relevant Study(ies) and shall cease conducting procedures on Subjects already enrolled in such Study(ies) as directed by Company, to the extent medically permissible and appropriate. Site shall return to Company within 30 calendar days of the effective date of termination any funds not expended or irrevocably obligated by Site prior to the effective date of the termination. Additionally, within 30 calendar days of the effective date of the termination, Site shall submit to Company a final invoice identifying any amounts Company may owe relative to the terminated Study(ies) and pursuant to the terms of this Agreement. Upon termination, Site shall, in accordance with Company's instructions, (i) preserve any data relating to the Study; (ii) turn over such data; and (iii) furnish Company an acceptable investigator's report for the Study.

15. MISCELLANEOUS

15.1 Amendments. Except as otherwise expressly provided herein, the terms of this Agreement may be amended only by the mutual written consent of the parties.

15.2 Use of Names. Company and Site shall not use each other's names (including the names of the other party's subsidiaries or parent, (if any)), symbols or marks, or any derivatives thereof in any form of publicity without the prior written consent of the owning party or parties, except that, without prior written consent of Site, Company may disclose on publicly-accessible clinical trial registries or through a Company-operated call center the general geographic location of Site (e.g., city, state, and/or country) and contact information of any party to this Agreement. In addition, and without prior written consent of Site, Company may identify the existence of this Agreement and/or, the name, and/or contact information of any party to this Agreement as required by applicable law. In addition, and without prior written consent of either party, Company and Site may disclose the other party's name in connection with publications hereunder.

15.3 Entire Agreement. This Agreement, any Order, and any amendments or Changes thereto, shall constitute the entire agreement between the parties hereto regarding the subject matter hereof and sets forth the entire terms and conditions under which this Agreement will be performed. There are no other agreements, oral or written, between the parties with respect to the subject matter of this Agreement, and all oral and written correspondence regarding the subject matter hereof is superseded by this Agreement. In the event of any inconsistency between this Agreement and any Order and the Protocol, if applicable, the terms of this Agreement shall govern, except as otherwise expressly agreed upon by the parties in a specific Order.

15.4 Counterparts. This Agreement and any Order, and any amendments or Changes may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on all parties notwithstanding that each of the parties may have signed different counterparts. Facsimiles or scanned copies of signatures or electronic images of signatures shall be considered original signatures unless prohibited by Applicable Law.

15.5 Severability. In the event any provision of this Agreement conflicts with the law under which this Agreement is to be construed or if any such provision is held illegal, invalid, or unenforceable, in whole or in part, by a competent authority, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with Applicable Laws. The legality, validity, and enforceability of the remaining provisions shall not be affected thereby, and shall remain in full force and effect.

15.6 Assignment and Sub-contracting. Neither the rights nor the obligations of Site under this Agreement may be assigned, transferred or otherwise disposed of, in whole or in part without the prior

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written consent of Company. In the event Company consents in writing to Site's use of a subcontractor or affiliate in the performance of Site's obligations hereunder, Site shall remain responsible for the proper performance of such Study, in accordance with this Agreement.

15.7 Waiver. No action or inaction by either party shall be construed as a waiver of such party's rights under this Agreement or as provided by Applicable Law. Except as expressly provided for in the Change Section, no other term of this Agreement may be waived except by an express notice in writing signed by the waiving party. The failure or delay of a party in enforcing any of its rights under this Agreement shall not be deemed a continuing waiver of such right. The waiver of one breach hereunder shall not constitute the waiver of any other or subsequent breach.

15.8 Equitable Relief. Each party understands and agrees that money damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching party shall be entitled to seek specific performance, injunctive, and other equitable relief as a remedy for any such breach. Such remedy shall not be deemed to be the exclusive remedy for breach of this Agreement but shall be in addition to any and all other remedies available at law or in equity.

15.9 Contractual Relationship. Site is engaged in an independent activity and not as an agent, employee, partner, or joint employer of Company. If applicable, Site represents and warrants that it is an employer subject to, and shall comply with, all Applicable Laws. Site shall be responsible for Site Representatives' and subcontractors' acts, errors, omissions, and conduct. Site acknowledges and agrees that Company shall have no responsibility or liability for treating Site Representatives as employees of Company for any purpose. Neither Site nor any Site Representative shall be eligible for coverage or to receive any benefit under any Company provided workers' compensation, employee plans or programs or employee compensation, bonus, incentives, retirement or other arrangements.

15.10 Governing Law. This Agreement shall be governed by the laws of the country where the services are performed, excluding conflict of law rules.

15.11 Survival. The parties' rights and obligations under any provisions set forth in this Agreement related to ownership of Intellectual Property, confidentiality, publications, use of names, Applicable Laws, governing law, Materials, subject injury, privacy, indemnification, and insurance, or which contemplate performance or observance subsequent to termination or expiration of this Agreement issued hereunder shall survive such expiration or termination.

15.12 Cooperation with Company Representatives. Site has been advised that, under separate agreements, Company may retain others (including without limitation contract research organizations) to perform certain services in connection with a Study. Site shall cooperate with, and to the extent appropriate, coordinate its performance hereunder with the services of such others so as to ensure successful completion of the Study.

15.13 Language. The official language of this Agreement is the English language. Should a party translate this Agreement into another language and a conflict in interpretation occur between versions, the original official language version shall prevail.

15.14 Notice. Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is: (i) delivered by hand; (ii) received by registered or certified mail, postage prepaid, return receipt requested; (iii) confirmed as received if by facsimile; or (iv) received by nationally recognized, overnight courier, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

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Executive Registrar
SGPGIMS,Lucknow

If to Company:

Amgen Technology Private Limited
Dynasty Business Park, 'A' Wing Level 4
Andheri-Kurla Road, Andheri (East)
Mumbai, India 400059

If to Site:

Sanjay Gandhi Post Graduate Institute
Rae Bareli Road
Lucknow, Uttar Pradesh-226014
India

With a Copy to:

International Legal Group
Amgen (Europe) GmbH
Dammstrasse 23
6301 Zug
Switzerland
Fax Number: +41 41 369 0411

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb '19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rakesh Kahoor
(print or type name)

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences INDIA

Title:

Date: 14.02.2019

05/03/2019
Dr. Amit Gupta
Professor & Head
Department of Nephrology
S.G.P.G.I.M.S., Lucknow

Amgen Technology Pvt. Ltd. Mumbai

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Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Institution**"); and Dr. Amit Gupta, Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 285105) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Agreement shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20150238 entitled "A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double-dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for

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participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within 5 business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within 5 business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: AMG 416 ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will supply the Site with the Required Material(s). The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

3.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

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4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study (**"Required Equipment"**): Laptop, AV Camera. Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop, AV Camera.

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop, AV Camera.

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Director, SGPGIMS Research Scheme Account Lucknow **"Payee"**
Tax ID	AAAJS3913N

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

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7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all

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cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb' 19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rukesh Kapoor
(print or type name)

Title:

Date: 14.02.2019

DR. AMIT GUPTA

(signature) 01/03/2019

By: AMIT GUPTA
(print or type name)

Title:

Date: 01/03/2019

Dr. Amit Gupta
Professor & Head
Department of Biochemistry
S.G.P.G.I.M.S., Lucknow

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Executive Registrar
SGPGIMS,Lucknow

Protocol Number	20150238
Site Number	30006
Investigator	Dr. Amit Gupta
Contract Number	
Maximum number of Subjects	10
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 4,86,390	10	Subject(s)	INR 48,63,900
SCREEN FAILURES	INR 12,005	1	per Subject	INR 1,20,050
ADMINISTRATIVE FEES				INR 50,000
MAXIMUM CONTRACT TOTAL*				INR 50,33,950

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs, laboratory costs. Amgen has provided thermohygrometer for temprature reading.*

SUBJECT FEES (Overheads 25%)

VISIT TABLE: STUDY	Schedule A
Screening	INR 12,005
Day 1	INR 20,690
Week 2	INR 17,160
Week 3	INR 16,700
Week 4	INR 17,620
Week 5	INR 17,300
Week 6	INR 17,160
Week 7	INR 16,700
Week 8	INR 17,160
Week 9	INR 17,300
Week 10	INR 17,160
Week 11	INR 16,700
Week 12	INR 17,550
Week 13	INR 17,300
Week 14	INR 17,160
Week 15	INR 16,700
Week 16	INR 17,160
Week 17	INR 17,300
Week 18	INR 17,160
Week 19	INR 16,700
Week 20	INR 17,160
Week 21	INR 17,300
Week 22	INR 17,160
Week 23	INR 16,700
Week 24	INR 17,160
Week 25	INR 17,300
Week 26	INR 17,160
Week 27	INR 12,915
Follow-Up	INR 12,850
Early Term	INR 13,855
SUBJECT VISIT TABLE SUBTOTAL(S)	Schedule A

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Completers, Screening to Week 27, Safety Follow-Up	INR 4,86,390
Early Termination	INR 13,855
MAXIMUM PER SUBJECT FEE	**INR 4,86,390**

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel reimbursement. Subject travel reimbursement is included at a rate of INR 900 00 per protocol required in-clinic visit

VISIT TABLE: SCREEN FAILURE	Schedule A
Screen Failure	INR 12,005
MAXIMUM SCREEN FAIL	**INR 12,005**

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
[1] Document storage/Archiving total 1	INR 0	1	per Site	INR 0
[2] Infrastructure Cost	INR 50,000	1	Total	INR 50,000
SUBTOTAL, ADMINISTRATIVE FEES				**INR 50,000**

1 Site has confirmed that archival fee is not applicable
2 Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastructure.

PAYMENT TERMS

Initial Payment	**50,000.00** *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

The EC for this study will be 'Bioethics Cee, IEC' and the payment of the EC fees will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."

2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SERVICE AGREEMENT

THIS SERVICE AGREEMENT (hereinafter as "Agreement"), executed at New Delhi on **July, 2020**, (hereinafter "the Execution Date")

By and Between,

Centre for Chronic Disease Control (CCDC), a society registered under the Indian Societies Registration Act, 1860 and having its registered office at Flat No. 70 Pocket-1, Sector-2, Dwarka, New Delhi 110075, India (hereinafter referred to as "CCDC" which expression shall unless be repugnant to context or meaning thereof shall mean and include its successors and assigns) as **First Party**;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences having its registered office at **SGPGIMS, Lucknow,** Uttar Pradesh – 226014 (hereinafter referred to as **"SGPGIMS, Lucknow"** which expression, unless repugnant to the context or meaning thereof, shall include its affiliates, successors in interest and permitted assigns) as **Second Party**.

CCDC and SGPGIMS, Lucknow are hereinafter collectively referred to as "Parties" and individually as "Party".

WHEREAS:

1. **Centre for Chronic Disease Control (CCDC)** is a registered society and is primarily intended to address the growing challenge of chronic diseases through knowledge generation, to inform policies and empower programmes for the prevention and control of chronic diseases, knowledge translation intended to operationalize research results by bridging the critical gaps between relevant research and effective implementation, through analytic work, capacity building, advocacy and development of educational resources for enhancing the empowerment of people and professionals.

2. **Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow (India)** is a University established under State Act in 1983. The institute offers its own degrees, which are duly recognized by the Medical Council of India. The Institute is rated amongst the top medical institutions in the country, delivering state-of-art tertiary medical care, super-specialty teaching, training and research. Dedicated faculty members endeavor to provide quality education, patient care and research and strive to meet the challenges and needs of the society. The Institute offers DM, M.Ch, MD, PhD, Post-Doctoral Fellowships (PDF) and Post-Doctoral Certificate Courses (PDCC), and Senior Residency in various specialties. The peers in the field have recognized the courses offered by the Institute and the candidates obtaining degrees from SGPGIMS have been highly placed both within the country and abroad.

3. **Purpose of entering into this MoU: CCDC, New Delhi** and **SGPGIMS, Lucknow**, have agreed to execute the following MoU with reference to the participation of **Dr. Sudeep Kumar, Professor-Department of Cardiology, SGPGIMS- Lucknow** to serve as a Regional Faculty at Lucknow center in the **Fourth Cycle of Certificate Course in Management of Hypertension (CCMH)**.

NOW THEREFORE IT IS HEREBY AGREED BY AND AMONGST THE PARTIES AS UNDER:-

1. Background

CCDC has undertaken to offer Certificate Course in Management of Hypertension (CCMH) Cycle-IV, a joint certificate program designed, delivered and implemented by Public Health Foundation of India (PHFI), New Delhi and Centre for Chronic Disease Control (CCDC), New Delhi, in collaboration with our partners International Society of Hypertension (ISH) and British & Irish Hypertension Society (BIHS) as an eight modular course from January 2021 based upon the funding from International Society of Hypertension (ISH).

The key features of the course are highlighted below:

1. The purpose of this said course is to train primary care physicians in prevention, care and management of hypertension with ultimate objective to improve patient outcomes.

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2. The said course is designed to enhance skills and competencies of primary care physicians in prevention, care and management of hypertension. The course will run as an intensive one-day dialectic lectures with eminent Cardiologists/Medicine Specialist as Regional Faculty, once a month for eight months covering eight modules on different aspects of hypertension. The program includes case based learning and group discussions on current issues in hypertension diagnosis, care, screening, management and prevention will be the focus of this said course.

3. Upon completion of the day long workshops through the said course, the participants will maintain contact with the Regional Faculty, so that the learning and discussion continue, lessons learned can be shared and best practices can be emulated.

4. The Certificate Course in Management of hypertension was conceptualized & launched its first cycle on 24th July 2016 as a 10 modular course (July 2016-April 2017) at 25 regional centres' (covering 21 cities in 13 states and 01 Union Territory) across India. The course was endorsed by 11 National Experts, 25 Regional Faculty and 28 Observers and have witnessed an enrollment of 612 participants. The class ratio is 1:15 with 1 Regional Faculty (Cardiologist / Medicine Specialist) for 15 participants.

5. The second cycle of the course was launched on 22nd October 2017 all across India as 10 modular course (Oct 2017 – July 2018) at 40 regional centres (covering 36 cities, 17 states and 01 Union Territory) across India and have witnessed an enrollment of 658 participants.

6. Cycle III of program was launched in 10 regional training centres with 10 participating faculty on 26th May 2019 as 8 modular course(May 2019 – Dec 2019) at 10 regional centre (covering 9 cities, 6 states and 1 UT) across India and had witnessed an enrollment of 615 participants.

7. CCMH cycle-IV will be launched in 10 regional training centres & 1 online centre (for all the participants who are from other cities) with 11 participating Faculty. Each center will enrol minimum 15 participants per centre. Thus, approximately 165 Primary Care Physicians are proposed to be trained in this fourth cycle starting January 2021 to August 2021.

2. Course – Objectives

Primary objective

- To enhance knowledge, skills and core competencies of practicing Primary Care Physicians in management of Hypertension.

Secondary objectives

- To develop a standard teaching protocol and module for evidence based learning on Hypertension.
- To build a network of Primary Care Physicians and specialists in the field of Hypertension.
- To update practicing/primary care physicians with the latest advancements in the field of Hypertension.

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3. Terms of Reference

Dr. Sudeep Kumar (from SGPGIMS- Lucknow) deliverables during the MoU:

On behalf of **SGPGIMS, Lucknow, Dr. Sudeep Kumar** will be responsible for completing below mentioned responsibilities:

3.1 Signing of this Agreement and successfully conducting and completing the first four course modules by **30th April, 2021.**

3.2 Successfully conducting & completing last four modules and exit exam by **31st August, 2021.**

Dr. Sudeep Kumar is required to share interim milestones regarding these deliverables regularly with CCDC, as per the project plan.

4. Period of Service Agreement

The Agreement shall be effective for a period starting from **July 2020 to August 2021**. It may be further extended for such period and on such terms and conditions as may be mutually agreed upon between both the parties.

5. Terms of Payment

CCDC will pay SGPGIMS, Lucknow a total amount of **Rs.60,000/-** for the entire duration of the Agreement as per the schedule detailed below in this section.

- The GST will be inclusive in the amount mentioned above. In case GST tax is applicable to you, please provide CCDC with your GST registration certificate.
- The amount mentioned above is also subject to TDS deduction as per prevailing Indian Income Tax Act and rules.
- Schedule of payment of the consultancy will be as follows:

  1. **50%** of the amount i.e. **Rs. 30,000/-** shall be payable upon satisfactory completion of the deliverable as mentioned in Clause 3.1.

  2. Remaining **50%** of the amount i.e. **Rs. 30,000/-** shall be payable upon satisfactory completion of the deliverable as mentioned in Clause 3.2.

- For conducting all monthly technical sessions, a fixed amount will be provided by CCDC to the regional faculty for conducting the session in a center.
- For each center, the session conduction charges will be **Rs.705/-** per participant per session (depending upon the total number of the participants registered under the respective center). This amount will be applicable for deduction of 1% TDS as per prevailing Income Tax Rules and provisions. On this payment TDS will be applicable as per prevailing Income Tax rates in India, as the case may be.

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- Four months advance payments for conducting technical sessions will be transferred electronically by CCDC to the specified bank account of the Regional Faculty one week prior to the conduction of the first module. The subsequent instalment for the conduction of sessions for the next four months (and the remaining two months) will be released after receiving the internal assessment sheet of all previous modules.
- The deliverables will be approved for suitability by the Project Leader at CCDC, whose opinion shall be final and binding. The payments will be released within the shortest possible time after receiving relevant invoices and documents and the PI's approval.
- CCDC may reimburse up to ₹ **20,000/-** on progressive basis towards office and other expenses of the Regional Faculty, subject to receipt of separate invoice.

6. Termination

6.1 CCDC shall have the sole right to terminate this Agreement with **SGPGIMS, Lucknow/Dr. Sudeep Kumar** without assigning any reasons thereof.

6.2 At the receipt of notice of termination from CCDC, **SGPGIMS, Lucknow/Dr. Sudeep Kumar** shall be liable to stop all the work immediately and shall not raise any invoice for the termination notice period.

6.3 Termination shall become effective in Fifteen (15) working days after receipt of written notice from CCDC.

7. Representation and Warranties

7.1 **SGPGIMS, Lucknow/Dr. Sudeep Kumar** has full legal capacity to enter into this Agreement and that there are no existing facts and/ or circumstances and/or contractual obligations with third parties and/or legal proceedings which prohibit and/or impair its capacity to enter into this Agreement;

7.2 **SGPGIMS, Lucknow/Dr. Sudeep Kumar** has the requisite capacity to fulfill all its obligations and activities under this Agreement;

7.3 **SGPGIMS, Lucknow/Dr. Sudeep Kumar** of its representatives shall not directly or indirectly infringe the Intellectual Property Rights of CCDC or disclose any confidential information or do anything which shall have material adverse impact on the goodwill and repute of CCDC.

8. Indemnity

SGPGIMS, Lucknow/Dr. Sudeep Kumar agrees to indemnify, keep indemnified and hold harmless CCDC against all claims, demands, damages, losses, expenses, suits or proceedings made against, incurred or suffered in connection with the performance of the Agreement, resulting from or arising out of (whether or not involving a third party claim) of any of its representations and warranties, covenants, and undertaking under this Agreement.

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SGPGIMS,Lucknow

9. Partial Invalidity

If any provision of this Agreement is declared by any judicial or any competent authority to be void, voidable, illegal or otherwise unenforceable, the Parties shall replace that provision with a provision which is valid and enforceable and most nearly gives effect to the original intent of unenforceable provision and the remaining provision of this Agreement shall remain in full force and effect.

10. Notices

All notices and other communication under this Agreement shall be in writing and in English and either delivered by hand or send by registered mail or courier by email or by facsimile telex or fax in each case in the name of the representatives given below at Clause 16 and at the addresses set out at the beginning of this Agreement.

11. Assignment

SGPGIMS, Lucknow/Dr. Sudeep Kumar shall not assign and/ or transfer any of their rights or interest or benefits under this agreement without the prior written consent of CCD.

12. Jurisdiction

This Agreement shall be governed by, and constructed in accordance with the laws of India. Further, the Parties agree that the competent courts at Delhi shall have jurisdiction on all matters relating to this Agreement including for grant of injunctive relief and enforcement of arbitral awards.

13. Resolution of Disputes

- In the event of any dispute relating to the interpretation or performance of this Agreement arising between the Parties, both Parties will first do their utmost to settle their dispute amicably.

- In the case of failure to resolve the dispute, all such disputes shall be referred to arbitration under the Arbitration and Conciliation ACT, 1996 (or an amendments thereof).

- The parties shall appoint its own arbitrators and the two arbitrators shall I turn appoint the third arbitrator, who shall preside over the arbitration. The place of such arbitration shall be New Delhi. The language of arbitration shall be English only.

- Awards relating to any dispute shall be final and binding on the Parties to such dispute as from the date they are made. The arbitrator shall give a reasoned decision or award. The Parties agree and undertake to carry out any decision or ward of the arbitrator relating to such dispute without delay. The Parties further agree that there will be no appeal to any court of law or other judicial authority.

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Executive Registrar
SGPGIMS,Lucknow

14. Copyright and other Intellectual property rights.

14.1 All documents received by Dr. Sudeep Kumar on behalf of SGPGIMS Lucknow under this MoU shall be CCDC's sole property and shall be treated as confidential and shall be delivered only to the CCDC authorized representatives on completion of work under this MoU. Dr. Kumar shall not communicate at any time to any other person, Government or authority external to CCDC any information known to him by reason of his association under this MoU, which has not been made public, except by authorization of CCDC; nor shall he use such information to his private advantage. These obligations do not lapse upon termination of its MoU with CCDC.

14.2 CCDC shall, solely and exclusively, own all rights in and to any work created by Dr. Sudeep Kumar on behalf of SGPGIMS, Lucknow within the scope of this MoU. Dr. Sudeep Kumar will require prior written approval from CCDC before reproducing, distributing or using this work. Dr. Sudeep Kumar shall not use any drafts, data, questionnaires, and extracts in any form after the completion of this project. For obtaining such permission a written request shall be placed to the First party and the same shall be approved or rejected within a due time period of 7 working days. The request should not be denied merely on frivolous grounds and the objective of such request should be given due importance.

As a Regional Faculty, Dr. Sudeep Kumar is responsible to keep CCDC well informed of any other separate activities, undertaken in any circumstances, existing right from time of signing of MoU or arising at any time during the term. In the event of a conflict of interest, you will inform CCDC and CCDC shall decide the future course regarding the execution of the activities agreed upon in this MoU, based on mutual consultation.

15. Other Terms & Conditions

15.1 This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof and may not be modified or amended except in a written agreement signed by both Parties.

15.2 Nothing contained in this Agreement shall constitute or be deemed to constitute a partnership between the Parties, and no Party shall hold himself out as an agent for the other Party or any of them, except with the express prior written consent of the other Parties. The rights, duties, obligations and liabilities of CCDC on one hand and of Dr. Sudeep Kumar on behalf of SGPGIMS, Lucknow on the other hand, under this Agreement shall be individual, not joint or collective, unless specifically provided for herein this Agreement.

15.3 Any amendment or change regarding this agreement shall be done in writing only if both the party mutually agrees for the same.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

16. Representatives for the Purposes of this Agreement

16.1 CCDC's representative for the purposes of this Agreement is.

Prof. D Prabhakaran – CCDC

16.2 SGPGIMS, Lucknow representative for the purpose of this Agreement is:

Dr. Sudeep Kumar-SGPGIMS, Lucknow

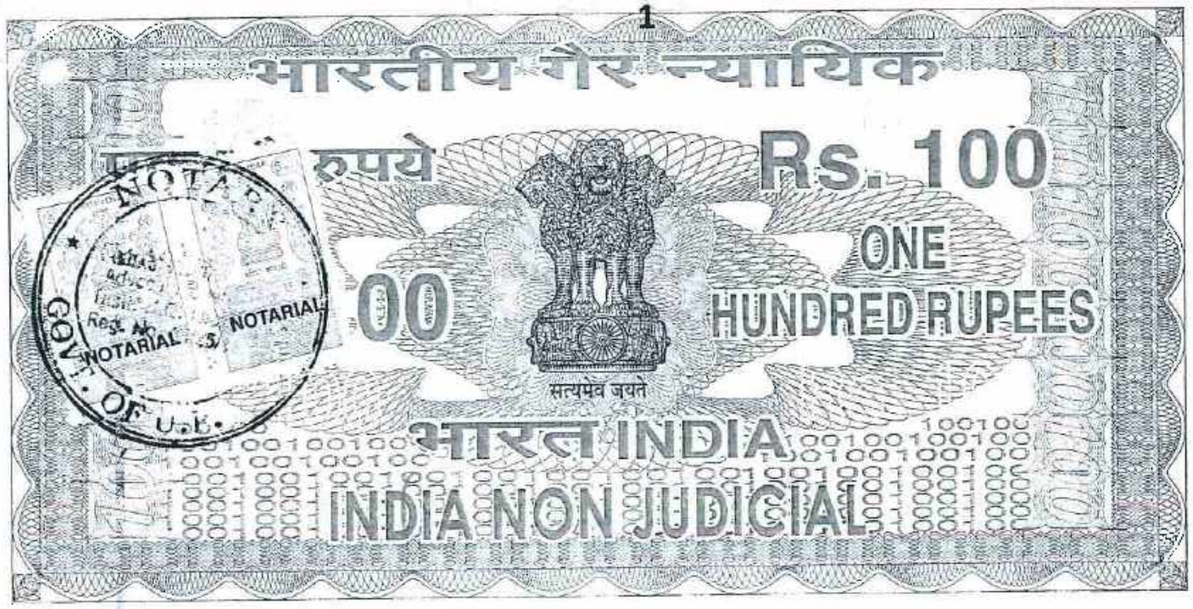
17. Miscellaneous

This MoU may be executed by the parties in two (2) separate counterparts each of which when so executed and delivered shall be original, but both of such counterparts shall together constitute one and the same instruments. All the Annexures, if any, in the MoU shall form a part of it.

The undersigned, being duly authorized thereto, have signed this MoU in two original copies in English at the place and on the date(s) indicated below:

For CCDC **Name:** Mr. Alex J **Designation:** Assistant Director, Finance **Authorized Signatory** **Date: 02-Sep-2020**	**For SGPGIMS- Lucknow** ame: Prof. R. K. DHIMAN esignation: Director Authorized Signatory Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA Date: 05/01/2021
Name: Prof D. Prabhakaran **Designation:** Executive Director - CCDC **Date:14-Sep-20**	**Name:** Dr. Sudeep Kumar **Designation:** Professor, Department of Cardiology, SGPGIMS, Lucknow **Date:** 22/Dec/2020

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



उत्तर प्रदेश UTTAR PRADESH

FA 104737

MEMORANDUM OF UNDERSTANDING

BETWEEN

ARMED FORCES MEDICAL SERVICES
MINISTRY OF DEFENCE, CHURCH ROAD, NEW DELHI, 110001.

AND

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCESRAEBARELI ROAD, HABIT MAU MAWAIYA, LUCKNOW UTTAR PRADESH.226014.

REGARDING

COLLABORATIVE RESEARCH AND TRAINING

[04 OCTOBER-2019]

Chandrika Pd. Mishra
Adv & Notary
HQ Collectorate
Lucknow U P INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This MoU is made and entered into on this [04th] day of [October] of [2019] between the Armed Forces Medical Services, a tri-service (Army, Navy and Air Force) defence organization, under Ministry of Defence, Government of India with its Headquarters at M Block, Church Road, New Delhi, 110001.

and

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Haibat Mau Mawaiya, Lucknow, Uttar Pradesh 226014, a University established under State Act in 1983. This MOU sets down the mutually agreed broad framework for joint research and academic activities in various fields of interest. It also incorporates the modalities for collaboration.

1. **Preamble.**

(a) Armed Forces Medical Services (AFMS) is a premier tri-service (Army, Navy and Air Force) organization having multiple hospitals with specialized medical/paramedical staff and facilities for patient care, training and research activities.

(b) Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow has the status of a State University. The institute offers its own degrees which are duly recognized by the Medical Council of India. The Institute is rated amongst the top medical institutions in the country, delivering state-of-art tertiary medical care, super-specialty teaching, training and research. Institute has the status of a State University and has the mandate to provide postgraduate teaching, training and to conduct research in the relevant disciplines of modern medicine and other allied sciences, including interdisciplinary fields of physical and biological sciences.

(c) The activities of AFMS and SGPGIMS, Lucknow are in several ways complementary. It is therefore felt that initiating collaborative research programs will be of considerable mutual benefit.

2. **Purpose.**

AFMS and SGPGIMS, Lucknow desire to implement, in the areas of mutual interest, cooperative and collaborative activities, which will address multidisciplinary scientific, technological and educational problems of relevance to the country.

Chandra Kant Prasad Mishra
Adv & Notary
HQ Collectorate
Lucknow (U.P.) INDIA
Regd. No. 23/98

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

3. Scope of Cooperation.

The following areas of cooperation have been identified under this agreement.
(a) **Faculty Exchange Programme.** The two parties will explore opportunities for interaction among members of faculty between SGPGIMS, Lucknow and AFMS institutions as well as creating Visiting/Adjunct Faculty positions. Each such visit will require approval of the relevant authorities.

(b) **Joint Research Projects.** The two parties will explore opportunities of undertaking joint research projects under opportunities that may be funded by Department of Health Research, Ministry of Health & Family Welfare; Department of Biotechnology, Ministry of Science & Technology; and Indian Council of Medical Research and will work together for the purpose of identifying the needs of the country in terms of research and technology and collaborate in undertaking research in identified areas relevant to the country's needs. They may also carry out joint research in technology for distance and computer-based learning.

(c) **Joint Academic Activities and Events.** AFMS and SGPGIMS, Lucknow may formulate joint academic activities such as short courses, seminars, workshops or conferences based on mutual interests and available expertise in the institutions.

(d) Financing. AFMS and SGPGIMS, Lucknow will approach the government agencies for funding the various initiatives envisaged under this MoU. The two institutions may also consider providing initiation grant or other kind of support from their own resources. In case of faculty exchange programs salaries and travel will be the responsibility of the parent institute; whereas expenses on local hospitality will be borne by the host institute. There are no further financial obligations for the contract partners as a result of this contract.

4. Legal Status.

This document is a statement of intent to foster genuine and mutually beneficial cooperation and is not legally binding on the parties. Any disputes shall be resolved through mutual discussion.

5. Validity.

This MoU is valid for an initial period of five years and becomes effective from the date it is signed by the partners. The partnership period may be extended by mutual consent. In case one partner wishes to terminate in writing the MoU, intimation will have to be sent at least six months in advance. However, specific

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Executive Registrar
SGPGIMS,Lucknow

Commitments made prior to such intimation shall be honored by both the partners.

In witness whereof undersigned, duly authorized thereto, have signed this MOU on this day 04 Oct-2019

Lt Gen Bipin Puri, PVSM, VSM, **PHS Director General** **Armed Forces Medical Services** **Date:** 05/K/19 **[OFFICIAL SEAL]**	**Professor Rakesh Kapoor** **Director** **Sanjay Gandhi Post Graduate Institute** **of Medical Sciences, Lucknow** **Date:** 5/10/19 **[OFFICIAL SEAL]**

Witness
① (A Khan) Lt Col
②

Witness
①
②

SIGNATURE & T.I. ATTESTED
Advocate & Notary
H.C. Collectorate
Lucknow U.P. INDIA
Reg. No. 3162/1999

Identify the deponent/Executant/Surety who has/have signed/Put T.I. before me.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

EN 099333

Agreement between SGPGI , Lucknow and NTPC NRHQ, Lucknow for implementing Telemedicine Network by SGPGI at two stations of NR-NTPC as a deposit work

This Agreement for deposit work (hereinafter referred to as Agreement) between Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh (hereinafter referred to as "SGPGI") and NTPC Limited, a company incorporated under companies Act, 1956, having its corporate office at Core 7, Institutional at Area, Lodhi Road, New Delhi-110001 hereinafter referred to as "NTPC".

1. **Preamble :**

1.1. Whereas SGPGI is a super- specialty hospital, established by the Govt. of Uttar Pradesh under State Act in 1983 as a center of excellence for providing tertiary care, education and research of high order and is chartered to function as university under the States of Uttaranchal, MP, Bihar, Orissa, West Bengal and Chhattisgarh. It is involved in development of telemedicine technology and gained necessary expertise to implement it instate health system. This technology will facilitate delivery of specialist health care, follow up and education at a distance with the help of modern information and Tele-communication technology.

1.2. Whereas NTPC a MAHARATNA, a Government of India Enterprise under its employee welfare Scheme, intends to use the potential of telemedicine technology to enable access to specialty health consultation for the employees of NTPC's projects located in Northern Region and Tele-CME for medical and paramedical professionals of the said hospitals of the projects

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Executive Registrar
SGPGIMS,Lucknow

by supporting setting up of a Telemedicine network between SGPGI and NTPC Northern Region projects.

1.3. Whereas NTPC hasunderstood the technology and accepted the project offered by SGPGI and intends to adopt the telemedicine technology to improve it's healthcare system in the Northern Region consisting of projects located at Rihand, Singrauli, Vindhyachal, Tanda, Unchahar, Auraiya and Meja.

1.4. Whereas, SGPGI Lucknow, and NTPC are willing to jointly participate in setting up the Telemedicine Network. It will start as a pilot project by setting up telemedicine at NTPC Hospital, at Rihand and Meja by connecting it with SGPGI through a Fiber backbone and network to be decided by SGPGI.

1.5. Whereas, the Chief Coordinator of the project will be Prof. S.K. Mishra, Professor & Head, Department of Endocrine Surgery and Nodal Officer, Telemedicine, SGPGI, Lucknow who will work under the supervision of the Director, SGPGI and GM(HR) NR, NTPC, will be the Coordinator of the project from NTPC side .

2. Scope of the Agreement:

This Agreement will cover the joint effort of SGPGI, and NTPC.

3. Responsibilities of SGPGI

3.1. **Pre-implementation Services:**

a) The scope of consulting service includes carrying out detailed study & evaluation of the proposed project site, as per requirement of the project and delivering plans, design documents and recommendations for setting up the proposed network including technical specification of the hardware, software, diagnostic equipment to be inter phased with Telemedicine system, tele-communication medium and its technical specifications in consultation with it's technical partners.

b) Site evaluation Teams from SGPGI and NTPC will visit the project sites to survey it and assess the site's preparedness, based on the following factors – Physical structure, civil, Engineering, Interiors Furniture & Fixtures, Accessibility, Local disease trends and Local medical expertise. The team will prepare a 'Site Evaluation Report' incorporating their observations.

c) Preparation of the Project Proposal and submission to appropriate authorities.

3.2. **Implementation of Methodology**

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Executive Registrar
SGPGIMS,Lucknow

(37)

a) The Telemedicine Centre will be opened in first phase at Rihandand MejaHospitalsof NTPC and then depending upon the usefulness of the facility the remaining five hospitals of NR may be connected on the same or improved pattern.

b) The school of Telemedicine & Premedical Informatics (STBMI) of SGPGI will establish and run the Telemedicine centre at NTPC Rihand and Meja.

c) Telecommunication equipment will be procured through GeM / Tendering process of SGPGI. Bandwidth will be hired from BSNL. The project will be extended on turnkey basis and all the money sanctioned for their project will be transferred to STBMI, SGPGI in advance after that SGPGI will initiate the process and will procure the listed equipment within three months. The telemedicine platform will be created in phase wise manner to cover all the NTPC hospitals situated in NR.

d) Rihandand MejaHospitals of NTPC will be connected with SGPGI in first phase through BSNL networkupto minimum one mpbsbandwidth. Remaining five hospitals of NTPC NRHQ will be connected on same pattern or improved technology in phase II.

e) BSNL line to be procured for the project will be in the scope of SGPGI. After completion of project it will be surrendered or if NTPC wish to continue, the same will be handed over to NTPC.

f) STBMI will implement the project on turnkey basis, which will include
   i. Procurement and installment of Health ATM and PC
   ii. Telemedicine videoconferencing software
   iii. High resolution display unit
   iv. Cost of bandwidth
   v. A3 Transparency Scanner
   vi. Electric fittings and fixtures etc. as required
   vii. Deployment of trained Human Resources (1-Project Manager at NRC – Lucknow, 1-Technician at SGPI, 1-Technician at Rihand, 1-Technician at Meja) for running the Centre.

g) The Telemedicine equipment (Health ATM will be procured by STBMI, SGPGI- Lucknow through GeM / tendering process of SGPGI.

h) The procurement of equipment is in the scope of SGPGI. All the assets acquired out of project by SGPGI under the agreement will belong to NTPC and will be handed over formally torespected hospitals of NTPC in proper running conditions after expiry of the agreement. The operation &

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SGPGIMS,Lucknow

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maintenance of the equipment will be taken care by the SGPGI till the project / agreement period.

i) STBMI will also provide Tele-education, knowledge & skill development session and Web streaming / casting programme on different recent topic / disease trends held across the country.

j) This phase will be completed within three months of release of fund by NTPC and subject to the availability of communication link at the time of installation.

3.3. **Maintenance of hardware and software and diagnostic equipment:**

a) SGPGI in collaboration with it'stechnical partner will be responsible for providing maintenance support for telemedicine hardware, software and diagnostic equipment free of cost for one year (warranty period) and subsequently on establishment of AMC. The Service Level Agreement (SLA) to be entered into by SGPGI with its technical partner shall also be in principle vetted by NTPC.

3.4. **Providing consultation and educational services:**

a) SGPGI will provide tele-consultation and tele-follow up and tele-educational services free of cost for a period of three years after which fresh agreement has to be executed. Detailed modalities like scheduling of these services will be worked out on mutually agreed time sharing basis. SGPGI will try its best to render its services but will not be bound down with any Service Level Agreement since SGPGI is not following any revenue model for its services in this project.

b) Towards the cost of project related to manpower, travel and other incidental expenses in the budget head of "Implementation Expense" SGPGI will follow its own financial rules.

c) Preparation of Documents such as Project Evaluation Frame work, Mid-term review report and final project report.

d) SGPGI shall appoint manpower on contract basis as per established procedure for recruitments of project manpower. Therefore, no obligation lies on the NTPC during and after project agreement. Their training will also be in the scope of SGPGI.

3.5. **Services offered by STBMI, SGPGI using available infrastructure:**

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a) A telemedicine center will be established at NTPC run hospital at Rihandand Mejawithin three months. The date of installation will be counted from date of money received at STBM, SGPGI Lucknow.

b) STBMI will provide Tele-follow-up services at least 2-30 sessions in a month depending upto the services sought form the Rihandand Meja hospitals.

c) Tele-education, Knowledge & skill development session at least three in a week or depending upon the demand of doctors of the Rihand&Meja hospitals it will be facilitated more.

d) Tele-CMEs session at least 5-10 session in a month

e) Web streaming / casting programme on the different recent topic/disease trends held across the country

f) Knowledge support, sharing of knowledge material like research publications, articles, journals available at STBMI domain etc.

3.6. **Project Beneficiary :**

a) Tele-follow-up services to the patient who have taken treatment of SGPGI, Lucknow. Patient need not to come to SGPGI for follow up.

b) Second Opinion for making diagnosis: Patients who live in the campus of NTPC & surrounding hilly & rural area or far from hospital would be given a second opinion.

c) In addition, severely & complicated patients can be managed locally and access to medical specialist accessed by SGPGI doctors, hence the system may provide fast response to critical medical care in spite of geographic barriers.

d) Local hospitals usually do not have enough medical expert and nursing staff who are able to manage seriously ill patient. By using these technologies, this kind of problems may be alleviated.

e) Doctor & paramedical staff involved in the process will have the opportunity to learn and update the knowledge & skill in terms of getting expert opinion from the super specialist doctors from SGPGI and other premier tertiary level hospital.

4. Responsibility of NRHQ and Payment Terms

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SGPGIMS,Lucknow

4.1. Total sum of Rs. 33,70,000/ (Rs. Thirty Three lacks seventy thousand only) details of which are annexed as annexure I to this Agreementwill be released to SGPGI within a period of 15days from the date of signing of thisAgreement.

4.2. For the second year annual running cost of Rs. 16,20,000 (Rs. sixteen lakhs twenty thousand only) shall be released to SGPGI within 15 days of start of second year ofAgreement and subject to submission of utilization certificate by SGPGI for utilization of Rs. 33,70,000/-

4.3. For the third year annual running cost of Rs. 17,51,800 (Rs. Seventeen lakhs fifty one thousand eight hundred only) shall be released to SGPGI within 15 days of start of third year of Agreement and subject to submission of utilization certificate by SGPGI for utilization of Rs. 16,20,000/-

4.4. NTPC shall be responsible for payment of Rs. 67,41,800/- (Rs 33,70,000/- + Rs.16,20,000/= + Rs.17,51,800/-) during the period of the Agreement.

4.5. In case any benefits occur to SGPGI on account of execution of agreement, the same will be passed to NTPC. Even if some budget is left in any sub head, the same will be intimated to NTPC as per the rule of SGPGI. In case of excess expenditure is to be made in any subhead, the approval of the funding agency i.e. NTPC will be sought thereafter the account section of the SGPGI can book the expenditure. Audited annual Utilization Certificate (UC) head wise will be furnished to NTPC.

4.6. As per the SGPGI procedure,the SGPGI cannot move any file for approval / procurement unless the amount, as per payment terms, is transferred into their account. Therefore, the fund towards fixed cost as well annual recurring cost will be transferred to SGPGI on annual basis in advance under this Agreement.

5. Monitoring of activities

5.1. There shall be a "standing monitoring committee" with representatives from SGPGI & NTPC to monitor on quarterly basis the implementation of the project. The venue and date of meeting will be decided on mutual consultation basis.

6. Validity of the Agreement

6.1. This Agreement will be in force for a period of three years from the date of its execution.

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SGPGIMS,Lucknow

8. Amendments to the Agreement

8.1. Amendment, if any, during the currency period of this Agreement, shall be made by the authorized representatives of both the parties on the basis of mutual understanding.

9. Resolution of Dispute

9.1. It is specifically agreed by and between the collaboration parties that all the differences or disputes arising out of the agreement or touching the subject matter of the agreement shall be resolved through mutual consultation. If the parties fail to resolve such a dispute or difference by mutual consultation, then the dispute maybe settled through Arbitration. The matter shall be referred to sole Arbitration appointed by NTPC. Arbitration will be conducted according to provisions of Arbitration & Conciliation Act, 1996 including any statutory modifications or re-enactment thereof and the rules made there under shall apply. The seat of arbitration shall be Lucknow or any other city whichever is most economical from point of view of travel and stay.

10. TERMINATION IN CASE OF DEFAULTS:

10.1. NTPC may without prejudice to any other remedy for breach of agreement,bywrittennoticeofdefaultsentto SGPGI,terminatethe agreement in wholeorinpart:.

a) If SGPGI fails to deliver any or all of the services within the time period(s) specified in the agreement or any extension thereof granted by NTPC in writing.

b) If SGPGI fails to perform any other obligation(s)under the agreement ;or

c) If SGPGI, in either of the above circumstances, does not cure its failure within a period of thirty (30) days after receipt of the default notice from NTPC.

10.2. In the event NTPC terminate the agreement in whole or in part, pursuant to Clause 10 (a,b,c), NTPC may get the services done, upon such terms and in such manner as it deems appropriate, similar to those not rendered, and SGPGI shall be liable to NTPC for any excess costs for such similar services. However, SGPGI shall continue performance of the agreement to the extent not terminated.

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11. Seal of the Parties

11.1. In witness thereof the Parties hereto have signed this Agreement on the day, month and year mentioned hereinbefore of their free will and accord.

Parties :

Signed and delivered for and on behalf of SGPGI Lucknow

Signature

Name

Designation

Seal

Signed and delivered for and on behalf of NTPC Limited

Signature

Name Pankaj Kumar,

Designation GM (HR), NTPC, NRHq, Lucknow.

पंकज कुमार
PANKAJ KUMAR
महाप्रबन्धक (मानव संसाधन)
General Manager (HR)
एन.टी.पी.सी. लि./ उ. क्षेत्र मुख्यालय, लखनऊ
N.T.P.C. LTD./N.R.H.Q., Lucknow

Seal

Witness (Name& Address)

1. Sangeeta Nodal officer Telemedicine, SGPGI,

2. Prasanta Kumar Pandhan Member Telemedicine IGIPGIMS.

Date:

Witness (Name & Address)

1. (ANIRUDH SINGH) DGMCHRI, NRHR.

2. (Manik Jaisal) Dy Legal (dew)

Date:

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Annexure-I

Details of the projected cost for setting up Tele Medicine Centre at Rihand & Meja

A. Fixed Costs

Sl. No.	Item Description	Cost (In Rupees)	Qty	Total Cost	Remarks
1.	**Health Kiosk- Budgetary offer annexed in Annexure-I**	5,60,000 + GST	02	11,20,000	GST as pee actual
	Hardware / Software (including PC, Telemedicine, videoconferencing software etc.				
2.	High Resolution display Unit	75,000	02	1,50,000	
3.	A3 Transparency Scanner	2,50,000	02	5,00,000	
4.	Renovation, furniture electrical fittings, fixtures or any other non-electronic item	50,000	02	1,00,000	
	Total			**18,70,000**	

B. Annual recurring cost for 1st year

Sl. No.	Item Description		Yearly Cost (In Rupees)	Qty	Total Cost (In Rupees)	Remarks
1.	Bandwidth Cost (BSNL 01 Mbps Annual plan with static IP)		50,000	02	1,00,000	
2.	Human Resources					
	A.	Manager-Operation @ 40,000 per month at SGPGI, Lucknow	4,80,000	01	4,80,000	
	B.	Telemedicine Technician @ 20,000 per month (one at SGPGI, One at Rihand & one at Meja)	2,40,000	03	7,20,000	

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3.	Maintenance of equipment	50,000	02	1,00,000	
4.	Contingency expenditure (Travel, stationary &misc expenditure)	50,000	02	1,00,000	
	Total			**15,00,000 (Rs Fifteen Lakh)**	

C. Details of the Human Resources to be deployed

Sl. No.	**Designation**	**No. of Post**	**Qualification**
1.	Project Manager at NRC, SGPGI, Lucknow	01	B.E. / B. Tech. in CS / IT / E & C, Master's in IT / CS or MCA with More than five years experience in IT facility management
2.	Telemedicine Technician (one at SGPGI & One at Rihand & one at Meja)	03	Graduation & diploma in IT / CS or Diploma in Telemedicine & HIMS / Health IT
3.	TOTAL	04	

D. Annual Recurring Costs during 2nd Year

Sl. No.	**Item Description**		**Yearly Cost (In Rupees)**	**Qty**	**Total Cost (In Rupees)**	**Remarks**
1.	Bandwidth Cost (BSNL 01 Mbps Annual plan with static IP)		50,000	02	1,00,000	
2.	Human Resources					
	A.	Manager-Operation @ 44,000 per month at SGPGI, Lucknow	5,28,000	01	5,28,000	@10% increment
	B.	Telemedicine Technician @ 22,000 per month (one at SGPGI, one at Rihand & one at Meja)	2,64,000	03	7,92,000	@10% increment

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3.	Maintenance of equipment	50,000	02	1,00,000	
4.	Contingency expenditure (Travel, stationary &misc expenditure)	50,000	02	1,00,000	
	Total			**16,20,000 (Rs Sixteen Lakh Twenty Thousand Only)**	

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E. Annual Recurring Costs during 3rd Year

Sl. No.	Item Description	Yearly Estimated Value (In Rupees)	Qty	Total Cost	Remarks
1.	Bandwidth Cost (BSNL 01 Mbps Annual plan with static IP)	50,000	02	1,00,000	
2.	Human Resources				
	A. Manager-Operation @ 48,400 per month at SGPGI, Lucknow	5,80,800	01	5,80,800	@10% increment
	B. Telemedicine Technician @ 24,200 per month (one at SGPGI, one at Rihand & one at Meja)	2,90,000	03	8,71,000	@10% increment
3.	Maintenance of equipment	50,000	02	1,00,000	
4.	Contingency expenditure (Travel, stationary &misc expenditure)	50,000	02	1,00,000	
	Total			**17,51,800 (Rs Seventeen Lakh Fifty One Thousand Only)**	

Summary of the Estimated Expenditure for Rihand&Meja

Sn	Expenditure Head	Amount (Rs.)
1	Fixed Estimated Expenditure in First Year	18,70,000
2	Recurring Estimated Expenditure in First Year	15,00,000
3	Recurring Estimated Expenditure in Second Year	16,20,000
4	Recurring Estimated Expenditure in Third Year	17,51,800
5	Total Estimated Expenditure in three years	**67,41,800**

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SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

EX 984131

The National Institute of Health & Family Welfare
Munirka, New Delhi - 110067

Memorandum of Understanding (MOU) between The National Institute of Health & Family Welfare (NIHFW), Munirka, New Delhi-110067 and Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow regarding conducting training programs under "Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies " (A Project of NIHFW in collaboration with MOHFW, New Delhi)

THIS CONTRACT is entered on this day ..... 2019 by and between, **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** and **The National Institute of Health and Family Welfare** (in short NIHFW). having its principal place of office at Munirka, New Delhi, 110067 and Hereinafter, NIHFW will be called as Client and **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** as Institute.

WHEREAS, the Client wishes to have the Institute perform the services hereinafter referred to, and

WHEREAS, the Institute is willing to provide these services as under

Now, therefore, the Parties hereby agree as follows:

1. **Services**

i. The Institute shall conduct training of Senior Hospital Administrators **under "Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies"(One**

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SGPGIMS,Lucknow

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Week) belonging the States of Bihar and Jharkhand. Around 30 Senior Hospital Administrators, not below the rank of Deputy Medical Superintendents and Medical Superintendents shall be trained and at least one mentor from the NIHFW will be supervising the training program. A total of 3 training programs per annum will be conducted by the Institute from ……,2019 to ……,2020.

The participants will be identified by name, designation, qualification, experience, area of expertise, by the state as agreed mutually by the Institute and client (through **Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies** at NIHFW in collaboration with MOHFW, New Delhi).

ii. The Institute shall conduct the training as per guidelines provided by Client.

iii. The Institute shall submit to the client the report related to the training program and expenditure of the training within a month of completion of the training program, providing details of the participants and internal/ external resource persons and over-all outcome of the training.

iv. The Institute shall ensure optimum quality in the delivery of training and shall provide evidence of acquisition of new knowledge and skills by participants.

v. The Institute shall hire/provide appropriate venue to organize training/workshop as may be suggested or directed and approved by the client.

2. **Term**

The Institute shall perform the services during the period commencing from ……..2019 after signing of this MOU and continue through the agreed period up to 31st March, 2020.The design and session plan of the training as per the standardized introductory document and resource material.

3. **Payment**

A. Ceiling

For services rendered as indicated at (I) of this contract, the client shall pay an amount of Rs. 13,06,000/- (Rupees Thirteen Lakh Six Thousand only) allocated for the activities of the 6 Days Training Course and an amount of Rs. 40,650/- (Rupees Fourty Thousand Six Hundred Fifty only) allocated for institutional overhead on Senior

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Hospital Administrators for one training course. The Total amount for one Training course is Rs. 13,46,650.00. Client will pay 90 % of the total amount of Rs. 13,46,650/- (Rupees Thirteen Lakh Fourty Six Thousand Six Hundred Fifty only)at same time and remaining balance (maximum 10%) is to be paid to the Institute after submission of details of actual expenditure incurred in the training by submitting Statement of expenditure and utilization certificate.

The project staff / NIHFW officials will deal in respect of client (NIHFW) regarding payments of their TA/DA etc. separately.

The norms for incurring expenditure are placed at annexure.

B. Schedule of Payment

The payment shall be made to the Institute by bank draft /RTGS in favors of the Institute Head or his / her authorized nominee

4. **Project Administration**

A. Coordinators:

The Client shall designate Dr. Manish Chaturvedi, Nodal Officer (**Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies**), Dr J. B. Babbar, Senior Consultant (Medical), Dr. Priyanka Singh, Junior Consultant (Medical) who will be responsible for coordination of activities under this contract including preparation, facilitation of the training and other required activities.

B. The Institute shall provide necessary support for coordination of activities under this training.

C. Reports.

The Institute shall submit the report to the client related to the training program, utilization certificate and a statement of expenditure duly signed by Accounts officer and Director, nominee by Director, within one month after

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completion of the training course and not later than 31st March,2020 positively.

5. **Performance Standards** The Institute undertakes to perform the services with the highest standards of professional and ethical competence and integrity.

6. **Inspectors and Auditing** The Institute shall permit the client and/or persons or auditors, appointed by the client to inspect and/or audit its accounts and records and other documents relating to submission of the proposal to provide the services and performance of the contract. In case the Institute fails to comply with the obligations, the client shall be fully empowered to terminate the contract.

7. **Confidentiality** The Institute shall not, during the term of this contract and within two years after its expiration, disclose any proprietary or confidential information relating to the services without the prior written consent of the client.

8. **Ownership of Material** Any studies, reports or other material, graphics, software or other material prepared by the Institute for the client under the contract shall belong to and remain the property of the Client. The Institute may retain a copy of such documents and software.

9. **Assignment** The Institute shall not outsource this contract or sub-contract any portion of it without the Client's prior written consent.

10. **Law Governing Contract and Language** The Contract shall be governed by the Indian laws.

11. **Termination** The client may terminate this contract with prior written notice of at ***least ten (10) working days*** to the Institute after the occurrence of any of the events specified below:

(a) If the Institute does not remedy a failure in the performance of its obligations under the contract within ***seven (7) working days*** after being notified, or within any further period as the client may have subsequently approved in writing;

(b) If the Institute, in the judgment of the client, has committed any irregularity in performing the Contract.

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(c) If the client, in its sole discretion and for any reason whatsoever, decides to terminate this Contract.

And, whereas in order to enable **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** and NIHFW, New Delhi to effectively discharge their respective responsibilities and obligations under the MOU, the Director, NIHFW and the Director, **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** do hereby commit to put in place effective systems to deliver on the measurable outcome set out in this MoU.

The Director, NIHFW, The Director, **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** having accepted the respective responsibilities and obligations described in this memorandum and having agreed to the terms and conditions contained herein, do set their hand to this MOU on this day of the.....,2019.

( )
For the Client
Director
NIHFW, New Delhi

( )
For the Institute
Director
SGPGIMS, Lucknow

S.G.P.G.I.M.S. Lucknow (U.P.) India Director

( )
For the Client
Head, Hospital Administration
SGPGIMS, Lucknow

( )
For the Institute
Faculty In-charge, Research Cell
SGPGIMS, Lucknow

Witness:
Name-
Signatures-

Witness:
Name-
Signatures-

Lt Col Varun Bajpai **VSM**
Executive Registrar
SGPGIMS,Lucknow

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सत्यमेव जयते

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	IN-DL59354563423124S
Certificate Issued Date	:	20-Jul-2020 03:07 PM
Account Reference	:	IMPACC (IV)/ dl988103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL98810327332907933210S
Purchased by	:	JSS MEDICAL RESEARCH INDIA PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS MEDICAL RESEARCH INDIA PVT LTD
Second Party	:	SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
Stamp Duty Paid By	:	JSS MEDICAL RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

.....Please write or type below this line.....

CLINICAL TRIAL AGREEMENT
DATED 21 Jul 2020

JSS Medical Research India Pvt Ltd, Vatika Mindscapes (Tower B), Plot 12/2, Sector 27D, Faridabad- 121003 (Haryana) India **(AS THE CRO)**
AND
Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014 **(AS THE SITE/INSTITUTION)**
AND
Dr. Vikas Agarwal, Professor, Clinical Immunology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014 **(AS THE PI)**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
SGPGIMS,Lucknow

This Clinical Trial Agreement (the "**Agreement**") is dated: 21 Jul 2020.

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BETWEEN:

1. **JSS Medical Research India Private Limited.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through Dr. Renu Razdan, Vice President, India being authorized to sign this Agreement on behalf of Sponsor, Medanta Institute of Education and Research (hereinafter referred to as "**JSS India/ CRO**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

1. **Dr. Vikas Agarwal,** working as **Professor** at **Clinical Immunology & Rheumatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014** (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   OR

2. **Sanjay Gandhi Postgraduate Institute of Medical Sciences,**, a [*hospital*] registered under the provisions of [Indian Companies Act, 1956 OR any other relevant law], having its registered office at **Raebareli Road, Lucknow, Uttar Pradesh 226014** , Dr. R K Dhiman, Director of SGPGIMS being authorized to sign this Agreement (hereinafter referred to as the "**Site**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. JSS India is a CRO and is in the business of providing Clinical Trial Site Management Services, Clinical Trial Monitoring Services and Clinical Data Management Services and certain other services related to any clinical study including site and principal investigator identification, regulatory, pharmacy services, identification and management of other agencies related to a clinical study translation of documents.

B. Medanta Institute of Education and Research (hereinafter referred to as "**Sponsor**") has engaged JSS India as a CRO for conducting the Clinical Trial entitled "*A Multi-center, Randomized Controlled, Phase III Study to evaluate the Clinical Outcomes and Safety of Tocilizumab along with Standard of Care in Patients with Cytokine Release Syndrome associated with COVID-19 infection*".

C. The Site is engaged in [Clinical Trials] and the PI is a Professor at the Site. The PI is authorized to conduct the Clinical Trial at the Site.

D. JSS India, on behalf of the Sponsor, desires to conduct the Clinical Trial in respect of the Drug under the direction and supervision of the PI using the facilities of the Site and the PI and the Site have represented willingness to participate in the Clinical Trial.

E. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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1. Definitions and Interpretations

1.1 In this Agreement:

"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordnance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by JSS India.

"**Clinical Trial**" or "**Study**" shall mean a clinical trial entitled ***"A Multi-center, Randomized Controlled, Phase III Study to evaluate the Clinical Outcomes and Safety of Tocilizumab along with Standard of Care in Patients with Cytokine Release Syndrome associated with COVID-19 infection"*** conducted as per the approved Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from JSS India in respect of the Clinical Trial, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as JSS India may, from time to time, provide.

"**Confidential Information**" shall mean and include, but is not limited to: any and all information and documents disclosed by JSS India in relation to the Clinical Trial/ this Agreement or developed hereunder by the PI, the Site or its associated staff, whether such information is disclosed in writing, graphically, electronically or in other machine-readable format, by way of sample or specimen, or in any other format by JSS India/ Sponsor. Confidential information includes but is not limited to formulations, drug products, clinical studies, results of studies, study protocol, personal information relating to patients of a study, pricing, discounts, business proposals, specifications, operation methods, business plans, marketing information and customer information which JSS India/ Sponsor provides or discloses to the Site and PI or to any of the Site's directors, officers, employees, representatives, agents and advisors under this Agreement.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, pandemics, inclement weather or other reason or cause beyond that Party's reasonable control.

"**Dispute Notice**" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean '**Tocilizumab**' drug in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

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"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and wellbeing of all such actual and potential research participants.

"Fee" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by JSS India, or if so authorized, by JSS India in respect of the Clinical Trial as provided in Schedule B, herein.

"ICH GCP Guidelines" shall mean the International Council for Harmonisation -Good Clinical Practice issued by Helsinki Declaration in June, 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"**Indian GCP**" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research.

"**Information Brochure**" shall mean the information brochure of Sponsor relating to the Clinical Trial.

"Informed Consent Form" or **"ICF"** shall mean a written consent form provided by JSS India which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.

"**Invoice**" shall mean an invoice raised by the PI and/ or the Site in respect of the Services performed by the PI and/or the Site, in accordance with this Agreement.

"**Subject**" shall mean the patient who is enrolled in the Clinical Trial by the PI as per the Ethics Committee approved Protocol and upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"Payment Milestone" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"Protocol" shall mean Protocol No. TCZ/COVID-19/01/2020 as provided by JSS India/ Sponsor and approved by the Ethics Committee.

"Price" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'C' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"**Screen Failure**" shall mean the screen failure as defined in the Protocol.

"**Serious Adverse Event**" or an "**SAE**" includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

"Services" shall mean the services to be provided by the PI and the Site as detailed in Schedule 'A'.

"Site Indemnitee" shall mean the Site and its employees and its associated staff.

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"Sponsor Property" shall mean all data and information generated or derived by the Site/ PI arising out of any Services performed by them and/ or resulting from the conduct of the Clinical Trial or this Agreement.

"Standard Operating Procedures" or **"SOP"** shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the Sponsor/ CRO.

1.2 In this Agreement:

1.2.1 words denoting the plural number include the singular and vice versa;

references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

references to this Agreement include the Recitals and the Schedules;

the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

references to any Party include its successors, transferees and permitted assignees.

2. **Scope of the Agreement**

The Site and the PI agrees to perform the Clinical Trial for and on behalf of the JSS India/ Sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by JSS India. The Site and the PI further agrees to adhere to ICH GCP, Indian GCP and all Applicable Laws and regulations for the conduct of the Clinical Trial.

3. **Term**

3.1 This Agreement shall commence on the Effective Date and shall continue for a period of 03 (three) years from the Effective Date or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. **Clinical Trial**

4.1 Clinical Trial Initiation: JSS India shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the JSS India may terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

4.2 Duration: The estimated duration for a Clinical Trial is defined in the Protocol including follow-ups. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions from JSS India.

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4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

4.4 Biological Materials: In the event the Protocol requires collection of bodily fluids from the Study Subjects ("Biological Materials") then the PI shall obtain prior informed consent of the Subjects in this regard.

5. Responsibilities and Obligations of the Parties

5.1 JSS India shall be responsible for the following:

i. Clinical Trial Documents: Providing all the Clinical Trial Documents in advance or on time to the PI and/or the Site on behalf of Sponsor.
ii. Other Duties: Site Monitoring, Medical Monitoring, Clinical Data Management, including electronic data capture Statistical Programming, Clinical Trial supplies, contract and vendor Management, Clinical Study Report preparation & IMP logistic management.

5.2 The PI and/or the Site shall be responsible for the following:

a. The PI shall be responsible that the Clinical Trial should be conducted as per the Protocol, GCP Guidelines and Investigator's undertaking. For the tasks performed, Standard Operating procedures are to be documented.

b. PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

c. Upon request by JSS India, the PI will provide JSS India all information needed by JSS India and/or Sponsor in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

d. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest. The PI will not postpone or cause delay in reporting any such information to JSS India and/or Sponsor irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

e. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

5.3 Regulatory Agency Audit: The PI and the Site will inform JSS India and Sponsor within twenty-four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India in any such investigation, and in the implementation of appropriate action plans for such observations.

6 Representations, Warranties and Covenants.

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6.1 JSS India represents, warrants and covenants as follows:

(a) Formation/ Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of the Clinical Trial.

(d) Freedom to Use: JSS India hereby represents and warrants that Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Site represents, warrants and covenants to JSS India and Sponsor as follows:

(a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Freedom to Use: The Site hereby represents and warrants that the JSS India/ Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been

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debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The Site agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.3 The PI represents, warrants and covenants to JSS India as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.
ii. Upon JSS India request from time to time, PI will certify in writing, the PI
iii. compliance with the foregoing provisions of this paragraph.

7 Use of Name

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

8 Ownership of Intellectual Property and Study Data

Sponsor shall have sole ownership and rights to the Study Data (defined below), Clinical Trial results including any deliverables, inventions or discoveries relating to the Drug/ Clinical Trial, whether patentable or not, made in the performance of this Agreement. The PI/ Site is obliged to report any inventions or discoveries promptly to JSS India.

9 Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least twenty five (25) years, following the latest of the following dates: (a) the date on

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which a marketing application for the particular Clinical Trial Drug is approved by the appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (*any other applicable regulation*) (b) the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India / Sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India/Sponsor so elect, comprise: (a) inspection of the PI's and/ or the Site's facilities and records relating to the rendering of Services to or for a Clinical Trial; (b) review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

10 Publications

The Sponsor shall retain ownership of all original Case Report Forms, data, documents, analyses and reports that result from the Clinical Trial ("**Study Data**"). Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. Accordingly, the PI and the Site agree that they will not independently publish, publicly disclose, present or discuss any results of or information pertaining to the Clinical Trial until a multi-center manuscript is published provided however, that if a multi-center manuscript is not published within one year after completion of the Clinical Trial at all Clinical Trial sites, Site/ PI will have the right to publish the Clinical Trial results generated by the PI. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information to Sponsor and JSS India. The PI and the Site agrees to delete any information that may be confidential or proprietary.

11 Fees

11.1 Budget: The CRO/ Sponsor, PI and/or the Site shall provide an estimate of the budget to the other Parties on or before site selection. The Parties shall negotiate and agree on the Budget and the Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

11.1.1 The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the JSS India unless the PI and/or the Site have taken the prior written consent of JSS India before administration of such tests or services.

11.2 Payment of Fees and Expenses to the PI and/or the Site: The CRO- JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol, the consideration for their services will be prorated according to the actual number of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

11.2.1 Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will raise its Invoice for the Fees to the JSS India, on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

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(b) the JSS India, if so authorized, shall pay the invoiced amount within forty-five (45) business days of the date of receipt of the Invoice. The payment shall be made through crossed cheque/DD, as applicable:

PAYEE INFORMATION:

The total study budget will be paid to below payee details (after TDS deduction)

Payee details:

PAYEE NAME	Director SGPGIMS Research account
GST No.	09AAAJS39BN2ZN
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAAJS3913N
BANK NAME	SBI
BANK BRANCH & ADDRESS	SGPGI branch, Raebareli Road, Lucknow, 226014
ACCOUNT NO.	10095237491
IFSC Code	SBIN0007789

11.2.2 Taxes: Any goods and services tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the Services offered in this Agreement shall be to the PI's and/or Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

11.2.3 Final Payment: Upon completion or termination of the Study, the PI and/or the Site shall provide a written notice to JSS that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12 Insurance

a. Sponsor shall maintain appropriate and adequate insurance coverage, as per applicable regulatory guidelines, against any liability arising during the implementation of the Clinical Trial, including a clinical trial insurance during the Term of this Agreement.

b. The JSS shall deliver copies of the certificate evidencing the insurance coverage in accordance with this Clause 12 to the Site and the PI.

13 Indemnification

13.1 Indemnity: JSS India on behalf of Sponsor shall indemnify, defend and hold harmless the Site Indemnitees, against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") incurred by or imposed on the Site Indemnitees in connection with any claims, suits, actions, demands or judgments made or instituted against the Site Indemnitees to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

13.2 Exclusions from Indemnification: The JSS India obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

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(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 13 above, directly or due to a third-party claim shall give written notice to the JSS India, against whom such indemnification rights are claimed. Pursuant to Clause 13 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the JSS India/Sponsor shall not relieve the JSS India/Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the JSS India/Sponsor or its defenses. With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 13 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from Sponsor; provided, however, that: (i) the Indemnified Party shall obtain the prior written consent of the JSS India/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if (A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against Sponsor, (B) such settlement does not expressly unconditionally release the JSS India/Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or (C) involves criminal or quasi-criminal allegations against the JSS India/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim; (ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by Sponsor in connection with such claim or legal proceeding; (iii) the JSS India/Sponsor shall be entitled to participate in the defenses of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and (iv) if the Indemnified Party abandons or fails to reasonably assume the defenses of any such claim or legal proceeding, JSS India/Sponsor may assume control of the defenses of such claim or legal proceeding at its own expense; provided, however, that if the JSS India/Sponsor shall control the defenses of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified

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Party, the JSS India/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if (A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party, (B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or (C) involves criminal or quasi-criminal allegations.

13.4 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site/ PI, and JSS India as contained in the Clinical Trial Agreement.

13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of JSS India/Sponsor in relation to the Study.

13.6 The CRO on behalf of Sponsor shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug in accordance with the Applicable Laws and/ or Ethics Committee's directives, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement. The CRO shall not be liable for payments for a Subjects' lost wages.

14 **Confidentiality**

a. Confidential Information disclosed by JSS India to the Site/ PI or developed hereunder by the PI, the Site or associated staff shall remain the confidential and proprietary property of the Sponsor, and shall only be disclosed to those who have a need to know the same and shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the said information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the said information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the Study, as provided in Clause 10 above. Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this clause shall remain in force for a period of [05] years from the date of execution of this Agreement

b. Confidential Information shall not include any information which:

(i) is already in the public domain at the time of disclosure;
(ii) has been independently developed by the Institution or Investigator;
(iii) is required to be disclosed to a governmental authority pursuant to a valid court order.

c. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records including applicable privacy laws, regulations, and other standards regarding the protection of personal data.

15 **Termination**

15.1 JSS India may terminate the Agreement by written notice of at least one (1) month in advance.

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15.2 The CRO may terminate this Agreement for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or its representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India, to meet with JSS India or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI.

g. Determination by JSS India in writing that business or scientific considerations require termination.

h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India or its representatives for use in the Study, are not completed and forwarded to JSS India or its designated representative, within the timelines prescribed by JSS India.

15.3 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India. However, JSS India shall have the sole right to determine the acceptability of a new PI.

15.4 In the event that JSS India exercise its right to terminate the Study/ Agreement based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

15.5 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial, and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

16 Miscellaneous

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to JSS India JSS Medical Research India Private Limited
Vatika Mindscapes (Tower B), 6th Floor,

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Plot 12/2, Sector 27D, Faridabad-121003,
Haryana, India
Attention: Dr. Renu Razdan
Designation: Sr. Vice President, India
Telephone: +91 129 6613 500
E-mail: renu.razdan@jssresearch.com

If to the PI:

Dr. Vikas Agarwal
Sanjay Gandhi Postgraduate Institute of
Medical Sciences, Raebareli Road, Lucknow,
Uttar Pradesh 226014
Designation: Professor at Clinical
Immunology & Rheumatology
Telephone: +91- 9793245857
E-mail: vikasagr@yahoo.com

If to the Site:

Sanjay Gandhi Postgraduate Institute of
Medical Sciences, Raebareli Road, Lucknow,
Uttar Pradesh 226014
Attention: Dr. R K Dhiman
Designation: Director
Telephone: 0522-2494001
E-mail: director@sgpgi.ac.in

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written amendment/ agreement signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by Sponsor, DCGI and Institutional Ethic Committee.

16.3 Independent Contractor Relationship: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India.

16.4 Assignment: This Agreement may be assigned by JSS India to any of its affiliates or to any third party with the prior written confirmation of the Sponsor. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India.

16.5 Third Party Beneficiary: The Sponsor shall be considered a third-party beneficiary of this Agreement, entitled to all the rights and benefits hereunder as if it were a direct party to this Agreement.

16.6 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

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16.7 Survival: Sections 8, 9, 13, 14, 15, 16.2, 16.3 and 16.11 of the Agreement shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.8 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.9 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.10 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Delhi alone shall have exclusive jurisdiction in respect thereof.

16.11 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be Lucknow, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.12 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

JSS India		**The Principal Investigator**	
By:		By:	
Print Name:	Mr. Kishor Kumar	Print Name:	Dr. Vikas Agarwal
Title:	Chief Financial Officer JSS Medical Research India Private Limited	Title:	Professor at Clinical Immunology
Date:	21 July 2020	Date:	23 JULY 2020

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SGPGIMS,Lucknow

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The Site

By:
Print Name: Dr. RK Dhiman,

Title: Director,
SGPGIMS, Lucknow

Date: 25.07.2020

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

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SGPGIMS,Lucknow

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CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("Agreement") is made as of ..... (the "Effective Date") by and among

Medclin Research Pvt. Ltd. Having its registered office at Acropolis, unit 10/5 , 10th floor 1858/1, Rajdanga Main Road, Kol-107("CRO")

And

Sanjay Gandhi Postgraduate Institute of Medical Science, New PMSSY Rd. Raibareli Rd, Lucknow, Uttar Pradesh, 226014.

Prof. Uday C Ghoshal, Department of Gastroenterology to be the signatory for this agreement and he will perform this research work.

WHEREAS,

Sponsor (Zydus Healthcare Limited, CTS No. 460/6, I. B. Patel Road, Village Pahadi, Goregaon (East), Mumbai 400063, Maharashtra) based on the representation and warranties given by the CRO, desires to engage CRO on non-exclusive basis to initiate study of "Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess effectiveness and safety of Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12® in the treatment of Non-Constipated Irritable Bowel Syndrome in adults aged 18 years to 65 years" (hereinafter referred to as the "Study")

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a. The CRO has approached the Institution and Principal Investigators to perform the study in accordance with the corresponding Protocol, and all applicable rules and regulations. The Institution and PI agree to conduct the study in accordance with the same.

b. The Institution is equipped to undertake the Study and the Institution, CRO and Principal Investigator have agreed to perform the Study according to the terms and conditions hereinafter set forth.

1. REPRESENTATIONS AND WARRANTEES:

a. Each party represents and warrants to and covenants with the other that:

i. It has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this agreement; wherever applicable,

ii. It has the corporate power and authority to enter into and perform its obligations under this Agreement, whenever applicable,

iii. This Agreement has been duly authorized, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

iv. Neither the execution and delivery of this Agreement by either party, nor the performance by such party of its obligations here under nor compliance by such party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any indenture, mortgage, lease, agreement, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such party;

b. CRO represents and warrants that

It has the facilities, professional, technical and clerical staff, experience, and expertise sufficient in quality and quantity to perform the Services and the Clinical Study pursuant to the Protocol within the time frame set forth herein and all appropriate permits and authorizations necessary to provide and perform, to the highest of professional standards, the services for the conduct of the clinical study in accordance with this agreement, the Protocol, ICH - GCP and all applicable standard operating procedures and has capability to perform or arrange for the performance of all services required by Sponsor.

c. Institution represent that

i. It is entitled to procure the services of Principal investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.

ii. The Institution shall notify Medelin if the Principal Investigator ceases to be employed by or associated with the Institution and shall use its best endeavors to find a replacement acceptable to both The Sponsor and CRO. In order to ensure high

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standard of clinical trials, if no mutually acceptable replacement can be found, The CRO may terminate this agreement pursuant to clause 22(d).

d. Principal Investigator represents :

i. A competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub investigators and research staff and the Institution.

ii. Free participation in Clinical Studies and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.

iii. Non-involvement in any regulatory or misconduct litigation or investigation by the Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Evaluation Agency (EMEA), The Drug Controller general of India (DCGI) or other regulatory authorities. No data produced in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

iv. That facilities appropriate to the Clinical Trial are available at the Trial Site and that there is support of medical and other staff of sufficient number and experience to perform the Clinical Trial efficiently and in accordance with the provisions of this Agreement.

2. OBLIGATIONS/RESPONSIBILITIES:

a. Principal Investigator:

i. Will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub investigators or research staff. The duties and responsibilities delegated will be only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.

ii. Will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is accountable for the compliance of Investigators to the terms of this Agreement.

iii. Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from Sponsor and CRO.

iv. Will comply with the policies and procedures of the organization / institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify CRO promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

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v. Shall be responsible for obtaining and maintaining all approvals from the relevant local research ethics committee/other Authorities for the conduct of the Clinical Trial keeping The CRO fully apprised of the progress of ethics committee submissions. The written evidence of review shall be provided prior to initiation. All other communications, upon request be made available to Medelin. The Principal investigator shall not consent to any change in the Protocol requested by the relevant ethics committee without the proper written consent of The Sponsor and CRO, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study. Investigator will notify The CRO and the responsible Institutional Review Board as soon as possible. Any emergency change to the Protocol must be followed by a written Amendment.

vi. Agrees to use best efforts to provide Sponsor's with the data called for in the Protocol, including copies of each research subject's signed informed consent form, a signed authorization as required under any applicable India regulations/policies and properly completed case report forms, in a timely manner. The PI and Institution will provide for (i) access to the research subject's medical records by Sponsor/CRO and other appropriate regulatory agencies and (ii) the facilities where the Study is being conducted (iii) Raw data (iv) the use of Study data by Sponsor/CRO for any purpose that it deems appropriate provided that the research subject's personal identifying information has been removed. In the event of a conflict between terms of the Protocol and this Agreement, the terms of this Agreement shall govern (v) any other relevant information necessary for Sponsor, other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. The Principal Investigator shall notify Sponsor immediately if another regulatory authority schedules or, without scheduling, begins such an inspection.

vii. Agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

viii. Shall promptly report to CRO any significant developments that may occur during the Study, including but not limited to adverse clinical events as described in the Protocol.

ix. Agrees to maintain records and data related to the Study in compliance with all applicable regulations, and in any event, for the period as per Indian GCP after the completion/termination of the study.

x. In the event that during the term of this Agreement, either the Institution or Principal Investigator becomes debarred or receives notice of an action or threat of an action with respect to its debarment, the Institution or Principal Investigator, as the case may be, shall notify Sponsor immediately.

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b. Institution:

i. The Institution shall ensure that all employees and agents of Institution who are assigned to perform services under the Agreement are made aware of the obligations contained in the Agreement and the Protocol and are bound by such obligations.

ii. The Institution and Principal Investigator shall all the time comply with all types of License, permission or certificates as required under laws, rules and regulations.

iii. The Institution shall bear all costs related to the performance of the Study except as expressly set forth in section 23.1 and attached budget.

iv. Institution shall apply its best efforts to retain the services of the Principal Investigator.

v. In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform The CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, who shall have a similar background and also knowledge of the Clinical Trial.

vi. Any successor to the Principal Investigator must be approved, in writing, by The Sponsor and CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this agreement and to sign each such document as evidence of such agreement (although failure to sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

vii. The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India, and agrees to immediately inform The Sponsor/CRO if such cases arise.

viii. The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with the Protocol and all other terms of this Agreement; Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs; Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP; All applicable laws and regulations.

c. Sponsor /CRO:

i. Medelin agrees to provide to the PI all information concerning the Study Material that is necessary for safe and proper handling and storage of the Study Material and for performance of the Study which is in accordance to the Protocol.

ii. Medelin shall be held responsible and therefore train all personnel involved in the clinical trial at site to ensure compliance to GCP and Protocol.

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iii. The CRO in collaboration with the Sponsor may make any changes, amendments, addendum or supplements to the Protocol from time to time, as it may think fit and shall inform PI by giving a written notice to abide by the same.

iv. The CRO in consultation with the Sponsor may designate a different investigator or other supporting personnel.

v. May visit Site with a prior written notice at reasonable times and with reasonable frequency during normal business hours to obtain information regarding the progress of Study.

3. PAYMENT:

i. Institution / Investigator fees for the services shall be made in the amounts and upon the terms specified in the Study Budget attached to and made a part of this agreement.

ii. Institution / Investigator shall not revise its prices for any reason unless mutually agreed in writing by all parties during the term of this Agreement. In any case, Institution / Investigator shall endure that the overall budget shall not exceed the total study budget as specified which shall form the part of this Agreement unless agreed by Sponsor / CRO.

iii. Institution / Investigator will not charge any amount to Sponsor / CRO for their services which were not provided to the Sponsor / CRO or agreed upon by and between the parties.

iv. Any income tax, withholding tax or similar taxes deductible from the payment will be deducted by CRO.

4. NO ADDITIONAL RESEARCH: No Additional Research. The Institution & PI Investigator ensures that no additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol.

5. SUBJECT ENROLMENT: Investigator has agreed to enroll in Study approximately 52 subjects within approximately three to four months. The same can be extended with an intimation from the CRO. If Investigator fails to enroll subjects at a rate adequate to meet the enrolment requirement, Sponsor/CRO shall be free to terminate the Study early (see Section 22(d) Termination).

6. ETHICS COMMITTEE ("EC"): Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct

7. STUDY DISAPPROVAL: Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with

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all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct.

8. DATA PROTECTION: The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. The Sponsor / CRO will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any other requirements. Such data may be disclosed or transferred to other members of sponsor team, to representatives and contractors working on behalf of The Sponsor. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause (13).

9. INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION: Investigator will obtain written informed consent from each study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow Sponsor/ CRO to inspect signed informed consent forms or photocopies there during monitoring visits or audits (see Monitoring and Audits, Section 15).

10. CONFIDENTIAL INFORMATION: During the course of the Study, Investigator may receive or generate information that is confidential to The Sponsor. Any information marked by The Sponsor as confidential and provided to the investigator before the execution of this agreement will also be treated as confidential information

11. OBLIGATIONS OF CONFIDENTIALITY: Unless The Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the EC or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 17, Publications, of this Agreement.

11.1 Disclosure Required by Law: If disclosure of Confidential Information to any party other than the EC is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator :

a) Notifies the sponsor in writing in 15 working days advance of the disclosure so as to allow The Sponsor to take legal action to protect its Confidential Information,

b) Discloses only that Confidential Information required to comply with the legal requirement, and

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c) Continues to maintain the confidentiality of this Confidential Information with respect to all other parties.

11.2 Individually Identifiable Health Information: If, in connection with this Study or performance of this Agreement, the Sponsor comes into contact with individually identifiable health information relating to subjects, the Sponsor agrees to maintain the confidentiality of such information and not to use it for any purpose.

11.3 Survival of Obligations: These obligations of confidentiality survive termination of this Agreement and continue for a period as required after completion of the studies.

11.4 Return of Confidential Information: If requested by The Sponsor in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

12. Study Product and Document:

a) All the trial product and document necessary to conduct this study, as described in the Protocol, shall be supplied free of charge to the PI/Institution. In certain circumstances the Sponsor/CRO may request the PI/Institution to purchase the control product and/or concomitant product. In such cases, the PI/Institute will be reimbursed on actuals.

b) All trial product/ documents and all other material being provided shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to this agreement. It is understood that the trial product is provided by the Sponsor for the sole purpose of conducting the clinical trial.

c) The sponsor makes no warranties, express or implied, concerning the trial product or its merchantability or fitness for a particular use or purpose, other than for its use in this clinical study.

d) Upon delivery, the PI and Institution shall be responsible for the Dispensing, administration, storage and handling of the trial product.

e) All used and unused products provided by the Sponsor shall be returned to the Sponsor/CRO or destroyed by the site as instructed by the Sponsor/CRO. The site shall conform with all laws and regulations pertaining to the destruction and provide the Sponsor and CRO with a destruction certificate of the same.

13. STUDY DATA AND STUDY RECORDS:

13.1 Study Data: During the course of the Study, Investigator will collect and submit certain data to The Sponsor/CRO, as specified in the Protocol. This may include case report forms or their equivalent, or other types of medical reports, subject diary, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data within the time periods.

a) **Ownership of Study Data**. Subject to Investigator's right to publish the results of the Study (see Section 17, Publications), The Sponsor is the exclusive owner of all Study Data.

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b) **Non-exclusive License**. The Sponsor grants Investigator no right to use study data for any purpose including research and/or education purpose.

13.2 Data Management and statistical Analysis: The CRO shall carry out the data management and statistical analysis. The CRO may consult and / or provide The Principal Investigator for interpretation during report writing.

13.3 Study Records: Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a) **Retention.** Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period as per Indian GCP after the completion/termination of the study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify The Sponsor and CRO before destroying any Study Records after the required retention period. Investigator further agrees to permit The Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

14. MONITORING AND AUDITS:

14.1 Monitoring and Audits: The Sponsor / CRO shall be entitled at its absolute discretion (and in such form as the Sponsor / CRO sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit The Sponsor's / CRO's representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by Sponsor / CRO will relieve the Investigator of any of its obligations hereunder.

a) **Cooperation.** Investigator will cooperate with the Sponsor / CRO in the conduct of audits and will ensure that Study Records are maintained in a way that facilitates such activities.

b) **Resolution of Discrepancies**. Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

c) **Data Clarification Form**: The CRO may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the PI or his/her nominee shall clarify within a specified time.

d) **Study Conduct Evaluations**. The Sponsor / CRO may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor / CRO or its representative will use these evaluations solely for internal purposes

15. INVENTIONS:

15.1 Notification. If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the Sponsor and CRO.

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15.2 Assignment. Investigator will assign all interest in any such Invention to the Sponsor, or its representative free of any obligation or consideration beyond that provided for in this Agreement.

15.3 Assistance. Investigator will provide reasonable assistance to the Sponsor or its representative in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

16. PUBLICATIONS: The findings of this study may be published in a scientific journal or presented at a scientific meeting with prior permission from Sponsor and CRO. The Sponsor reserves the right to review all manuscripts prior to submission for publication or any paper before it is presented. In accordance with standard editorial and ethical practice, the Sponsor will generally support publication of multicentric trials only in their entirety and not as individual center data. Authorship will be determined by mutual agreement between The Sponsor in conjunction with the CRO and the Principal investigator(s).

17. DEBARMENT AND EXCLUSION: Investigators certify that s/he is not debarred and that s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and after its termination, Investigator will notify the Sponsor/CRO promptly if either of these certifications needs to be amended in light of new information.

18. USE OF NAME: Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify The PI and Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

18.1 Assignment and Delegation: The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the CRO, any attempt to assign, delegate, or subcontract is invalid. The Sponsor / CRO will authorize delegation or subcontracting any duties.

18.2 Affiliates: As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with The Sponsor / CRO.

18.3 Successors and Assigns: This Agreement will bind and inure to the benefit of the successors and permitted assigns of each party.

19. CONFLICT WITH ATTACHMENTS: If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

20. Liability and Indemnification:
The PI/CRO shall indemnify, defend and hold harmless the indemnity, from and against any demands, claims, actions, which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from participation in this Clinical Trial.

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a) Sponsor shall maintain with the CRO, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this section and shall also provide the clinical trial liability coverage.

b) CRO shall maintain the aforementioned insurance during and after the subsistence of the Clinical Trial. The CRO shall provide the Institution with written evidence of such insurance upon the written request of the Indemnity. This obligation to maintain insurance shall survive the termination of this Agreement.

c) In the event a claim is made or an action is brought against the Sponsor and/or Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the CRO's representative and shall assist the CRO's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses.

d) Violation of the Protocol, scientific misconduct or negligence by CRO or the Institution/Principal Investigator, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the Principal Investigator, then the Institution/Principal Investigator will be liable to reimburse to the Sponsor the expenses on such medical management and financial compensation that The Sponsor has paid;

e) The Sponsor`s representative shall indemnify, defend and hold harmless the indemnity, from and against any demands, claims, actions, which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from participation in this Clinical Trial. Notwithstanding anything contained herein, the liability of The Sponsor will be limited to The Sponsorship amount paid to CRO.

f) In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its additional personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to The Sponsor's / CRO's representative and shall assist The Sponsor's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses.

g) Notwithstanding the foregoing, The Sponsor's representative shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless The Sponsor, officers, directors, agents and employees for loss or damage resulting from:

   1. Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

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II. Failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

III. Any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

21. TERM: The term of this Agreement shall commence on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol unless sooner terminated as provided herein.
Termination Conditions. This Agreement terminates upon the earlier of any of, the following events:

a) **Disapproval by EC.** If, through no fault of Investigator, the Study is never initiated because of EC disapproval, this Agreement will terminate immediately.

b) **Study Completion.** For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by The Sponsor / CRO of all Protocol-required data; and receipt of all payments due to either party.

c) **Termination upon Notice:** CRO reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

d) **Immediate Termination by The CRO:** The CRO further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the CRO's opinion pose risks to the health or all being of Study subjects

e) **Termination upon Notice by Investigator:** The Principal Investigator may terminate the study, if The Sponsor / CRO does not comply with the agreement related to finance and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to The Sponsor / CRO fifteen days prior to termination and The Sponsor / CRO shall have fifteen days to cure its default.

f) **Immediate Termination by Investigator.** Investigator reserves the right to terminate the Study immediately upon notification to The Sponsor / CRO if requested to do so by the responsible EC or if such termination is required to protect the health of Study subjects.

g) **Payment upon Termination.** If the Study is terminated early in accordance with Section 22 Termination Conditions, above, The Sponsor / CRO will provide a termination payment equal to the amount owed for work already performed, in accordance with Exhibit A, less' payments already made. If the Study was never initiated because of disapproval by the EC (see Section 22b, Disapproval by EC , above), The Sponsor / CRO will reimburse Investigator for EC fees and for any other expenses that were prospectively approved, in writing, by The Sponsor or its representative.

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h) **Return of Materials.** Unless The Sponsor / CRO instructs otherwise in writing, Investigator will promptly return all materials supplied by The Sponsor / CRO for Study conduct, unused Case Report Forms, other study related material and any The Sponsor / CRO - supplied Equipment.

i) **Survival of Obligations.** Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification, and Debarment and Exclusion survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

22. FORCE MAJEURE: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance cause a delay or failure in performance ('a Delay') and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator / Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to Sponsor / CRO. Sponsor / CRO shall have the right to terminate an agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

23. NOTICE: Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to CRO:
Dr Monjori Mitra (Research Director, Medelin Research Pvt. Ltd); Phone: 9831075734

If to Institution:
Prof. R. K. Dhiman, The Director of SGPGIMS, Lucknow
Phone: 05222494001/2/3
OR
If to Principal Investigator:
Dr.Uday Chand Ghoshal
Phone: 9628842456

24. ENTIRE AGREEMENT: This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.
To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial will be retained for a period as per required Regulations after the completion/termination of the study whichever is later. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform The Sponsor, the Parties shall discuss in good faith in order to find an alternative solution

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for the proper archiving of these elements in. Subjects' files should be retained as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of The Sponsor

25. GOVERNING LAW: This agreement shall be interpreted and enforced under the laws of India and courts of India shall have exclusive jurisdiction to resolve any dispute under this Agreement. Any dispute or difference which may at any time arise between the parties hereto as to the construction, meaning or effect hereof or as to any clause, matter or thing herein contained or as to the rights or liabilities of the parties hereunder then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within 90 days, then such a question or dispute shall be referred to the arbitration of a sole arbitrator to be mutually appointed by both the parties, under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996 and the rules thereunder, as amended from time to time. The venue of such Arbitration shall be in Lucknow and the arbitration proceedings shall be conducted in English. The decision of such arbitrator shall be final, binding and conclusive on the Parties. The parties hereto agree that the Courts in Lucknow, India alone shall have exclusive jurisdiction in respect of any matters pertaining to, arising out of or in connection with Agreement.

Prof. Uday C Ghoshal will do this research work and He will be the signatory in this document in addition to authority of SGPGIMS.
Executed by the parties
PI, CONTRACT RESEARCH ORGANIZATION and INSTITUTION

CRO: Medclin Research Pvt. Ltd., Kolkata	**The Principal Investigator**	**The Institution**
Signature:	Signature:	Signature:
Name: Dr.Monjori Mitra	Name: Prof. Uday C Ghoshal	Name: Prof. R. K. Dhiman
Designation: Research Director	Designation: Principal Investigator	Designation: Director of SGPGI, Lucknow
Date: 07/Oct/2020	Date: 12/10/2020	Date: 16/10/2020
Stamp: PVT LTD. * MEDCLIN	Stamp:	Stamp: Director SGPGIMS, Lko.

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EXHIBIT A

Budget		
Study Name	Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess efficacy and safety of Providac (Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12®) in the treatment of Irritable Bowel Syndrome in adults aged 18 years to 65 years.	
CRO Name :	Medclin Research Pvt Ltd, Kolkata	
Cost Head	**Details**	
Research Grant Including Manpower And Travel Allowances	**52 Subjects**	**338000**
Institutional overhead charges	25%	65000
Gut Microbiota	Analysis	500000
EC Fees	On actuals	25000
Total Study Fees		928000

a) The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess effectiveness and safety of Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12® in the treatment of Non-Constipated Irritable Bowel Syndrome in adults aged 18 years to 65 years.

b) The investigator agrees to the protocol of this trial and will perform the study in accordance with ICMR Good Clinical Practice, and applicable laws, rules and regulations.

EXHIBIT B

SL. No	Milestone	Amount
1	Study Start up(At the time of SIV)	240000
2	30 subject Enrolled	98000
3	last subject Last Visit(Institutional Overhead)	65000

For Gut Microbiota

SL. No	Milestone	Percentage	Amount
1	Before Analysis	60%	300000
2	Completion of Analysis	40%	200000

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Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ BB 805237

Novartis Healthcare Private Limited, (FIRST PARTY);

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, (SECOND PART);

AND

Dr. Jayantee Kalita (THIRD PART);

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of [18th DECEMBER 2020] ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, located at ***Uttar Pradesh*** ("**Institution**") registered under the provision of the State Legislature Act and having its address at Raebareli road, lucknow-226014, Uttar Pradesh, India which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Jayantee Kalita as clinical practitioner in the field of ***Neurology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: AMG334 (hereafter the "Trial Drug") in accordance with a protocol entitled "***A 12-week phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of once monthly subcutaneous erenumab 70 mg in adult chronic migraine patients, CAMG334A2304***" and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. **CONFORMANCE WITH LAW AND ACCEPTED PRACTICE**

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by

Novartis. all, as amended from time to

time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: SAUMYA MATHEW

Title: COUNTRY TRIAL OPERATIONS LEAD

Date: 18·DEC·2020

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____ Name: Prof. R. K. DHIMAN

Prof. R K Dhiman Director
Sanjay Gandhi Post Graduate
Title: Director Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date: 07.01.2021

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Jayantee Kalita Dr. J. KALITA Prof. Department of Neurology S.G.P.G.I.M.S., LUCKNOW

Title: Professor, Department of Neurology

Date: 01/Jan/2021

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA45269656888723S
Certificate Issued Date	:	14-Oct-2020 04:33 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ SHIVAJINAGAR1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08856096926998205
Purchased by	:	GEORGE CLINICAL INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	GEORGE CLINICAL INDIA PVT LTD
Second Party	:	SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL
Stamp Duty Paid By	:	GEORGE CLINICAL INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Authorised Signatory

Please write or type below this line

CLINICAL STUDY AGREEMENT

BETWEEN

VISTERRA, INC (Sponsor)

Address: 275 2nd Ave, Waltham, MA 02451, USA

AND

Protocol: VIS649-201 Vs 3.1 20 Mar 20
Clinical Study Agreement, George Clinical, V0.1.0 05 Aug 20
[1509] [03 Feb 2021]

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

GEORGE CLINICAL India Private Limited (GC India)

Address: Plot No. 5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road
Bangalore - 560 001, Karnataka, India
Business registration number: **U73100AP2012FTC083414**

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS)**(Clinical Site)**
Address: Department of Nephrology, SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, RAEBARLI ROAD, LUCKNOW-226014 (U.P.)
In the presence of: Dr. Narayan Prasad (**Principal Investigator**)

This agreement is effective from the last signature date (**Effective Date**).

BACKGROUND:

A. The **Sponsor** is performing a clinical study entitled "A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Multiple Dose Proof of Concept Study to Evaluate the Efficacy and Safety of Multiple Intravenous Doses of VIS649 in Patients with Immunoglobulin A (IgA) Nephropathy; VIS649-201"; VIS649 (Protocol Number 649-201) (the **Clinical Study**) involving the compound known as VIS649 (the **Trial Drug**).

B. GC India is responsible for the conduct of the Clinical Study in India as the local representative for the Sponsor.

C. The Clinical Site has the know-how, qualifications, facilities, personnel and equipment required to conduct a study under GCP and the Clinical Site wishes to participate in the Clinical Study in accordance with the terms and conditions of this Agreement.

D. The Clinical Study will be conducted on the terms and conditions below.

In this Agreement:

1. **Agreement** means this Agreement, including all the Schedules.

2. **Affiliate**: means a company which (directly or indirectly) controls, is controlled by or is under common control with the Sponsor or GC India.

3. **Background IP** of a party means information, techniques, know-how, software and materials existing prior to the start of the Agreement (regardless of the form or medium in which they are disclosed or stored) provided by or on behalf of that party to the other for use in the Clinical Study (whether before or after the date of this Agreement) or

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used by that other party in conducting the Clinical Study, and all Intellectual Property in them.

4. **GCP** means Good Clinical Practice.

5. **CRF** means a printed, optical or electronic document or database designed to record all the information required by the Protocol to be reported to GC India on each Eligible Subject.

6. **Eligible Subject** means a person recruited to participate in the Clinical Study.

7. **Ethics Committee** means an independent ethics committee established under the GCP to review the Clinical Study on behalf of the Clinical Site.

8. **GCP** includes the India GCP and the ICH-GCP.

9. **ICH-GCP** means Guideline for Good Clinical Practice of the International Conference on Harmonization.

10. **Intellectual Property** means all present and future industrial and intellectual property rights, including inventions, patents, copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trademarks, know-how, trade secrets and the right to have confidential information kept confidential, and any and all other rights to intellectual property which exist anywhere in the world. It also includes an application or right to apply for any of those rights.

11. **Parties** means Sponsor, GC India and Clinical Site and **Party**, is a reference to either of them; a reference to a Party includes its Personnel.

12. **Personnel** means employees, agents and/or authorised representatives, and includes in the case of the Clinical Site, the Principal Investigator.

13. **Principal investigator** means the person responsible for conducting the Clinical Study at the Clinical Site.

14. **Protocol** means the document identified in **Exhibit A** which describes the objective(s), design, methodology, statistical considerations and organisation of the Clinical Study, and subject to **clause 2.2**, as amended from time to time, as agreed by the parties, and most recently approved by the Reviewing HREC

15. **Sponsor** means Visterra, Inc..

16. **Study Materials** means all the materials and information provided to Clinical Site or its Personnel by GC India or Sponsor, created for the Clinical Study or required to be submitted to GC India or Sponsor. It includes all reports, data, results, Case Report Forms (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how, whether patentable or not, relating to the Clinical Study, which are discovered or developed as a result of the Clinical Study. It excludes the Clinical Site's ordinary patient records.

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NOW IT IS AGREED as follows:

RESPONSIBILITIES OF GC INDIA

1.1 Before execution of this Agreement, GC India and Sponsor must provide the Principal Investigator, and through the Principal Investigator the Clinical Site and the Ethics Committee, with all current and relevant information regarding the Study Drug as reasonably required to justify the nature, scope and duration of the Clinical Study.

1.2 In consideration of the Clinical Site performing the Clinical Study, GC India agrees to:

(1) pay the Clinical Site in accordance with this Agreement;

(2) provide the Clinical Site with all materials, access to its Personnel, facilities or information reasonably required to perform the Clinical Study satisfactorily;

(3) implement and maintain quality assurance and quality control systems with written standard operating procedures to ensure that the Clinical Study can be conducted, and data generated, documented, recorded and reported in compliance with all the documents referred to in **clause 2.1**;

(4) assist Sponsor and the Clinical Site to apply for approval of the Clinical Study according to relevant laws, and to obtain necessary regulatory approvals, notices or authorisations to perform the Clinical Study;

(5) provide relevant information to Sponsor who will be responsible for notifying and submitting the necessary documentation to the relevant regulatory authorities;

(6) appoint a project manager and other appropriately trained and qualified personnel, with the Clinical Study knowledge, necessary to monitor the Clinical Study and advise on Clinical Study related medical questions;

(7) Monitor the application of the Study Drug in other places and advise the Clinical Site, through the Principal Investigator if a relevant trial on the Study Drug ceases elsewhere or the Study Drug is withdrawn from a market for safety reasons; and

(8) Notify the Clinical Site of any adverse events (including serious adverse events) that occur during the course of the Study (either at the Study Site or other study sites, including overseas sites) which may require alteration of the conduct of the Study, or which may affect the rights, interests, safety or well-being of Study Participants.

RESPONSIBILITIES OF THE CLINICAL SITE

2.1 The Clinical Site agrees to conduct the Clinical Study and must ensure that Principal Investigator and Clinical Site's Personnel comply with and conduct the Clinical Study in accordance with:

(1) the **Protocol (Exhibit A)**, any conditions of the Ethics Committee, and the **Budget (Exhibit B)** and do not amend or deviate from the Protocol or the Budget without GC India's prior written consent; and

(2) all applicable international, national and local laws and regulations, guidelines and directives, including but not limited to the ICH GCP, India GCP, applicable statutory provisions, this Agreement and GC India's and Sponsor's directions.

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2.2 The Clinical Site undertakes and agrees to:

(1) appoint Personnel who are properly registered with appropriate professional registration bodies, and who have not been disqualified from practice or disbarred or banned from conducting clinical trials by any applicable regulatory authority. If Clinical Site becomes aware of any disqualification of any Personnel it will notify GC India promptly;

(2) provide a list of all Personnel and copies of their curriculum vitae to GC India;

(3) ensure that all Personnel:

i. are made aware of the obligations in this Agreement and are bound by those obligations;

ii. attend all Clinical Study meetings and training sessions, as are reasonably required;

(4) ensure that if any Personnel becomes unavailable before completion of the Clinical Study or, if in GC India's reasonable opinion, is unsuitable for the tasks to be performed, to replace that person with another appropriately qualified, experienced and trained staff member within a reasonable time following their unavailability or written notice from GC India, so that the quality and schedule of Clinical Study is not affected. Clinical Site must promptly provide GC India with the curriculum vitae of that person;

(5) meet the deadlines of the Clinical Study in this Agreement and the Protocol;

(6) ensure that the Principal Investigator supervises the screening and recruitment of Eligible Subjects into the Clinical Study in accordance with the Protocol;

(7) Use best endeavours to recruit the target number of Eligible Subjects, within the recruitment period specified in [the Budget (exhibit B)] and that Eligible Subjects enrolment is completed on or before the inclusion period has ended (estimated date: **30 Jun 2021**]) The Clinical Study is conducted under competitive enrolment. If no Eligible Subjects are recruited by the Clinical Site within 60 days of initiation of the Clinical Study by the Clinical Site, GC India may terminate this Agreement immediately;

(8) Follow the adverse event and serious adverse event or other specified event reporting process set out in the Protocol (including reporting to relevant regulatory authorities, GC India, the Sponsor and the Ethics Committee); Clinical Site must make medical decisions relevant to the Clinical Study in a timely manner, and employ appropriate measures to ensure the safety of Eligible Subjects;

(9) Obtain any approvals required (such as Ethics Committee approval and Clinical Site's Board of Directors approval) to undertake the Clinical Study or to amend the Protocol. Neither the Clinical Site nor the Principal Investigator may consent to any change in the Protocol requested by a local Ethics Committee or competent authority without GC India's prior written consent;

(10) Ensure that all data collected for the Clinical Study is collected within the agreed time period, accurately and completely and respond promptly to all data queries; ensure that the required Clinical Study data and other Study Materials are sent to GC India promptly; and all End points (as defined in the Protocol) are followed-up until the end of the Clinical Study; and documentation for these submitted to GC India, regardless of whether the Eligible Subject has discontinued the Trial Drug before the end of the Clinical Study;

(11) Ensure that the records of Eligible Subjects remain complete and accurate in accordance with relevant regulations and this Agreement and ensure that all CRFs are complete and accurately reflect source documents;

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(12) Ensure that any clarifying or missing information is prepared and/or corrected following an Eligible Subject's visit, as provided in the Protocol, and is submitted to GC India within 2 working days after completion of Eligible Subject's visit and data; ensure that any request by or on behalf of GC India or its delegate for verification, clarification or correction of data are provided to GC India within 5 business days of receiving the request;

(13) Take all necessary steps to ensure the safety and integrity of Clinical Study data; and to ensure that the Clinical Site's Personnel, and any other third parties who has access to any confidential or personally identifiable information collected in the Clinical Study, receive appropriate privacy and security training, which is updated periodically as necessary;

(14) ensure that any personal information of Eligible Subjects obtained or held as a result of the conduct of the Clinical Study is collected, used, stored and disclosed by it in accordance with Applicable Privacy Laws; **Applicable Privacy Laws** means any legislation, code or guideline which applies in India and which relates to the protection of personal information;

(15) any Clinical Study equipment supplied by GC India or the Sponsor to Clinical Site is only used as specified in the Protocol; and

(16) retain and preserve a copy of all Study Materials, including copies of signed consent forms, completed CRFs, Protocol, information relating to the Trial Drug, correspondence and investigator files for at least 15 years from Clinical Study completion. Clinical Site must notify GC India before destroying any Study Materials and if reasonably required by GC India, must retain the Study Materials for a longer period at GC India's expense.

2.3 The Clinical Site must obtain informed consent to participate in the Clinical Study from each Eligible Subject before their enrolment in the Clinical Study. The consent forms must:

(1) be signed and dated before any study related procedures are performed in relation to the Eligible Subject;

(2) confirm the Eligible Subject's consent to participate in the Clinical Study as well as his/her understanding of the content of Clinical Study;

(3) permit the Eligible Subject's 'protected health information' to be obtained and used for the purpose of the Clinical Study; and

(4) permit disclosure of the protected health information by GC India, the Clinical Site and its Principal Investigator to the Sponsor and other professionals involved in the Clinical Study for purposes of the Clinical Study.

CLINICAL STUDY PAYMENTS

3.1 Budget

The **Budget** attached as Exhibit B describes all the activities Clinical Site and Principal Investigator must perform to complete the Clinical Study and the expenses that the Clinical Site may claim.

3.2 Payments

In consideration of the Clinical Site conducting the Clinical Study, GC India will pay the Clinical Site as nominated in the Budget in the manner and on the basis of the prices

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and at the times set out in the Budget. Follow-up for each Eligible Subject is considered complete when:

(1) CRFs have been completed to Eligible Subject death, Eligible Subject withdrawal or the end of the study follow-up period, whichever is first;

(2) Satisfactory information has been provided on potential study endpoints, serious adverse events and medical events of interest, as outlined in the Protocol; and

(3) GC India has confirmed that data collection and entry is complete and all data queries have been adequately resolved.

3.3 GC India may make prepayments which will be deducted from the further payments from GC India to Clinical Site.

3.4 Final payment will be made after Clinical Study completion but will be withheld until:

(1) all completed CRFs, are delivered to GC India and accepted by GC India as complete;

(2) all queries to the Principal Investigator have been resolved to GC India's reasonable satisfaction;

(3) Database lock has occurred;

(4) Return and receipt of all essential documents from the Principal Investigator;

(5) the Ethics Committee has been informed of study completion by the Principal Investigator; and

(6) Return of and receipt by GC India of any equipment provided to the Principal Investigator.

3.5 A change in scope that increases the cost of conducting the Clinical Study may be made only by a written agreement between Clinical Site and GC India. The amendment must be executed by authorised personnel, must include a statement of additional amounts to be paid in connection with the scope change and must be attached as an annex to this Agreement. E-mail or other electronic communication are not considered as written documentation for this purpose.

3.6 If there is a change in the scope of the Clinical Study that reduces the cost of conducting the Clinical Study compared to the Budget, the Budget will be amended accordingly, and the Parties agree to reconcile corresponding payment reductions in good faith.

3.7 GC India reserves the right to refuse to pay to Clinical Site payments specific to patients entered into the Clinical Study who do not meet the entry criteria specified in the Protocol. If an Eligible Subject discontinues their participation in the Clinical Study or the Clinical Study is terminated as a whole, only those costs incurred up to the date of discontinuation or termination, including costs of final visit and completion of all CRFs will be paid.

3.8 The payments in this clause constitute full payment for the Clinical Study and neither GC India nor the Sponsor has any other payment obligations.

3.9 If any tax is payable by Clinical Site on the income it receives for services supplied under this Agreement, the Clinical Site must pay that amount.

3.10 Neither this Agreement nor any consideration paid under it is contingent upon the Clinical Site's use or purchase of any of Sponsor's products

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SGPGIMS,Lucknow

TIMELINES

4.1 **Study Milestones**

Clinical Study Milestones	Estimated Dates
Protocol approved	30 Mar 2020
First Subject first visit	04 Aug 2020
Last Subject first visit	26 Nov 2021
Last - Subject last visit	31 Mar 2023
Final database lock	28 Apr 2023

4.2 Clinical Site must use all reasonable efforts to complete the Clinical Study according to the timelines above. Clinical Site must keep GC India continuously informed about the progress of the Clinical Study, and must immediately inform GC India in writing if Clinical Site reasonably anticipates 1 month or more delay in complying with those timelines. If those timelines are inconsistent with the timelines specified in the Protocol, the timelines in the Protocol prevail.

PRINICIPAL INVESTIGATOR

5.1 The Principal Investigator is responsible on a day to day basis for the conduct of the Clinical Study. The Principal Investigator does not have authority to amend this Agreement or the Protocol.

5.2 If the Principal Investigator leaves the Clinical Site or ceases to be available for any reason, the Clinical Site must immediately notify GC India, and GC India and the Clinical Site may negotiate to substitute the Principal Investigator. Clinical Site must use its best efforts to identify and obtain a substitute Principal Investigator acceptable to GC India and the Sponsor, and guarantee that the quality and agreed timelines of the Clinical Study will not be affected. If GC India and the Clinical Site cannot agree on a substitute Principal Investigator, or if GC India does not approve of the substitute Principal Investigator, GC India may immediately terminate this agreement in accordance with **clause 11**.

5.3 All medical and scientific communications to the Clinical Site, whether or not containing Confidential Information, must be addressed to the Principal Investigator. All information directed to GC India must be addressed to GC India's project manager.

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5.4 The Principal Investigator must disclose his or her economic interest and financial arrangements as specified by GC India and as required by applicable law.

INDEMNITY AND LIABILITY

6.1 Indemnity by the Sponsor

Sponsor indemnifies GC India under separate agreement between GC India and Sponsor. GC India indemnifies the Principal Investigator, Clinical Site and Ethics Committee (each an **Indemnified Party**) against any claim by or on behalf of an Eligible Subject for personal injury or death directly caused by the Study Drug or procedure required by the Protocol, provided the Principal Investigator and Clinical Site have complied with the Protocol, applicable laws and all reasonable instructions of GC India and Sponsor. GC India's liability to indemnify Indemnified Parties will be reduced proportionately to the extent that medical malpractice or the Indemnified Party's negligent or wrongful act or omission or material breach of this Agreement contributed to its loss.

6.2 Liability

6.2.1 The Clinical Site is liable for any loss, liability, cost and expense (**Loss**) arising from or in connection with the medical malpractice, negligence, wrongful act or omission, or wilful misconduct of Clinical Site and Clinical Site's Personnel or in relation to the non-payment, non-observance, or non-performance of any obligations under this Agreement.

6.2.2 The Clinical Site acknowledges and agrees that GC India and Sponsor make no representation or warranties in favour of the Clinical Site or its Personnel in respect of **clause 6.2.1**. The Clinical Site accordingly releases GC India and Sponsor from any compensation obligations in respect of **clause 6.2.1**.

6.2.3 If GC India and Sponsor incur any Loss which arises from the reasons in **clause 6.2.1**, Clinical Site will compensate GC India and Sponsor promptly on demand.

6.3 The Clinical Site agrees that:

(1) treatment of Eligible Subjects at the Clinical Site remains the responsibility of the Principal Investigator or other treating physician(s) at the Clinical Site, who can access all of the Eligible Subjects' clinical information, can make a complete assessment of the Eligible Subjects, and provide the most informed medical advice; and

(2) clinical judgement must prevail at all times before any treatment is administered to Eligible Subjects.

6.4 Clinical Site will be liable to GC India and Sponsor for any breach of this Agreement by the Clinical Site, the Principal Investigator or any other Personnel involved in the Clinical Study.

6.5 Despite any other clause in this Agreement but except for a breach of the confidentiality section, neither Party or Sponsor is liable to the other Party for any loss of profits, consequential, indirect or special damages, loss of business or goodwill.

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6.6 The Sponsor agrees to pay, and directs GC India to pay on Sponsor's behalf, compensation and medical management costs to Eligible Subjects suffering personal injury (including death) relating to his/her participation in the Clinical Trial to the extent required by and in accordance with applicable laws and rules in India. Sponsor shall reimburse GC India for such costs which have been approved by Sponsor, acting reasonably and without delay.

INSURANCE

7.1 The Sponsor has notified GC India that it maintains clinical trial insurance and comprehensive liability insurance as required by applicable law and will provide a certificate of insurance on request.

7.2 GC India maintains insurance with respect to its activities and indemnity obligations under this Agreement. GC India will provide a certificate of its insurance to Clinical Site and Principal Investigator on request.

7.3 Even though Sponsor maintains insurance, Clinical Site and Principal Investigator must also maintain their own liability insurance policies. Clinical Site and Principal Investigator must maintain such insurances as are reasonably available and necessary to provide indemnity in relation to any liability which they may incur in conducting the Clinical Study.

7.4 Clinical Site guarantees that, during the period of this Agreement, the Clinical Site, the Principal Investigator and Clinical Site's Personnel will not do anything knowingly to invalidate the Sponsor's or GC India's insurance policy.

CONFIDENTIALITY

8.1 All information disclosed by Sponsor or GC India to Clinical Site or its Personnel or produced during the Clinical Study, including the Protocol, investigator's brochure, CRFs, Clinical Study results and financial terms of this Agreement (**Confidential Information**) is confidential. Clinical Site and Principal Investigator each agree to keep the Confidential Information confidential and not use it, or disclose it to any third party without GC India's and Sponsor's prior written consent.

8.2 Information will not be subject to this **clause 8** if:

(1) the information was independently received from a third party who was free to disclose it;

(2) the information is in or has entered the public domain, other than as a result of breach of this Agreement by Clinical Site, Principal Investigator or other Personnel;

(3) the information was already known to Clinical Site and this can be established by prior written records; or

(4) the information was independently developed by or for Clinical Site, without use or reference to the Confidential Information.

8.3 Nothing in **clause 8** prevents the Clinical Site and the Principal Investigator from disclosing Confidential Information from GC India if required to be disclosed by law, regulatory authority or court order. If Confidential Information is disclosed under this **clause 8.3**, Clinical Site must provide GC India, Sponsor or their respective Affiliates

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with reasonable assistance and notice to resist disclosure or ensure confidential treatment for any required disclosure.

8.4 The Clinical Site may disclose Confidential Information to its Personnel who need to know the Confidential Information to undertake the Clinical Study. The Clinical Site must inform those Personnel of the obligations in this Agreement relating to Confidential Information and must ensure that they comply with those obligations.

8.5 The obligations of confidence under this clause 8 apply during the term of this Agreement and survive for 10 years after termination of this Agreement.

INTELLECTUAL PROPERTY & PATENTS

9.1 Intellectual Property

9.1.1 Sponsor and GC India grants to Clinical Site and its Personnel the right to use their Background IP including the Study Materials as required to carry out the Clinical Study and perform this Agreement. Except for this right, neither the Clinical Site nor any of its Personnel acquires any right or interest in any Intellectual Property provided by or on behalf of the Sponsor or GC India.

9.1.2 To carry out the Clinical Study, Clinical Site may use its own Background IP. Clinical Site's Background IP remains its sole property. Clinical Site grants GC India and Sponsor a non-exclusive, perpetual, royalty-free licence to use (including the right to sub-licence) its Background IP for the purposes of commercialisation of the Study Materials and Trial Drug and for further research.

9.1.3 All Intellectual Property in the Study Materials and Trial Drug is owned by Sponsor, or will vest automatically upon its creation in Sponsor. Clinical Site presently assigns to Sponsor all Intellectual Property rights in the Study Materials and Trial Drug created in the course of conducting the Clinical Study. Clinical Site must execute or ensure that its Personnel execute any documents reasonably necessary to give effect to this assignment, at Sponsor's expense.

9.1.4 Clinical Site must promptly disclose in writing to GC India and Sponsor full particulars of any Intellectual Property that Clinical Site or Principal Investigator make, discover or conceive in the course of the Clinical Study that is related to the Study Materials.

9.2 Inventions

9.2.1 The Clinical Site and the Principal Investigator must promptly disclose to GC India and Sponsor, any discovery or invention made, developed, conceived, reduced to practice or resulting from performance of the Clinical Study or related to the Trial Drug, Study Materials, or Confidential Information (**Invention**).

9.2.2 All Intellectual Property in any Invention will be owned by Sponsor and Clinical Site hereby assign such Inventions and Intellectual Property in any Inventions to Sponsor.. Sponsor has the sole right to obtain patents on Inventions in any country in the world. The Clinical Site must assign and must ensure that its Personnel assign all Intellectual Property in any Invention to the Sponsor, or its nominated Affiliates. The Clinical Site must fully cooperate, and must ensure that its Personnel fully cooperate, with GC India and the Sponsor to give effect to this assignment. These obligations survive termination of this Agreement.

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9.2.3 No additional compensation is payable to the Principal Investigator or its Personnel for any Inventions assigned under **clause 9.2.2**.

9.2.4 If Sponsor files patent applications relating to an Invention, the Clinical Site must assist GC India and/or Sponsor to prepare those patent application(s) and must execute any documents requested by Sponsor to ensure title vests in Sponsor. Clinical Site's assistance is at Sponsor's expense.

PUBLICATION & PROMOTIONAL ACTIVITIES

10.1 Publication

10.1.1 The Principal Investigator and the Clinical Site each undertakes not to make any publication or release relating to the Clinical Study or its results without GC India's and Sponsor's prior written consent.

10.1.2 In multicentre studies, the Clinical Site and the Principal Investigator agree not to publish the results of the Clinical Study before the results of the multicentre study are published.

10.1.3 If no multicentre publication occurs within 18 months of Clinical Study completion at all global Clinical Study sites and Sponsor's receipt of all the data from all the global Clinical Study sites, the Principal Investigator or Clinical Site may publish or present the results from their own Clinical Site only subject to the procedures in this **clause 10** and in accordance with copyright law.

10.1.4 Clinical Site and the Principal Investigator must provide GC India and Sponsor with a copy of the proposed presentation or publication for review and comment at least 45 days before proposed presentation or submission for publication.

10.1.5 During the 45 day period, GC India and Sponsor may:

(1) comment on the proposed publication and Clinical Site and Principal Investigator must consider those comments;

(2) request delay of publication for no more than 120 days to allow Sponsor to file patent applications or take other measures to protect Intellectual Property; Clinical Site and Principal Investigator must comply with that request; or

(3) request that Clinical Site or Principal Investigator remove specified Confidential Information (other than results of the Clinical Study); Clinical Site must remove whatever Confidential Information is required to protect Confidential Information or Intellectual Property of GC India or Sponsor.

10.1.6 If Clinical Site receives no comments from GC India or Sponsor within 45 days of giving them a copy of the proposed publication, it may make the publication, subject to section 10.1.2 and 10.1.3.

10.1.7 Any person named as an author will be given a reasonable opportunity to review the publication. Any person acknowledged as an investigator of the Clinical Study in the publication will be given a reasonable opportunity to request removal of his or her name from the publication.

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10.2 Promotional activities

Clinical Site may not issue a press release that refers to the Protocol, Clinical Study or any other study conducted by Sponsor or GC India, or that uses Sponsor's or GC India's name or trademarks without their prior written permission. Clinical Site may identify GC India as a contract partner for the Clinical Study.

TERM AND TERMINATION

11.1 Term

This Agreement commences on the **Commencement Date** (the date it is last signed by all Parties). In the ordinary course of events, this Agreement terminates when GC India makes its final payment to Clinical Site.

11.2 Termination

11.2.1 GC India may terminate this Agreement by written notice to Clinical Site immediately:

(1) at any time, if a governmental or regulatory authority requests that the Clinical Study is terminated; or

(2) at any time 60 days after the Commencement Date, if Clinical Site has not enrolled any Eligible Subjects.

11.2.2 GC India may terminate this Agreement for any reason other than those mentioned in **clause 11.2.1** with 30 days' written notice. If GC India terminates early under this clause, GC India will pay Clinical Site's reasonable costs up until termination relating to the Clinical Study, incurred and calculated in accordance with the Budget.

11.2.3 Any Party may terminate this Agreement immediately by written notice to the other Party if it believes on reasonable grounds that:

(1) continuing the Clinical Study poses an unacceptable risk to the rights, interests, safety or well-being of Eligible Subjects; and

(2) terminating this Agreement is the most appropriate way to respond to that risk.

11.2.4 In addition, either Party may terminate this Agreement immediately by written notice if the other Party:

(1) breaches this Agreement or the Protocol and fails to rectify the breach to the other Party's satisfaction within 30 days of receiving a notice specifying the breach and requiring its remedy; or

(2) is declared insolvent or has an administrator or receiver appointed over any of its assets or ceases to carry on business.

11.2.5 GC India may terminate this Agreement immediately by written notice if the Clinical Site breaches either of **clauses 12.3 (Debarment)** or **12.4 (Anti bribery)**. Clinical Site will not be entitled to further payment or compensation if the Agreement is terminated under this **clause 11.2.5**.

11.2.6 If this Agreement is terminated under **clauses 11.2.1, 11.2.3, or 11.2.4,** GC India must pay the Clinical Site for actual activities performed in accordance with this Agreement and the Protocol and reasonable non-cancellable expenses incurred before notice of

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termination. Any funds paid in advance will be prorated and any excess funds will be returned to GC India.

11.2.7 Termination of this Agreement by a Party does not affect the Parties' rights and obligations accrued before the effective date of the termination.

11.2.8 The following clauses survive termination of this Agreement: **clauses 2.2, 6, 7, 8, 9, 10, 11, 14, 15, 19, and 29**. Any other rights or obligations which by their nature should survive will remain in full force and effect following termination or expiry of this Agreement.

11.3 Obligations following termination

11.3.1 If this Agreement is terminated for any reason, clinical Site must promptly deliver to GC India all Clinical Study data, Study Materials and Confidential Information and all unused Trial Drugs or other related materials, subject to applicable retention requirements imposed by law.

11.3.2 On receipt of notice of termination for any reason whatsoever, the Clinical Site must:

(1) Take all appropriate action to close the Clinical Study promptly, in accordance with GC India's instructions and applicable law;
(2) Cooperate with GC India and Sponsor to ensure that Eligible Subjects who may be affected by termination receive adequate medical care;
(3) Use all reasonable efforts (i) to complete reports for all Eligible Subjects that have been entered into the Clinical Study before the termination date; and/or (ii) write a final report for that portion of the Clinical Study that has been completed before the termination date.
(4) If GC India requests, the Clinical Site must refer Eligible Subjects to other clinical sites designated by GC India for continued participation in the Clinical Study;
(5) Refrain from incurring additional costs or expenses to the extent reasonably possible and medically permissible; and
(6) Immediately cease enrolling patients in the Clinical Study and cease administering the Trial Drug and conducting medical procedures on Eligible Subjects to the extent medically permissible.

WARRANTY

12.1 The Clinical Site represents and warrants on behalf of the Clinical Site and the Principal Investigator to GC India and Sponsor that:

(1) its policies are not inconsistent with this Agreement, the Protocol or the GCP;

(2) its execution or performance of this Agreement does not and will not contravene its constitution or any applicable law or agreement binding on the Clinical Site.

(3) it will carry out its obligations under this Agreement with due care, skill and diligence and will employ techniques of a high quality and standard and best practices;

(4) it has full capacity to perform any activity contemplated by this Agreement; and

(5) it has procured any consent/permit and approval for the execution and performance of this Agreement.

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12.2 **Conflict of Interest**

The Clinical Site and the Principal Investigator confirm that there is no conflict of interests between the Parties that may affect their performance of the Clinical Study or adversely affect the Clinical Study's integrity. If a conflict of interest arises during their performance of the Clinical Study, Clinical Site or Principal Investigator must promptly notify GC India.

12.3 **Debarment**

Clinical Site warrants that to the best of its knowledge, it, the Principal Investigator and its other Personnel, are properly registered with appropriate medical registration bodies and have not been disqualified from practice or banned from conducting clinical studies by a regulatory authority. Clinical Site must notify GC India as soon as it becomes aware of any disqualification or ban. If Clinical Site, the Principal Investigator or any other Personnel is disqualified, or otherwise ineligible, GC India may terminate this Agreement immediately.

12.4 **Anti Bribery**

Clinical Site warrants that it:

(1) has not offered, promised or paid, directly or indirectly, a Benefit to a government official (including, but not limited to, a healthcare professional employed by a government-owned healthcare facility) to induce the government official to act in any way in connection with his or her official duties with respect to services performed under this Agreement or to otherwise obtain an improper advantage for the Clinical Site, Sponsor, or GC India (**Improper Payment**);

(2) has not received an Improper Payment; and

(3) will not offer, promise, pay, authorise or receive any Improper Payment in the future.

For the purposes of this clause, **Benefit** includes but is not limited to money, financial or other advantage, travel expenses, entertainment, business or investment opportunities, charitable donations or any other thing of value.

12.5 **Compliance with applicable law**

Clinical Site must not engage in any conduct on GC India's behalf or Sponsor's behalf or part of the Clinical Trial which violates, or potentially violates any applicable local or foreign laws or regulations.

MANAGEMENT OF TRIAL DRUG

13.1 Clinical Site must:

(1) supply and manage the Trial Drug following usual hospital supply, storage and disposal practices;
(2) ensure that all Trial Drug is used strictly according to the Protocol and is not used for any other purpose, unless agreed in writing by the Sponsor;
(3) provide a written explanation accounting for any missing Trial Drug;
(4) keep all Trial Drug under appropriate storage conditions (including any conditions specified in the Protocol) and in a secure area accessible only to authorised Personnel;

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(5) ensure that complete and current records are maintained of (i) the names of the Eligible Subjects who received the Trial Drug, including the date and the amount of Trial Drug dispensed; and (ii) the dates and amount of the Trial Drug broken, spilled or lost; and

(6) not charge Eligible Subjects or third parties for Trial Drug or for any services reimbursed by GC India under this Agreement.

13.2 At the completion or termination of the Clinical Study, Clinical Site must provide to GC India a written accounting of the quantities of the Trial Drug used in the Clinical Study. Clinical Site must return any unused Trial Drug to GC India, or if requested by GC India, destroy it and provide evidence of the destruction. If GC India requests, Clinical Site must give a copy of its drug destruction policy and procedure to GC India.

13.3 Clinical Site must not sell the Trial Drug, and guarantees that all the Trial Drug will only be administered to Eligible Subjects according the Protocol. The above mentioned procedure will be managed by one special entrusted person.

NOTICES

14.1 Any notice, consent, approval or other communication in connection with this Agreement (each, a Notice) must be in writing, in English, and be delivered or sent to the address or email of the recipient as follows (or as varied by notice):

(1) if to GC India and/or Sponsor:

Plot No. 5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road

Bangalore - 560 001, Karnataka, India

Telephone: +91 80 4942 1400

Name: Abby Abraham

Email: aabraham@georgeclinical.com

(2) if to CLINICAL SITE:

Address: Department of Nephrology C BLOCK Sanjay Gandhi Post Graduate Institute Of Medical Sciences Raebareli Road Lucknow, India.

Post Code: 226014

Telephone: +91 - 5222495187

Name: Prof R K Dhiman
Email: director@sgpgi.ac.in

(3) if to Principal Investigator: Dr. Narayan Prasad

Address: Professor & Head
Department of Nephrology C BLOCK Sanjay Gandhi Post Graduate Institute Of Medical Sciences Raebareli Road Lucknow – India.

Code: 226014
Telephone: +91 - 5222495187

Name: Dr.Narayan Prasad

Email: narayan.nephro@gmail.com

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14.2 A Notice takes effect from the time received and is taken to be received by the recipient:

(1) if delivered by hand, on the day of delivery;

(2) if sent by post, on the third (seventh, if sent to another country) Business Day after the date of posting;

(3) if sent by facsimile, on the day shown on the transmission report (from the machine which sent the facsimile) that the entire facsimile was sent to the recipient;

(4) if sent by email, on the day the machine (which sent the email) reports the email was successfully sent (provided no error or bounce back is received);

However, if received after 5:00pm or on a day that is not a Business Day, it is be taken to be received at 9:00am on the next Business Day. A **Business Day** is a day which is not a Saturday, Sunday, or public holiday in India.

ACCESS

15.1 Clinical Site must allow GC India, Sponsor, their respective employees and agents, and authorized representatives of any regulatory or governmental authorities access to the Clinical Site to examine the Clinical Site's facilities and its personnel and to inspect and copy all Clinical Study data, documents and records relating to the Clinical Study to monitor compliance with this Agreement and applicable laws, rules and regulations. Access must be with reasonable notice and during normal business hours. Clinical Site must ensure that the Principal Investigator and all relevant key Personnel are available during monitoring visits to the Clinical Site and assist with any audit of records as reasonably requested by GC India;

15.2 If Clinical Site is contacted by a regulatory authority in connection with the Clinical Study, Clinical Site must notify GC India immediately unless prevented by law and must give GC India and Sponsor copies of the notice and related documents, the right to review and comment on such documents, and allow GC India and Sponsor the right to be present at any such inspection or inspections. If the inspection or audit occurs without notice to the Clinical Site, then the Clinical Site must notify GC India immediately, and no later than 24 hours following the arrival of the inspector or auditor. GC India may request a meeting after the inspection with the Clinical Site, and Clinical Site must ensure that the Principal Investigator attends.

TRANSFERABILITY

16. GC India may transfer any rights under this Agreement to the Sponsor, without consent of the Clinical Site.

INDEPENDENT CONTRACTOR

17.1 Clinical Site acts as an independent contractor undertaking the Clinical Study. Nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the parties and no Party will hold itself out as an agent for another or Sponsor.

17.2 Neither the Clinical Site, nor any of its Personnel has authority directly or indirectly, to act on behalf of, or to commit or bind GC India or Sponsor or to incur any liabilities or

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expenses on behalf of GC India or Sponsor or to enter into any oral or written agreement in the name or on behalf of GC India or Sponsor.

17.3 Neither GC India nor Sponsor guarantees the salary of the Principal Investigator or any other Personnel. The Clinical Site is solely responsible for paying salaries and employment benefits to its Personnel, and as employer, will also be responsible for all other employer related obligations, including income and payroll taxes, insurances, and pension contributions and making all other deductions required by law.

TAXES

18. All amounts in this Agreement include all taxes, duties, fees, costs & expenses, unless expressly stated otherwise.

SEVERABILITY

19. Any clause of this Agreement which is prohibited or unenforceable is ineffective to the extent of the prohibition or unenforceability, but the validity or enforceability of the remaining clauses of this Agreement will not be affected.

WAIVER

20. A right or remedy created by this Agreement cannot be waived except in writing signed by the Party entitled to that right. Delay by a Party in exercising a right or remedy does not constitute a waiver of that right or remedy, nor does a waiver (either wholly or in part) by a Party operate as a subsequent waiver of the same right or of any other right of that Party.

COUNTERPARTS

21. This Agreement may be executed in a number of counterparts. All counterparts taken together constitute one instrument. A Party may sign any one counterpart. This Agreement may be delivered by email and the Parties may rely on an electronic signature as though it were an original signature

FORCE MAJEURE

22.1 A Party will not be liable for failure or delay in the performance of its obligations under this Agreement for the period and to the extent that its failure or delay was directly due to a **Force Majeure Event**.

22.2 A Party relying on **clause 22.1** must:

(1) Promptly notify the other Party of the circumstances and effect of the Force Majeure Event; and

(2) Take all steps reasonably necessary to mitigate the effects of the Force Majeure Event on the performance of its obligations.

22.3 If the Force Majeure Event persists for more than 3 months, the other Party may immediately terminate the Agreement by written notice, without any damages being due to the Party affected by the Force Majeure Event.

22.4 A **Force Majeure Event** means an event which is not within the reasonable control of a Party and not caused by its own act or omission, including (but not limited to) acts of God, natural events, fire, war, events of terrorism, embargo, strike, riot, or act of government or regulatory agency.

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ASSIGNMENT

23. The Clinical Site may not assign or transfer any of its rights or obligations under this Agreement without first obtaining GC India's and Sponsor's written consent. Sponsor may assign any of its rights or obligations under this Agreement without consent of the Clinical Site.

ENTIRE AGREEMENT

24. This Agreement constitutes the entire agreement between the parties in relation to the Clinical Study and supersedes all prior representations, agreements, statements and understandings, whether verbal or in writing in relation to the Clinical Study.

CONFLICT

25. If any terms of this Agreement are in conflict with any terms of the Protocol or the Budget, the Agreement and Budget will prevail with respect to legal terms and the Protocol will prevail with respect to clinical terms.

AMENDMENTS

26. This Agreement may only be amended by a written document signed by all Parties. The Protocol may only be amended in writing by the Parties and approved by the Ethics Committee.

INTEGRATION

27. The Protocol and any amendments to it and the Exhibits attached to this Agreement are an integral part of this Agreement and are incorporated in it by reference.

APPLICABLE LAW AND DISPUTES

28. The laws applicable in ~~Bangalore~~ Lucknow, India govern this Agreement. If any disputes arise in connection with this Agreement, and the dispute cannot be solved pursuant to clause 29, the parties submit to the non-exclusive jurisdiction of the courts in ~~Bangalore,~~ Lucknow India.

29. DISPUTE RESOLUTION

29.1 If a dispute arises in connection with this Agreement, the parties must first attempt to negotiate in good faith to resolve the dispute. However, nothing in this clause 29 prevents a party from obtaining urgent injunctive relief to protect their intellectual property rights.

29.2 If the dispute is not resolved within 14 days after good faith negotiations commence, either party may refer the dispute to mediation under the Arbitration and Conciliation Act 1996, in India.

29.3 If the dispute is not resolved within 21 days of the commencement of mediation, either party may commence proceedings in any court of competent jurisdiction.

29.4 Unless specifically provided otherwise, each party must continue to perform its obligations under this agreement, despite the existence of a dispute.

29.5 Nothing herein shall prevent either party from seeking equitable or injunctive relief through the court system.

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Executive Registrar
SGPGIMS,Lucknow

EXECUTED as an Agreement between the parties.

VISTERRA, INC.

By: David Oldach MD

24 FEB 2021

David Oldach, MD
Printed Name
Chief Medical Officer, Visterra
Title

Initials: DWO

On behalf of **George Clinical India Private Limited (GC India)**		On behalf of **CLINICAL SITE**	
Signed:		Signed:	
Name:	Abby Abraham	Name:	Prof R K Dhiman
Position:	Country Head, India	Position:	Director
Date:	15 / Feb / 2021	Date:	/ /

George Clinical India Private Limited

22/2/21

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

The Principal Investigator acknowledges this Agreement and understands the obligations it imposes

O/C
4/Cdr

Acknowledged by the **Principal Investigator**

Signed: 3.3.21

(Prof. Narayan Prasad)
Professor & Head
Deptt. of Nephrology
S.G.P.G.I.M.S., Lucknow-226014
Reg. No. BR-27804/94

Name: Dr. Narayan Prasad – MBBS, MD, DM

Position: Professor & Head

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EXHIBIT A

PROTOCOL A Multicenter, Randomized, Double-Blind,Placebo-Controlled, Multiple Dose Study to Evaluate the Efficacy and Safety of VIS649 in Participants with Immunoglobulin A (IgA) Nephropathy

To be submitted separately

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EXHIBIT B – BUDGET

Per Subject Fee:
Site (PI) target to enrol 4 subjects during the enrolment period for the study.

GC India will pay the adjusted cost of **INR 663,685.00** per Eligible Subject randomised in accordance with the Protocol and who has completed the Clinical Study as per the payment schedule below

(NOTE: this payment is inclusive of the overhead, hospital administration and all miscellaneous e.g. printing fee, courier fee, and so on).

Such amount will be divided as follows: (INR)

Visit	Total Fees breakdown
Screening	34586.00
D1 Pre infusion (M0)	45400.00
D1 Post infusion (M0)	
D8 (M0)	14501.00
D18 (M0)	11533.00
D30 (M1)	44599.00
D60 (M2)	44599.00
D90 (M3)	44599.00
D120 (M4)	44599.00
D150 (M5)	44599.00
D180 (M6)	45019.00
D210 (M7)	44599.00
D240 (M8)	44599.00
D270 (M9)	44599.00
D300 (M10)	44599.00
D330 (M11)	45044.00
D360 (M12 - ET)	25174.00
D390 (M13)	12433.00
D420 (M14)	12433.00
D485 (M16 - EOS)	16171.00
Total	663,685.00

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Unscheduled Visit	13944.00

Conditional (Invoiced) Items	Max. qty per patient	Unit cost	Unit cost with O/H	Max. cost per Patient
Serious adverse event Report	all will be reimbursed	2,327	2,327	N/A
Re-consent	1	1,020	1,020	1,244
12-Lead ECG (includes interpretation and report)	1	1,867	1,867	1,867
Initial Physcial examination(include Medical history,assement of Cardiovascular, respiratory, gastrointestinal, neurological, weight, height and Vital sign)	1	5,270	5,270	6,430
Serum Chemistry (Local Lab)	15	1,257	1,257	18,855
Hematology (Local Lab)	7	691	691	4,837
Collection & shipping of archived biopsy slide (kits provided)	1	1,949	1,949	1,949
Pathology re read	1	3,689	3,689	3,689
Infusion supplies: Saline, infusion line and filter		Pass through		
Overnight facility charge, Simple	12	14,332	14,332	171,984
PK Blood Blood draw optinal sub-study M0, 2 hr & M11, 2 hr post infusion timepoint	2	356	356	712
Total cost for Invoiced Items per Patient				₹211,567.00

Screen Failures:	Max. Qty	Maximum cost
Screen Failure Visit	1 PER EVERY 1 ENROLLED PATIENTS	34,586
Re-screening	1 PER PATIENT	34,586

Site Costs (Invoiced Items)	Max Cost
Local Ethics Committee Fee, IRB Fee	25000 + 18% GST
Archival Fee (15 years)	60000
Study Start-Up Fee/Site Set-Up Fee	80000
Pharmacy: Set-Up Fee	60000
Study coordinator salary Rs.25,000(per month) X 30 Months	750,000
Pharmacist salary Rs.25,000(per month) X 30 Months	750,000

Equipment Cost	
Infusion Pump	63,000.00/- +Tax

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SGPGIMS,Lucknow

(A4)

In case of subjects included but not having completed the Clinical Study the amount to be paid will be calculated according to the fees of the visits actually performed by this subject. Where visits are conducted but not all per Protocol tests performed, GC India reserves the right to withhold partial payment at its discretion. No payment will be made for an ineligible subject incorrectly randomised into the Clinical Study or in case the subject did not complete the Clinical Study due to negligence, malpractice, breach of Protocol, or any wilfully wrong act or omission on the part of the Investigator or CLINICAL SITE.

In addition to the per subject payment, GC India will cover the following costs:

1. GC India will reimburse the CLINICAL SITE for Eligible Subject's reasonable travel and meal expenses up to a maximum of INR 1,500 per Eligible Subject visit ("**Subject Expenses**"), as agreed between GC India and Clinical Site. Reimbursement for Subject Expenses will be included in the per patient grant payable to the Investigator by GC India, which will be based on per Eligible Subject for each completed visit.

2. Reimbursement of the Subject Expenses to the CLINICAL SITE is subject to the CLINICAL SITE providing to GC India's nominated Clinical Study monitor and the monitor's approval of:
   (a) receipts or other supporting evidence of Subject Expenses; and
   (b) receipts or other satisfactory evidence that CLINICAL SITE has paid such Subject Expenses to the relevant Eligible Subjects.

3. Unless otherwise agreed by GC India in writing, GC India will not be liable for any other payment other than those specified in this Agreement.
   All payments to the CLINICAL SITE will be made according to the bank details provided in Exhibit C.

Lt Col Varun Bajpai VSM
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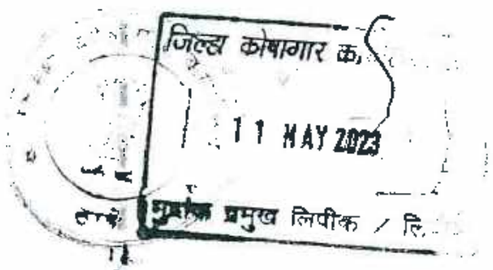
SGPGIMS,Lucknow

EXHIBIT C

1.	**CLINICAL SITE**	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Nephrology, C BLOCK , Raebareli, Road Lucknow 226014
2.	**CLINICAL SITE'S Payment Details:** Director SGPGIMS RESEARCH ACCOUNT	
3.	**CLINICAL SITE's**	Bank Name: State Bank Of India Bank Address: PGI Branch Raebareli Road Lucknow Name Account Holder: Director SGPGIMS RESEARCH ACCOUNT Account Number: 10095237491 PAN No.: AAAJS3913N GST No.: 09AAAJS3913N2ZN IFSC Code: SBIN0007789
4.	**Invoice Payment Notice Details**	Contact Name: George Clinical India Pvt Ltd. Address: Plot No. 5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road, Bangalore - 560 001, Karnataka, India
5.	**CLINICAL SITE** **Payment Notice Details**	Contact Name: Dr. Narayan Prasad – MBBS, MD, DM Email address: narayan.nephro@gmail.com Full Address: Department of Nephrology, C BLOCK Sanjay Gandhi Post Graduate Institute Of Medical Sciences Raebareli Road Lucknow 226014
6.	**Currency**	INR
7.	**VAT or GST**	(a) All amounts in this Agreement include all taxes, duties, fees, costs & expenses, unless expressly stated otherwise. (b) If any VAT/GST is payable by the Clinical Site and/or Principal Investigator on any amounts payable under this Agreement and this has been expressly agreed by GC India and Sponsor, the GST/VAT must be shown on a validly issued and accurate tax invoice at the local applicable GST/VAT rate. (c) If any VAT/GST may be refundable to the Clinical Site and/or Principal Investigator, the Clinical Site and/or Principal Investigator shall seek the appropriate refund and reimburse Sponsor for the VAT accordingly. (d) The Clinical Site and/or Principal Investigator (as payee) is solely liable for and will pay when due all GST/VAT, taxes, fees, duties, assessments and other governmental charges of any kind imposed by a taxing authority for the services performed under this Agreement. (e) Each Party will pay costs of bank transfers within its own country.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ 54AA 348725



Amendment #1
Clinical Study Agreement

This amendment dated 30 March 2023 to the Clinical Study Agreement (the "Amendment") is entered into by and between Sanjay Gandhi Postgraduate Institute of Medical Sciences, a clinical research site with its principal office and place of business at Raibareily Road, Lucknow - 226014, Uttar Pradesh, India ("**Institution**"), Dr. Jayantee Kalita, having an address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibarcily Road, Lucknow - 226014, Uttar Pradesh, India ("**Principal Investigator**") and Medpace Clinical Research LLC, located at 5375, Medpace Way, Cincinnati, Ohio 45227 ("Medpace"), collectively, (the "Parties").

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WITNESSETH:

WHEREAS, the Parties entered into a Clinical Study Agreement as of 28 January 2021 (the "Agreement") pursuant to which Institution is conducting a Study based on Protocol No. VIB0551.P3.S1, entitled "A Randomized, Double-Blind, Multicenter, Placebo-Controlled Phase 3 Study With Open-Label Period To Evaluate The Efficacy And Safety Of Inebilizumab In Adults With Myasthenia Gravis", (the "Protocol"); and

WHEREAS, the Parties desire to amend the Agreement to amend the budget in Schedule A of the Agreement contained therein.

NOW THEREFORE, the Parties hereby agree as follows:

1. Schedule A of the Agreement shall be deleted in its entirety and replaced with the Schedule A appended to this Amendment.

2. All other provisions of the Agreement shall remain unchanged and in effect.

[SIGNATURE PAGE TO FOLLOW]

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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IN WITNESS WHEREOF, the Parties hereto have executed this Amendment by proper persons thereunto duly authorized

FOR MEDPACE, ON ITS OWN BEHALF
AND AS PAYMENT AGENT OF SPONSOR

By: _____

Name: Taher Sadriwala

Title: Sr. Associate Director – Clinical Trial Management

Date: 01/Jun/2023

INSTITUTION

By: _____ 03/07/23

Name: _____

Prof. R.K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Title: _____

Date: _____

Read and Acknowledged by:
Principal Investigator

By: _____

Name: Prof. Jayantee Kalita

Date: 16/Jun/2023

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

VIELA BIO

PROTOCOL ID: VIB0551.P3.S1

// DR JAYANTEE KALITA //

PROTOCOL VERSION 6.0

SITE: //4105//

SCHEDULE A VERSION: VERSION #2.0

COUNTRY: INDIA

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Executive Registrar
SGPGIMS,Lucknow

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SCHEDULE A

A1 STUDY BUDGET

Medpace, as Sponsor's payment agent, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. All fees listed include overhead, taxes, and subject stipend or travel reimbursement, as applicable. VAT is not applicable because Medpace Clinical Research, LLC is a US-based corporation. Should any changes to VAT law occur during the term of this Agreement, the party legally responsible shall be liable for VAT. Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject (Including 25% IOH and 18% GST)

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit 2/Day 1.

1.1.1	*Randomized Control Period-AcHR-Ab+ Population*	*INR 670,107.00*
1.1.2	*Randomized Control Period-MuSK-Ab+ Population*	*INR 473,031.00*
1.1.3	*Open Label Period*	*INR 554,746.03*

A2 SETUP FEES & VISIT PAYMENTS

☒ Please check box if Payee must submit an invoice to Medpace prior to receiving payment. Payment will be made within forty-five (45) days of receipt of invoice.

A2.1 Setup Fees

2.1.1	*Administrative Fee*	*INR 40,000 + 18% GST*
2.1.2	*Pharmacy Start-Up Fee*	*INR 75,000 + 18% GST*

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation;
- IRB/EC approval; and
- Medpace's receipt of the fully executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

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SGPGIMS,Lucknow

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Table 1 - Fees for Completed Clinical Visits for Randomized Control Period- Act-R-Ab+ Population

VISIT	VISIT FEE		25% IOH FEE		VISIT FEE INCLUDING 18% GST	
Visit 1/Screening	INR	30,797	INR	7,699	INR	45,426
Visit 2/Day 1	INR	64,262	INR	16,066	INR	94,786
Visit 3/Day 15	INR	43,778	INR	10,945	INR	64,573
Visit 4/Day 29	INR	34,622	INR	8,656	INR	51,067
Visit 5/Day 57	INR	28,622	INR	7,156	INR	42,217
Visit 6/Day 85	INR	34,784	INR	8,696	INR	51,306
Visit 7/Day 126	INR	27,476	INR	6,869	INR	40,527
Visit 8/Day 183	INR	59,010	INR	14,753	INR	87,040
Visit 9/Day 225	INR	27,950	INR	6,988	INR	41,226
Visit 10/Day 267	INR	34,671	INR	8,668	INR	51,140
Visit 11/Day 309	INR	27,476	INR	6,869	INR	40,527
Visit 12/Day 365	INR	40,867	INR	10,216	INR	60,271
TOTAL PER PATIENT	**INR**	**4,54,310**	**INR**	**1,13,578**	**INR**	**6,70,107**
Remote Visit due to COVID-19	INR	17,592	INR	4,398	INR	25,948

Table 2 - Fees for Completed Clinical Visits for Randomized Control Period- MuSK-Ab+ Population

VISIT	VISIT FEE		25% IOH		VISIT FEE INCLUDING 18% GST	
Visit 1/Screening	INR	30,797	INR	7,699.25	INR	45,425.58
Visit 2/Day 1	INR	64,262	INR	16,065.50	INR	94,786.45
Visit 3/Day 15	INR	43,778	INR	10,944.50	INR	64,572.55
Visit 4/Day 29	INR	34,622	INR	8,655.50	INR	51,067.45
Visit 5/Day 57	INR	28,622	INR	7,155.50	INR	42,217.45
Visit 6/Day 85	INR	34,784	INR	8,696.00	INR	51,306.40
Visit 7/Day 126	INR	27,476	INR	6,869.00	INR	40,527.10
Visit 8/Day 183	INR	56,358	INR	14,089.50	INR	83,128.05
TOTAL PER PATIENT	**INR**	**3,20,699**	**INR**	**80,175**	**INR**	**4,73,031**
Remote Visit due to COVID-19	INR	17,592	INR	4,398.00	INR	25,948.20

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SGPGIMS,Lucknow

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Table 3- Fees for Completed Clinical Visits for Open Label Period

VISIT	FEE	25% IOH	FEE INCLUDING 18% GST
Visit 1/OLE Day 1	INR 27,505.00	INR 6,876.25	INR 40,569.88
Visit 2/OLE Day 15	INR 33,784.00	INR 8,446.00	INR 49,831.40
Visit 3/OLE Day 92	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 4/OLE Day 183	INR 55,018.00	INR 13,754.50	INR 81,151.55
Visit 5/OLE Day 275	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 6/OLE Day 365	INR 36,810.00	INR 9,202.50	INR 54,294.75
Visit 7/OLE Day 456	INR 29,310.00	INR 7,327.50	INR 43,232.25
Visit 8/OLE Day 547	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 9/OLE Day 730	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 10/OLE Day 911	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 11/OLE Day 1093/ET	INR 33,013.00	INR 8,253.25	INR 48,694.18
TOTAL PER PATIENT	**INR 3,76,099.00**	**INR 94,024.75**	**INR 5,54,746.03**
Safety Follow up	INR 22,199.00	INR 5,549.75	INR 32,743.53

A2.3 Screen Failures

Table 4 - Screen Failures

VISIT OF FAILURE	COST	25% IOH	COST INCLUDING 18% GST
Visit 1/Screening	INR 30,797	INR 7,699.25	INR 45,425.58

Payment for a max of 10 screen failures will be made for whom Medpace has received all appropriate documentation of procedures/visits completed with the next scheduled payment owed to the Payee. Eligible screen failure payment will be based on the order (by date) of when the subject is consented. Payment for additional screen failures must be pre-approve by Medpace/Sponsor.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Medpace after.

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor;
- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A2.5 Archiving Fee — 350,000 plus 18% GST

Payable with final payment. The expectation is that the study site will be responsible to maintain study documents for 25 years after site closure unless notified by the sponsor.

The final payment shall be reconfirmed and paid as per the quotation submitted and on receipt of sponsor's approval.

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A2.6 Unscheduled Visit Due to Worsening MG Symptoms (Including 25% IOH) INR +18% GST — 21,118.00

Payable with final payment. An unscheduled visit should be performed if a patient complains of worsening MG symptoms and use of rescue therapy is being considered. This should be performed before the rescue therapy is initiated. This Unscheduled visit should follow the procedures as outlined in the protocol. If an Unscheduled Visit is performed for a different reason, then it is only necessary to perform those specific procedures. Unscheduled Visit must be entered into EDC prior to database lock and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit.

Total includes Adverse Events Assessment, Patient Daily Reimbursement, Study Coordinator Fee, and Physician's Fee. All other procedures should be invoiced at cost if completed

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Additional Procedures

Payment will be made for procedures listed below if required by the protocol and not considered as standard of care.

Table 5 - Unitized Procedures

FEES	COST	COST INCLUDING 18% GST
Optional B-cell Repertoire Profiling Substudy	INR 800	INR 944
Optional DNA Sample	INR 800	INR 944

A3.2 OLE - Day 1 Visit — INR 70,848 + 18% GST, if applicable

Payable if the OLE - Day 1 visit occurs on a separate date from the Day 365 visit.

A3.3 Rescue Medication

Rescue Medications to be paid at actual cost upon receipt of invoice and supporting documentation, if not covered by a third party as standard of care and costs are reasonable and customary.

A3.4 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Medpace/Sponsor.

A3.5 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Medpace/Sponsor.

A4 MEDPACE RIGHTS

Medpace reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Medpace within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.

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Executive Registrar
SGPGIMS,Lucknow

A5 MEDPACE INVOICING

All payment inquiries and invoices submitted shall include the Protocol number and Principal Investigator name and be sent to the following:

Email: siteinvoices@medpace.com
Phone: 513-579-9911

Medpace Clinical Research, LLC
Attn: Clinical Operations Site Payments
5375 Medpace Way
Cincinnati, Ohio 45227

All invoices must be submitted to Medpace within ninety (90) days of occurrence or up to thirty (30) days after receipt of the final payment.

A6 PAYEE INFORMATION

All payments made by Medpace as set forth herein shall be payable solely to Payee at the address set forth below. Any such payments which are due to any other party performing services in connection with the Study shall be a matter solely between Payee and such party.

Table 6 - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name	Director SGPGIMS Research Scheme
Payee Mailing Address	Administrative Building, SGPGIMS, Raebareli Road, Lucknow
Contact Name	Dr. Jayantee Kalita
Email Address	icvantock@yahoo.com
Bank	State Bank of India
Account №	10095237491
IBAN №	N/A
BIC Code/Swift Code	SBINNEB500
IFSC Code (India)	SBIN0007789
Tax ID #**	AAAJS3913N

**Required for Medpace Accounting tracking purposes only

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Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Base Certificate No.	:	IN-UP03136416437070T
Certificate No.	:	**IN-UP03137310303929T**
Certificate Issued Date	:	08-Jul-2021 04:39 PM
Account Reference	:	NEWIMPACC (SV)/ up14243404/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14243404943991886924 93T
Purchased by	:	Dr Anshika Srivastava
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	MOU
Consideration Price (Rs.)	:	
First Party	:	Dr Anshika Srivastava
Second Party	:	DBT SGPGI
Stamp Duty Paid By	:	Dr Anshika Srivastava
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on Twenty July day of Two thousand and twenty one BY AND BETWEEN President of India, acting through ...Secretary....., Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor in-office and assigns) of the ONE PART;

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India a society under the Societies Registration Act– 1860, having its registered office in/at **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road,Lucknow-226014, Uttar Pradesh, India** hereinafter referred to as **SGPGIMS** (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of **human genetics and developmental genetics** decided to support a project submitted by **Dr. Anshika Srivastava, Assistant Professor & PI, Department Of Medical Genetics, SGPGIMS, Lucknow** for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **Probing the dynamic balance of histone H2AUb1 regulatory axis in hypertrophic cardiomyopathy and early heart development.**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs. 60.61600 (Rupees Sixty Lakh Sixty One Thousand Six Hundred Only)(Sanction Letter no- No. BT/12/IYBA/2019/13)** over a period of three years from March 2, 2020, to March 01, 2023 for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF Sanjay Gandhi Post Graduate Institute of Medical Sciences (Institute/NGO)

2.1. To provide their contribution of NIL for3 years from date of sanction of the project as detailed in Annexure–II. *(If a jointly supported project)*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be threeyears from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by **Dr. Anshika Srivastava** will be the joint property of **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** and DBT, Government of India. It shall be the responsibility of **Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road,Lucknow-226014, Uttar Pradesh, India** to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.) arising out of the PROJECT.

Anshika

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of **Sanjay Gandhi Post Graduate Institute of Medical Sciences(SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, **Dr. Anshika Srivastava** shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and **Sanjay Gandhi Post Graduate Institute of Medical Sciences(SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India.**

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice,

Anshika

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made thereunder shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

1. Vandana Sc 'C'

2. Rajul Sc 'C'

Signed by ----------

Dr. Prakash Chauhan
Scientist 'C'
Department of Biotechnology
Govt. of India
C.G.O. Complex, Lodhi Road
New Delhi-110 003

For and on behalf of The President of India

Witnesses:

1. (SMT. SARITA AGARWAL)
Professor
Dept. of Genetics
SANJAY GANDHI POST GRADUATE
INSTITUTE OF MEDICAL SCIENCES
LUCKNOW-226 014 (INDIA)

Signed by ----------

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow-INDIA

(Designation)

2.

Dr. Moinak Banerjee
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
LUCKNOW-226014, INDIA

For and on behalf of

...

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Annexure - I

Detailed Project Activities

Detailed Methodology

Below is the objective-wise description of detailed methodology and overall experimental approach as shown in figure 3.

Objective 1: Determine the pathogenic mechanism of ASXL3-dependent histone H2A deubiquitination in cardiogenesis:hESCs ASXL3-mutation models and successful cardiac directed differentiation: I willcreate BRS patient specific mutations (c.1448dupT; T484NfsX5 and c.1897_1898delCA;Q633VfsX13) in human embryonic stem cells (HUES9) using CRISPR/Cas9. As shown in our previous studies performed in patient fibroblasts that heterozygous mutations in ASXL3results in nonsense mediated decay and both the mutations are associated with congenitalHCM as evident through our Asxl3-/- mice (Figure 2). hESCs will undergo cardiac-directed differentiation using sequential application of a highly efficient protocol relying onapplication of cytokines at specific time points hESCs.[14]

Immunohistochemistry (IHC): A hypertrophic phenotype will be validated using cell sizequantification with immunofluorescence imaging and with a qRT-PCR assay of NPPA. I will quantify the human cardiomyocytes diameter with WGA. Ki67 and PH3 staining willquantify proliferation and cells undergoing mitosis defects.

RNA-seq analysis: RNA will be isolated from five biologic replicates for each genotype(wildtype, heterozygous and homozygous). Random culture condition effects will beminimized by pooling samples from at least 3 different differentiation batches. Five biologic replicates will be obtained for each model to maximize the accuracy of RNA-Seq analysis at30M paired end reads per sample. I will employ an existing RNA-Seq processing pipeline tomap RNA-Seq reads (STAR) and quantify mRNA transcript abundance (RSEM).[15-17] I willassess differential expression for each target gene using the software package EBSeq andcontrol for false discovery rate (FDR) using established methods.[18] Enrichment of differential expression signals at the pathway level (gene set enrichment analysis, or GSEA) will beperformed using Fisher's exact test.

ATAC-seq: ATAC-seq will be performed on five biologic replicates for each genotype (wildtype, heterozygous and homozygous) in parallel with RNA-seq sample collection asabove. Nuclei will be isolated and a transposase reaction performed using protocol outlined by Scott LJ et al. [19] Analysis of ATAC-seq data will focus on quantification of

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availability oftranscription factor binding sites that are known recognition sequences for hypertrophicsignaling transcription factors and/or transcription factors that are differentially expressedbased on the RNA-seq data. For the former, quantification ofbinding site availability isimportant since the transcription factor may be activated through phosphorylation (or otherpost-translational modification) but may not necessarily be upregulated at the mRNA level thus, the ATAC-seq methodology will be able to detect this level of activation that would bemissed by solely RNA-seq analysis.

Objective 2: Determine the pathogenic mechanism of TRIM37-dependent histone H2Aubiquitination in cardiogenesis: hESCs TRIM37-mutation models: I will create patient specific mutations usingCRISPR/Cas9 and will perform the cardiac differentiation as outlined in objective 1.

Immunohistochemistry: IHC analysis will be performed as outlined in objective 1.

RNA-seq: Experiments will be performed and analyzed as outlined in objective 1.

ATAC-seq: ATAC sequencing will be performed as outlined in objective 1.

Objective 3: Determine shared genetic mechanism and pathways in hypertrophiccardiomyopathy caused due to mutations in H2AUb1 regulatory axis members: This aim will directly compare two different genetic models of cardiac hypertrophy - one witha mutation in the histone H2A ubiquitin ligasegene TRIM37 and one with a mutation in thehistone H2A deubiquitinase ASXL3. Ihypothesize that there will be both shared anddistinct hypertrophic pathways activated betweenthe two models. Distinction of these pathwayswill have implications for therapeutic interventionfor cardiac hypertrophy.

The above-mentioned activities will be undertaken by Dr. Anshika Srivastava (PI) ***(Department of Medical Genetics, SGPGIMS, Lucknow)*** under the project entitled ***"Probing the dynamic balance of histone H2AUb1 regulatory axisin hypertrophic cardiomyopathy and early heart development."***

Objectives:

1. Determine the pathogenic mechanism of ASXL3-dependent histone H2A deubiquitination in cardiogenesis.
2. Determine the pathogenic mechanism of TRIM37-dependent histone H2A ubiquitination in cardiogenesis.
3. Determine shared genetic mechanism and pathways in hypertrophiccardiomyopathy caused due to mutations in H2AUb1 regulatory axis members.

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SGPGIMS,Lucknow

Annexure – II

Details of Funds

Dr. Anshika Srivastava

Assistant Professor

Department of Medical Genetics

Raebareli Road, SGPGIMS, Lucknow

(Rs in Lakhs)

Items	*I year*	*II year*	*III year*	Total
Non-recurring	10.00	0.00	0.00	10.00
Manpower	4.872	4.872	4.872	14.616
Consumables/Training/ Travel/ Contingencies	10.00	10.00	10.00	30.00
Overhead	1.00	1.00	1.00	3.00
Cash Award	1.00	1.00	1.00	3.00
Total	**26.872**	**16.872**	**16.872**	**60.616**

Anshika

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Executive Registrar
SGPGIMS,Lucknow

Annexure - IV

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further instalments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial

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SGPGIMS,Lucknow

year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest,the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: www.dbtindia.org / www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure - VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure - VII.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

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18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

Signature of Project Coordinator
(applicable only for multi-institutional projects)
Date :

Signature of Executive Authority of Institute/ University With seal

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date :

Signature of Principal Investigator :
Date :

Dr. [illegible]
Associate Professor
Dept. of Medical Oncology
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014, India

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SGPGIMS,Lucknow

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Dr. S.M.S.
Dr. U. K. Misra
[Study: EPID066]
25 July 2019

महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ UW 337558

Treasury Allotment Date and No. 18.04.2019 (UW 337558)	Serial No. 1598/19 Date 26.04.2019
Nature of Document/Article No.	
Whether it is to be Registered -	If Registrable Name of S.R.O.-
Property Description in brief	As per the Document
Stamp Purchaser's Name	**Abbott India Limited,** 16, Godrej BKC, Bandra (E), Mumbai-51
If through other person then Name & Address	Anil Gonde,
Name of the Other Party	-
Stamp Duty Amount	Rs.100/-
Stamp Purchaser's Signature and Date	Shri **Jay R. Birwadkar,** Stamp Vendor, Lic. No. 1206030 Kumbhar Chawl, Netivali, Kalyan (E) 421 306 (M) 9890732173

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्या पासुन सहा महीन्यात वापरणे बंधनकारक, अन्यथा अधिकारी

18 APR 2019

EPIDEMIOLOGICAL STUDY AGREEMENT

Abbott India Limited ("Abbott") desires to retain , **Sanjay Gandhi Post Graduate Institute of Medical Sciences**, at, **Raebarel Road, Lucknow, Uttar Pradesh-226014**,India ("Institution") to provide services in support of Institution's employee's **Dr. Usha Kant Misra** (the "Investigator") conduct of a non-interventional, epidemiological study (the "Study") in relation to" **A Cross-Sectional, Multicenter Study To Determine The Sociodemographic Characteristics, Clinical Profile, And Usage Pattern Of Antiepileptic Drugs In Persons With Epilepsy In India"** effective as of the date this Epidemiological Study Agreement (the "Agreement") is fully executed (the "Effective Date"). In consideration of the mutual promises set forth herein, the parties agree as follows:

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Executive Registrar
SGPGIMS,Lucknow

1. Conduct of Study.

(a) Investigator will conduct the Study pursuant to the terms of this Agreement and in strict adherence to EPIDIO66 study entitled "*A Cross-Sectional, Multicenter Study To Determine The Sociodemographic Characteristics, Clinical Profile, And Usage Pattern Of Antiepileptic Drugs In Persons With Epilepsy In India*" (the "Protocol"), as the same may be amended from time to time in writing by Abbott, and with any other written instruction that may be provided by Abbott. The parties further agree that this Study is epidemiological and will not utilize any Abbott product(s) ("Abbott Product(s)"). Subjects may already be prescribed an Abbott Product prior to, during or after the Study however this is incidental to the conduct of the Study and any such decision to prescribe Abbott Product to any subject at any time shall be the sole decision of the relevant subject's doctor and unrelated to the Study.

(b) Investigator hereby represents and warrants that any and all personnel working by or on behalf of the Investigator, with respect to the Study, are employed by Investigator and will work under the supervision of the Investigator. Further, Investigator shall be responsible for making payments, if applicable, to such personnel upon receipt of funds from Abbott. Investigator will ensure that such personnel will comply with the terms and conditions of this Agreement and Investigator shall remain responsible and liable for the acts or omissions of such personnel as if such activities had been performed by Investigator.

(c) Investigator shall use best efforts to complete enrollment of 10 patients (hereinafter referred to as "subjects") within 03 months of Study initiation. The Investigator's site will be discontinued by the sponsor if there is no enrollment of patients within 01 month of site initiation. Abbott may terminate this Agreement immediately if (i) IRB or IEC (defined below) approval or NOC from Institutional Ethics Committee, if required, is not obtained after central Ethics committee approval within 5-8 weeks of receipt of all necessary materials for IRB/IEC submission; or (ii) all essential documents have not been executed and received by Abbott within 4 weeks of Investigator's receipt of IRB or IEC's written approval, if such approval is required.

Contacts. Investigator's contact(s) at Abbott will be **Sneha Nair-Head- Clinical Operations, Abbott India Limited ,16th Floor, Godrej BKC,Plot C – 68, "G" Block, Bandra Kurla Complex, Near MCA Club, Bandra (East),Mumbai 400 051, India, O:+91 22-38160910, M: 9970780488, Fax # 91-22 2871 7499**, or whomever Abbott may designate in writing. Abbott's contact(s) at Investigator will be retain, **Dr. Usha Kant Misra, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014, Phone: + 91- 8004904627.**

2. Compliance with Law.

(a) Investigator represents warrants and covenants that he/she will conduct the Study and perform his/her obligations under this Agreement in compliance with all applicable laws, regulations and guidelines. In furtherance of the foregoing obligations and as required by law, Investigator will further ensure that an Institutional Review Board ("IRB"), an Independent Ethics Committee ("IEC"), or both, as applicable, approves and oversees the conduct of the Study. Investigator will comply with the directives of the IRB or IEC, or both, as applicable, respecting the conduct of the Study, and will notify Abbott to the extent any such directives vary from the Protocol.

(b) Prior to the initiation of the Study, Investigator will and will ensure that any subinvestigator for the Study provides Abbott with all essential regulatory documents requested by Abbott including but not limited to current Curriculum Vitae and medical license, or equivalent, to ensure compliance with applicable regulations. Investigator will comply with all applicable requirements regarding reporting and management of conflicts of interest.

(c) Investigator agrees that if services are paid for or provided without charge by Abbott, neither Investigator, nor his/her agents shall separately bill or seek reimbursement for such services from any third party including, without limitation, the subject, any private provider of insurance, or any government program or other public provider of insurance.

3. Safety Reporting. Institution and Investigator shall comply with the safety reporting obligations attached hereto and incorporated herein as Exhibit B ("Safety Reporting Obligations").

Study Supplies. Due to the epidemiological nature of this Study, Abbott will not be providing any Abbott Product(s) or reimbursement for any Abbott Product(s). Abbott will provide to Investigator, at no cost, sufficient quantities of the case report forms or access to an electronic data capture system ("CRFs") as well as any other materials and information specified by the Protocol or that Abbott deems necessary to conduct the Study (together, the "Study Materials"). All Study Materials and other information provided by Abbott in connection with this Agreement will not be used for any purpose other than to conduct the Study pursuant to the Protocol and will remain the sole property of Abbott. Upon termination of the Study or at

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Abbott's request, the Study Materials will be returned or destroyed pursuant to the Protocol, and Institution will document such disposition, pursuant to Abbott's direction.

4. Delivery of Progress and Post-Study Reports. Upon request, Institution will submit oral or written reports on the progress of the Study to Abbott. Within forty-five (45) days following the completion or termination of the Study, Institution will furnish Abbott with the following, unless Abbott directs otherwise in writing.

   (a) the final IRB or IEC report on the Study prepared by the Investigator for the IRB or IEC or both, as applicable;
   (b) all completed, used and unused CRFs not previously delivered to Abbott; and
   (c) all data, reports and other information generated in relation to the Study.

5. Monitoring and Audits; Record Retention.

   (a) Institution will permit Abbott and/or any Abbott designee access to Study sites during normal business hours to monitor the conduct of the Study as well as to audit records, CRFs, source documents, and other data relating to the Study. Institution may redact such records as may be legally required to protect subject confidentiality consistent with **Section 9** (Subject Confidentiality and Data Protection) of this Agreement. If Abbott requests corrective and/or preventive action as a result of its monitoring or audit activities, Institution shall comply with the timely creation and implementation of a corrective action and/or preventive action plan. Abbott's right to audit shall survive the expiration of this Agreement.

   (b) Institution will ensure that subject data, as required in the Protocol, is entered into the CRFs (whether electronic or paper) within five (5) business days of subject visit.

   (c) Unless prohibited by law, Institution will notify Abbott immediately upon receiving any requests by any regulatory authority to inspect or have access to documents related to the Study and will promptly provide Abbott with a copy of any such request, to include copies of any documents received from or provided to regulatory authorities. In the event a regulatory citation or notice is issued which relates to the services under this Agreement, Institution agrees to produce a summary that includes an explanation of the issues identified by the regulatory authority, any response to the significant issues identified by the regulatory authority, and an explanation of the applicability of such regulatory citation or notice to the service(s) provided hereunder. Institution agrees to provide Abbott with such summary within fifteen (15) days of Institution's receipt of any regulatory citation or notice.

   (d) Institution shall retain the Study documents in accordance with applicable laws and regulations or the Protocol, whichever retention period is longer. At Abbott's request and expense, Institution shall retain the Study documents for an even longer period. Institution shall provide Abbott at least sixty (60) days' written notice before deleting any Study documents from its files.

6. Compensation.

   (a) Abbott shall pay Institution in accordance with the Study budget set forth in **Exhibit A** (the "Budget"). In addition, Institution's employees, including Investigator, may be reimbursed for reasonable and necessary expenses related to travel, consistent with Abbott's travel policy (including economy coach air travel, reasonable and customary lodging and meal rates based on the geographic region of travel), and may be provided meals as may be necessary for the publication/ presentation of study results/data or at investigator meetings or other Abbott required meetings. The parties agree that the amounts set forth in the Budget represent the fair market value for the services to be rendered and have not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between or among Institution and Abbott.

   (b) The Budget is based on the full performance of services and compliance with the terms of this Agreement (including the Protocol). Abbott will not remit payments for CRFs containing incomplete or inaccurate data or data collected from subjects enrolled in violation of the Protocol ("Non-conforming CRFs"). If Abbott has paid for such Non-conforming CRFs such payment will be deducted from the next payment (or the final payment, as described in **Section 7(d)** below).

   (c) All payments shall be made in accordance with the terms of **Exhibit A** and only after all parties have signed this Agreement. If applicable, reimbursement of IRB/IEC fees is contingent upon completion of the IRB/IEC's review and final decision regarding all submitted Study documents including, but not limited to, the Protocol and/or Protocol revisions. Abbott will not be obligated to reimburse Institution for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

   (d) The final payment due to Institution under this Agreement shall be payable upon completion of all services contemplated hereunder, delivery to Abbott of all CRFs, and return to Abbott of all items described in **Section 5**

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(Delivery of Progress and Post-Study Reports) and will be accompanied by a financial reconciliation performed by Abbott. If the total amount Abbott has paid is less than the amount to which Institution is entitled hereunder as revealed by the reconciliation, Abbott shall pay the outstanding amount due. If Abbott is due a refund for any uncarned fees or overpayments, Institution shall remit the amount of such refund with supporting documentation to Abbott at: Clinical Operations, Abbott India Ltd.,16th Floor, Godrej BKC,Plot C – 68, "G" Block Bandra Kurla Complex,Near MCA Club, Bandra (East),Mumbai 400 051, India. Any payments due from one party to the other under the reconciliation shall be made within forty-five (60) days of the notice and invoice of amount due.

(e) In the event of a payment dispute, Institution and Investigator shall not withhold Study data or information pending resolution of the dispute because such withholding may cause irreparable harm to the Study.

(f) Upon written notice, Abbott may delegate certain of its payment obligations to a contract research organization ("CRO"). In such event, Institution and Investigator agree that as to any payments delegated by Abbott to a CRO, Institution and Investigator shall first seek redress from the CRO for compensation.

(g) Investigator shall be responsible for direct compensation of Investigator, including any subinvestigators, from funds paid by Abbott to Institution under the Study Budget. Neither Investigator nor any subinvestigators shall receive any separate compensation from Abbott.

(h) In this study; Abbott has delegated its Fee payment obligations under this Agreement to **JSS Medical Research India Pvt Ltd**. The Investigator will hence approach Site Management Organization (SMO) for queries or concerns in relation to compensation under this Agreement.

7. Confidentiality.

(a) During the Term of this Agreement, including any extensions thereof, and for a period of ten (10) years after the expiration or termination of this Agreement, Institution, its employees (including Investigator), agents, subcontractors and affiliates (collectively, "Receiving Party") shall not disclose Confidential Information without Abbott's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Abbott shall remain in place for so long as the applicable Confidential Information retains its status as a trade secret under applicable law. "Confidential Information" shall include any information provided to Receiving Party by or on behalf of Abbott, including but not limited to the Protocol, Abbott Product, Study Materials, and all materials and information concerning Abbott or the Study or developed as a result of conducting the Study, except any portion thereof which:

(i) is known to the Receiving Party prior to receipt, as evidenced by its written records;
(ii) is disclosed to the Receiving Party by a third party who has a right to make such disclosure in a non-confidential manner; or
(iii) is or becomes part of the public domain through no fault of the Receiving Party.

(b) The Receiving Party shall not use Confidential Information for any purpose other than as indicated in this Agreement without Abbott's prior written approval.

(c) Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall give Abbott prompt written notice (and in any case at least five (5) business days notice) to allow Abbott to take action to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Abbott waives compliance with the terms of this **Section 8**, Receiving Party shall furnish only that portion of the Confidential Information which is legally required based on the written opinion of legal counsel.

(d) Receiving Party will not disclose to Abbott any information which is confidential or proprietary to a third party unless Institution has first obtained the prior written approval of such third party and Abbott.

8. Subject Confidentiality and Data Protection.

(a) The parties will comply with all applicable laws and regulations regarding Study subject confidentiality and data protection. Investigator will be responsible on behalf of the Institution for obtaining a signed subject authorization document for the use and disclosure of data and an Informed Consent Form, if required (collectively, "ICF") from each Study subject prior to the subject's participation in the Study. The ICF must permit Abbott and its representatives involved with or evaluating the Study to access, process, obtain copies, transfer and retain Study data. Each ICF must conform with the Protocol and be compliant with: International Conference on Harmonisation, Harmonised

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Tripartite Guidelines for Good Clinical Practice ("ICH"); all applicable laws and regulatory requirements; and must be approved in writing by Abbott, and if applicable by the IRB/IEC. A Study subject's participation in the Study will be contingent upon the execution of a proper ICF.

(b) Where Institution and/or Investigator collects, retains, processes or discloses information identifying or, in combination with other information, identifiable to a living individual, including Study subjects and others participating in or associated with the Study (the "Personal Data") it shall only do so in accordance with this Agreement, with all applicable laws and with Abbott's written instructions. Institution and Investigator shall maintain appropriate safeguards to ensure the confidentiality and security of the Personal Data. Institution and Investigator shall promptly inform Abbott of any unauthorized access to or disclosure of Personal Data (the "Security Breach"), including the timing and nature of the Security Breach. Institution and Investigator shall take all reasonable measures to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, Institution will undertake to ensure that all necessary agreements are implemented and in place.

(c) Investigator acknowledges and consents to, and shall cause all subinvestigators for the Study to acknowledge and consent to, Abbott's collection, use, processing, and disclosure of Investigator's and sub-investigator's Personal Data including details of his/her name, address, qualifications and clinical trial experience. Additional uses or disclosures may include financial information (including compensation and reimbursement payments), public registration of the Study on web sites designed for this purpose such as www.clinicaltrials.gov, assessments by Abbott of Investigator's suitability for future studies, and for purposes of complying with applicable laws. Investigator understands and expressly agrees and shall cause all subinvestigators for the Study to expressly agree that this information may, if necessary for these purposes, be made available to ethics committees, government authorities and other companies within the Abbott group of companies located both in the country in which the Study is carried out and in other countries, including in the United States or elsewhere as required by applicable law or as necessary for the purposes of Good Clinical Practice or data protection audits or inspections.

9. Publicity. Institution shall not and shall ensure Receiving Party shall not disclose the existence or terms of this Agreement or use the name, trademark, servicemark or logo of Abbott in any publicity, advertising or information, which is disseminated to any third person or to the general public without Abbott's prior written approval. Institution understands that the terms and conditions of this Agreement, including the amount of any payment made hereunder, may be disclosed and made public by Abbott as required by law or regulation or where Abbott deems appropriate.

10. Inventions. Any information, invention, data or discovery (whether patentable or copyrightable or not), innovation, communication or report, conceived, reduced to practice, made, generated or developed by the Receiving Party that either results from use of Abbott Product(s) or results from conduct of the Study will be promptly disclosed to Abbott, assigned to Abbott and will be the sole property of Abbott. Institution and Investigator each agree, upon Abbott's request and at Abbott's expense, to execute or cause to have executed such documents and to take such other actions as Abbott deems necessary or appropriate to obtain patent or other proprietary protection in Abbott's name covering any of the foregoing.

11. Publications and Presentations.

(a) Publication Requirements. To foster the highest standards of conduct related to scientific publications, including manuscripts, abstracts, and poster/oral presentations (collectively, "Publication(s)"), Abbott is committed to transparency and ethical publication practices. If Investigator serves as an author on any Publication emanating from the Study, Investigator must comply with the Requirements for Scientific Publications attached hereto as **Exhibit B.**

(b) Procedures. As the Study sponsor, Abbott retains the first right to disclose the results of the Study through a Publication or any other public disclosure (collectively, a "Study Results Disclosure"). Accordingly, following the earliest of: (i) Abbott's Study Results Disclosure; or (ii) twelve (12) months after completion or termination of the Study at all Study sites, Institution and Investigator shall have the right to prepare and submit for Publication a Study Result Disclosure in appropriate scientific journals or other professional publications. If Institution or Investigator prepares a Study Results Disclosure, Institution shall provide or shall require Investigator to provide Abbott, at least sixty (60) days prior to any submission of a work for a Study Results Disclosure, with a draft of the same for Abbott's review and comment to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. Abbott shall return comments to Institution or Investigator within sixty (60) days after receipt of the draft Study Results Disclosure (the "Review Period"). In addition, Institution or Investigator shall delay any proposed Study Results Disclosure an additional sixty (60) days in addition to the Review Period in the event Abbott so requests to enable Abbott to secure patent or other proprietary protection (the "Delay Period"). Institution agrees and shall require Investigator to agree to keep the proposed Study Results Disclosure confidential until the Review Period and, if elected by Abbott, the Delay Period has expired. Institution agrees and shall require Investigator to agree that due consideration will be given to Abbott comments; and further, Abbott Confidential Information (other than the results of the Study generated hereunder) shall be deleted from any

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SGPGIMS,Lucknow

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Study Results Disclosure. In the event that Institution or Investigator and Abbott differ in their opinion or interpretation of data in the Study Results Disclosure, the parties shall resolve such differences in good faith through appropriate scientific debate.

12. Representations and Warranties. Institution represents and warrants that:

(a) the terms of this Agreement are valid and binding obligations of Institution, and are not inconsistent with any other contractual or legal obligation it or Investigator may have or with Institution's policies and procedures or the policies and procedures of any institution or company with which each of Institution or Investigator is associated;

(b) Institution's performance of the services and acceptance of compensation, including the acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator or Institution (including its employees and agents) hereunder, is in compliance with all policies and procedures of Institution, and that Investigator's performance of such services does not present a conflict of interest with Investigator's official duties;

(c) Investigator has received any required authorization, written or otherwise, from Institution for Investigator's performance of the services and acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator hereunder;

(d) If Investigator leaves Institution's employment during the Term, then Institution will promptly notify Abbott in writing and will obtain a written acknowledgement by Investigator's new employer that Investigator is participating in the Study under the terms of this Agreement;

(e) Institution and Investigator have the experience, capabilities, adequate subject population, and resources, including but not limited to sufficient personnel and equipment, to efficiently and expeditiously perform the Study in a professional and competent manner;

(f) any subinvestigators used by Institution for the Study will be selected based upon a consideration of the following: (i) training and expertise in relevant fields; (ii) appropriate research facilities; (iii) experience with the relevant subject population so that the subinvestigator has a reasonably high likelihood of recruiting the appropriate research participants and following through to the completion of the Study; (iv) prior scientific research or clinical experience; and (v) ability to conduct the Study in accordance with applicable legal and regulatory requirements;

(g) Investigator is not under investigation or subject to any disciplinary action by any medical board, and Investigator has a medical license, or equivalent, that has not been restricted or suspended by any medical board in any way. In the event that any of foregoing occurs, Investigator shall immediately notify Abbott, and Abbott shall have the right to immediately terminate this Agreement;

(h) Institution shall ensure that Investigator does not alter in any way Investigator's normal practice for prescribing medications to patients or be influenced in any way to prescribe an Abbott product in place of any other therapy due to the conduct of this Study or payment to Institution of any compensation from Abbott for conducting this Study; and

(i) if any significant changes occur during the Term with regard to the circumstances surrounding this Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of Institution or Investigator's involvement in this Agreement), Institution agrees to immediately notify Abbott in writing of any such changes.

13. Term and Termination.

(a) This Agreement will be effective on the Effective Date and shall expire on the later of: (i) one (1) year from the Effective Date; (ii) the date of Study database lock if there is subject enrollment under this Agreement; or (iii) the date of completion of all the obligations of the parties hereunder (the "Term"), unless terminated earlier as provided below.

(b) Abbott may terminate this Agreement at any time upon written notice. Either party may terminate this Agreement upon written notice if (i) the other party has breached a material term of the Agreement, or (ii) if the Study is terminated by any governmental or regulatory authority.

(c) Termination or expiration of this Agreement will not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Institution will discontinue all then-enrolled subjects from the Study.

14. Insurance. Each party agrees to maintain a policy or policies of insurance or self-insurance sufficient to satisfy its respective duties and obligations under this Agreement to the extent such duties and obligations are commercially

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(14)

insurable. Each party further agrees to provide written evidence of such insurance (including certificates of insurance or other evidence providing reasonable assurances) to the other party within seven (7) business days following receipt of written request by the other party therefore.

15. Debarment and Exclusion. Institution represents and warrants that none of Institution, any Institution employees, including investigator, agents and subcontractors performing services hereunder, including any subinvestigators, have ever been, are currently, or are the subject of a proceeding that could lead to Institution or such employees, agents or subcontractors becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual, nor are they listed on the United States Food and Drug Administrations (the "FDA") Disqualified/Restricted List for clinical investigators. Institution further covenants, represents and warrants that if, during the Term, Institution, or any of Institution's employees, including Investigator, agents or subcontractors, including any subinvestigators, performing services hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual or added to FDA's Disqualified/Restricted List for clinical investigators, Institution will immediately notify Abbott, and Abbott will have the right to immediately terminate this Agreement. The provision of this paragraph regarding notice of acts occurring during the Term will survive termination or expiration of this Agreement. For purposes of this provision, the following definitions will apply:

    (a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from providing services in any capacity to a person that has an approved or pending drug product application.

    (b) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to Title 21 of USC Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

    (c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General of the U.S. Department of Health and Human Services; or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration.

    (d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of Title 21 of USC Section 335a(a) or Title 42 of USC Section 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

    (e) "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

16. Independent Contractor. Each of Institution and Investigator's relationship to Abbott under this Agreement is that of an independent contractor, and neither Institution nor Investigator has authority to bind or act on behalf of Abbott.

17. Assignment. Institution may not assign this Agreement to any other party, or subcontract any of its services hereunder, without Abbott's prior written consent. Any attempted assignment without Abbott's prior written consent will be null and void and will constitute a material breach of this Agreement. Any permitted assignee shall assume all obligations of Institution under this Agreement. Assignment shall not relieve Institution of responsibility for the performance of any accrued obligation. Further, in the event that Institution is permitted to subcontract any duty hereunder to any third party, such subcontractor shall execute an agreement in a form acceptable to Abbott obligating such subcontractor to comply with the terms and conditions hereof, and Institution shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by Institution.

18. Subinvestigators. Institution will not use any subinvestigator for the Study without Abbott's prior written consent, and only upon Institution's agreement to ensure any subinvestigators compliance with the terms and conditions of this Agreement.

19. Notices. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile.

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(13)

If to Institution
Dr. Usha Kant Misra

Address: , Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014

Phone: +91- 8004904627.

If to Investigator:
Dr. Usha Kant Misra

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow Uttar Pradesh-226014

Phone: + 91- 8004904627.

If to Abbott:
Sneha Nair,
Head- Clinical Operations,
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C- 68, BKC,Near MCA Club,
Bandra (E)
Maharashtra- 400051, India
Direct 91-22 38160910,
Mobile No : +91-9970780488

with a copy to:
Kaiyomarz Marfatia
Director- Legal & Secretarial
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C-68, BKC,Near MCA Club,
Bandra (E)
Mumbai-400051,
Maharashtra, India
Phone:91-022-28717488

20. Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.

21. Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

22. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.

23. Applicable Law, Place of Venue-The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof. The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, India will have sole jurisdiction over the litigation

24. Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the Parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Act. The arbitration shall take place in Mumbai and shall be conducted in the English language. The award of the arbitrator shall be final and binding on both parties.
The parties bind themselves to carry out the awards of the arbitrator. This Section shall survive termination or expiration of this Agreement.

25. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties. This Agreement is being signed in the English language only. If another language version is created, it shall not affect the interpretation of this Agreement and the English language version shall prevail.

26. Financial disclosure certification: Prior to the initiation of the study, institution will ensure that each investigator and any sub investigator(a) completes and returns to Abbot the financial disclosure certification Investigator understands and will be required to certify that investigator and all sub investigator conducting the study, and their immediate families may not have a direct ownership interest(e.g., intellectual property rights) in the Abbott Product, nor may they be compensated with

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Executive Registrar
SGPGIMS,Lucknow

(12)

If to Institution
Dr. Usha Kant Misra

Address:, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014

Phone: + 91- 8004904627.

If to Investigator:
Dr. Usha Kant Misra

Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow Uttar Pradesh-226014

Phone. + 91- 8004904627.

If to Abbott:
Sneha Nair,
Head- Clinical Operations,
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C- 68, BKC,Near MCA Club,
Bandra (E)
Maharashtra- 400051, India
Direct 91-22 38160910,
Mobile No : +91-9970780488

with a copy to:
Kaiyomarz Marfatia
Director- Legal & Secretarial
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C-68, BKC,Near MCA Club,
Bandra (E)
Mumbai-400051,
Maharashtra, India
Phone:91-022-28717488

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24. Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the Parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Act. The arbitration shall take place in Lucknow and shall be conducted in the English language. The award of the arbitrator shall be final and binding on both parties. The parties bind themselves to carry out the awards of the arbitrator This Section shall survive termination or expiration of this Agreement.

25. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties. This Agreement is being signed in the English language only. If another language version is created, it shall not affect the interpretation of this Agreement and the English language version shall prevail.

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Abbott securities in exchange for being an Investigator or subinvestigator in the Study. Investigator and any subinve... will promptly notify Abbott of any change in the accuracy of the Financial Disclosure Certification during the Term and for one (1) year following completion of the Study.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBOTT INDIA LIMITED

By: _____

Name: Sneha Nair

Title: Head-Clinical Operations

Date: 25/07/2019

INVESTIGATOR NAME

By: _____

Name: Dr. Usha Kant Misra

Title _____

Date: _____

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES

By: _____

Name: Prof. Rakesh Kapoor

Title: Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Date: 03.09.2019

Exhibit A - Budget
Attachment 1 to Exhibit A
Exhibit B - Safety Reporting Obligations
Exhibit C- Requirements for Scientific Publications

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SGPGIMS,Lucknow

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EXHIBIT A
BUDGET

INVESTIGATOR	Dr. Usha Kant Misra
ADDRESS	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow. Uttar Pradesh-226014
PHONE	+ 91- 8004904627

DISEASE BEING STUDIED: Epilepsy	PROTOCOL: EPIDI066	Visits: Baseline
Number of subjects required per Protocol/Study by Investigator		80
Total per subject cost (see **Attachment 1**, per subject breakdown; payments to be made per the Subject Visit Payments schedule, described below, every 3 months)		INR 1000(Visit) = 1000*
Total cost for all CRFs for all subjects		INR 80,000**
ADDITIONAL STUDY FEES: Payments will be made as follows, in accordance with Compensation Section of the Agreement.		
TOTAL COMPENSATION)		INR 80000

*** On completion of visit 1(Baseline)**
**** depends on the total no of patients enrolled / CRF completed**

SUBJECT VISIT PAYMENT SCHEDULE: Payments will be made as follows, in accordance with the Compensation Section of the Agreement:

Subject Visit Payments: Payments for subject visits will be made quarterly following enrollment of the first subject. Payments will be made after data is entered by Investigator into the CRFs and reviewed by Abbott, and will correspond to amounts listed in **Attachment 1 to Exhibit A**. Investigator understands that such payments are subject to subsequent verification by Abbott and will be adjusted per Section 7(d) (Compensation) of the Agreement if necessary. Total payment mentioned in the agreement is for a recruitment of 20 patients.
A CRO, JSS Medical Research India Private Limited has been contracted to provide the site with a CRC for subject recruitment, source documentation& data entry purpose. The cost of the CRC will be paid by Abbott India Limited to JSS Medical Research India Private Limited.

A final payment shall be made following termination of the Study, delivery to Abbott of the remaining Completed CRF(s), final reconciliation of any remaining amounts due, and the return to Abbott of all items described in Section 4 (Study Supplies) of the Agreement. Abbott will not be obligated to reimburse Investigator for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

CHECQUE PAYMENT INFORMATION:

Cheque shall be made payable to:	**DIRECTOR SGPGIMS RESEARCH ACCOUNT**
Individual's name and address	Dr. Usha Kant Misra Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014
Individual's name and e-mail address at site to receive detailed payment information:	Dr. Usha Kant Misra drukmisra@rediffmail.com
Individual's name and address to receive Invoices at Abbott:	Dr. Prachi Sudhir Bhoyer Site Management, JSS Medical Research India Private Limited
Pan Card Number of Institute:	**AAAJS3913N**

(Information must be accurate for FDA purposes)

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Executive Registrar
SGPGIMS,Lucknow

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NEFT payment Information:

Payee Name:	**DIRECTOR SGPGIMS RESEARCH ACCOUNT**
Bank Account No.	**10095237491**
IFSC Code:	**SBIN0007789**
Bank Name, Branch & address:	**STATE BANK OF INDIA** **SGPGIMS, LUCKNOW.**
GSTN, If applicable:	**09AAAJS3913N2ZN**

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Executive Registrar
SGPGIMS,Lucknow

(8)

ATTACHMENT 1 TO EXHIBIT A

Study Budget Breakdown

- For participation as Principal Investigator

  1. Scope of work

  Table 1: Subject grant

  Fee Per completed CRF per Subject- 1000

  Other Payment terms:

- Cost for minimum 80 patients completing the study = 80*1000
- Total Investigator Grant = INR 80,000/-
- Per patient grant as outlined in table 1, is inclusive of overheads
- With reference to clause 8/g towards compensation: Abbott India Limited has delegated its payment obligation towards the investigators to a service provider (i.e. JSS Medical Research India Private Limited). Thus payment shall be made from Abbott to Investigator through (JSS Research).
- An invoice addressed to Abbott India Limited will have to be provided by the investigator (on institution letterhead) to the personnel from JSS Research India Private Limited prior to release payment. A template for the same will be shared by JSS Research. Any and all invoices raised by the institution/ site under the agreement shall be paid by the Abbott within 60 days from the date of the receipt of the invoice from the institution/ site to the Abbott.
- Travel Expenses: Expenses towards domestic travels, hotel stay, meal and car rental for any of the study related meeting would be done by Abbott with prior written approval from Abbott.
- All payments under this agreement are subject to applicable taxes including service tax and the same shall be borne by Abbott. As per the Indian Tax Laws TDS would be applicable. A TDS certificate would be provided to your site before the end of the financial year.
- Payment will be released within 60 days of receipt of the invoice.

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SGPGIMS,Lucknow

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EXHIBIT B

SAFETY REPORTING OBLIGATIONS

(a) Institution and Investigator shall comply with all applicable adverse event reporting and other regulatory obligations applicable for investigators and Abbott shall comply with all applicable adverse event reporting and other regulatory obligations applicable for sponsors. In addition, Institution and Investigator shall report to Abbott the following Pharmacovigilance-relevant information if spontaneously reported to Institution or Investigator and only in case relating to an Abbott product(s):

(i) adverse reactions (a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility);

(ii) product exposure (including maternal, paternal or fetal exposure) associated with a pregnancy;

(iii) trans-mammary exposure of an infant (transmission via breast milk) to a product;

(iv) overdose (i.e. administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorized product information (Note: Clinical judgment should always be applied));

(v) abuse (i.e. persistent or sporadic, intentional non-therapeutic excessive use of a product by patient/consumer which is accompanied by harmful physical or psychological effects)

(vi) misuse (i.e. intentional and therapeutic but inappropriate use of a product by patient/consumer not in accordance with the authorized product information);

(vii) off-label use (i.e. intentional prescribed therapeutic use of a product not in accordance with the authorized product information);

(viii) occupational exposure (i.e. exposure to a product as a result of one's professional or non-professional occupation);

(ix) medication errors (i.e. unintended failure by patient/consumer or health care professional in the drug treatment process that leads to, or has the potential to lead to, harm to the patient);

(x) lack of therapeutic efficacy (i.e., "lack of effect" reports), which will be handled as a serious adverse reaction if associated with vaccine or contraceptive product or drugs used for critical conditions or for the treatment of life-threatening diseases;

(xi) suspected transmission of an infectious agent, which will be classified as a serious adverse reaction;

(xii) an unexpected therapeutic or clinical benefit from use of the product.

(b) Such information shall be reported by Institution and/or Investigator to Abbott within 24 hours of becoming aware of such occurrences. Institution and Investigator shall promptly make available to Abbott such records as may be necessary and pertinent to investigate such occurrences.

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Executive Registrar
SGPGIMS,Lucknow

Exhibit C

REQUIREMENTS FOR SCIENTIFIC PUBLICATIONS

1. Criteria for Authorship. Based on the October 2007 guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit must be based on:

   (a) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and
   (b) Drafting or revising the article for important intellectual content; and
   (c) Final approval of the version to be published.

   A person must meet all three of the above criteria to warrant authorship.

2. Acknowledgement of Medical Writers and Other Contributors. Those individuals who have made a significant contribution to the Study or Publication, but do not meet the criteria for authorship noted above, must be listed in an acknowledgments section, including disclosure of the source of any financial support given to such contributors. All persons must give written permission to be acknowledged.

3. Conflict of Interest. In the interest of transparency and maintaining the highest possible standards of conduct, authors will comply with each journal's or congress's requirements for conflict of interest disclosure in the Publication. Such conflict of interest disclosure requirements may include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.

4. Sponsorship. Authors must acknowledge Abbott as the funding source of a Study, and must also comply with additional sponsorship-related disclosures required by the journal or congress.

5. Access to Data. Abbott will provide all authors with the final Protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports needed to prepare the planned Publication. Abbott will provide a copy of the Protocol and plan for statistical analysis when requested by a medical journal considering a submitted manuscript for publication, with the understanding that the documents are confidential, the property of Abbott, and should not be disclosed to any third party without Abbott's prior written permission.

6. Redundant Publication. Duplicate or redundant publication of the Study results in peer-reviewed journals is not permitted. Secondary Publications that present significant and scientifically sound additional analyses or groupings of data are permitted. Publication of foreign language translations of the original manuscript, in accordance with the policies of the journals involved is permitted. Encore presentation of data, when permitted by scientific congress policy, is permitted.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र शासन
GOVERNMENT OF MAHARASHTRA
ई-सुरक्षित बँक व कोषागार पावती
e-SECURED BANK & TREASURY RECEIPT (e-SBTR)

16256323503175

Bank/Branch: IBKL - 6910820/BANDRA KURLA COMPLEX, MUMBAI
Pmt Txn id : 216266650 Stationery No: 16256323503175
Pmt DtTime : 23-MAY-2019@18:01:43 Print DtTime : 23-MAY-2019 20:11:19
ChallanIdNo: 69103332019052350892 GRAS GRN : MH001849764201920S
District : 7101-MUMBAI Office Name : IGR182-BOM1_MUMBAI CITY
GRN Date : 23-May-2019@18:01:42

StDuty Schm: 0030045501-75/STAMP DUTY
StDuty Amt : R 5,000/- (Rs Five, Zero Zero Zero only)

RgnFee Schm: 0030063301-70/Registration Fees
RgnFee Amt : R 0/- (Rs Zero only)

Article : 13-Bond
Prop Mvblty: N.A. Consideration: R 25,00,000/-
Prop Descr : 101AWINGFULCRUMHIRANANDANIBUSINESSPARKSAHARROADANDHERIEMUM400099

Duty Payer: PAN-AADCP2043E,PPD PHARMACEUTICAL DEVELOPMENT INDIA PVT LTD

Other Party: PAN-AAAJS3913N,DIRECTOR SGPGIMS RESEARCH ACCOUNTS

Bank official1 Name & Signature

Bank official2 Name & Signature

--- --- Space for customer/office use - - - Please write below this line --- ---

IDBI BANK LTD.

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("Agreement"), is entered into as of _____ day of _____, ("Effective Date") by and between PPD Pharmaceutical Development India Private Limited, 101-A Wing, 'Fulcrum', Hiranandani Business Park, Sahar Road, Andheri East Mumbai 400 099, India ("PPD"), and Sanjay Gandhi Postgraduate Institute of Medical Sciences ("Institution"), with its principal place of business at Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India, represented by Dr. Rakesh Kapoor, a duly authorized representative with authority to contract on behalf of the Institution and Dr.Narayan Prasad ("Principal Investigator"), with his/her offices located at Sanjay Gandhi Postgraduate Institute of Medical Sciences Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India.

PPD, Institution and Principal Investigator are herein referred to each as a "Party" and, collectively, as the "Parties".

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WHEREAS

I. PPD is a global contract research organization that is currently assisting GlaxoSmithKline Research & Development Limited,980 Great West Road Brentford, Middlesex TW8 9GS,United Kingdom ("GSK") or one of its Affiliates in the conduct of the clinical trial in accordance with the protocol entitled "A Phase 3 randomized, open-label, active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of GSK1278863 compared to darbepoetin alfa" ("Clinical Trial"), Protocol Number: "PHI200808" and any amendments thereto ("Protocol"). GSK is the Sponsor of the Clinical Trial. PPD is an Affiliate of PPD International Holdings Inc and has been engaged by PPD International Holdings Inc to support the performance of the Clinical Trial;

II. The Institution and Principal Investigator desire to participate in the conduct of the Clinical Trial, in accordance with the Protocol, herein attached as **Schedule 1**;

III. The Parties agree to conduct the Clinical Trial in accordance with the terms and conditions hereinafter set forth.

THEREFORE, IT IS AGREED AS FOLLOWS:

1. Clinical Trial Performance

1.1 Institution and Principal Investigator shall provide certain services ("Services") related to the conduct of the Clinical Trial, in accordance with the Protocol, hereto attached as **Schedule 1** (and any subsequent amendments made thereto in accordance with this Agreement, and with all applicable laws, rules and regulations relating to the Clinical Trial. The Protocol is subject to approval by the appropriate Institutional Review Board or Ethics Committee or equivalent body (collectively "IRB"). The informed consent ("Informed Consent") is subject to approval by the IRB. If there is any discrepancy or conflict between the terms contained in the Protocol and this Agreement, the terms of the Protocol shall govern and control with respect to clinical matters and the terms of the Agreement shall govern and control with respect to all other matters.

1.2 Prior to the commencement of the Services, Institution and Principal Investigator shall review the Protocol and notify PPD if they cannot comply with any of the terms contained therein. If in the course of performing the Services, in accordance with generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the subjects ("Subject(s)") a deviation from the Protocol is required, such standards will be followed. In such case, the Party aware of the need for a deviation shall immediately notify PPD and GSK of the facts supporting such deviation as soon as the facts are known to such Party. The notification shall also be confirmed in writing within three (3) working days of the original notification being made to PPD and GSK.

1.3 The Institution and Principal Investigator agree to carry out the Services in strict compliance with:

(a) all specifications and timelines established in this Agreement;

(b) the Protocol and any amendments to the Protocol;

(c) the provisions of the current version of the World Medical Association's Declaration of Helsinki, in particular, neither the Institution nor the Principal Investigator must at any time jeopardise the health or well-being of any patient by unwarranted continuation of the Clinical Trial;

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(d) applicable national laws, regulations and guidelines including without limitation the "Ethical Guidelines for Biomedical Research on Human Subjects" based on the ICH-GCP laid down by Indian Council of Medical Research (ICMR), and the Guideline for Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Institution and Principal Investigator. (ICH Topic E6, Consolidated Guideline 1.5.96);

(e) (if the Trial is conducted under an Investigational New Drug (IND) the conditions specified in the Statement of Agreement and in accordance with Rule 122DA(3) of the Drugs and Cosmetics Rules under the Drugs and Cosmetics Act, 1945 (the "Act"); and

(f) Indian GCP and Schedule Y of the Drugs and Cosmetics Act and its amendments.

(g) If the Clinical Trial includes the collection by Institution of human biological materials from Subjects for research use, Institution will comply with all applicable laws, rules, regulations and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Study and with respect to any such human biological materials from the Clinical Trial retained in Institution's possession. Institution and GSK will mutually agree to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Clinical Trial and for research use of any human biological materials, with ethics approval. Institution agrees that any human biological materials collected as part of the Clinical Trial that are transferred to GSK or a GSK contractor, or held by Institution for GSK, will be under the custodianship and control of GSK.

1.4 The Clinical Trial shall be conducted only at the following location: Sanjay Gandhi Postgraduate Institute of Medical Sciences,Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India

1.5 The Institution agrees that the Clinical Trial will be conducted under the direction of the Principal Investigator in accordance with the Protocol and this Agreement.

1.6 The Principal Investigator will perform Services as agreed under this Agreement personally. In the event the Principal Investigator can no longer function in such capacity, then PPD and the Institution shall attempt to agree on a replacement. PPD shall have the right to approve any new principal investigator designated by the Institution. The new principal investigator shall be required to agree to the terms and conditions of this Agreement. If a mutually acceptable replacement cannot be agreed upon, PPD may terminate this Agreement in accordance with Clause 16.

1.7 The Institution and the Principal Investigator shall not subcontract any Services to another person or entity without PPD's prior written approval.

1.8 Notwithstanding anything herein to the contrary, if during the term of this Agreement, information that becomes available to PPD or GSK which affects the safety or efficacy of the Clinical Trial Product (as that term is defined at Clause 3.1 below), or if the Clinical Trial Product is approved by any regulatory agency, the Parties shall negotiate, in good faith, a modification of this Agreement to either (i) reduce the number of Subjects to be studied; and/or (ii) terminate the Clinical Trial, and/or (iii) modify any other relevant provision of this Agreement.

2. Term of Clinical Trial

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2.1 This Agreement shall take effect on the Effective Date and shall continue until 20 May 2021 ("Expiration Period"), unless terminated in accordance with Clause 16.

2.2 In the event that the Clinical Trial is extended beyond the Expiration Period, the Parties agree that such an extension will be covered by this Agreement and shall not necessitate any amendment to this Agreement. Any continuation of the Services under this Agreement shall be confirmed in writing by PPD, prior to the Expiration Period.

2.3 Notwithstanding the above, the Services will not commence until PPD is granted appropriate IRB and regulatory approval and the Institution has received copies of said approvals.

2.4 Patient recruitment at the Institution is scheduled to start in April 2017 and to be completed by 12 Nov 2019. The Institution shall use its best efforts to complete Subject enrolment by 12 Nov 2019. The Institution shall enroll 15 Subjects in the Clinical Trial ("Enrolment Maximum"). The Institution will not enroll more Subjects than the Enrolment Maximum and neither PPD nor GSK will be obligated to make any payment with respect to any Subject enrolled in excess of the Enrolment Maximum. If, during the Clinical Trial, it becomes apparent that Institution and/or Principal Investigator are not able to complete the Clinical Trial on schedule, they will notify PPD immediately.

2.5 In the event the Institution is unable to complete the enrolment by such date, PPD may reassign the Institution's enrolment slots, thereby reducing the number of Subjects enrolling at the Institution in the Clinical Trial. The Institution acknowledges that the Clinical Trial is part of a multi-center clinical trial. When the enrolment goal of 4500 Subjects for the Clinical Trial as a whole is reached, enrolment will be closed at all institutions, including the Institution, regardless of whether the Institution or any other institution has reached its individual enrolment goal.

2.6 All Subject visits will be completed no later than 25 Feb 2021 ("Visits Completed Date"). All case report form ("CRF") information associated with a Subject's visit must be satisfactorily completed within seven (7) calendar days after the Subject's visit or, if applicable, receipt of the Subject's test results. All final CRF data will be entered into the CRF and submitted to PPD no later than 20 May 2021. All data queries from PPD must be completed and returned to PPD within seven (7) calendar days or, if during final clean up, one (1) calendar day, or such other time set by PPD.

3. Supply of the Clinical Trial Product and Equipment

3.1 During the course of the Clinical Trial, PPD shall procure that GSK will provide the Institution with Daprodustat (GSK1278863) ("Clinical Trial Product") and Placebo and related devices, or other materials as GSK determines necessary for the conduct of the Clinical Trial (collectively, the "Materials").

3.2 The Parties acknowledge that GSK shall be responsible for packaging, labelling and shipping the Clinical Trial Product supplies to the Institution at GSK's own expense and in full compliance with all applicable laws.

3.3 The Clinical Trial Product will be distributed by GSK directly to the Institution's pharmacy, which should already be aware of storage and conservation conditions required for the Clinical Trial Product.

3.4 The Principal Investigator and the Institution: (i) shall use the Materials only to conduct the Clinical Trial in accordance with the Protocol; (ii) shall not chemically, physically, or otherwise modify the Materials, except if specifically required by the Protocol; and (iii) shall handle, store, and ship or dispose of the Materials with appropriate care in compliance with all applicable local, state, and federal laws, rules, and regulations including, but not limited to, those governing hazardous substances.

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3.5 Upon termination of the Clinical Trial or this Agreement, all unused Materials provided by GSK shall be promptly returned at GSK's expense, to an address provided by GSK or, at GSK's option and expense, destroyed with the destruction certified in writing.

3.6 Any Materials provided by GSK or by PPD in the course of the Clinical Trial may not be transferred to any other location or to any third party without the prior written consent of PPD.

3.7 Equipment

(a)Loaned Equipment ("Loaned Equipment") means any equipment temporarily provided to Institution by PPD or Sponsor pursuant to this Agreement only for use in the Study, including, but not limited to computer hardware and software if provided for the Principal Investigator and other staff to use, collect, enter, and report Study data to Sponsor.

b. Transferred Equipment ("Transferred Equipment") means any equipment permanently transferred to Institution by Sponsor or a Sponsor Affiliate pursuant to this Agreement, including, but not limited to computer hardware and software if provided for the Principal Investigator and Study Staff to use, collect, enter, and report Study data to Sponsor.

c. If applicable, with respect to Loaned Equipment provided by Sponsor for use in the Study, Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by PPD or Sponsor, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of Sponsor, and that, at the completion of the Study or at Sponsor's request, Institution will return the Loaned Equipment and all related training materials and documentation to Sponsor or to a vendor designated by PPD or Sponsor.

d. Investigator and Study Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will be responsible for arranging and paying for any required internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. If Institution fails to return the Loaned Equipment within the timeframe specified by PPD or Sponsor, Institution will be responsible for reimbursing PPD for any penalties, late fees, and/or replacement costs.

e. Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights;

(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment; or

(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

4. Obligations of the Parties

4.1 *Institution obligations*

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Institution shall:

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(a) be responsible for providing, at its sole cost and expense, the premises, adequate personnel, equipment (subject to Clause 3.7) and other resources necessary to conduct the Clinical Trial, in accordance with this Agreement, the Protocol and the conditions imposed by the IRB;

(b) ensure that the Principal Investigator observes current legislation, strictly complies with this Agreement, the Protocol, ethical regulations on clinical trials with medicines and collaborates in the performance of monitoring visits by PPD, audits by auditors appointed by PPD/GSK or its Affiliates and inspections by competent health authorities;

(c) promptly advise PPD as soon as possible if Institution observes or becomes aware of: (i) material non-compliance with the Protocol, ICH Good Clinical Practice guidelines, or any applicable laws, rules or regulations, (ii) incomplete or inaccurate recording of data or any significant misconduct, (iii) any changes of personnel, facilities or clinical research methods at the Institution that may affect the Clinical Trial, or (iv) any other matters, events, conditions or difficulties that may jeopardize the proper conduct of the Clinical Trial;

(d) notify PPD and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product, in accordance with Clause 11 below and the procedures set forth in the Protocol (**Schedule 1**);

(e) maintain adequate records with respect to Clinical Trial Subject identification, clinical observations, laboratory tests, and Clinical Trial Product receipt and disposition;

(f) cooperate with PPD and GSK or its Affiliates in their efforts to monitor the Clinical Trial at the Institution premises;

(g) use the data obtained from the Clinical Trial Subjects only for the purposes and in connection with the Clinical Trial and as outlined in the Protocol; and

(h) obtain written consent from all individuals providing services on behalf of Institution with respect to the Clinical Trial, including (without limitation) sub-investigators, study coordinators and other Institution employees, agents or subcontractors ("Study Staff") that allows GSK, GSK's Affiliates, and third party suppliers working for GSK or its Affiliates to hold and process personal data provided with respect to Study Staff anywhere in the world, both manually and electronically, for all purposes relating to the performance of this Agreement, for the purposes of administering and managing the business activities of any company in the GSK's group, and for compliance with applicable procedures, laws, and regulations.

4.2 *Principal Investigator Obligations*

Principal Investigator shall:

(a) be responsible for overseeing all medical aspects of the Clinical Trial;

(b) ensure that the Clinical Trial activities are performed in accordance with the Protocol, the guidelines provided by the correspondent IRB, the terms of this Agreement and any other local applicable legislation to the performance of clinical trials in human subjects;

(c) oversee the submission of IRB and Ethical Approval;

(d) oversee the enrolment of patients at the Institution, in accordance with the inclusion/exclusion criteria defined in the Protocol;

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(e) inform all individuals to be enrolled in the Clinical Trial before they agree to participate in the Clinical Trial about the purpose(s), methods and conditions of conducting the Clinical Trial, its expected therapeutic benefit and Clinical Trial-related risk;

(f) oversee and review all case report forms ("CRFs") for accuracy and completeness and to provide these forms and any other Clinical Trial data or samples to PPD in accordance with Clause 2.6 and in the format and manner agreed upon by the Parties and in an anonymised form;

(g) obtain a signed Informed Consent from each Subject recruited for the Clinical Trial (or if permitted, their legal representative), in accordance with this Agreement, applicable local laws and regulations. The form of such Informed Consent must be the most current form approved by the IRB, GSK and PPD, and must contain language necessary to permit regulatory agencies, the IRB, GSK and its Affiliates and PPD to have full access to and use of personally identifiable information, including patient health information, as defined in applicable privacy laws, rules and regulations and according to internationally recognized standards and data protection principles;

(h) not allow a Clinical Trial Subject to be enrolled simultaneously in this Clinical Trial and another clinical trial without PPD and GSK prior written approval;

(i) ensure that all Clinical Trial data, Clinical Trial records and CRFs, including any documents which identify and link each Clinical Trial Subject to their CRF, are stored securely, such that they are accessible only with the knowledge of the Institution and the Principal Investigator;

(j) promptly report (in writing) any serious or unexpected adverse events to the GSK, PPD and the IRB; in accordance with Clause 11 below and following the procedures set forth in the Protocol;

(k) notify GSK, PPD, and the IRB, in writing, of any deviations from the Protocol;

(l) engage with GSK in the collaboration of the final report of the Clinical Trial, granting approval thereto upon signing it;

(m) report on the progress of the Clinical Trial to the IRB (as appropriate);

(n) perform the Services in accordance with the highest professional standards of skill, care and diligence and in compliance with all applicable laws and regulations;

(o) notify PPD of any provisions in its local law, or of any changes in that law, which do or could affect the Principal Investigator's ability to conduct the Clinical Trial or to perform his/her duties as defined in this Agreement;

(p) provide PPD with the complete results of the tests and all of the data obtained during the Clinical Trial;

(q) submit all data and other information related to the Clinical Trial in a timely manner;

(r) cooperate with PPD, GSK and its Affiliates and regulatory authorities in all their efforts to monitor the Clinical Trial and conduct audits and inspections;

(s) within twenty four (24) hours of first knowledge of any SAE (as that term is defined at Clause 11.1 below), notify PPD, and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product and follow the procedures set forth in the Protocol and Clause 11;

(t) if he/she is not able to continue as Principal Investigator by reason of retirement, transfer or similar reasons, he/she shall provide written notice to PPD as soon as possible and at least within three (3) weeks of such departure; and

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(u) inform the patients involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file whose ownership correspond solely to GSK. Principal Investigator shall collect and process all personal data in accordance with applicable local regulation on personal data on behalf of GSK and only throughout the duration of the agreement signed with GSK and only for the purposes established in the said agreement.

4.3 PPD Obligations

PPD shall:

(a) be responsible for obtaining regulatory approval for the Clinical Trial;

(b) be responsible for the submission to the IRB and any competent regulatory authority.

(c) be responsible for the monitoring of the Clinical Trial;

(d) provide to the Institution the Protocol, Informed Consent forms and required number of CRFs; and

(e) inform the Institution and the Principal Investigator of chemical/pharmaceutical, toxicological, pharmacological and clinical data and results to justify the design and duration of the Clinical Trial.

5. Funding of the Clinical Trial and Payments

5.1 As consideration for the performance under the terms and conditions of this Agreement, PPD will pay the Institution in accordance with **Schedule 2.** Institution will not be compensated for any Subjects who were enrolled without a properly executed informed consent form or who do not meet the inclusion/exclusion criteria for the Clinical Trial. The Institution shall be responsible for compensating all other entities and individuals who were involved in the conduct of the Clinical Trial, including (without limitation) the Principal Investigator and the Study Staff.

5.2 Payments under this Agreement are pass-through payments from GSK. PPD shall make payment to the Institution, in accordance with **Schedule 2**.

5.3 Payments are dependent upon the reports and other information pursuant to Clauses 4.1 and 4.2 being submitted in a timely and satisfactory manner. Payment for partially completed Services, e.g, early withdrawal of Subject, shall be made on a pro-rata basis for Services performed according to **Schedule 2**. No payment will be due or paid for Services performed that are deemed violations of or deviations from the Protocol or this Agreement.

5.4 Invoices are payable within sixty (60) days following receipt of a valid invoice, as described in Section 2 of **Schedule 2**, but Institution hereby acknowledges and agree that payments due under this Agreement shall be made by PPD once said payments are received by PPD from GSK. PPD shall exercise reasonable efforts to ensure timely receipt of pass-through payments from GSK.

5.5 Payments for Services rendered under this Agreement shall be made in full in accordance with the Agreement, without deductions for taxes of any kind. Any taxes due and payable as a result of the payments by PPD to the Institution shall be Institution's sole responsibility and Institution shall pay all such taxes for which it is liable in a timely manner.

5.6 PPD will reimburse the Institution for travel costs incurred by Subjects in accordance with **Schedule 2**.

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5.7 The Institution acknowledges and agrees that it shall be solely responsible for paying the appropriate amount of all federal and local taxes/including VAT with respect to all fees and compensation paid pursuant to this Agreement.

5.8 Institution and Principal Investigator agree that GSK or its Affiliates may make public the amount of funding provided to the Institution by PPD for the conduct of the Clinical Trial and may identify the Institution and the Principal Investigator as part of this disclosure. Institution has obtained the Principal Investigator's consent to this disclosure.

5.9 The amounts paid under this agreement are bona fide fair market value compensation for the work conducted under this Agreement. The parties agrees that no payments by GSK pursuant to this agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of GSK products. Notwithstanding the foregoing, commercially reasonable payments to a subcontractor who is performing services under the terms of this agreement that meet the criteria for bona fide services are not considered to be a pass-through rebate or discount payments (even if the subcontractor is a GSK customer).

5.10 Statement of Investigator Financial Interest form

The Principal Investigator hereby acknowledges the requirements of the FDA Financial Disclosure Rule and agrees to fill in and return to PPD, upon PPD or PPD representative's request, the Statement of Investigator Financial Interest form before the start of the Study. The Principal Investigator also consents to the disclosure of the so filled Form to the FDA if necessary.

5.11 Institution and Principal Investigator shall not charge any Subject or third-party payor for Clinical Trial procedures required by the Protocol that are paid for by PPD or GSK under this Agreement or for any Clinical Trial Product that is provided or paid for by PPD or GSK under this Agreement.

5.12 All of Sponsor's payment obligations are conditioned upon Institution reporting to PPD and/or Sponsor all data required by the Protocol and other governing documents for the Study, including all adverse events, and upon Institution's compliance with standards identified in this Agreement

6. Clinical Trial Subject

6.1 Informed Consent of each of the Subjects participating in the Clinical Trial shall be obtained in accordance with applicable local laws and regulations in India, including completion of the approved Informed Consent form, which has been approved by the IRB. The Institution/Principal Investigator shall administer the Clinical Trial Product only to Subjects from whom Informed Consent has been properly obtained by the Principal Investigator under Clause 4.2(g) and this Clause 6. The Institution/Principal Investigator shall maintain adequate documentation of its obtainment of the Informed Consent of each Subject.

6.2 PPD, the Institution and the Principal Investigator shall hold in confidence the identity of the Subjects and shall comply with all applicable laws regarding the confidentiality of their identities and their individual medical records.

6.3 The method of explanation to the patient and the obtaining of consent should be conducted in accordance with the directions of the IRB and is a Principal Investigator responsibility. Each Subject shall be provided with their own copy of the patient information sheet which they can retain for their own records.

7. Clinical Trial Results and Intellectual Property

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7.1 The Parties are in agreement that all of the Materials and data gained through the conduct of the Services shall be the property of GSK.

7.2 GSK shall exclusively own all rights, title ("Rights") in and to any invention, and interest in and to inventions (in any clinical specimens or samples obtained from the Subject), discoveries, know-how, patents (whether patentable or not), copyright, trade secrets and other intellectual rights, including but not limited to inventions, discoveries and technology relating to the Clinical Trial Product or otherwise generated by the Clinical Trial (collectively, "Inventions"). The Institution and Principal Investigator hereby irrevocably transfer and assign any and all their Rights in any Invention to GSK. The Inventions will be the sole property of GSK.

7.3 The Institution and Principal Investigator agree to: (i) immediately notify in writing to PPD of any Invention, and (ii) to cooperate and assist GSK to apply for and to execute applications, assignments, affidavits, or other documents, reasonably necessary to obtain any patent, copyright, trademark or other statutory protection for the Inventions, as GSK deems appropriate, and (iii) to treat all Inventions as confidential information in accordance with Clause 8.

7.4 Neither the Institution nor the Principal Investigator shall acquire any rights of any kind with respect to the Inventions or to the Clinical Trial Product.

7.5 The obligations of this Clause shall survive after the term or termination of this Agreement.

8. Confidential Information

8.1 Institution/Principal Investigator and their employees and agents and third parties involved in the study by the Principal Investigator and/or Institution shall not disclose to any third party or use for any purposes other than for the performance of the Clinical Trial any data, records or other information (hereinafter, collectively "Information") disclosed to Institution/Principal Investigator by GSK or PPD or generated as a result of this Clinical Trial without the prior written consent of GSK and shall sign a written non-disclosure agreement. Such Information shall remain the confidential and proprietary property of GSK and shall be disclosed only to Institution/Principal Investigator and their employees or agents who have a "need to know". The obligation of nondisclosure shall not apply to the following Information:

(a) that is generally known to the public or that becomes publicly available through no act or omission on the part of Institution/Principal Investigator;

(b) that is disclosed to Institution/Principal Investigator by a third party legally entitled to disclose such information;

(c) which the Institution/Principal Investigator, as applicable, can demonstrate that it possessed prior to, or developed independently from, disclosure or development of this Agreement;

(d) that is required by law to a government authority or by order of a court of competent jurisdiction, provided that (i) such disclosure is subject to all applicable governmental or judicial protection available for like material; (ii) reasonable advance notice is given to GSK; and (iii) all reasonable steps to limit the scope of such disclosure have been taken.

8.2 The obligations of this Clause shall survive after the term or termination of this Agreement.

9. Publications

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9.1 SPONSOR will post a Study Protocol summary on a publicly available protocol register prior to the enrollment of Study subjects.

9.2 SPONSOR will post a Study results summary on a publicly available results register no later than twelve (12) months following completion of the Study at all Study sites. Posting of summary Study results may occur prior to publication of Study results in the peer-reviewed literature.

9.3 SPONSOR will seek to publish the Study results in the searchable, peer reviewed scientific literature in the form of a publication or presentation of Study results from all Study sites (a "Multicenter Publication"). In the event a proposed manuscript is not accepted for publication or publication is otherwise not feasible (e.g., early-stage studies of a terminated product), SPONSOR will include results conclusions and context on the SPONSOR's Clinical Study Register to supplement the Study results summary.

9.4 Any participation of Principal Investigator or other representatives of Institution as a named author of this Multicentre Publication will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts, and Institution and Principal Investigator acknowledge that the enrollment of Study subjects alone is not a qualification for authorship. If the Principal Investigator or other representative of Institution is a named author of the Multicenter Publication SPONSOR and Institution (on behalf of such authors at Institution) agree that authors: (a) will have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication; (b) will adhere to ICMJE requirements regarding authorship; (c) will disclose as part of the Multicenter Publication that SPONSOR financially supported the Study and any personal financial relationship with SPONSOR; that SPONSOR has made substantial contributions to the study and that SPONSOR has given or will give final approval to the version of the Multicenter Publication ultimately published; and (d) upon completion of author activities will certify in writing to the foregoing and that the authored publication is fair, accurate, and balanced.

9.5 Institution and Principal Investigator agree that SPONSOR may make public the names of the Principal Investigator and the Institution as part of a list of investigators and institutions conducting the Study when making either protocol or results summary register postings. Institution and Principal Investigator agree that SPONSOR may make public the amount of funding provided to Institution by SPONSOR for the conduct of the Study and may identify Institution and Principal Investigator as part of this disclosure. Principal Investigator agrees that, if Principal Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Drug or that otherwise relates to SPONSOR, Principal Investigator will disclose that he/she was an investigator for the Study.

9.6 Site, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Site's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any SPONSOR Confidential Information other than the Study results from Institution's Study data. Institution shall submit to SPONSOR for review and comment any proposed Institution Publication at least sixty (60) days prior to submitting the Institution Publication to any third party. If SPONSOR requests a delay in order to enable intellectual property rights to be secured, Institution agrees to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after SPONSOR's request. Institution also agrees that any Institutional Publication shall only be made after the Multicenter Publication, provided that the Multicenter Publication is submitted within twelve (12) months after conclusion of the Study at all sites. Institution agrees that SPONSOR's financial support of the Study will be disclosed in any Institution Publication and will require all authors of such Institution Publication to disclose any financial relationship with SPONSOR. Institution shall ensure that Principal Investigator complies with the obligations identified in this subsection.

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9.7 The obligations of this Section shall survive termination of this Agreement.

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10. **Data Protection**

10.1 Institution and Principal Investigator shall comply and shall require any of the persons or entities performing the Services on their behalf to comply, with all applicable laws, rules, regulations, and guidelines governing the privacy of personally identifiable information and patient health information in India.

10.2 PPD guarantees that the Protocol establishes the mechanisms that allow the disassociation of data with a personal nature of the Subjects participating in the Clinical Trial.

10.3 Institution assures PPD and GSK that the Principal Investigator shall inform the Subjects involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file which is owned by GSK. All personal data collected shall be treated with the privacy, confidentiality and safety measures established by the relevant applicable regulation.

11. **Adverse Events Reporting**

11.1 For the purposes of this Agreement an Adverse Event ("AE") shall mean any untoward medical occurrence whether thought to have been caused by the Materials or the Clinical Trial or not and Serious Adverse Event ("SAE") shall mean any adverse event which is fatal, life threatening, disabling or incapacitating, requires in-patient treatment or prolongs existing hospitalization, is a congenital anomaly in the off-spring of the patient or which may require intervention to prevent the previously stated outcomes.

11.2 Any SAE must be reported as defined in the Protocol within twenty four (24) hours of first knowledge of any SAE and using the electronic Case Report Form ("eCRF"). This applies also for any event that could affect the safety of the study participants or the conduct of the Clinical Trial.

11.3 The Institution is responsible for ensuring that the Principal Investigator notifies GSK, the Institution and the Responsible Ethics Committee of any Adverse Events (including Serious Adverse Events) that occur during the course of the Clinical Trial in accordance with the Protocol, and relevant ethical and regulatory guidelines, and in the case of the Institution and the Responsible Ethics Committee with their policies and procedures.

11.4 Nothing in this Agreement shall remove or restrict any obligation on Institution and/or Principal Investigator to report clinical safety information arising during the Clinical Trial to the regulatory authorities in India, in accordance with the local requirements or comply with any other legal or administrative obligation in connection with the Clinical Trial.

11.5 The Institution shall monitor the Subjects in accordance with the Protocol. The Institution shall require the Principal Investigator to promptly (within twenty-four (24) hours of the occurrence of any SAE) report via the electronic eCRF all SAEs that may be associated with the administration of the Clinical Trial Product that occurs during the course of the Clinical Trial. Failure to comply with this Clause shall constitute reasonable grounds for PPD to terminate this Agreement as provided in Clause 16.

11.6 In the event that GSK maintains its own Investigator Brochure(s) ("IB(s)") for the Clinical Trial Product(s) being investigated under the Clinical Trial, regardless of the indication under study, GSK will provide these IB(s), and any updates and/or supplements to these IB(s), to the Institution during the course of the Clinical Trial for information purposes.

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11.7 Outputs from the Clinical Trial Independent Data Monitoring Committee ("IDMC") (including, but not limited to, meeting minutes, interim analyses and any recommendations or requests made by the IDMC to Institution, which address the safety of the Clinical Trial Subjects) and other pertinent data will be provided by Institution to PPD as they become available.

11.8 Sponsor agrees to reimburse the Institution/Principal Investigator for reasonable and necessary medical expenses incurred as a direct result of diagnosing and treating of an SAE related to the Trial Product and study related procedure and incurred during the course of the Clinical Trial, provided that the Trial Product was administered in accordance with the Protocol and the SAE did not occur as a direct result of the Institution or Principal Investigator's negligence or misconduct. The Institution/Principal Investigator agrees to treat any such illness or injury. Payments will be made following an invoice per treatment and confirmation by Sponsor or PPD that the treatment has been performed as a result of such SAE. Institution or Principal Investigator will provide all information reasonably requested by Sponsor or PPD to confirm such treatment.

11.9 Without prejudice to the foregoing if injury is suffered by a Clinical Trial Subject while participating in the Clinical Trial, the Sponsor agrees to operate in good faith in accordance with the guidelines entitled "GlaxoSmithKline's – Clinical Trial Compensation Guidelines" (refer **Schedule 5**) and Indian GCP, and the Principal Investigator shall make clear to the Clinical Trial Subjects that the Clinical Trial is being conducted subject to these Guidelines.

12. Recordkeeping and Audits

12.1 The Institution and Principal Investigator shall keep complete and systematic data related to the Clinical Trial and the Services performed and any other records generated as a part of this Agreement for a minimum period of twenty five (25) years, or as agreed by the Parties, or as required by applicable local regulation.

12.2 Upon the expiration of the above time period, prior to disposing of such records the Institution/Principal Investigator shall notify GSK and if GSK requests, shall deliver such records to GSK rather than dispose of them.

12.3 During the Institution's regular business hours and with reasonable advance notice, PPD, GSK or its Affiliates or their designee may audit the Institution's records, facilities, equipment, or procedures related to Institution's obligations under this Agreement. Such audits may include, without limitation, Institution's records related to the Clinical Trial and the performance of the Services, in order to verify Institution's compliance.

12.4 If any governmental or regulatory authority notifies the Institution/Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Clinical Trial and/or the Services under this Agreement, Institution/Principal Investigator shall co-operate with the authority and notify PPD and GSK as soon as is practicable (to the extent possible, within two (2) business days and prior to the inspection or action), allow the authority to conduct an inspection or take other legal action, allow PPD and GSK to be present at the inspection or participate in any response to the action, and provide PPD with copies of any reports issued by the authority and Institution's proposed response for GSK's prior review and approval (such approval not to be unreasonably withheld).

13. Insurance

13.1 PPD declares that an insurance policy to cover the conduct of the Clinical Trial, in pursuance of current national laws, is in place and hereto attached as **Schedule 3**. Said policy shall be maintained and updated throughout the duration of the Clinical Trial.

13.2 The insurance of the Sponsor does not relieve the Investigator, Institution and/or their agents participating in the Clinical Trial from their obligation to be liable and responsible to GSK and

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PPD for their own negligence and wilful misconduct, or their failure to adhere to the terms of the Protocol or any laws or regulation applicable to the Clinical Trial. The Principal Investigator and Institution each represent and warrant that they possess, through insurance or otherwise sufficient financial resources to meet their obligations under this Agreement. The Institution shall provide evidence of its insurance upon request by PPD.

14. Representations and Warranties

14.1 Institution and Principal Investigator represent and warrant to the best of their knowledge, that the Institution and the Principal Investigator are not bound by any other agreement which could prevent, or be violated by, or under which there would be a default as a result of, the execution and performance of this Agreement, and that each will not enter into any such conflicting agreements during the term of this Agreement.

14.2 Institution represents and warrants that all persons involved in the Clinical Trial and the Principal Investigator (i) have not been debarred or convicted of a crime which could lead to debarment under any applicable law, rule or regulation; (ii) have not been disqualified as a testing facility under applicable local regulation; or (iii) are not disqualified as a clinical investigator under applicable local regulation. If such persons later become debarred or receive notice of any action or threat of action with respect to debarment and Institution/Principal Investigator gain knowledge thereof, PPD will immediately be notified.

14.3 Institution represents to Sponsor that medical care for the disease or condition to which the Study relates is available to Study subjects following the Study in accordance with local standard of care through the usual operations of the local healthcare system, and that upon completion of the Study, Institution will appropriate transition Study subjects from the Study to such medical care or refer Study subjects to a health care provider for such medical care.

14.4 Institution shall indemnify GSK and PPD against all direct losses, damages, liabilities and expenses (including legal expenses) incurred by PPD and/or GSK as a result of any breach of the warranties contained in this Clause.

14.5 Principal Investigator hereby warrants that he is authorized to perform the Services at the Institution premises under his/her own name and that the performance of the correspondent agreement and the acceptance of any payments is not in violation of legal or internal regulations of the Institution or other entity to which Principal Investigator is associated or any agreement to which Principal Investigator is bound. Likewise, Principal Investigator further warrants that he/she has obtained all required consents from and/ or filed all required notifications to/from the Institution board or other regulatory or self-regulatory authority, board or committee.

15. Limitation of Liability and Indemnification

15.1 Institution and Principal Investigator shall indemnify, defend and hold harmless PPD and GSK and its Affiliates from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by PPD or GSK or its Affiliates as a result of the negligence or willful misconduct of Institution and/or Principal Investigator.

15.2 A Party shall give written notice to the other Parties as soon as is practicable of the details of any claim or proceedings brought or threatened against it by a third party in respect of which a claim will or may be made under Clause 15.1 above.

15.3 Upon request by Institution and/or Principal Investigator, indemnification of Institution and Principal Investigator by GSK shall be governed by a separate letter agreement between GSK, Institution and Principal Investigator.

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15.4 Nothing in this Clause 15 or otherwise in this Agreement shall exclude or in any way limit Institution' liability for (i) fraud, (ii) death or personal injury caused by its negligence; and (iii) any liability to the extent the same may not be excluded or limited as a matter of law.

15.5 No Party shall be liable to the other Parties for any punitive, exemplary damages or for an indirect or consequential loss or damage resulting from any breach of this Agreement even if the other Parties have been advised of the possibility of such damages.

15.6 Each Party's agreement to indemnify and hold the other Party or Parties harmless is conditional on the indemnified Party (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within ten (10) days after the indemnified Party has knowledge of such claim, demand or action, (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand, and (iv) not compromising or settling such claim or demand without the indemnifying Party's written consent.

15.7 The obligations of this Clause shall survive termination of this Agreement.

16. Termination

16.1 PPD may terminate this Agreement at any time, without cause, by giving thirty (30) days written notice to the Institution and Principal Investigator if any of the following conditions occur:

(a) the authorization and approval to perform the Clinical Trial in India is withdrawn by the IRB or any other competent authority;

(b) if PPD's agreement with GSK is terminated;

(c) if available data indicate that it is not safe to continue to administer the Clinical Trial Product to Subjects;

(d) if overall Clinical Trial enrolment has not been met, even if the enrolment at the Institution has not been completed;

(e) the Principal Investigator is unable to continue and an acceptable successor is not agreed upon;

(f) adherence to the Protocol is poor, or Clinical Trial data recording is chronically inaccurate or incomplete;

(g) the Clinical Trial is terminated;

(h) material breach of this Agreement; or

(i) by mutual agreement of the Parties.

16.2 In the event this Agreement is terminated for any reason prior to the end of the Clinical Trial, the Institution shall take all reasonable steps required by PPD, including communicating with the Subjects, to facilitate completion of the Clinical Trial at an alternative clinical site designated by PPD. In such event, PPD will (except where the termination was as a result of the breach by the Institution of its obligation under this Agreement) reimburse the Institution for its reasonable direct costs incurred in connection with such transfer, as well as for reasonable non-reimbursed costs incurred and non-cancellable commitments made prior to the receipt by the Institution that the Agreement will be terminated.

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16.3 Termination of this Agreement by any Party shall not affect the rights and obligations of the Parties that have accrued prior to the effective date of the termination.

17. Effect of Termination

17.1 In the event of termination, the sum payable under this Agreement shall be limited to prorated fees based on actual Services performed pursuant to the Protocol as determined in accordance with **Schedule 2**.

17.2 Upon completion of the Clinical Trial or earlier termination thereof, Institution and/or Principal Investigator shall ensure that all data, information, reports and Clinical Trial results are properly recorded in eCRFs and submitted to PPD, and shall return to PPD all Information.

17.3 Upon completion of the Clinical Trial or early termination thereof, all unused Clinical Trial Product, and/or Materials furnished to Institution and/or Principal Investigator by or on behalf of GSK or PPD shall be returned to PPD, as described in Clause 3.

17.4 Immediately upon receipt of a notice of termination, Institution and Principal Investigator shall cease entering Subjects into the Clinical Trial, cease conducting procedures to the extent medically permissible on Subjects already entered into the Protocol, and refrain from incurring additional costs and expenses to the extent possible

17.5 All provisions of this Agreement that by their nature would be expected to survive termination of this Agreement shall survive such termination, including - but not limited to – Clauses 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18, 19 and 20.

18. Compliance with Laws and Human Rights

18.1 Each Party shall perform its obligations under this Agreement in a manner that complies with all applicable international, national and local laws in relation to, or otherwise relevant to, its obligations under this Agreement and shall promptly notify the other Parties if it receives a written allegation of non-compliance with any such law by any person which relates to its performance of such obligations.

18.2 Institution and the Principal Investigator (the "Site") agree to the terms of **Schedule 4**.

18.3 Each Party expressly agrees that this Agreement is the result of arms-length negotiations, and that neither Party has entered into this Agreement with a corrupt motive to obtain or retain business or to secure an unfair business advantage.

18.4 Each Party hereby warrants and undertake that they shall at all material times keep and maintain accurate and up to date accounting records to ensure that all transactions relating to this Agreement are sufficiently documented.

18.5 Institution represents that, with respect to employment and conducting the Clinical Trial under this Agreement, Institution will:

(a) not use child labor in circumstances that could cause physical or emotional impairment to the child;

(b) not use forced labor (prison, indentured, bonded or otherwise);

(c) provide a safe and healthy workplace; safe housing (if housing is provided by Institution to its employees); and access to clean water, food, and emergency healthcare in the event of accidents in the workplace;

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(d) not discriminate against employees on any grounds (including race, religion, disability or gender);

(e) not use corporal punishment or cruel or abusive disciplinary practices;

(f) pay at least the minimum wage and provide any legally mandated benefits;

(g) comply with laws on working hours and employment rights;

(h) respect employees' right to join and form independent trade unions;

(i) encourage subcontractors under this Agreement to comply with these standards;

(j) maintain a complaints process to address any breach of these standards.

19. Applicable law and competent jurisdiction

19.1 This Agreement shall be governed by and interpreted in accordance with the laws of India.

19.2 The Parties, expressly waiving any other jurisdiction to which they might be entitled, agree to submit any disputes arising out or in connection with this Agreement (whether of a contractual or non-contractual nature) to the Courts of Lucknow.

20. Miscellaneous

20.1 Independent Contractor

The Institution, including its agents and employees, shall be an independent contractor at all times, and shall not be an agent of PPD or GSK and shall have no actual, apparent or implied authority to bind PPD or GSK in any manner or to any obligation whatsoever. The Principal Investigator shall not be or be deemed to be an employee of PPD or GSK and shall not be entitled to any benefits available to employees of PPD or GSK.

20.2 Assignment

Institution shall not assign this Agreement in whole or in part to any other Party and shall not appoint any other person as Principal Investigator without PPD's written consent. PPD may assign this Agreement in whole or in part, including to any corporate parent, affiliate or subsidiary of PPD, without the Principal Investigator's/Institution's consent.

This Agreement shall be binding upon the Parties, their legal representatives, successors and permitted assigns. Institution and Principal Investigator acknowledge and agree that GSK and each of its Affiliates is a third party beneficiary to this Agreement and shall be entitled to enforce all of the rights and benefits of this Agreement at all times as if it were a party to this Agreement.

20.3 Use of Name

No Party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement which uses the other Parties names, symbols, or trademarks without the other Parties prior written approval.

20.4 Notices

(a) All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices may be sent by facsimile or e-mail, if confirmed by also sending as described above.

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(b) Notices pertaining to this Agreement shall be sent to:

If to Institution:
Attn:Dr. Rakesh Kapoor
Address: Sanjay Gandhi Postgraduate Institute of Medical Sciences,Raibarcli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India.

Tel.: 8004263199
Fax: NA
E-mail address: narayan@sgpgi.ac.in

If to PPD:
Attn.: Rashmi Chitgupi
Title: Associate Director , Clinical Management
PPD Pharmaceutical Development India Private Limited
101-A Wing, 'Fulcrum'
Hiranandani Business Park,Sahar Road
Andheri East Mumbai 400 099 India
Tel.: +91 22 4247 2900
Fax: +91 22 4248 6900
E-mail address: Rashmi.Chitgupi@ppdi.com

If to the Principal Investigator:
Attn: Dr Narayan Prasad
Address: Sanjay Gandhi Postgraduate Institute of Medical Sciences,Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India.
Tel.: 8004263199
Fax: NA
E-mail address: narayan@sgpgi.ac.in

20.5 Severability

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected.

20.6 Waiver; Modification of Agreement

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by any Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by any Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

20.7 Force Majeure

If any Party is delayed in performing an obligation under this Agreement by strike, lockout, or other labor troubles of a third party; by restrictive governmental or judicial order not directly related to this Agreement; or by riots, insurrection, war, inclement weather, or Acts of God; performance is excused for the period of such delay. The delayed Party shall promptly notify the other Parties in writing of the delaying event.

20.8 Entire Agreement

This Agreement and its exhibits constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes any prior agreement, understanding or arrangement between the Parties, whether oral or in writing. No

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representation, undertaking or promise shall be taken to have been given or be implied from anything said or written in negotiations between the Parties prior to this Agreement except as expressly stated in this Agreement.

20.9 Miscellaneous

(a) For the purposes of this Agreement, "Affiliate" means any entity that controls, is controlled by, or is under common control with, a party to this Agreement. In this context, "control" shall mean (i) ownership by one entity, directly or indirectly, of at least forty percent (40%) of the voting stock of another entity; (ii) power of one entity to direct the management or policies of another entity, by contract or otherwise; or (iii) any other relationship between GSK or Institution and an entity which GSK and Institution have agreed in writing may be considered an "Affiliate" of GSK or Institution (as the case may be).

(b) PPD or GSK may provide the following supportive measures to strengthen the Institution's research capacity for the benefit of the community. Site will be provided with Handicam for AV recording of informed consent process and thermohygrometer for 2-8 degree and room temperature (2 in quantity).PPD, GSK and the Institution agree that any of these measures that may be provided by PPD or GSK are not intended to be for the exclusive benefit of the Clinical Trial or of GSK studies generally, or to induce the Institution to participate in the Clinical Trial or to induce or reward any use, purchase, recommendation, or prescription of GSK products. GSK and the Institution also agree that any of these measures that may be provided by PPD or GSK are intended to be sustainable by the Institution and the local community following the Clinical Trial.

(c) GSK and the Institution have sought agreement with key interested external parties, including ethics committees, research investigators, national government, health ministry, local health authorities, ethics groups, non-governmental organisations, or representatives of the communities who might participate in the Clinical Trial, that it is appropriate to conduct the Clinical Trial at the Institution, including discussion of the standard of care to be provided during the study, the scientific rationale for interventions (including placebo), the provision of healthcare for subjects after the study, and the fate of any capacity built for the conduct of the study.

(d) The Institution agrees that any nationally-licensed medicinal products that are not the subject of the Clinical Trial but are required for the routine care of a Clinical Trial subject during and after the Clinical Trial for the disease or condition to which the Clinical Trial relates are expected to be available to the Clinical Trial subject and funded through the usual operations of the local healthcare system independently from the Clinical Trial and without expectation of GSK support.

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Sanjay Gandhi Postgraduate Institute of Medical Science

Name:
Position:
Date: 03.09.2019

Dr. Narayan Prasad

Name:
Position: Professor
Date: 2.8.19

(Prof. Narayan Prasad)
Department of Nephrology
S.G.P.G.I.M.S., Lucknow-226014
Reg. No. 6R-27804/94

PPD Pharmaceutical Development India Private Limited

27MAY2019

Name:
Position:
Date:

Associate Director - Clinical Management
PPD Pharmaceutical Development India Pvt. Ltd.
101-A Wing, Fulcrum, Hiranandani Business Park
Saki Vihar Road, Andheri East
Mumbai – 400 099, India.

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SCHEDULE 1

PROTOCOL

TITLE PAGE

Division: Worldwide Development
Information Type: Protocol Amendment

Title:	A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa.

Compound Number: GSK1278863

Development Phase: IIIA

Effective Date: 12-OCT-2016

Protocol Amendment Number: 02

Author (s): Meadowcroft, Amy; Eler, Lara; Davies, Rich; Barnes, Allison; Waterhouse, Brian; Mahar, Kelly; Cizman, Borut; Sikirica, Vanja; Marquita, West; Miller, Maria; Cobitz, Alexander

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SCHEDULE 2

FUNDING OF CLINICAL TRIAL AND PAYMENTS

1. Financial Support

a) PPD will pay a sum of INR 4,49,136.00 plus GST where applicable for every complete and evaluable Subject as defined below.

b) A complete and evaluable Subject is defined as follows:

- all procedures must be performed according to the Protocol and ICH GCP guidelines;
- a Subject will only be included according to the inclusion/exclusion criteria set out in the Protocol;
- all data are documented accurately, completely.

c) All payments will be on a *pro rata* basis. For Subjects who do not complete, the payment schedule will be evaluated according to the number of visits performed (see attachment).

d) Payments will be made quarterly according to the actual Services performed (after source data verification and CRF retrieval by PPD). The final payment will be made after resolution of all queries to the following bank account:

Bank account holder: Sanjay Gandhi Postgraduate Institute of Medical Sciences
PAN No: AAAJS3913N

e) All costs should be invoiced within one (1) month of termination of the Clinical Trial to ensure payment.

f) Central Laboratory costs will be paid by the GSK.

g) Institution shall reimburse Subjects for their travel expenses up to a value of 1000.00 INR per visit. PPD shall reimburse the Institution for the travel expenses on receipt of a valid invoice together with supporting documentation of the expense being incurred.

2. Invoicing Instructions

PPD's payment obligation is also conditioned upon Institution submitting valid invoices. The Institution shall submit valid invoices at end of every six (6) months for Services performed during that six (6) month period to the attention of;

PPD Pharmaceutical Development India Private Limited

101-A Wing, 'Fulcrum',
Hiranandani Business Park,
Sahar Road, Andheri East
Mumbai 400 099
INDIA
Telephone: +91 22 4247 2900
Facsimile: +91 22 4248 6900

The following information must be indicated on each invoice:

(i) Invoice number

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(ii) Invoice date
(iii) Protocol number
(iv) Institution contact details (address, GST number, telephone, fax and contact person)
(v) Dates on which Services were performed.
(vi) Total amount of fees for the Services

Failure to provide the required information will delay approval and the invoice may be returned for revisions. All invoices shall become payable sixty (60) days following receipt and approval by PPD.

All fees payable by PPD will be exclusive of GST, VAT, and similar indirect taxes as per the existing rules in India. PPD will pay the vendor on receipt of a legal tax invoice raised according to the terms of this agreement and the indirect tax / GST laws applicable in India.

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Exhibit A
Payment Schedule
200808

Payment by PPD shall be made payable to the payee and at the address indicated on the PAF or other applicable form provided to PPD prior to the execution of this Agreement ("Payee") as follows:

Bank account holder: Sanjay Gandhi Postgraduate Institute of Medical Sciences
PAN No: AAAJS3913N

Institution may request to revise the payee details provided herein during the course of the Study. In such cases, the parties agree that no amendment to this Agreement shall be required provided that Institution provides written notification to PPD with the revised payee details and, if applicable, a revised PAF The parties further agree that PPD assumes no liability for incorrect payee details provided by Institution.

Cost per Subject: The Institution will be paid, **in accordance with the rate set forth in the budget, per** completed subject and as outlined on the Exhibit A, less 10% percent withholding. Payments will be made on a quarterly basis in US dollars and will be based on completed visits and applicable data entered into the subject electronic case report forms (eCRFs).

Screen Failures: The Institution will be paid for six (6) Screen Failures (as defined below) without pre-approval from Sponsor and to a maximum of fifteen (15) with express pre-approval from GSK.. Additional Screen Failures may be considered upon sponsor approval. Institution will be reimbursed in accordance with the rates set forth for the Screen Run-in visit in the Budget, as verified in the CRF. For purposes of this Agreement, a Screen Failure shall mean any subject, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the Initial screen, Full Screen, Run In and/or Day 1 visit but does not randomize into the Study.

IRB Fees: Central IRB is defined as the IRB selected by the Sponsor. Local IRB Fees will be submitted by the Institution and reimbursable directly to the Institution upon the receipt of correct and itemized invoices by PPD.

Pharmacy Start-Up Fees: Payee will receive a one-time fee **in accordance with the rate set forth in the budget** to cover set-up of the pharmacy services on this Study. The pharmacy start-up fees will be payable upon PPD's receipt of a correct and itemized invoice from Payee

Patient Stipend/Compensation: Patient stipend/compensation is included in the costs per subject and will be paid to Institution at the rate stated in the attached budget on a quarterly basis based on completed visits. In the event that any patient stipend/compensation is paid by PPD to the Institution but not actually paid to the Study subject by the Institution, Institution will promptly refund that amount to PPD.

Invoices: All correct invoices pertaining to this Study should be addressed to PPD and submitted for reimbursement to the following:

PPD Pharmaceutical Development India Private Limited
101-A Wing Fulcrum,
Hiranandani Business Park,Sahar Road
Anderi East,Mumbai – 400 099
InvestigatorPayments@ppdi.com

All invoices for Study payments, as outlined in this payment schedule, must be submitted to PPD within 90 days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.

GST: All fees payable by PPD will be exclusive of GST and similar indirect taxes as per the existing rules

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in India. PPD will pay the vendor on receipt of a legal tax invoice raised according to the terms of this agreement and the indirect tax / GST laws applicable in India.

Unscheduled Visits: An Unscheduled Visit indicates a subject visit which is not expressly set forth in the Protocol, but is otherwise required for the study. Unscheduled Visits will be reimbursed on a per procedure basis in accordance with the rates set forth in the Budget. In the event a medically necessary procedure is not included in the Budget, Institution must receive prior written approval before procedure is performed. Amount of compensation for a procedure not included in Budget will be approved at the time written approval is provided.

Final Payment: The final payment, which corresponds to the remaining 10% of costs, shall be made upon completion of the close-out visit and upon receipt of (i) all completed and corrected case report forms and queries, of (ii) all Study documentation, of (iii) all unused Study drug has been accounted for and (iv) all study equipment and supplies returned as specified by PPD and Sponsor.

If at the completion of the Study, PPD has advanced sums under the terms of this Agreement that exceed the earned amount for all Study subject visits completed, Payee shall reimburse to PPD any amount by which amounts advanced by PPD exceed the fees earned within ninety (90) days.

No other additional funding requests will be considered without the prior written consent of PPD.

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Sponsor:	GSK									
Protocol:	GSK200908	Day 1 through Week 52								
Site:	Dr. Narayan Prasad									
PI:	Sanjay Gandhi Postgraduate Institute of Medical Sciences	Initial Screen (Week -8)	Full Screen (Week -8)	Run-in (Week -4)	Day 1	Abbreviated Study visit	Full Study Visit	Abbreviated Study visit	Abbreviated Study visit
Date:									
Currency:	Indian Rupee								
						Week 2	Week 4	Week 8	Week 12
Procedures	**Unit Cost**								
IWRS call	INR 716.00	INR 716.00		INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00
Informed Consent	INR 1,006.00	INR 1,006.00								
Entry Criteria	INR 1,076.00		INR 1,076.00		INR 1,076.00					
History: medical, hospitalization, transfusion; demography, height, weight	INR 4,153.00		INR 4,153.00							
Vital Signs (SBP/DBP, HR)	INR 492.00		INR 492.00	INR 492.00	INR 1,076.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00
Kt/Vurea for dialysis adequacy	Invoice				Invoice		Invoice			
ECG	INR 1,538.00				INR 1,538.00					
HemoCue Hgb	INR 802.00	INR 802.00		INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00
Iron TherapyTransfusions	Invoice		Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
Rescue Medications	Invoice						Invoice	Invoice	Invoice	Invoice
Central Laboratory Collection (hematology, clinical chemistry, ferritin, total iron, UIBC, Hepcidin, Lipids (non-fasting), HbA1c, hsCRP, IPT-Unstrad sI and FSH (if required) Storage biomarkers)	INR 973.00		INR 973.00	INR 973.00	INR 973.00		INR 973.00	INR 973.00	INR 973.00	INR 973.00
Pregnancy Test (HRP only)	Invoice			Invoice	Invoice		Invoice			
Adverse Events	INR 500.00		INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00
Concomitant Medications	INR 700.00		INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00
Symptoms of ACKD questionnaire	INR 749.00		INR 749.00		INR 749.00			INR 749.00	INR 749.00	INR 749.00
Patient Global Impression of Change (PGI-C)	INR 430.00							INR 430.00	INR 430.00	INR 430.00
Patient Global Impressions of Severity (PGI-S)	INR 716.00		INR 716.00		INR 716.00			INR 716.00	INR 716.00	INR 716.00
Kidney Ultrasound	INR 10,353.00			Invoice						
SF-36	INR 716.00				INR 716.00			INR 716.00	INR 716.00	INR 716.00
Work Productivity and Activity Impairment Questionnaire (WPAI-AIIS-CPV)	INR 716.00				INR 716.00			INR 716.00	INR 716.00	INR 716.00
Non-Procedures										
Study Coordinator	INR 2,297.00	INR 2,297.00		INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00
Physician	INR 4,700.00	INR 4,700.00		INR 4,700.00	INR 4,700.00		INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00
Pharmacy Dispensing	INR 529.00			INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00
Patient Compensation	INR 1,000.00	INR 1,000.00		INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00
Total Per Visit		INR 10,521.00	INR 9,350.00	INR 12,709.00	INR 19,204.00	INR 7,036.00	INR 12,709.00	INR 16,036.00	INR 16,036.00	INR 16,036.00
Total OH Per Visit	25%	INR 2,630.25	INR 2,339.75	INR 3,177.25	INR 4,801.00	INR 1,759.00	INR 3,177.25	INR 4,009.00	INR 4,009.00	INR 4,009.00
Total Per Visit (with OH)		INR 13,151.25	INR 11,690.75	INR 15,886.25	INR 24,005.00	INR 8,795.00	INR 15,886.25	INR 20,045.00	INR 20,045.00	INR 20,045.00
Total Costs Per Repeat Visit (with OH)		INR 11,151.25	INR 11,690.75	INR 15,886.25	INR 24,005.00	INR 8,795.00	INR 15,886.25	INR 20,045.00	INR 20,045.00	INR 20,045.00
Total Cost Per Patient (with OH) (To include, Screening, Run-in, Day 1 through 52 Week Treatment Period, Year 2, 3, and 4 , End of Study Visit and 1 Follow up Visit)										

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Full Study Visit	Abbreviated Study visit	Abbreviated Study visit	Full Study Visit	Abbreviated Study visit	Abbreviated Study visit	Full Study Visit	Abbreviated Study visit	Abbreviated Study visit	Week 52
Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	
INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00
INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 1,476.00
Invoice			Invoice			Invoice			
INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 1,538.00
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	INR 802.00
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00
Invoice			Invoice			Invoice			Invoice
INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00
INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00
			INR 749.00						INR 749.00
			INR 430.00						INR 430.00
			INR 716.00						INR 716.00
			INR 716.00						INR 716.00
			INR 716.00						INR 716.00
INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00
INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00
INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00
INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00
INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 16,035.00	INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 19,558.00
INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 4,009.00	INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 4,639.50
INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 20,045.00	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 23,197.50
INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 20,045.00	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 23,197.50

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Year 2			Year 3			Year 4					
Week 64 and Week 88	Week 76	Week 100	Week 112 and Week 136	Week 124	Week 148	Week 160 and Week 184	Week 172 and Week 196	Week 208	Unscheduled Visit	End of Study	Follow-up* (4-6 weeks after stopping study treatment)
INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00
INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 1,476.00	INR 492.00
Invoice			Invoice			Invoice		Invoice			
		INR 1,538.00			INR 1,538.00			INR 1,538.00			
INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00		
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice			
INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice		Invoice	Invoice
INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00
INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00
		INR 716.00			INR 716.00			INR 716.00		INR 716.00	
INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00
INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00
INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00		
INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00
INR 12,709.00	INR 12,709.00	INR 14,963.00	INR 12,709.00	INR 12,709.00	INR 14,963.00	INR 12,709.00	INR 12,709.00	INR 14,963.00	INR 12,709.00	INR 13,076.00	INR 11,376.00
INR 3,177.25	INR 3,177.25	INR 3,740.75	INR 3,177.25	INR 3,177.25	INR 3,740.75	INR 3,177.25	INR 3,177.25	INR 3,740.75	INR 3,177.25	INR 3,269.50	INR 2,844.50
INR 15,886.25	INR 15,886.25	INR 18,703.75	INR 15,886.25	INR 15,886.25	INR 18,703.75	INR 15,886.25	INR 15,886.25	INR 18,703.75	INR 15,886.25	INR 16,347.50	INR 14,222.50
INR 31,772.50	INR 15,886.25	INR 18,703.75	INR 31,772.50	INR 15,886.25	INR 18,703.75	INR 31,772.50	INR 31,772.50	INR 18,703.75	INR 15,886.25	INR 16,347.50	INR 14,222.50
										INR	5,45,388.75

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Study Treatment Discontinuation Visit (within 2 weeks of discontinuing study treatment)	Study Treatment Discontinuation In-Clinic Follow up Visit to study end	Study Treatment Discontinuation Phone Follow Up Call to study end
INR 716.00		
INR 1,476.00	INR 492.00	
INR 1,530.00		
INR 802.00	INR 802.00	
Invoice	Invoice	
INR 973.00	INR 973.00	
Invoice (Urine Pregnancy Test for FRP only)		
INR 500.00	INR 500.00	INR 500.00
INR 700.00	INR 700.00	INR 700.00
INR 749.00		
INR 430.00		
INR 716.00		
INR 716.00		
INR 716.00		
INR 2,297.00	INR 2,297.00	INR 2,297.00
INR 4,700.00	INR 4,700.00	
INR 1,000.00	INR 1,000.00	
INR 18,029.00	INR 11,464.00	INR 3,497.00
INR 4,507.25	INR 2,866.00	INR 874.25
INR 45,073.00	INR 14,330.00	INR 4,371.25
INR 45,073.00	INR 2,57,940.00	INR 78,682.50
INR 45,073.00	INR 2,57,940.00	INR 78,682.50

Homecare Visit Year 2+	Retention Activities	Phone/Third Party medical records follow up visit
INR 4,280.91	INR 9,418.00	INR 9,418.00
INR 4,280.91	INR 9,418.00	INR 9,418.00
INR 4,280.91	INR 9,418.00	INR 9,418.00
INR 4,280.91	INR 9,418.00	INR 9,418.00

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Invoiced Items	Base Rate		OH		Total w/OH	
Urine Pregnancy Test	INR	334.00	INR	83.50	INR	417.50
Serum Pregnancy Test	INR	300.00	INR	75.00	INR	375.00
Kt/V urea for patients transitioning into dialysis(adequecy)	INR	3,040.00	INR	760.00	INR	3,800.00
Kidney Ultrasound	INR	10,353.00	INR	2,588.25	INR	12,941.25
Optional Genetic Consent	INR	1,432.00	INR	358.00	INR	1,790.00
Iron Therapy Transfusions	INR	12,710.00	INR	3,177.50	INR	15,887.50
Rescue Medications	INR	1,350.00	INR	337.50	INR	1,687.50

* Additional follow up visits will be paid based on the rates set forth above and in accordance with the protocol.

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SCHEDULE 3

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GSK INSURANCE POLICY

CERTIFICATE OF INSURANCE

MAGMA HDI
General Insurance Company Ltd

Name of the Insured	GlaxoSmithKline Consumer Healthcare Ltd
Address of the Insured	R&D Centre, Plot no.-67, Sector-32,Gurgaon - 122001
Additional Insured Name	1.GlaxoSmithKline Consumer Healthcare Ltd 2.GlaxoSmithKline Asia Pvt Ltd 3 GlaxoSmithKline Pharmaceuticals Ltd 4.Chiron Panacea Vaccines Private Limited 5.Chiron Behring Vaccines Private Limited

Insured: All subsidiaries and affiliated engaged in clinical trials in the name of the named insured including the CRO's (Contract Research Organisations) and investigators.

This is to certify that policies of insurance listed below have been issued to the insured named above and are in force at this time. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this certificate may be issued or may pertain, the insurance afforded by the policies describes herein is subject to all terms , exclusions and conditions of such policies.

1. Type of Insurance:	CLINICAL TRIALS Insurance Cover
2. Country:	Clinical Trials in India
3. Policy No.:	P0016200031999/100203
4. Policy Inception Date:	January 1 2016
5. Policy Expiration Date:	December 31 2016
6. No.of Subjects:	Number of Patients-301
7. Study Title:	A Phase 3 randomized, open-label (Sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa.
8. Protocol Number:	200909
9. Study Start Date:	30-Jun-16
10.Study End Date:	15-May-21
11.Limits of Liability:	INR 100'135'162 any one occurrence & in the annual aggregate
12.Deductible:	INR 2'503'379 each occurrence
13. Sponsor:	GlaxoSmithKline Research & Development Limited,980 Great West Road,Brentford,Middlesex, TW8 9GS,UK
14. Claims Handling	Claims payable by MAGMA HDI GENERAL INSURANCE CO. LTD
List of Investigators:	NA
Special Remarks if any	"The coverage provided by this policy covers the trial for its entire duration. Coverage is therefore given for the entire life of the trial. No amendment or renewal is required with regard to the policy period"

This Certificate is issued as a matter of information only and confers no rights upon the certificate holder. This certificate does not amend, extend or alter the coverage afforded by the policies listed above.

for MAGMA HDI GENERAL INSURANCE CO. LTD

Authorised Signatory
PLACE : Mumbai
03/08/2016

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SCHEDULE 4

GSK ANTI-BRIBERY AND ANTI-CORRUPTION TERMS

1. Site acknowledges that it has received and read GSK's 'Prevention of Corruption – Third Party Guidelines' (either in hard copy or at http://www.gsk.com/policies/Prevention-of-Corruption-Third-Party-Guidelines.pdf) and agrees to perform its obligations under the Agreement in accordance with the principles set out therein.

2. Site shall comply fully at all time with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which the Site conducts business with GSK.

3. Site agrees that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery.

4. Site shall not contact, or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative.

   For the purpose of this Agreement "Government Official" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organisation such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision making role, has responsibility for performing regulatory inspections, government authorisations or licenses, or otherwise has the capacity to take decisions with the potential to affect GSK business.

5. Site represents that except as disclosed to GSK in writing prior to the commencement of this Agreement, it has not been convicted of or pleaded guilty to a criminal offence, including one involving fraud or corruption, that it is not now, to the best of its knowledge, the subject of any government investigation for such offenses, and that it is not now listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

6. Site represents and warrants that except as disclosed to GSK in writing prior to the commencement of this Agreement: (1) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (2) it shall maintain arms length relations with all third parties with which it deals for or on behalf of GSK in performance of this Agreement.

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7. GSK shall have the right during the term of this Agreement to conduct an investigation and audit of Site's activities under this Agreement to monitor compliance with the terms of this Agreement. Site shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSK.

8. Site shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Site must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

9. Site agrees that in the event that GSK believes that there has been a possible violation of the terms of this Agreement, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.

10. GSK shall be entitled to terminate this Agreement with immediately on written notice to Site, if Site fails to perform its obligations in accordance with this Schedule 4. Site shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Schedule 4. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to Site upon the termination of this Agreement, Site hereby expressly agrees (to the extent possible under the laws of the territory) to waive or to repay to GSK any such compensation or indemnity.

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SCHEDULE 5

GLAXOSMITHKLINE'S – CLINICAL TRIAL COMPENSATION GUIDELINES

GlaxoSmithKline (GSK) will adhere to the following broad guidelines in the event of injury caused to the patient attributable to participation in the trial in question.

1. Basic Principles

1.1 Notwithstanding the absence of legal commitment, GSK will pay compensation to the patient-volunteers suffering study related injury (including death) in accordance with these guidelines.

1.2 Compensation will be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.

1.3 Compensation will be paid to the child injured in utero through the participation of the subject's mother in a clinical trial as if the child were a patient-volunteer with the full benefit of these guidelines.

1.4 Compensation will only be paid for the more serious injuries of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.

1.5 Where there is an adverse reaction to a medicinal product under trial and injury is caused by the procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it were caused directly by the medicinal product under trial.

1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the trial should exclude a patient from consideration for compensation under these guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.

1.7 For the avoidance of doubt, compensation will be paid regardless of whether the patient is able to prove that GSK has been negligent in relation to research or development of the medicinal product under trial or that the product is defective and therefore, as the producer, GSK is subject to strict liability in relation of injuries caused by it.

2. Types of Clinical Research Covered

2.1 These guidelines apply to injury caused to patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended to treat but for which the product license does not exist or does not authorize supply for administration under the conditions of the trial.

2.2 These guidelines do not apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital, for which separate guidelines for compensation already exist at the facility where the study is carried out

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2.3 These guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply of administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial. These guidelines do not apply to post-marketing surveillance and ancillary care.

2.4 These guidelines do not apply to clinical trials which have not been initiated or directly sponsored by GSK. Where trials of products are initiated independently by doctors, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).

3. Limitations

3.1 Compensation will not be paid to research participants receiving placebo in consideration of its failure to provide a therapeutic benefit.

3.2 Compensation will not be paid for natural progression of an underlying disease.

3.3 Compensation will not be available for adverse effects due to concomitant medications allowed as per protocol/routine procedures as part of standard of care.

3.4 No compensation should be paid for the failure of a medicinal product to have its intended effect or to provide any other benefit to the patient.

3.5 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.

3.6 No compensation should be paid (or it should be abated as the case may be) to the extent that the injury has arisen:

(a) through a significant departure from the agreed protocol;

(b) through a wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction;

(c) through a contributory negligence by the patient.

3.7 Compensation may not be provided if it is determined (by the Investigator and the IEC) that the injury has arisen through:

(a) wrongful act or default of a third party;

(b) contributory negligence by the research participant (e.g. willful or reckless non-adherence to protocol procedures/instructions by the research participants as described in the ICDs).

4. Assessment of Compensation

4.1 The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by the Indian Courts in cases where legal liability is admitted.

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4.2 Compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):

(a) the seriousness of the disease being treated, the degree of probability that adverse reaction will occur and any warnings given;

(b) the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given a particular patient's circumstances. As an extreme example, there may be patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

4.3 In any case where GSK concedes that a payment should be made to a patient but there exists a difference of opinion between GSK and patient as to the appropriate level of compensation, GSK shall seek at its own cost (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his/her opinion should be given substantial weight by GSK in reaching its decision on the appropriate payment to be made.

5. Miscellaneous

5.1 Claims pursuant to the guidelines should be made by the patient to GSK, preferably via the investigator, setting out details of the nature and background of the claim and, subject to the patient providing on request an authority for GSK to review any medical records relevant to the claim. GSK should consider the claim expeditiously.

5.2 The undertaking given by GSK extends to injury arising (at whatever time) from all administration, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the request of the investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor.

5.3 The fact that GSK has agreed to abide by these guidelines in respect of a trial does not affect the right of a patient to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, patients will normally be asked to accept that any payment made under the guidelines will be in full settlement of their claims.

5.4 GSK should encourage the investigator to make clear to participating patients that the trial is being conducted subject to GSK's guidelines relating to compensation for injury arising in the course of clinical trials and the copy of these guidelines should be made available to the participating patients.

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

EN 049307

Rajendra Kumar Notary Mohanlalganj Lucknow Reg.No. 31(85)2009

I identified the deponent who has signed before me

Sworn & Verified Before Me

SUBCONTRACT AGREEMENT

This is a subcontract under a grant from **Malaysian Palm Oil Board,** No. 6, Persiaran Institusi, Bandar Baru Bangi, 43000 Kajang, Selangor Malaysia, to **Wayne State University**, 5057 Woodward Avenue, Detroit, Michigan 48202 entitled *"Palm Tocotrienol in Hemodialysis Patients Study (PATCH STUDY)"*. The parties under this subcontract are **Wayne State University**, hereinafter referred to as THE UNIVERSITY, and **Sanjay Gandhi Post-Graduate Institute of Medical Sciences, Raebarely Road, Lucknow 226014, India,** hereinafter referred to as THE SUBCONTRACTOR.

This subcontract sets forth the terms for the performance and administration of work under the above grant and consists of:

Subcontract Document
Attachment I - Statement of Work
Attachment II - Approved Budget
Attachment III – Memorandum of Agreement

EXECUTION AND MODIFICATION

An agreement shall exist when this document has been signed by duly authorized representatives of the parties. Modifications shall be made by written agreement of the authorized representatives of the parties.

09/01/2019

Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Mohanlalganj, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

PERIOD OF PERFORMANCE

The period of performance of this contract shall begin on **November 15, 2018** and shall not extend beyond **December 14, 2019** unless agreed to in writing by both parties hereto.

SCOPE OF WORK

The work to be done under this subcontract is specified in **Attachment I**.

TOTAL ESTIMATED COST

As compensation THE UNIVERSITY agrees to reimburse THE SUBCONTRACTOR for performance of the work described in Attachment I in an amount not to exceed **$30,000 USD (Attachment II)**.

WAYNE STATE UNIVERSITY PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR

Dr. Pramod Khosla
Wayne State University
School of Liberal Arts and Science
3009 Science Hall
Detroit, MI 48202
313 577-0448
aa0987@wayne.edu

The Principal Investigator/Project Director shall be responsible for the technical, scientific and programmatic aspects of the subcontract.

WAYNE STATE UNIVERSITY AUTHORIZED SUBCONTRACTING REPRESENTATIVE

Patty Yuhas Kieleszewski
Associate Director, Contract Administration
Sponsored Programs Administration
5057 Woodward Avenue Suite 13200
Detroit, Michigan 48202, USA
+1 (313) 577-3726

The Authorized Subcontracting Representative shall be responsible for the business management aspects of the subcontract as the Wayne State University official empowered to execute agreements and modifications thereto.

SUBCONTRACTOR PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR

09/01/2019
Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Mohanlalganj, Lucknow

Dr Anita Saxena
Professor
Sanjay Gandhi Post-Graduate Institute of Medical Sciences (SGPGIMS)
Department of Nephrology
Raebareli Road, Lucknow 226014,
India
Tel +91 9453019812

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

anitimmy@yahoo.com

The Subcontractor Principal Investigator/Project Director shall direct the subcontract project and is responsible to the subcontracting institution for the proper management and conduct of the grant program. The above named person may not be changed without approval by THE UNIVERSITY.

1. PAYMENT

Invoices are to be submitted according to **PAYMENT SCHEDULE** on Attachment II. Two (2) copies of all invoices, detailing current charges and total-to-date charges, should be sent to the **Wayne State University Sponsored Program Administration at 5057 Woodward Avenue Suite 13200 Detroit, MI 48202** or emailed to subkinvoices@wayne.edu. Please indicate project **#4-22508** on all invoices. The final invoice, clearly marked **FINAL**, must be submitted within **45 days** after the expiration date of this subcontract.

2. ALLOWABLE COSTS

THE SUBCONTRACTOR'S normal policies governing salaries, wages and fringe benefits shall apply to all THE SUBCONTRACTOR'S employees paid from this subcontract. THE SUBCONTRACTOR'S standard policy on travel and travel reimbursement shall apply to all costs for travel and transportation charged to this subcontract.

3. REBUDGETING OF FUNDS

It is understood that THE SUBCONTRACTOR'S budget as attached hereto (Attachment II) is an estimate and that there may be a need to depart from it to cover certain unanticipated requirements of the work. Any rebudget requires prior approval from THE UNIVERSITY.

4. RELATION TO THE PRIME GRANT

This subcontract is subject to all terms and conditions stated in the Memorandum of Agreement for Research and Development awarded by the Malaysian Palm Oil Board to THE UNIVERSITY which is incorporated herein by reference (see Attachment III), and THE SUBCONTRACTOR hereby agrees to accept and does accept as binding upon THE SUBCONTRACTOR each and every provision of said grant that is binding upon THE UNIVERSITY. THE SUBCONTRACTOR agrees to assume and does assume all the responsibility of THE UNIVERSITY to the Malaysian Palm Oil Board for the terms of the said referenced grant so far as they relate to services to be performed by THE SUBCONTRACTOR. This paragraph shall not be construed so as to require THE SUBCONTRACTOR to furnish or perform any services other than those expressly specified in this subcontract or amendments hereto.

5. ACCOUNTS, AUDITS AND RECORDS

(A) THE SUBCONTRACTOR shall maintain books, records, documents and other evidence, accounting procedures and practices, sufficient to reflect properly all direct and indirect costs of whatever nature it claims to have been incurred for the performance of this subcontract. The foregoing constitutes "records" for the purpose of this subcontract.

(B) THE SUBCONTRACTOR'S facilities, or such part thereof as may be engaged in the performance of this subcontract, and its records shall be subject at reasonable, mutually agreeable times during normal business hours and upon reasonable advance notice to inspection and audit by THE UNIVERSITY'S financial officer or its authorized representatives.

09/01/2019

Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankahi
Mohanlalganj, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(C) THE SUBCONTRACTOR shall preserve and make available its records until the expiration of three (3) years after submission of the final report for the budget period which they cover or until audit is completed and all resulting questions are resolved, whichever occurs first.

6. INDEMNITY

THE SUBCONTRACTOR will save, indemnify, defend and hold harmless THE UNIVERSITY, its agents, directors, and employees from any and all liability that may arise as a result of the negligent actions and/or omissions of THE SUBCONTRACTOR, its agents, and employees under the performance of this subcontract.

THE UNIVERSITY will save, indemnify, defend and hold harmless THE SUBCONTRACTOR, its agents, and employees from any and all liability that may arise as a result of the negligent actions or omissions of THE UNIVERSITY, its agents, and employees to the extent allowed under Michigan law.

7. EQUAL OPPORTUNITY

During the performance of this subcontract, THE SUBCONTRACTOR agrees as follows:

(A) THE SUBCONTRACTOR will not discriminate against any employee or applicant for employment because of race, color, religion, sex, age, marital status or national origin or because of handicap except where a bona fide occupational qualification exists.

(B) THE SUBCONTRACTOR will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and of the rules, regulations and relevant orders of the Secretary of Labor.

(C) In the event of THE SUBCONTRACTOR'S noncompliance with this Equal Opportunity Provision this contract may be cancelled, terminated, or suspended in whole or in part, as deemed appropriate by THE UNIVERSITY.

8. AUTHORITY AND RELATIONSHIP OF PARTIES

The nature of the relationship which THE SUBCONTRACTOR shall have to THE UNIVERSITY shall be that of an independent contractor. This subcontract shall not be construed to contain any authority, either express or implied, enabling THE SUBCONTRACTOR to incur any expense or perform any act on behalf of THE UNIVERSITY. Nothing in this subcontract shall prevent or impair the right of THE UNIVERSITY to apply for, receive, administer or perform the conditions of any public or private grant or contract. Nothing in this agreement shall operate to impair the tax-exempt status of THE UNIVERSITY.

9. ASSIGNMENT

THE SUBCONTRACTOR shall not assign, transfer, or convey this subcontract or any part hereof, or any interest herein, nor shall THE SUBCONTRACTOR subcontract for the performance of any of its obligations hereunder, without the prior written consent of THE UNIVERSITY.

Rajendra Kumar
Adv. & Notary
Vill. Post-Kankarg

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

10. INTEGRATION CLAUSE

This subcontract represents and embodies all the agreements and negotiations between the parties hereto and no oral agreements, representations, or correspondence shall be held to vary the provisions hereof.

11. STATE OF GOVERNING LAW

THE UNIVERSITY and The SUBCONTRACTOR agree to remain silent.

12. TERMINATION

THE UNIVERSITY may terminate this subcontract upon written notice to THE SUBCONTRACTOR at any time prior to the completion of this subcontract. In addition, either party may terminate this subcontract for any reason upon thirty (30) days written notice. THE SUBCONTRACTOR shall be reimbursed for uncancellable obligations properly incurred prior to the date of notice of termination.

13. PUBLICATIONS

THE SUBCONTRACTOR agrees to acknowledge the support of THE UNIVERSITY and/or the awarding Sponsor whenever activities funded in whole or in part by this subcontract are published in any news media. All major publications resulting from this work will be prepared jointly by the parties with major responsibility assigned as per specifics of the particular publication. The terms and conditions in Section 7- PUBLICATIONS in the Memorandum of Agreement for Research and Development (Attachment III) shall remain in full effect for twelve months after the expiration of the Memorandum of Agreement for Research and Development.

NOTARY Rajendra Kumar Adv. & Notary Teh. Mohanlalganj Lucknow Reg.No. 31/1992

IN WITNESS WHEREOF, the parties have caused this contract to be effective as of **Nov 15, 2018**, with signatory approval of their duly authorized representatives.

WAYNE STATE UNIVERSITY

SIGNED:_____

09/1/2019

Rajendra Kumar Adv. & Notary Vill. Garhi Post-Kankaha Mohanlalganj, Lucknow

DATE: 09.01.2019

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS)

SIGNED

Title:_____

DATE:_____

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WS018xxx

PROFESSOR DR ANITA SAXENA
PRINCIPAL INVESTIGATOR
SANJAY GANDHI POST-GRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS)

SIGNED _____

NOTARY
Rajendra Kumar
Adv. & Notary
Teh. Mohanlalganj
Lucknow
Reg.No. 31(25)2009

DATE 09.01.2019

09/01/2019
Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Nankaha
Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WSU18xxx

ATTACHMENT I

STATEMENT OF WORK

The Bangladesh arm of the multi-centered PATCH study will be a randomized, double blind, placebo-controlled, parallel design study involving the Sanjay Gandhi post-Graduate Institute of Medical Sciences (SGPGIMS) in Lucknow, India. The protocols to be followed have been detailed in our previous intervention studies with TT (Daud et al, 2013) and omega-3- supplements (Daud et al, 2012). The protocol is also in line with the procedures used in the recent tocopherol and lipoic acid intervention trial (Himmelfarb et al, 2014). SGPGIMS will recruit upto 75 eligible patients undergoing thrice weekly or twice weekly dialysis. Patients will be administered 300mg TRF per hemodialysis session under direct supervision and 300mg TRF during non-dialysis days as a take home supplement. The administrations of TRF/placebo will last for up to 12 months. Compliance will be monitored by capsule counting method as well as by direct observation during regular thrice-weekly dialysis sessions. Changes in diet will be monitored via multiple 24-hr diet recalls at baseline and at 3–month intervals. Blood will be collected at t=0 (baseline), 3, 6, and if needed at 9 and 12 months, plasma will be isolated and stored at SGPGIMS at -80 degrees until subsequent analyses by Wayne State. SGPGIMS will also provide us with the results from routine blood measurements that they undertake as part of the patients' standard care. No blood samples will be collected for the study which is not part of the patient's routine care. An additional sample will be collected 3 months after the study finishes (documenting any residual effects of the supplement).

NOTARY
Rajendra Kumar
Adv. & Notary
Distt. Lucknow

09/01/2019
Rajendra Kumar
Adv. & Notary
Distt. Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ATTACHMENT II - APPROVED BUDGET

ATTACHMENT II-APPROVED BUDGET FOR THE PERIOD 11/1/18 TO 12/14/19

PERSONNEL	- U$	6,000.00
PATIENT CARE	- U$	5,000.00
MEDICAL INSURANCE	- U$	5,000.00
RESEARCH SUPPLIES	- U$	6,000.00
STUDY MEASURES	- U$	3,000.00
MAINTENANCE	- U$	2,000.00
SAMPLE SHIPMENT	- U$	1, 000.00
TRAVEL	- U$	2, 000.00
TOTAL DIRECT COSTS	- $	30,000.00
OVERHEAD/SERVICE TAX		
TOTAL COST	- $	30,000.00

PAYMENT SCHEDULE

Invoice for $5,000 USD upon full execution of Subcontract WSU18059.

Invoice for $10,000 USD on June 1, 2019.

Invoice (marked FINAL) for $15,000 USD upon completion of project.

Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Mohanlalganj, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ATTACHMENT III

Memorandum of Agreement for Research and Development

(see attached)

NOTARY
Rajendra Kumar
Adv. & Notary
Teh. Mohanlalganj
Lucknow
Reg.No. 31(66)2009

09/01/2019
Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankalha
Teh. Mohanlalganj, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ VL 053892

प्रधान मुद्रांक कार्यालय, मुंबई
- 5 JUL 2019
सक्षम अधिकारी

E-Track Number : 116566
Center Number : 235925
Reference for Payment : PO.....

श्री. दि. क. गवई

AGREEMENT FOR CLINICAL TRIALS

This Agreement for Clinical Trials (the "Agreement") is effective on **11-July-2019**, (the "Effective Date") between

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road Lucknow - 226014, Uttar Pradesh, India (hereinafter referred to as "**Institution**")

and

GLAXOSMITHKLINE PHARMACEUTICALS LIMITED, a company registered under the Companies Act, 1956 and having its registered office at Dr. Annie Besant Road, Worli, Mumbai 400030 (hereinafter referred to as "**GSK**").

WHEREAS GSK is a pharmaceutical company involved in the research, distribution and sale of vaccines for use in humans;

WHEREAS GlaxoSmithKline Biologicals S.A., rue de l'Institut 89, B - 1330 Rixensart, Belgium (hereinafter referred to as "**GSK Bio**" or "**Sponsor**") is the sponsor of the Study (as

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Executive Registrar
SGPGIMS,Lucknow

defined below) and has subcontracted the conduct of the Study to its affiliated local company, GSK;

WHEREAS Institution is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare

WHEREAS GSK is willing to contract with Institution to undertake the conduct of a sponsored study on the investigational Vaccine (as defined later) entitled "A phase ***III***, randomized, open study to assess the immunogenicity, reactogenicity and safety of two different formulations of GlaxoSmithKline (GSK) Biologicals' oral live attenuated human rotavirus (HRV) vaccine, *Rotarix*, when given as a two-dose primary vaccination, in healthy infants with no previous history of rotavirus illness or vaccination." (hereinafter referred to as the "**Study**"). Such Study will be conducted under the oversight and responsibility of Investigator at Institution; and

WHEREAS Investigator shall conduct the Study and Institution is willing to provide certain resources in furtherance thereof.

NOW, THEREFORE, in consideration of the promises and the mutual covenants and conditions hereinafter recited, the parties do hereby agree as follows:

I. INSTITUTION AND PRINCIPAL INVESTIGATOR

a) Institution represents and warrants that it holds the necessary registrations and authorisations to perform the Study under this Agreement.

b) Save as may be agreed from time to time by GSK and Institution, Principal Investigator shall take primary responsibility for the conduct of the Study at the Study site on behalf of Institution.

c) The Institution represents that it is entitled to procure the services of Dr. Piyali Bhattacharya to act as principal investigator for the Study ("**Principal Investigator**" or "**Investigator**") and shall be responsible for the performance of the obligations of the Principal Investigator and other Study staff set out in this Agreement. Institution represents that Investigator and other Study staff holds the necessary registration and has the necessary expertise, time and resources to perform the Study.

d) Institution shall procure and shall ensure that Principal Investigator procures the performance of the obligations of the Study staff as set out in this Agreement with all due skill, care and diligence. Institution shall provide qualified personnel, facilities and resources, as required, to perform this Agreement.

e) Where Institution is not the principal employer of Principal Investigator, Investigator represents that Principal Investigator has notified his/her principal employer of his/her proposed participation in the Study and, where relevant, his/her supervision of the Study staff and that his/her principal employer has consented to his participation in the Study. Any financial or other arrangement relating to the Investigator's involvement in the Study will be agreed directly between Institution and the principal employer of Investigator.

f) The Institution and the Principal Investigator represent that the Principal Investigator has the necessary expertise to perform the Study, that the Principal

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Executive Registrar
SGPGIMS,Lucknow

Investigator is not involved in any litigation or investigation conducted by any public authority, and that no data produced by him in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

g) The Institution shall forthwith notify GSK if Dr. Piyali Bhattacharya ceases to be employed by or associated with the Institution or is disqualified or barred from performing obligations herein, or any conflict of interest arises which has not been previously disclosed to GSK or is otherwise unavailable to perform his/her obligations under this Agreement and shall use its best endeavors to find a replacement acceptable to both GSK and the Institution. If no mutually acceptable replacement can be found GSK may terminate this Agreement pursuant to clause XV below.

h) Principal Investigator represents he/she is free to participate in the Study and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict Principal Investigator's performance of the obligations detailed in this Agreement.

i) Principal Investigator is not involved in any regulatory or misconduct litigation or investigation by the DCGI, Medical Council of India, US Food and Drug Administration, the Medicines and Healthcare products Regulatory Agency, the European Medicines Agency, the General Medical Council or other regulatory authorities. No data produced by Principal Investigator in any previous study / clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

j) Principal Investigator has considered, and is satisfied that, facilities appropriate to the Study are available to Investigator at the Study Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the Institution to perform the Study efficiently and in accordance with its obligations under the Agreement.

k) Principal Investigator carries medical liability insurance (or the Institution carries medical liability insurance covering him) and details and evidence of the coverage (including violation of approved protocol, scientific misconduct or negligence) will be provided to GSK upon request.

l) During the Study, Principal Investigator will not serve as an investigator or other significant participant in any study / clinical trial for another sponsor if such activity might adversely affect his ability to perform his obligations under this Agreement.

m) Neither Principal Investigator, nor his spouse nor any dependent children, have entered into and will not enter into any financial arrangements with GSK to hold financial interests in GSK namely (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Study could be influenced by the outcome of the Study, (ii) any proprietary interest in the product being tested, (iii) any significant equity interest in GSK and (iv) any significant payments from GSK such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria. In the case of subparagraphs (iii) and (iv) the Investigator

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Executive Registrar
SGPGIMS,Lucknow

understands that such prohibitions relate to the period that the Investigator is carrying out the Study and for one (1) year following completion of the Study.

II. STUDY CONDUCT

a) GSK Bio is the Sponsor of the Study. The Study shall be carried out under the strict supervision of the Principal Investigator and in accordance with the protocol reference ***Amendment 3 Final: 31*** October 2017 set out in Schedule A attached hereto (**"the Protocol"**). The Principal Investigator undertakes to comply with all rules in force within the Institution and represent that such rules are not in conflict with this Agreement.

b) The Principal Investigator shall be responsible for obtaining and maintaining all approvals from the relevant local ethics committee for the conduct of the Study and the Principal Investigator shall keep GSK fully appraised of the progress of ethics committee submissions and shall upon request provide GSK with all correspondence relating to such submissions. The Principal Investigator shall not consent to any change in the Protocol requested by a relevant ethics committee without the prior written consent of GSK.

c) It is further agreed by the Institution and the Principal Investigator that the Study shall be carried out by scientifically qualified staff in accordance with:

i) the principles that have their origin in the World Medical Association Declaration of Helsinki entitled "Ethical Principles for Medical Research Involving Human Subjects" (latest version), the ICH Harmonised Tripartite Guideline for Good Clinical Practice (GCP);

ii) all applicable laws, including without limitation: the Drugs & Cosmetics Act 1940 and Rules, notifications, circulars, office orders and any other directives thereunder or issued by office of the Drugs Controller General of India (DCGI) or similar such administrative body, Information Technology Act 2000 and Rules pertaining to sensitive personal information thereunder, Electronic Health Record (EHR) Standards for India, 2016, other medical privacy laws or regulations, as well as by obtaining any required subject consent or authorization to allow GSK access to Study subject's personal and medical information as may be necessary to monitor the Study and to receive and use Study data and all legal and ethics requirements of the country in which the Study is performed (collectively herein "**Applicable Laws**";

iii) the Protocol;

iv) and in strict compliance with the terms of this Agreement.

Should there be any inconsistency between the Protocol and the other terms of the Agreement, the terms of the Protocol shall prevail to the extent of such inconsistency.

d) Prior to commencing the Study, the Principal Investigator or a person designated by the Principal Investigator shall inform each subject of the nature of the Study and obtain the subject's or the subject's legal representative's written signed

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Executive Registrar
SGPGIMS,Lucknow

consent whenever possible, or failing that, oral witnessed informed consent of that subject to undergo the Study.

e) The Principal Investigator agrees to exercise his/her due diligence to complete the Study according to the timing agreed upon in the Protocol.

f) Neither the Institution nor the Principal Investigator shall during the term of this Agreement conduct any other trial which might adversely affect the Institution or Principal Investigator's ability to perform their obligations under this Agreement.

g) Neither the Institution nor the Principal Investigator shall have the right to sub-contract all or part of the Study conduct to any third party without the prior written consent of GSK. The Institution shall enter into written agreements with any approved subcontractor with terms and conditions required by and consistent with this Agreement. The Institution and the Principal Investigator shall be completely responsible for the satisfactory performance of all services assigned to sub-contractors, and the Institution and the Investigator acknowledge that the acts or omissions of any subcontractors shall be deemed to be the acts or omissions of the Institution and/or the Principal Investigator with respect to the performance of any obligation of either the Institution or the Principal Investigator under this Agreement.

h) In the event Institution/Principal Investigator observes or becomes aware of material non-compliance with the Protocol, the GCPs or any Applicable Laws, incomplete or inaccurate recording of data, or any significant misconduct or other matters of concern relating to the performance of the Study, Institution/Principal Investigator shall promptly inform GSK, and shall cooperate with GSK to take appropriate and timely measures to remedy such non-compliance or other matter of concern.

i) The Institution must have adequate security measures to ensure the safety and integrity of the investigational Vaccine, and Study records and reports, equipment and any Study related materials held or located at the Study Site.

III. SUPPLY OF MATERIALS

a) GSK shall supply the Institution / Principal Investigator with approximate 45 Vaccines each of HRV lyophilized vaccine and HRV liquid vaccine ("**the Vaccine**") as shall be required for the purpose of the Study and the Principal Investigator acknowledges that he/she has no claim to the Vaccine so supplied and that it shall remain the sole and exclusive property of GSK and shall be used by the Principal Investigator and/or the Institution solely for the purposes of this Study and in accordance with the terms of this Agreement or other Study related documents. Further Vaccine supplies may be made based on subject recruitment.

b) The Institution represents to have complete facilities and infrastructure required for storage for the Vaccine.

c) The Principal Investigator and the Institution shall use the Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify the Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, and ship or dispose of Vaccine in compliance with all Applicable Laws and instructions as may be mentioned on the Vaccine label/pack or communicated by GSK from to time, including, but not limited to, those governing

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

hazardous substances. The Principal Investigator and the Institution shall not charge any Study subject or third-party payor for any Vaccine, or for Study procedures for which payment by GSK has or will be made under this Agreement.

d) The Vaccine shall be returned to GSK/ the Sponsor or drug depot working under Sponsor's responsibility in case of:
   - Recall intimation by GSK/ Sponsor
   - Complaint from the Institution/PI
   - As and when required by GSK/Sponsor

   The Vaccine can be also returned for destruction to the GSK/Sponsor or drug depot working under the Sponsor's responsibility.

   The Vaccines to be returned must be identified and stored in a dedicated area within the Institution's premises at the label storage temperature conditions unless otherwise authorized.

IV. ELECTRONIC CASE REPORT FORMS AND EQUIPMENT / SYSTEMS

a) GSK might lend computer equipment and, where appropriate, software systems or other materials or equipment to the Institution for the sole purpose of performing the Study. Any equipment or material that is not part of the compensation paid to the Institution for the performance of the Study, as referenced under section XI b) 6. of this Agreement, shall be returned to GSK as provided for in section IV b) (viii) below.

b) In the event GSK provides computer equipment and/or software systems; (including but not limited to the web-based case report from system for Study staff to use to collect, enter and report Study data to GSK electronically, the Institution hereby agrees that:

   i) Study staff will make themselves available for training in using the systems;

   ii) the systems will be used only for the Study and only as described in written directions provided by GSK;

   iii) the computer equipment and if appropriate the systems and other equipment will be kept in a safe and secure location, and will be used only by Study staff designated by Site Principal Investigator as responsible for entering Study data;

   iv) Case Report Forms (CRFs") information associated with a study subject's visit must be satisfactorily completed within three (3) days after the subject's visit or, if applicable, receipt of the study subject's test results;

   v) All data queries from GSK must be completed and returned to GSK within seven (7) days or, if during final clean up, one (1) day, or such other time set by GSK;

   vi) Institution will take suitable precautions and measures to prevent theft, damage or loss to the computer equipment;

   vii) Institution will be responsible for arranging and paying for any required internet connection as necessary to use the systems; and

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

viii) at the completion or early termination of the Study or at GSK's request, Institution will return to GSK the computer and all system related training materials and documentation provided to the Institution and/or Study staff, as well as other materials or equipment lend to the Institution for the purposes of the Study.

V. CONFIDENTIALITY

a) "GSK Confidential Information" means: (1) all information (including, without limitation, Study protocols, case report forms, clinical data, other data, reports, specifications, Study budget, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of GSK or GSK's affiliates that are provided to Institution in connection with this Agreement or the Study; (2) Study data, results, information fixed in any tangible medium, or reports created by Institution, Investigators, or Study staff in connection with the Study (except for Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

b) GSK Confidential Information and all tangible expressions, in any media, of GSK Confidential Information are the sole property of GSK.

c) Institution agrees not to use GSK Confidential Information for any purposes other than to conduct the Study. Institution agrees not to disclose GSK Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard GSK Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

d) The contents of this Agreement shall not be disclosed to third parties unless agreed to by both parties.

e) The obligations of confidentiality and non-use shall not apply to information:

i) which at the time of receipt by the Principal Investigator and/or the Institution is in the public domain;

ii) which after receipt by the Principal Investigator and/or the Institution becomes part of the public domain by publication or otherwise by lawful and proper means;

iii) which the Principal Investigator and/or the Institution can establish by competent proof was in their possession before receipt from us and was acquired with free rights of disposal directly or indirectly from a source wholly independent of us;

iv) which the Principal Investigator and/or the Institution subsequently receive from a third party with good legal title thereto or which had the right to disclose or transfer such information.

In the event that the Principal Investigator and/or the Institution hereto are required by applicable statute or regulation or by judicial or administrative process

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to disclose any part of the GSK Confidential Information which is disclosed to them hereunder, the Principal Investigator and/or the Institution shall (i) promptly notify GSK of each such requirement and identify the Information so required thereby, so that GSK may seek an appropriate protective order or other remedy and/or waive compliance by the Principal Investigator and/or the Institution with the provisions of this Agreement and (ii) consult with GSK on the advisability of taking legally available steps to resist or narrow the scope of such requirement.

f) Notwithstanding anything to the contrary contained in this Agreement, it is agreed between the Parties and the Principal Investigator and/or the Institution hereby acknowledges that GSK, its group companies and/or its or their authorized third parties shall have access to the contents of this Agreement including personal information and sensitive personal data or information of Principal Investigator and/or the Institution as contained in this Agreement (but not of the Study subjects) . The Principal Investigator and/or the Institution hereby expressly permits such disclosure and waives any right to object in future.

g) The obligations of this Section shall survive termination or expiration of this Agreement.

VI. STUDY TRANSPARENCY AND PUBLICATION

a) GSK will post a Study Protocol summary on a publicly available protocol register prior to the enrollment of Study subjects.

b) Post Study completion, GSK will post a Study results summary on a publicly available results register. Posting of summary Study results may occur prior to publication of Study results in the peer-reviewed literature.

c) GSK will seek to publish the Study results from all Study sites (a "Multicenter Publication") in the searchable, peer reviewed scientific literature in the form of journal manuscripts and in some cases, in the form of presentations of Study results at international congresses. Where publication in the searchable, peer reviewed scientific literature is not feasible, the Study results summary shall be posted on publicly available register(s).

d) First publication(s) ("Primary Publication") and all consequent Multicenter Publication(s) or disclosure(s) of the Study results shall be coordinated by GSK in order to ensure compliance with GSK policies and SOPs. The Primary Publication shall disclose at least the primary and secondary efficacy endpoints and safety results, and when medically informative, exploratory analyses. For a multicentre Study, the Primary Publication(s) or disclosure(s) of Study results shall be a complete joint Multicenter Publication(s) or disclosure(s). Thereafter, any other publications will reference the original publication(s). Primary Publication(s) of Study results shall be accompanied by public disclosure(s) of the full Study Protocol in publicly available registers.

e) Any participation of Principal Investigator or other representatives of Institution as a named author of a Multicenter Publication will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts, and Institution and Principal Investigator acknowledge that the enrollment of Study subjects alone is not a qualification for

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authorship. Institution, Principal Investigator and GSK who are involved as authors in preparing a publication are responsible for ensuring that authorship in such publications is attributed appropriately in accordance with the criteria for authorship described in the Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org/) (or, if more stringent, the authorship criteria of the specific journal) and that the publication is developed according to the recommendation from the International Society for Medical Publication Professionals (ISMPP) about Good Publication Practice for Communicating Company Sponsored Medical Research (C Graf et al. Good Publication Practice for Communicating Company Sponsored Medical Research: the GPP2 guidelines. BMJ 2009;339:b4330).

f) Institution and Principal Investigator agree that all significant contributions made by individuals and organizations shall be acknowledged. The contributions of writers and individuals not listed as authors, the role and involvement of GSK in the Study and any writing and/or coordination support to develop Primary Publications, as well as Institution Publications or Written Materials shall also be described and disclosed.

g) If the Principal Investigator or other representative of Institution is a named author of the Multicenter Publication, GSK and Institution (on behalf of such authors at Institution) agree that authors:

i) Will enter a written agreement with GSK confirming the key principles of obligations related to development of publications and agreement thereto prior to starting the work on the development of the Multicenter Publication

ii) will have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication;

iii) will adhere to ICMJE requirements regarding authorship;

iv) will disclose as part of the Multicenter Publication that GSK financially supported the Study and any personal financial relationship with GSK;

v) will disclose that they have made substantial contributions to the Study and have given or will give final approval to the version of the Multicenter Publication ultimately published;

vi) and upon completion of author activities will certify in writing to the foregoing and that the authored publication is fair, accurate, and balanced.

h) Institution, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any GSK Confidential Information other than the Study results from Institution's Study data.

i) Institution and Principal Investigator shall, and shall ensure that any other persons under their control submit to GSK for review and comment any proposed publication, presentation, poster, abstract, material for use for teaching purposes

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or otherwise disclosing the Study results (hereinafter jointly referred to as the "Written Material") at least sixty (60) days prior to disclosing such Written Material to any third party and shall allow GSK a period to review the same not to be shorter than 60 days for manuscripts, posters, presentations and material for use for teaching purposes or otherwise disclosing the Study results or 21 working days for abstracts. If GSK requests a delay in order to file patent applications or seek similar protection of any inventions, know-how or other intellectual or industrial property rights disclosed in the proposed Written Material, Institution and the Principal Investigator agree to delay submitting such Written Material to any third party for up to one hundred twenty (120) days after GSK's request. Institution and Principal Investigator agree to incorporate in the Written Material any and all reasonable comments made by GSK.

j) Institution also agrees that any Institution Publication shall only be made after the Multicenter Publication. Institution agrees that GSK's financial support of the Study will be disclosed in any Institution Publication and will require all authors of such Institution Publication to disclose any financial relationship with GSK. Institution shall ensure that Investigator complies with the obligations identified in this subsection.

k) Study subjects' Personal Information, such as name or initials, shall not be publicly disclosed at any time.

l) Institution and Principal Investigator acknowledge that GSK may be required by Applicable Laws or industry codes of practice or GSK policy to disclose specific information, including but not limited to, the fact that GSK has funded the conduct of the Study, the names and address of the Principal Investigator and the Institution as well as details of any payment or benefit in kind made to or for the benefit of the Institution or the Principal Investigator. By executing this Agreement, the Institution agrees that GSK or its affiliates may publicly disclose such information as required under any Applicable Laws or industry codes of practice or GSK policy and that it has obtained the consent of the Principal Investigator to such disclosure. Moreover, Institution shall ensure that Principal Investigator agrees that, if Principal Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Drug or that otherwise relates to GSK, Principal Investigator will disclose that he/she was an investigator for the Study.

m) In order to achieve an optimal scientific outcome of publication activities if considered appropriate, GSK, Principal Investigator or other Institution personnel involved with the Study may participate in the Publication Steering Committee ("PSC") for the Study or core writing team(s) and may, if requested by GSK in writing, present the Study results at congresses or conferences identified by GSK. Institution agrees that Principal Investigator or other Institution personnel involved with the Study are allowed to participate in such PSC, core writing team(s) and speaking engagements at peer-reviewed plenary sessions of scientific congresses. Participation will consist as appropriate of: (1) attending either in person or via teleconference the various meetings of the PSC which will be called from time to time to develop the publication plan for the Study, review proposals for publications submitted to the PSC, define publication timelines, endorse the scientific meetings at which and medical journals in which results from the Study should be presented, recommend and endorse authorship. Members of the PSC, will be expected to participate in a minimum of two (2) and a maximum of twelve (12) meetings of the PSC; (2) attending either in person or via teleconference the various meetings or otherwise participating in activities of core writing teams for

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any publications as approved in the publication plan with an aim to review the progress of any such publications; (3) if requested by GSK in writing, present the Study results on congress(es) or conference(s) identified by GSK for any publication as approved in the plan as author on such publication.

n) Persons participating as a member of a PSC, in core writing team(s) activities or presenting Study results at conferences or congresses will not receive any payment, honorarium or other fee for participation in such activities nor ownership to nor other title or interest in work product arising out of such activities. However, GSK will reimburse such persons or the Institution (as the case may be and as advised by such persons) for their reasonable travelling and lodging expenses while travelling at GSK's request, provided that travel and lodging expenses have been authorized by GSK in writing in advance and that GSK receives proper original receipts.

o) The obligations of this Section shall survive termination of this Agreement.

VII. RESULTS AND INTELLECTUAL PROPERTY

a) The Principal Investigator and the Institution agree to communicate the results of the Study promptly to GSK in such format as GSK shall require. The Principal Investigator and the Institution shall immediately assign to GSK all Intellectual Property rights (including know-how and copyright) and interests in all countries in any inventions or developments arising from the Study and agree to assist GSK in connection with any application for Letters Patent or other forms of protection and do all such other things and execute all such documents and authorizations as may be necessary in connection with any such applications. GSK will have the sole rights to decide in which countries to apply for and obtain Letters Patent or other forms of protection and shall be liable for all expenses incurred in filing, prosecuting to grant and maintaining in force such Letters Patent or other forms of protection.

b) All background IP owned or controlled by a Party hereto shall remain the property of such Party.

c) The obligations of this Section shall survive termination or expiration of this Agreement.

VIII. INDEPENDENT CONTRACTOR

a) The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind, which purports to bind the other without the other's prior written authorization. It is hereby expressly understood that GSK shall not be responsible for any aspects of the employment of the Institution personnel involved in the conduct of the Study, unless otherwise specifically agreed upon in writing by GSK, and neither the Principal Investigator nor any other member of the Institution staff shall at any time be or be deemed to be, or to act as, employees of GSK.

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IX. INDEMNIFICATION – INSURANCE

a) GSK shall through its insurance program provide free medical management and compensation for damages in relation to bodily injury (including death) attributable to the administration of the Vaccine in accordance with the Protocol or the participation in the Study as envisaged in Schedule Y of the Drugs & Cosmetics Rules, 1945 (collectively referred as "**Study Related Injury**").

b) Subject to sub-clause (d) and (e) of this clause IX, GSK will:

i) hold the Principal Investigator, his/her Study-staff (who are identified to be working on the Study), the Institution harmless and indemnify the same against damages and legal costs and expenses arising out of any legal action in relation with such Study Related Injury;

ii) cover the costs of treatment of Study subjects for Study Related Injury;

PROVIDED HOWEVER THAT GSK shall not be liable if such injury results from any wrongful act, omission or negligence or failure to conduct the Study in accordance with the Protocol on the part of Institution, Investigator, Study staff any person undertaking or involved in the conduct of the Study AND PROVIDED FURTHER THAT no admissions or settlements are made without the prior written approval of GSK, GSK is promptly informed of any claims or prospective claims and is given full conduct and control of any defence proceedings/negotiations.

c) Institution shall maintain all appropriate insurance including medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon GSK's request, Institution shall have its insurance carrier (or shall cause the medical professional to have his or her insurance carrier) furnish to GSK certificates that all insurance required under this Agreement is in force.

d) In no event will GSK be liable on any theory of liability, whether in an equitable, legal, or common law action arising hereunder for contract, strict liability, indemnity, tort (including negligence), or otherwise, for damages which, in the aggregate, exceed the amount GSK has paid under the Agreement as fees which gave rise to the cause of action, provided this limitation excludes any liability imposed by any authority and calculated under any Applicable Law.

e) GSK will be not liable for any indirect, or incidental or consequential damages of any type, including lost profits, arising out of or in connection with this Agreement or its termination or suspension.

f) Institution shall indemnify and hold harmless GSK, its affiliates, and each of their respective officers, directors, employees, agents and contractors (collectively, the "GSK Indemnitees") from and against any and all costs, charges, damages, expenses, fees (including without limitation reasonable attorneys' fees) and losses (including, without limitation fees and costs incurred in recovering the same) incurred by any GSK Indemnitee that arises from Institution's or Principal Investigator's breach, negligence, gross negligence or wilful misconduct or a breach by Institution or any of its agents, contractors or subcontractors of this Agreement.

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X. COMPENSATION

a) GSK agrees to pay for up to a maximum of 90 subjects included in the screening sequence, (at a cost of 11400/- per screened subject).

b) GSK also agrees to pay, for each subject enrolled and properly documented as detailed in the Protocol, the following fees, in INR and this up to a maximum of 90 subjects included in the Study:

Total study budget	**Unit cost**	**No. of subjects**	**Amount**
Study assessments	6300	90	567000
Investigator's fees	3600	90	324000
Study personnel's fees	1500	90	135000
Total			1026000
Overheads (to specify	25%		256500
Travel reimbursement	1500	90	135000
Others (to specify) Archival costs (for 25 years)	100000		100000
Miscellaneous	20000		20000
Total study budget			1537500

(hereinafter referred to as the "Study Budget")

Visit Activities	Cost in INR		
	Visit 1	2	3
Informed consent	800	0	0
Check Inclusion/Exclusion Criteria	700	0	0
Physical Examination – General	800	700	0
Vaccine/Treatment Administration	400	400	0
Record, Concomitant Medication/Vaccine	300	300	300
Blood Draw, Complex	800	0	800
Study Coordinator, Complex - per visit	500	500	500
Physician, Complex - per visit	1200	1200	1200

c) The maximum Study Budget assigned to the Principal Investigator amounts to 1537500 (Study costs). The Principal Investigator shall be responsible for allocating and paying all costs of Study within the limit of the Study Budget to all co-investigators and sub-investigators working for the Study.

Payment of this Study Budget will be made upon achieving the following milestones:

Milestone payment	
I	First Payment: post site initiation visit: An amount of Rs.20000 will be released after site initiation visit.
II	Subsequent payments:
1	Towards subject visit: once in every two months based on subjects visits shown in eTRACK
2	Screen failure travel reimbursement payment: 10% of screen failures will be provided travel reimbursement.
3	Cost involved in medical management and additional costs: once in every

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	two months; shall be made on the receipt of the invoice and supporting documents
III	Post query resolution: An amount of Rs.50000 will be put on hold from the second last invoice. The said payment will be made after post query resolution.
IV	Post close out: archival payment will be made.

d) Payments shall be remitted by GSK in INR n a milestone-completion basis, within thirty (30) days after receipt of duly documented invoice or supporting documentation demonstrating completion of the milestone. If the number of the subjects is less than the then-current target number set forth in Section XI a), the Study Budget and the installments will be reduced accordingly.

The Study Budget shall cover all Study expenditure such as, but not limited to investigators fees, GE/IP surveillance fees, Study personnel's fees, laboratory costs, (including personal and material), travel costs linked to public disclosure activities (if and to the extent requested by GSK) such as Publication Steering Committee meetings, core writing team meetings and presentations of Study results at conferences or congresses, overheads and others (including but not limited to administrative costs, taxes, insurances, ERC submission costs, etc).

Such Study Budget has been agreed upon by the parties prior to start the Study, therefore GSK shall in no event accept any overspending and the Principal Investigator and the Institution undertakes to complete the Study within such Study Budget.

Payment instructions shall be specified in Schedule B attached hereto (please fill in the Schedule B – Payment Instructions Sheet).

Bank transfer costs shall be supported by GSK.

e) The Institution will receive the fees mentioned in sub-paragraphs (a) and (b) above for every subject evaluable according to the Protocol. The fee mentioned under (b) above shall be paid only with respect to evaluable subject and when the vaccination's calendar as foreseen in the Protocol has been scrupulously respected. In the event of non-evaluable subject(s), only the screening costs specified in sub-paragraph (a) will be paid. The non-evaluable subject's criteria are defined in the Protocol and include, but are not limited to, the following events:

i) subject or vaccine number not allocated;

ii) Study vaccine dose not administered but subject number allocated;

iii) administration of vaccine forbidden in the Protocol;

iv) wrong vaccine vial given;

v) deliberately breaking the randomization code at investigator site, violating the allowable reasons for breaking the code (i.e. SAE, etc.);

vi) Study vaccine dose not administered according to Protocol;

vii) Protocol violation;

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viii) non-compliance with vaccination schedule;

ix) non-compliance with blood sampling schedule;

(For points viii) and ix), if the rate for non-compliance exceeds 15%, the payment for these subset of subjects will not be made - example: if 30% of total subjects did not comply with vaccination and/or blood sampling schedule, 30% of volunteers fees will not be paid by GSK - The computation will be detailed on the last payment).

x) essential serological data missing when proven due to Principal Investigator's delinquency;

xi) other reasons due to Principal Investigator's shortcoming.

f) Institution/Principal Investigator agree to include at least 90 subjects within a period of 4-5 months after receipt of the Vaccine. After this period GSK reserves the right to terminate this Agreement without any obligation to pay compensation (except for actual expenses incurred with respect to the Study) in the event that such minimum number of subjects has not been included.

If Institution/Principal Investigator are able to find more subjects than are specified in the Protocol, and provided that GSK has agreed to the inclusion of any such additional subjects in the Study, GSK agrees to pay you the sum per subject referred to in sub-paragraphs XI (a), if applicable, and (b) above in respect of each extra subject so agreed.

g) The Principal Investigator hereby acknowledges the requirements of the FDA Financial Disclosure Rule and agrees to fill in and return to GSK, upon GSK representative's request, the Statement of Investigator Financial Interest form attached hereto as Schedule C before the start of the Study. The Principal Investigator also consents to the disclosure of the so filled Form to the FDA if necessary.

h) GSK will not make any payment, or, if payment has been made by GSK, Institution will repay to GSK any payments, for work associated with the Study if GSK determines that the Study results is not evaluable and/or is rejected by regulatory authorities because of a violation of the Protocol or any Applicable Laws and guidelines by Institution, Investigator, or Study staff.

i) All payments made by GSK to Institution shall be subject to applicable tax deduction(s) at source as required under Income Tax Act 1961.

j) As required under the Goods and Services Tax ("GST") laws as amended from time to time and any rules and regulations thereunder ("GST Laws"), it is agreed that the Institution will pass on any benefit due to reduction in rate of tax or from input tax credit by way of commensurate reduction in prices. Further, invoices shall be raised by the Institution in compliance with all Applicable Laws including but not limited to the GST Laws. The Institution warrants to comply with all required provisions of GST Laws including but not limited to invoice compliance, reporting compliance, payment of taxes and information and document compliance as well as provide GSK such support as may be required including but not limited to

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providing information such as, its GSTIN, GST registered address, GST compliance rating, etc. amongst others and maintenance of appropriate level of GST compliance rating with a view to enable GSK to avail GST input tax credit for the taxes paid and such other requirements.

k) The Institution hereby acknowledges and agrees that if it fails to comply with the GST Laws, and any covenants as mentioned above and as such renders GSK ineligible for any GST input tax credit amongst other consequences, GSK shall have the right to (i) withhold entire invoice payment until the non-compliance so noticed is corrected and GSK is able to avail corresponding input tax credits; (ii) cause the Institution to rectify the said non-compliance during a the cure time given for the same; or (iii) terminate this Agreement; at the sole option and discretion of GSK, and it may exercise such other rights and remedies as per the terms of this Agreement.

l) The Institution hereby further acknowledges that if it receives any invoice from GSK, whether or not in full, or if it receives any advance payments from GSK, any subsequent alleged non-compliance of the GST Laws and/or requirements therein which renders GSK to lose the applicable input tax credit or any loss to GSK in any form, GSK will have the right to seek a financial refund or set-off such amounts against any payments payable (past, present or future payments) to the Institution.

XI. RECORDKEEPING – ACCESS - MONITORING

a) Institution shall make records regarding the Study as required by the Protocol, Applicable Laws, or ICH Good Clinical Practices, and in accordance with Institution's standard procedures. Institution will retain such records for a minimum of twenty-five (25) years from the issue date of the Clinical Study Report/Summary or equivalent, subject to a request from GSK/ Sponsor under sub-clause (d) below. GSK will inform the Institution / Principal Investigator of the date on which the GSK required retention period will expire. After the expiration of this period, Institution is responsible for complying with any remaining relevant local, organizational, state, national and/or regulatory guidelines for records retention.

b) GSK shall inform the Institution and the Principal Investigator of the name and telephone number of the person(s) appointed by GSK to monitor compliance of the Study with the ICH GCP and to conduct source data verification (hereinafter the "Monitor"). Authorized representatives of GSK, such as the Monitor, upon reasonable advance notice and during regular business hours, shall have the right to inspect Institution's facilities used in the conduct of the Study and to inspect and copy all records relating to the Study (including, without limitation, access to records as necessary for Study monitoring or to audit the conduct of the Study in accordance with GSK standards or Institution's business processes and practices that involve the Processing of Personal Information). GSK will maintain the confidentiality of any subject-identifiable medical records.

c) If any governmental or regulatory authority notifies Institution that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify GSK, allow GSK to be present at the inspection/action or participate in any response to the

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inspection/action, and provide GSK with copies of any reports issued by the authority and Institution's proposed response.

d) Without prejudice to sub-clause (a), GSK / Sponsor may require Institution to return, delete or destroy portions of the Study records as follows: Institution shall return, delete or destroy all Personal Information provided by GSK / Sponsor and shall delete or destroy all Personal Information generated in performing the Study, including without limitation all originals and copies of such Personal Information in any medium, and any materials derived from or incorporating such Personal Information, within ten (10) days after GSK/ Sponsor's request for such return, deletion or destruction for any reason(the "Return Date").

e) In the event that Institution determines, in its reasonable discretion, that returning, deleting or destroying Personal Information is infeasible on the Return Date, or if Applicable Law prevents or precludes the return, deletion or destruction of any such Personal Information by Institution on the Return Date, Institution shall notify GSK in writing, in reasonable detail, of the reason for not returning, deleting or destroying such Personal Information on the Return Date. In such case, (i) Institution shall return, delete, or destroy the Personal Information as soon as possible after the Return Date, (ii) Institution shall extend the protections to Personal Information which is not returned, deleted or destroyed on the Return Date for as long as such Personal Information is retained by Institution, and (iii) Institution shall not Process such Personal Information without GSK's express prior written consent on or after the date occurring ten (10) days prior to the Return Date.

f) The obligations of this Section shall survive termination of this Agreement.

g) Monitoring and Audit

(i) GSK shall have the right during the terms of this Agreement to conduct an audit of the Institution and Principal Investigator's activities under this Agreement. Institution and Principal Investigator shall cooperate fully with such audit, the scope, method, nature and duration of which shall be at the reasonable discretion of GSK.

(ii) The Institution will allow regular monitoring visits, access for the purposes of audit to GSK and to regulatory authorities and as specified in the Protocol and permit access to the original Study records, reports, other Study related materials and its staff as soon as is reasonably possible upon request by GSK, or the Sponsor or regulatory authorities or any third party designated by the Sponsor or GSK. Any such access to take place at times mutually agreed during business hours and subject to such reasonable conditions relating to occupational health and safety, security, and confidentiality as the Institution may require.

(iii) The Institution will provide GSK with all reasonable assistance and cooperation to rectify any matter raised by a regulatory authority or as a result of an audit of the Institution or Study. This includes execution of any documents reasonably requested by GSK or regulatory authority in connection with the requirements of regulatory authority or GSK as a result of such an audit. The cost will be borne by the Sponsor unless such rectification is due to the default of the Institution or the Principal Investigator.

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XII. ENTIRE AGREEMENT – MODIFICATION OF AGREEMENT

a) This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument.

b) No terms or provisions of this Agreement shall be varied or modified except that the parties may amend this Agreement by written instrument specifically referring to and executed in the same manner as this Agreement. The Principal Investigator will make sure and remain responsible for the compliance with the provisions hereof by any of the sub- or co-investigator(s) involved in the conduct of the Study.

XIII. FORCE MAJEURE

a) Neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance ("a Delay") and shall perform its obligations to the extent possible to overcome the effect of such event. In the event of a Delay lasting for eight (8) weeks or more the non-affected party shall have the right to terminate this Agreement immediately by notice in writing to the other Party.

b) This section does not excuse either Party from performing its obligations in relation to confidentiality and protection of personal information.

XIV. TERM AND TERMINATION

a) This Agreement shall take effect on the Effective Date and shall continue to be valid for a period of three (03) years from the Effective Date or until completion or discontinuation of the Study in accordance with the Protocol, whichever is earlier, unless terminated as provided below. At the end of the term of the Agreement (unless determined earlier) if parties wish to and mutually agree to renew the arrangement herein, parties may enter into such documents as mutually agreed to effect the renewal. Notwithstanding the above, compensation of travel costs linked to public disclosure activities (if requested by GSK) such as presentations at congresses, core writing team meetings and Publication Steering Committee meetings shall be possible for 30 months from the termination of this Agreement.

b) GSK reserves the right to temporarily suspend or prematurely discontinue the Study (including terminating the Agreement) either at a single site or at all sites at any time for any reasons including, but not limited to, safety or ethical issues or severe non-compliance. GSK may also terminate this Agreement if the Principal Investigator is no longer able (for whatever reason) to act as Principal Investigator and no replacement mutually acceptable to the Institution and GSK can be found. Reasons for suspension or early termination will be documented in the Study file at GSK.

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c) If GSK determines such suspension or early termination is needed, GSK shall discuss the reasons for taking such action with the Principal Investigator and/or the Institution. When feasible, GSK shall provide advance notification to the Principal Investigator of the impending action prior to it taking effect.

d) In the event the Study is suspended or terminated for any reasons whatsoever, GSK will promptly inform the Principal Investigator with a written notification related thereto. Upon receipt of such written notification, the Principal Investigator will inform the appropriate regulatory authorities and all co-investigators or sub-investigator conducting this Study of the suspension or early termination of the Study as well as the reasons for such decision. In addition, if so required by Applicable Laws, the Principal Investigator shall inform the Institutional Review Board/Independent Ethics Committee ("IEC/IRB") promptly and provide the reason(s) for the suspension or early termination of the Study.

e) If a Study is prematurely discontinued, the Principal Investigator shall return to GSK all Study data. In addition, arrangements will be made for all unused quantities of Vaccine in accordance with the GSK procedures applicable to the Study.

f) In the case of a multicentre Study, which as the case may be will be confirmed in the attached Protocol, GSK will have the right to decide, at any time, during the duration of the present Agreement, to put an end to the recruitment of subjects, when the total number of required subjects for the multicentre Study has been reached, even if the number of subjects mentioned above has still not been reached. GSK will notify the Principal Investigator of its decision in writing and the Principal Investigator will have to stop the recruitment of subjects within a delay that will not exceed one (1) week.

XV. EFFECT OF TERMINATION

a) Upon notice of termination of this Agreement, Institution and the Principal Investigator shall cease enrolling subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

b) Upon notice of termination of this Agreement, Institution and the Principal Investigator shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination, which GSK has agreed to pay under this Agreement. If, upon the effective date of termination, GSK has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, GSK may deduct an equivalent amount from any payment then or later due from GSK to Institution under this or any other arrangement between the parties.

c) Upon termination of this Agreement, all unused Vaccines and all GSK Confidential Information (except for such records that Institution is required by Applicable Law to retain) in Institution's and Principal Investigator's possession shall be promptly delivered to GSK at GSK's expense, or, at GSK's option, destroyed with the destruction certified in writing.

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d) Upon termination or expiration of this Agreement for any reason, the Institution/ Principal Investigator agrees to transfer to GSK all paper or e-Case Report Forms duly completed (where applicable) within two (2) working days of the last contact with the subjects or receipt of the last data.

e) The obligations which by their nature extend beyond termination including but not limited to clauses III(d), IV, V, VI, VII, IX, XI and XV shall survive suspension or termination of this Agreement.

f) Termination shall not affect the rights or obligations of either party accrued as of such effective date of termination or that may arise subsequently with respect to transactions initiated or completed prior to the effective date of such termination.

XVI. USE OF PARTIES' NAMES

Neither party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement, or the Study, which uses the other party's name, symbols, or trademarks without the other party's prior written approval.

XVII. NOTICES

All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices pertaining to this Agreement shall be sent to:

If to Institution:
Name: Dr. Piyali Bhattacharya
Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road – Lucknow – 226014,
Uttar Pradesh, India

If to GSK:
Name: Dr. Sanjay Gandhi
Address: Glaxosmithkline Pharmaceuticals Ltd
Dr Annie Besant Road,
Mumbai – 400 030, Maharashtra, India

XVIII. ASSIGNMENT

GSK may assign its rights and duties under this Agreement without Institution's consent. Any assignment by Institution is valid only upon the prior written consent of GSK. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

XIX. SEVERABILITY

Any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected.

XX. GOVERNING LAW AND DISPUTE RESOLUTION

In case of a dispute or difference between the Parties arising out of, or touching upon the terms including effect, interpretation or scope of this Agreement, the Parties hereto shall make best endeavor to resolve the dispute by mutual discussions. This Agreement shall be governed by and interpreted in accordance with the laws of India, and any dispute under this Agreement shall be brought in the courts of Lucknow.

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XXI. ANTI-BRIBERY ANTI-CORRUPTION AND ETHICAL STANDARDS AND HUMAN RIGHTS

A. ANTI-BRIBERY ANTI-CORRUPTION

a) Institution and Principal Investigator agree that, in connection with the performance of this Agreement, Institution and Principal Investigator shall comply and require Study staff to comply fully at all times with all Applicable Laws and regulations, including but not limited to anti-corruption laws, and that it has not, and covenants that it will not commit any act of bribery, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents or any other third parties, subject to its control or determining influence, from doing so. For the avoidance of doubt this includes facilitating payments, which are unofficial, improper, small payments or gifts offered or made to government officials to secure or expedite a routine or necessary action to which we are legally entitled.

b) In the event GSK has reasonable doubt that the Institution and Principal Investigator have failed to perform its obligations in accordance with this Clause XXI, GSK shall have a right to immediately suspend all operations under this Agreement with notice to the Institution and Principal Investigator in this regard, pending GSK's assessment of such failure, and to inter alia call upon the Institution and Principal Investigator to provide within 7 days of such notice, justifiable and satisfactory response thereto including furnishing any records /documentary proof /information in relation to the alleged doubt / failure. If the Institution and Principal Investigator fail to comply with this request of GSK within 30 days or if after reviewing the documents/information as provided by the Institution and Principal Investigator to GSK, GSK comes to a conclusion that that there has been a failure of Clause XXI by the Institution and Principal Investigator, GSK shall be entitled to terminate this Agreement immediately. Institution and Principal Investigator shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause XXI.

c) Institution and Principal Investigator shall not contact, or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative. For the purpose of this agreement "Government Official" (where 'government' means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means: (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organisation such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under applicable local laws (including anti-bribery and corruption laws) and not already covered by any of the above; and/or; (e) any person acting in an official capacity for or on behalf of any of the above.

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d) Institution and Principal Investigator shall inform GSK in writing, if, during the course of this Agreement, it is convicted of or pleads guilty to a criminal offence involving fraud or corruption, or becomes the subject of any government investigation for such offenses, or is listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

e) Institution and Principal Investigator represent and warrant that except as disclosed to GSK in writing prior to the commencement of this Agreement: (1) none of their significant shareholders (>25% shareholding) or senior management have influence over GSK's business; (2) no significant shareholders (>25% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services, are currently or have been in the past two years a Government Official with actual or perceived influence which could affect GSK business; (3) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed in the previous subsection (2) having a public or private role which involves making decisions which could affect GSK business or providing services or products to, or on behalf of GSK; (4) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; (5) it shall maintain arm's length relations with all third parties with which it deals for or on behalf of GSK in performance of this Agreement. Institution and Principal Investigator shall inform GSK in writing at the earliest possible opportunity of any conflict of interest as described in this Clause that arises during the performance of this Agreement.

f) Institution and Principal Investigator shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Institution and Principal Investigator must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

g) Institution and Principal Investigator agree that in the event that GSK believes that there has been a possible violation of the terms of this Agreement, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.

h) Institution and Principal Investigator shall provide anti-bribery and anti-corruption training to relevant personnel, including any relevant subcontractors, who act on behalf of GSK or interact with government officials during the course of any services provided to GSK. Institution and Principal Investigator shall provide GSK the opportunity to evaluate the training to determine whether it abides by GSK's standards and shall conduct additional training, as requested by GSK. Institution and Principal Investigator, upon request by GSK, shall certify that the anti-bribery and anti-corruption training has taken place.

B. ETHICAL STANDARDS AND HUMAN RIGHTS

a) Unless otherwise required or prohibited by law, the Institution and Principal Investigator warrant that in relation to its performance of this Agreement:

a. it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be

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foreseen to cause either physical or emotional impairment to the development of such child

b. it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;

c. it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by the Institution and Principal Investigator to its employees is safe for habitation. The Institution and Principal Investigator provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the Institution and Principal Investigator 's workplace;

d. it does not discriminate against any employees on any ground (including race, religion, disability or gender);

e. it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

f. it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

g. it complies with the Applicable Laws on working hours and employment rights in the countries in which it operates;

h. it is respectful of its employees right to join and form independent trade unions and freedom of association; and

b) The Institution and Principal Investigator are responsible for controlling its own supply chain and shall encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by the Institution and Principal Investigator when performing its obligations under this Agreement.

c) The Institution and Principal Investigator shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, the Institution and Principal Investigator shall report the alleged complaint and proposed remedy to GSK.

d) GSK reserves the right upon reasonable notice (unless inspection is for cause, in which case no notice shall be necessary) to enter upon the Institution and Principal Investigator's premises to monitor compliance with the provisions of this Clause XXI, and the Institution and Principal Investigator shall, subject to compliance with Applicable Laws, provide to GSK any relevant documents requested by GSK in relation thereto.

XXII. MEDICAL CONFIDENTIALITY, PRIVACY AND SECURITY OF PERSONAL INFORMATION

a) Definitions

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a. "**GSK Data**" means any data or information that is provided to or obtained by Supplier or Supplier personnel in connection with the negotiation and execution of the Agreement or the performance of Supplier's obligations under the Agreement, including any such data and information that either: (i) is created, generated, collected or Processed by Supplier personnel in the performance of Supplier's obligations under the Agreement, or (ii) resides in or is accessed through GSK's information systems or Supplier Information Systems, as well as any data and information derived from the foregoing.
b. "**Study Personal Information**" means any GSK Data that constitutes Personal Information (as defined below). Study Personal Information will relate to Study subjects, as required to be handled for conduct of Study in accordance with Protocol:
c. "**Personal Information**" shall mean any information or set of information relating to a person that identifies such person or could reasonably be used to identify such person.
d. **"Processing"** (and its conjugates, including without limitation "Process") means any operation or set of operations that is performed upon any information or data, including, without limitation, collection, recording, retention, alteration, use, disclosure, access, transfer, storage, or destruction of Personal Information
e. Study Personal Information will be Processed by Supplier as necessary for, and for the purposes of, the provision of services or other obligations set forth in the Agreement.
f. Unless stated otherwise in the Agreement, or agreed in writing between the parties, Study Personal Information will be Processed for the term of the Agreement, and any such additional period as may be stated therein.
g. "**Supplier**" for the purpose of this clause shall mean Institution and Principal Investigator
h. "**Supplier Information Systems**" (SIS) means all hardware, software, operating systems, database systems, software tools and network components used by or on behalf of Supplier to receive, maintain, Process, store, access or transmit GSK Data.

b) Retention and Return of GSK DATA.

a. **Retention.**
   i. Subject to clause XII (Recordkeeping – Access – Monitoring) Supplier shall retain GSK Data only for as long as specified in the Agreement or as otherwise necessary to satisfy the purposes for which it was provided to Supplier, except only to the extent longer retention is required by Applicable Law.
b. **Return.**
   i. Subject to clause XII (Recordkeeping – Access – Monitoring) Supplier shall (at its sole cost) return, delete or destroy, as specified by GSK, all GSK Data then in its possession or under its control, including without limitation all originals and copies of such GSK Data, upon GSK's request for any reason. Supplier shall certify compliance with this requirement by written notice to GSK received no later than thirty (30) days following such return, deletion or destruction of all GSK Data. Supplier will use

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destruction methods that meet or exceed current industry standards, to GSK's reasonable satisfaction. Unless otherwise agreed in writing with GSK, Supplier shall return any GSK owned physical assets.

c) Data Handling.

a. **Encryption.** When transferring GSK Data, and in communications between GSK and Supplier, Supplier will use encryption when transmitted over non-secure channels including email and remote connectivity. Supplier will use solutions that meet or exceed current industry standards, to GSK's reasonable satisfaction.

d) Data Security Breach Reporting and Incident Response.

a. Upon discovering any accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, GSK Data (a "Data Security Breach") or a potential compromise of Supplier systems that could result in a Data Security Breach, Supplier will send an e-mail to csir@gsk.com notifying GSK without undue delay, and in any case within (6) six hours. Supplier shall work with GSK in good faith to identify a root cause and remediate a Data Security Breach.

e) Information Protection Policies

a. The Supplier will implement mandatory security policies, standards, and procedures for staff and all subcontractors, vendors, or agents who have access to GSK Data, including Personal Information. These policies and procedures will cover:
b. measures, standards, procedures, rules and norms that will provide an industry-standard level of security;
c. staff functions and obligations relevant to the protection of GSK Data, including mandatory training;
d. procedures for reporting, managing and responding to security incidents relating to GSK Data; and
e. procedures for backup and restoration of GSK Data. Unless agreed otherwise in writing with GSK, Supplier will ensure that offline backup copies of GSK Data will be kept for thirty (30) days.
f. The Supplier will perform periodic risk assessment to ensure that these policies, standards and procedures are kept up to date, continue to be aligned with industry standards, and are revised as necessary whenever relevant changes are made to the SIS that uses or houses GSK Data, or to how that system is organised.

f) Physical and Environmental Security

a. Supplier must ensure that GSK Data is physically secured against unauthorised access.
b. Physical access to SIS must be restricted to authorized Supplier or approved sub-contractor personnel requiring access to perform their current role in line with access granting procedures and rules which provide security against unauthorized access, accidental or deliberate

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damage and interference. Environmental controls will be established to detect, prevent and control destruction due to environmental hazard.

g) Disposal of media

a. When media or storage devices are to be disposed of or reused, Supplier will implement industry-standard procedures to prevent any subsequent retrieval of GSK Data before devices are withdrawn from the inventory. When media are to leave the physically secured premises (compliant with 3.5.1 above) as a result of maintenance operations, Supplier will implement encryption of GSK Data stored on the media.

h) Network Security

a. The Supplier will maintain industry-standard network security using equipment and techniques including firewalls, intrusion detection and prevention systems, access control lists and secure routing protocols.

i) Access Control

a. Supplier will ensure that:
   i. Technical mechanisms are designed and implemented to ensure that GSK Data within the SIS is logically segregated from other customers' data.
   ii. Procedures are implemented to define user roles and their privileges, how access is granted, changed and terminated; addresses appropriate segregation of duties; and to define the logging and monitoring requirements and mechanisms.
   iii. Access rights are implemented adhering to the "least privilege" approach (i.e., authorised staff will be granted the minimum access required to perform their roles).
   iv. All employees of the Supplier are assigned unique User-IDs that are not shared. Every account will be attributable to an individual.
   v. Access to SIS is controlled through a defined system of user administration, identification, authentication and authorisation where only appropriately authorized persons can grant, modify or revoke access. Administrators granting or modifying access credentials for IT Systems perform appropriate identity proofing to ensure that access is granted to the proper person.
   vi. A strong password policy is documented, established, operated, and enforced. Passwords, personal identifying numbers (PINs) or passphrases and any data that can be used to derive them must be encrypted in storage and transmission. Account credential secrets will be protected at all times from unauthorized disclosure, alteration, or use.
   vii. Intrusion detection and prevention mechanisms are implemented on SIS. This will include logging, monitoring or blocking of unauthorised access attempts, modification of data, and unusual network activity indicating malware, unauthorised access or access attempts, or other unauthorized activities. Supplier will appropriately monitor and escalate detected issues to ensure the security of GSK Data.

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j) Virus and Malware Controls

a. Supplier will securely configure and maintain malware protection through use of network devices and software.
b. Supplier will apply security patches promptly following a change management process, with critical security patches implemented within thirty (30) days and non-critical security patches within ninety (90) days.
c. Supplier will maintain all hardware and software used to Process GSK Data at supported version levels.
d. Supplier will ensure that Independent Testing is performed at least annually to verify SIS is free of Known Vulnerabilities that may be used to gain unauthorized access to the SIS or GSK Data.
e. "Known Vulnerability" means those vulnerabilities documented and compiled by independent third parties, including the NIST National Vulnerability Database, a U.S. government repository of standards based vulnerability management data found at the nvd.nist.gov website, and other sites such as the Open Web Application Security Project (OWASP) found at the www.owasp.org website, United States Computer Emergency Readiness Team (US-CERT) found at the www.us-cert.gov website, and UK National Cyber Security Centre (NCSC) found at the www.ncsc.gov.uk website.
f. "Independent Testing" means testing via automated tools, by a qualified independent third party; or alternatively, by an internal group with expertise in security vulnerability assessment and independent from the development and support organization.
g. When the Supplier is providing application software, including web application or code, the Supplier will test for Known Vulnerabilities prior to each delivery and provide the results of Testing with the plan for remediation to GSK upon request.

k) Personnel

a. The Supplier will implement a mandatory security training program for personnel. This program will include data classification obligations; physical security controls; security practices and security incident reporting.
b. Supplier shall perform screening of Supplier Personnel at the time of hiring the Supplier Personnel that is, to the extent that permitted by such Applicable Laws in the country of hire, consistent with GSK's minimum required screening criteria:
c. An identity check.
d. A criminal record check.
e. Verification of education qualifications or other skills claimed.
f. A debarment check, where required.
g. Verification of entitlement to employment through the use of work permits or similar documents.
h. Verification of pertinent licenses including, motor vehicle licenses, certifications and operating documents that are required by law or required due to the nature of the position/job description and/or responsibilities.
i. Previous employment reference check.

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j. Verification of dates of employment claimed for the previous five (5) years.
k. Check on participation in animal rights activism. GSK reserves the right to perform these checks if Supplier cannot perform them.
l. Financial/credit check.

l) Business Continuity

a. Supplier will maintain and test at least annually a comprehensive business continuity plan which is designed to ensure availability of Supplier's critical business activities in the event of major failures or disasters, including the loss of an office facility or a data centre.
b. Supplier's business continuity plan will address the services provided to GSK and must aim to achieve recovery of services to GSK within an appropriate period acceptable to GSK. Unless otherwise agreed in writing with GSK, the Business Continuity Plans will provide for recovery of services within forty-five (45) days with no more than loss of one (1) day of updates to GSK Data.
c. **DATA PRIVACY**

m) Personal Information.

a. Before Processing any Study Personal Information Supplier shall ensure, taking into account industry good practice, the costs of implementation and the nature, scope, context and purpose of Processing, as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, that appropriate technical and organisational controls are in place to prevent unauthorised or unlawful Processing of any Study Personal Information it may hold and to protect any such Personal Information from accidental loss, damage or destruction.
b. Supplier shall:
c. only Process Study Personal Information in accordance with the documented instructions of GSK (including to the extent necessary to provide the Service and to comply with its obligations under this Agreement);
d. inform GSK if, in Supplier's opinion, any of GSK's instructions would breach data protection Laws; and
e. assist GSK with undertaking an assessment of the impact of Processing Study Personal Information, and with any consultations with a supervisory authority, if and to the extent an assessment or consultation is required to be carried out under data protection laws.

n) Data Subject Rights

a. Supplier shall:
   i. implement appropriate technical and organisational measures for the fulfilment of GSK's obligation to respond to requests by data subjects to exercise their rights of access, rectification or erasure, to restrict or object to Processing of Personal Information, or to data portability; and
   ii. if a data subject makes a written request to Supplier to exercise any of the rights referred to in clause 4.2.1, forward the request to GSK promptly, and in any event within five (5) days from the

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date on which Supplier received the request, and upon GSK's reasonable written request, provide GSK with all co-operation and assistance reasonably requested by GSK in relation to that request to enable GSK to respond to that request in compliance with applicable deadlines and information requirements.

o) Sharing of Personal Data

a. Supplier shall:

i. not engage another processor without prior specific or general written authorisation of GSK and in the case of general written authorisation, inform GSK of any intended changes concerning the addition or replacement of other processors, thereby giving GSK the opportunity to object to such changes;

ii. before disclosing Study Personal Information to any processor, enter into a contract with that processor under which the processor agrees to comply with obligations equivalent to those set out in the Agreement, including this Schedule; and

iii. before disclosing Study Personal Information to any of its employees and representatives, and the employees and representatives of each of its processors, in each case who have access to Study Personal Information, ensure that those persons:

iv. have undergone appropriate training in data protection and the care and handling of Personal Information; and

v. are bound to hold the information in confidence to at least the same standard as required under this Agreement (whether under a written agreement or otherwise).

p) No Transfer.

a. The Supplier shall not transfer any Study Personal Information to any jurisdiction not previously agreed in writing with GSK, or transfer any Study Personal Information to any third party, without the further prior written consent of GSK, which consent may be subject to the Supplier (or the relevant third party) entering into a data transfer agreement with GSK and entering into such other arrangements as GSK may reasonably require to satisfy the requirements that GSK or any of its affiliates may have as data controllers under any Applicable Law. Where GSK consents to any such transfer, Supplier shall comply with the Applicable Law governing the transfer of Personal Information to a jurisdiction different from that in which the data Processing is currently performed.

q) Third Party Data.

a. All or part of the GSK Data may contain Personal Information that is licensed to GSK by third parties. At GSK's request, Supplier shall enter into any agreements with such third parties as may reasonably be required to enable the Processing of such Personal Information.

r) Compliance with Laws.

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a. The Supplier will comply with all Applicable Laws as applicable to its business or the performance of its obligations under the Agreement, as such Laws may be revised from time to time.
b. Upon GSK's reasonable written request, Supplier shall provide all information necessary to demonstrate compliance with such Laws.
c. Supplier shall promptly notify GSK if it receives any complaint, notice or communication which relates directly or indirectly to the Processing of Personal Information, or to either party's compliance with data protection Laws, and shall fully co-operate and assist GSK in relation to any such complaint, notice, communication or non-compliance.

s) GSK Security Review Rights.

a. GSK and its agents, auditors (internal and external), regulators and other representatives as GSK may designate may inspect, examine and review the systems, records, data, practices and procedures of Supplier (and any subcontractors it may use) that are used in rendering the services under the Agreement to verify the integrity of GSK Data and compliance with the data privacy, confidentiality and security requirements of the Agreement.

t) Institution represents and warrants that it has completed the GSK assessment and Conflict of Interest process ("**Assessment**"). Institution further represents, warrants and covenants that:

i) the responses provided by Institution and Principal Investigator in the Assessment are true, accurate and complete as of the Effective Date of the Agreement;

ii) the privacy, security and data handling practices adopted and maintained by Institution shall be in effect and consistently applied as long as Institution conducts the Study in connection with, or otherwise retains, Personal Information for or on behalf of GSK; and

iii) Institution shall promptly notify GSK in writing within five (5) business days in the event of any material change in Institution 's privacy, security, or data handling practices.

u) The provisions contained in this Clause XXII shall survive the expiration or termination of this Agreement.

XXIII. TRANSPARENCY

a) Institution and Principal Investigator acknowledge GSK's ongoing commitment to transparency in its dealings with healthcare professionals worldwide. By signing this Agreement, Institution and Principal Investigator agree and consent that GSK or its affiliated company may disclose and publish specific information regarding this Agreement, including but not limited to the services provided by Institution and Principal Investigator, their names, location, affiliation with any institutions, any payment or benefit in kind that Institution and Principal Investigator receive pursuant to this Agreement.

b) If GSK or its affiliated company is required to report any payment, or other item or service of value provided to Institution and Principal Investigator under this

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Agreement, Institution and Principal Investigator acknowledge and agree that GSK or its affiliated company will report all such information to the applicable authority.

c) Institution and Principal Investigator agree and acknowledge that that this Agreement is not consideration for any understanding in relation to prescription, recommendation or other arrangement in relation to any GlaxoSmithKline group products.

IN WITNESS WHEREOF, the parties caused this Agreement to be executed, as of the date first written above, in multiple counterparts (each of which will be deemed to be an original, and all of which together will constitute one and the same Agreement) by their duly authorized representatives who, by signing, confirm their authority to bind their respective party.

For and on behalf of GLAXOSMITHKLINE PHARMACEUTICALS LIMITED	
By : Name : Dr. Sanjay Gandhi Title : Vice President – Vaccines Area Medical Lead (Gavi, Asia) & Lead LML (Clinical R&D, EM)	By : Name : Title :

GlaxoSmithKline Pharmaceuticals Ltd. Mumbai

For and on behalf of	By my signature I indicate my agreement to fulfill the role and obligations of Principal Investigator under this Agreement and consent to the disclosure of my name and Institution(s) with which I am affiliated as well as the details of any payment or benefit in kind made to me or for my benefit under this Agreement in publicly accessible worldwide registers.
Sanjay Gandhi Post Graduate Institute Of Medical Sciences, Uttar Pradesh	**Principal Investigator**
By : Name: PROF. RAKESH KAPOOR Title: DIRECTOR	By : Name: Dr. Piyali Bhattacharya Title:

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014

Attachments to the present Agreement :

Schedule A : Protocol
Schedule B : Payment instructions sheet
Schedule C : Statement of Investigator Financial Interest Form

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SGPGIMS,Lucknow

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SCHEDULE A

The Protocol
(Attached)

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SCHEDULE B
PAYMENT INSTRUCTIONS SHEET

PLEASE SELECT THE 'MODE OF PAYMENT' (BANK TRANSFER OR CHEQUE) AND COMPLETE ALL ITEMS.

o **Bank transfer**

Please give the EXACT name and address of the bank account holder.

Name of account holder	DIRECTOR SGPGI RESEARCH ACCOUNT
Address	Raebareli Road Lucknow – 226014, Uttar Pradesh, India
Account number	10095237491
Bank's name / branch name	State Bank Of India
Bank SWIFT code	SBIN0007789
	Telephone: NA Fax: NA
Bank Routing number (if any)	NA

NOTE:

TO AVOID PAYMENT ISSUES:

Please ask for the SWIFT code of the bank (8 or 11 characters)

Please ask for the ROUTING NUMBER of the bank.

SWIFT code: This code identifies each bank; using this code on any wire transfer, will avoid that a person in 'our' bank has to look for the beneficiary's bank address; this authorizes an immediate payment.

Routing number or Sort code: All banks identify their branches following rules that are different in each country; in Belgium, the first 3 digits of the account number identify the bank and branch (and 3 digits are enough), but other countries use other identifying systems (the RIB in France, the Sort Code in the UK, the Routing Number or ABA in the US, ...). With this additional information, there is no risk the beneficiary's bank takes time to find the beneficiary's account.

Piyali Bhattacharya

Principal Investigator's signature or Administrative Director signature

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Executive Registrar
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SCHEDULE C

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STATEMENT OF INVESTIGATOR FINANCIAL INTEREST IN GLAXOSMITHKLINE (TO BE ENCLOSED)

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Executive Registrar
SGPGIMS,Lucknow

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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL62586797715625R
Certificate Issued Date	:	26-Mar-2019 03:49 PM
Account Reference	:	IMPACC (IV)/ dl732103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL73210330334234198919R
Purchased by	:	JSS Medical Research India Private Limited
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS Medical Research India Private Limited
Second Party	:	Not Applicable
Stamp Duty Paid By	:	JSS Medical Research India Private Limited
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

DATED 23 May 2019

12/2, 6th Floor, Tower-B, Vatika Mindscapes,
Sector- 27D, Faridabad-121003, Haryana
JSS MEDICAL RESEARCH INDIA PVT LIMITED
(AS THE CRO)
Dr. Gyan Chand
Professor, Department of Endocrine and Breast Surgery
(AS THE PRINCIPAL INVESTIGATOR)
AND
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow -226014
(AS THE SITE/INSTITUTION)

JSS Medical Research India Pvt. Ltd. Faridabad

CLINICAL TRIAL AGREEMENT

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Executive Registrar
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This Clinical Trial Agreement (the "**Agreement**") is dated: 23 May 2019

BETWEEN:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(32)

1. **JSS Medical Research India Pvt Ltd.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through its[Senior Vice President, Dr. Renu Razdan] being authorized to sign this Agreement (hereinafter referred to as "**JSS India**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

2. **Dr. Gyan Chand,** working as Professor at Sanjay Gandhi Postgraduate Institute, Lucknow. Centre having his residence at Lucknow (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

3. **Sanjay Gandhi Postgraduate Institute**, a [*hospital*] registered under the provisions of [Indian Companies Act, 1956 OR *any other relevant law*], having its registered office at Raebareli Road, Lucknow, Uttar Pradesh 226014 acting through its Director being authorized to sign this Agreement (hereinafter referred to as the "**Site**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

The Sponsor, JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. The Sponsor is in the business of developing, manufacturing and/or distributing pharmaceutical products, in Chronic Ulcers.

B. JSS India is a CRO.

C. The Site is engaged in [Clinical Trial]and the PI is an [*Consultant*] at the Site.

D. The Sponsor desires to conduct a clinical trial in respect of the Drug, and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.

E. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

1. Definitions and Interpretations

1.1 In this Agreement:

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"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordnance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by the Sponsor.

"**Clinical trial**" shall mean a clinical trial conducted as per the Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from the Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as the Sponsor may, from time to time, provide.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party's reasonable control.

"**Dispute Notice**" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean the chemical compound invented by the Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and well being of all such actual and potential research participants.

"**Feasibility Study**" shall mean shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

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"Fee" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by the Sponsor, or if so authorized by JSS India in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

"ICH GCP Guidelines" shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June, 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Indian GCP" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research. **"Information Brochure"** shall mean the information brochure of the Sponsor.

"Informed Consent Form" or **"ICF"** shall mean a written consent form provided by the Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.

"Investigational Products" shall mean the chemical compound invented by the Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by the Sponsor.

"Invoice" shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

"Subject" shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"Payment Milestone" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"Protocol" shall mean Protocol No. [2015-DFU-301] as provided by the Sponsor.

"Price" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'D' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"Screen Failure" shall mean the screen failure as defined in the Protocol.

"Serious Adverse Event" or an **"SAE"** includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

"Services" shall mean the services detailed in Schedule 'A'.

"Site Indemnitee" shall mean the Site and its employees and its associated staff.

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"Sponsor Property" shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India.

"**Standard Operating Procedures**" or "**SOP**" shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

1.2 In this Agreement:

1.2.1 words denoting the plural number include the singular and vice versa;

1.2.2 references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

1.2.3 references to this Agreement include the Recitals and the Schedules;

1.2.4 the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

1.2.5 references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

1.2.6 references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

1.2.7 references to any Party include its successors, transferees and permitted assignees.

2. Scope of the Agreement

The PI agrees to perform the Clinical Trial for and on behalf of the Sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by the Sponsor.

3. Term

3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. Clinical Trial

4.1 Clinical Trial Initiation: JSS India and/or the Sponsor shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the Sponsor and/or JSS India may

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terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

4.2 Duration: The estimated duration for a Clinical Trial is [*as defined in the Protocol including follow-ups*]. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions of the Sponsor and/or JSS India.

4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

5. Responsibilities and Obligations of the Parties

5.1 The Sponsor shall be responsible for the following:

5.1.1 Clinical Trial Documents and Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to JSS India and the PI.

5.1.2 Approvals and Consents: Procuring and providing any approvals and consents required to be taken by the Sponsor in [*the country of its jurisdiction and/or India*].

5.2 JSS India shall be responsible for the following:

5.2.1 Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of Sponsor.

5.3 The PI and/or the Site shall be responsible for the following:

a. The PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

b. Upon request by JSS India and/or the Sponsor, the PI will provide JSS India and / or the Sponsor all information needed by JSS India and/or the Sponsor in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

c. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or the Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the Sponsor and JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest. The PI will not postpone or cause delay in reporting any such information to JSS India and/or the Sponsor irrespective of whether

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more detailed information may become available at a later time, or because the available information is not yet confirmed.

d. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or the Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

5.4 Regulatory Agency Audit: The PI and the Site will inform JSS India and the Sponsor within twenty four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India and the Sponsor with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India and/or the Sponsor in any such investigation, and in the implementation of appropriate action plans for such observations.

6.Representations, Warranties and Covenants.

6.1 JSS India represents, warrants and covenants to the Sponsor as follows:

(a) Formation/Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause the Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of a Project.

(d) Freedom to Use: JSS India hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

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JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Sponsor represents, warrants and covenants to JSS India as follows.

(a) Formation/Power and Authority: The Sponsor is duly formed and validly existing under the laws of the country of its origin and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Sponsor represents and warrants that it is in full compliance at all times and will continue to be in compliance at all times with all Applicable Laws of the country of its origin and the laws of India.

(c) Permits: Prior to commencement of a Project, the Sponsor shall identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of such Project, in accordance with the Applicable Laws, in the country of its origin and country where Clinical Trial has be undertaken. The Sponsor shall be solely responsible for procuring and maintaining each such permit and approval in the country of its origin. Unless impossible, expressly prohibited by Applicable Laws or otherwise requested by JSS India in writing, the Sponsor shall procure and maintain in the name of the Sponsor all permits and approvals for which it is responsible.

(d) Debar: The Sponsor certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

The Sponsor agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term.

(e) Freedom to Use: The Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India, the PI and/or the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

6.3 The Site represents, warrants and covenants to JSS India and the Sponsor as follows:

(a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

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(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll up to [13] Subjects or such higher numbers as agreed upon with JSS India and the Sponsor in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Freedom to Use: The Site hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The Site agrees that it will promptly notify JSS India and/or the Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India and/or the Sponsor's request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.4 The PI represents, warrants and covenants to JSS India and the Sponsor as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll up to [13] Subjects or such higher

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numbers as agreed upon with [*JSS India/ the Sponsor*] in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India and/or the Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

ii. Upon JSS India and/or the Sponsor's request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7. Use of Name

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or the Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

8. Ownership of Property and Data

The Sponsor shall have sole ownership and rights to any inventions or discoveries relating to the Drug, whether patentable or not, made in the performance of this Agreement.

9. Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the [Drug Controller General of India], and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH) region, (b) the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India and/or the Sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India and/or the Sponsor so elect, comprise: (a) inspection of the PI's and/or the Site's facilities and records relating to the rendering of services to or for a Clinical Trial; (b) review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

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10. Publications

(13)

JSS India and/or the Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information to the Sponsor and/or JSS India. The PI and the Site agrees to delete any information that may be confidential or proprietary.

11. Fees

a. Budget: The Sponsor, PI and/or the Site shall provide an estimate of the budget to the other Parties on Site selection. The Parties shall negotiate and agree on the Budget. The Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

i. The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India and/or the Sponsor. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the Sponsor and/ or JSS India unless the PI and/or the Site have taken the written consent of JSS India and/or the Sponsor before administration of such tests or services.

b. Payment of Fees and Expenses to the PI and/or the Site: The Sponsor, or if so authorized by the Sponsor, JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol , the consideration for their services will be pro rated according to the actual number of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

i. Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will issue its invoice for the Fees to the Sponsor and/or JSS India, if so authorized, [on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

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(b) the Sponsor or JSS India, if so authorized, shall pay the invoiced amount within thirty (30) business days of the date of the invoice. The payment shall be made through wire transfer into the following account, or, through crossed cheque/DD, as applicable:

Payee details:

PAYEE NAME	Director, SGPGIMS RESEARCH SCHEME ACCOUNT, LUCKNOW
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAAJS3913N
BANK NAME & BRANCH ADDRESS	STATE BANK OF INDIA SGPGIMS BRANCH RAEBARELI ROAD, LUCKNOW 226014

ii. Taxes: Any goods and service tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to the PI's and/or the Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

iii. Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to JSS India and/or the Sponsor that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12. Insurance

a. The Sponsor shall maintain all adequate insurance coverage, which will include adequate clinical trial insurance of the study.

b. The Sponsor shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4.1 to the Site, the PI, the Clinical Trial and JSS India.

13. Indemnification

13.1 Indemnity: The Sponsor agrees to indemnify, defend and hold harmless the Site, the PI, the Site Indemnitees, the Clinical Trial, and JSS India and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") incurred by or imposed on the Site Indemnitees or the Site, the PI, the Clinical Trial or JSS India or any of the associated staff in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Clinical Trial and/or JSS India to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study

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procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

13.2 Exclusions from Indemnification: The Sponsor's obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and/ or JSS India and/ or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 13 above, directly or due to a third party claim shall give written notice to the Sponsor, against whom such indemnification rights are claimed.

Pursuant to Clause 13 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the Sponsor shall not relieve the Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the Sponsor or its defenses.

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With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 13 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of the Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if the Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from the Sponsor; provided, however, that:

(i) the Indemnified Party shall obtain the prior written consent of the Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if

(A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against the Sponsor,

(B) such settlement does not expressly unconditionally release the Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or

(C) involves criminal or quasi-criminal allegations against the Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim;

(ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by the Sponsor in connection with such claim or legal proceeding;

(iii) the Sponsor shall be entitled to participate in the defense of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and

(iv) if the Indemnified Party abandons or fails to reasonably assume the defense of any such claim or legal proceeding, the Sponsor may assume control of the defense of such claim or legal proceeding at its own expense; provided, however, that if the Sponsor shall control the defense of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if

(A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party,

(B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or

(C) involves criminal or quasi-criminal allegations.

13.4.3 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site, the Clinical Trial and JSS India as contained in the Clinical Trial Agreement.

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13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of Sponsor in relation to the Study.

13.6 The Sponsor shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs. Sponsor shall also pay cash compensation, to subject or legal heirs of subject, awarded by ethics committee (or any court) in case of death or permanent disability. The Sponsor shall not be liable for payments for a Subjects' lost wages.

14 Confidentiality

a. All of the information disclosed by JSS India and/or the Sponsor or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and/or the Sponsor and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

b. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 Termination

15.1 JSS India may terminate the Clinical Trial by written notice of at least one (1) month in advance.

15.2 The Sponsor may terminate for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India and/or the Sponsor that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or the Sponsor representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

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d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India and/or the Sponsor, to meet with JSS India and/or the Sponsor or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI

g. Determination by JSS India and/or the Sponsor in writing that business or scientific considerations require termination.

h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India and/or the Sponsor or its representatives for use in the Study, are not completed and forwarded to JSS India and/or the Sponsor or its designated representative, within the timelines prescribed by JSS India and/or the Sponsor.

15.2 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India and/or the Sponsor. However JSS India and/or the Sponsor shall have the sole right to determine the acceptability of a new PI.

15.3 In the event that JSS India and/or the Sponsor exercise its right to terminate the Study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

15.4 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the Sponsor and/or JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

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16 Miscellaneous

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to JSS India:

JSS Medical Research India Pvt Ltd

12/2, 6th Floor, Vatika Mindscapes, Sector 27D, Faridabad-121003, Haryana, India

New Delhi—110020, India

Attention: Dr Renu Razdan

Designation: Senior Vice President-India

Telephone: +91 129 6613 500

E-mail: renu.razdan@jssresearch.com

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If to PI: Dr. Gyan Chand
Sanjay Gandhi Postgraduate Institute
Raebareli Road, Lucknow, Uttar Pradesh 226020
Designation: Professor
Telephone: +91- 9451546353

If to site: Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow, Uttar Pradesh 226020
Attention: Director, Institution
Telephone: +91-522-266800

If the Sponsor delivers, ships, or mails materials or documents to JSS India, or requests in writing that JSS India deliver, ship, or mail materials or documents to the Sponsor or to third parties, then the expense and risk of loss for such deliveries, shipments, or mailings shall be borne by the Sponsor. JSS India disclaims any liability for the actions or omissions of third-Party delivery services or carriers.

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written instrument signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by JSS India and the Sponsor [and the appropriate Institutional Review Board (as per Indemnity Agreement Pg. 8)].

16.3 Independent Contractor Relationship: The Parties are independent contractors, and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India and/or the Sponsor.

16.4 Assignment: This Agreement may be assigned by JSS India and/or the Sponsor to any of its affiliates or to any third party without prior written confirmation of other parties. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India and/or the Sponsor.

16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more

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than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

16.6 Survival: Sections 8,9, 13, 14, 15, 16.2, 16.3 and 16.11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.7 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.8 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.9 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Lucknow alone shall have exclusive jurisdiction in respect thereof.

16.10 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and the Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be Lucknow, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.11 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

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IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

JSS India

By: _____

Print Name: Dr. Renu Razdan

Title: Senior Vice-President

Date: May 23, 2019

Medical Research India Pvt. Ltd. Faridabad

The Principal Investigator

By: _____

Print Name: Dr. Gyan Chand

Print Title: Professor, Endocrine Surgery

Date: 29 July 2019

Dr. Gyan Chand
Professor
Dept. of Endocrine Surgeon
S.G.P.G.I. M.S., Lucknow

The Site

By: _____

Print Name: Prof. Rakesh Kapoor

Print Title: Director

Date: 08. 08. 2019

DIRECTOR
Sanjay Gandhi Post Gra...
...stitute of Medical Scienc...
LUCKNOW-226 014, INDIA

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Schedule A

[List of services to be provided by the PI and/or the Site]

Sl. No.	Activities	JSS India	PI/Site
1.	Execution of Clinical Trial Agreement	☒	☒
2.	Sharing Essential Documents	☒	
3.	Review of Site Specific Informed Consent Document	☒	(☒)
4.	IEC Submission of Dossier, IEC notifications of updates/documents		☒
5.	Execution of Informed Consent Form from subjects		☒
6.	Inclusion/Exclusion Assessment		☒
7.	Medical Management		☒
8.	IP Handling, Accountability & Storage		☒
9.	IP Administration/dispensing		☒
10.	Glucometer, test strips and lancets accountability and dispensing		☒
11.	Laboratory Sample Collection and Centrifuge		☒
12.	Telephonic Contact & Follow-up with patients as per study protocol		☒
13.	eCRF Entries/ Completion on time (within 3 days of subject visit)		☒
14.	eCRF Signatures		☒
15.	Safety Reporting (e.g. AES/SAEs)		☒
16.	Randomization		☒
17.	Query Resolution (During the study; Post close-out, if any)		☒
18.	Query Signatures (During the study; Post close-out, if any)		☒
19.	Source Documentation		☒
20.	Documentation of ICF procedure including AV consenting as applicable		☒

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21.	Patient diary retrieval and review		☒
22.	12-Lead ECG, X ray, MRI, CT, neurological assessment for DFU, Doppler etc.		☒
23.	Providing Clinical Supplies and Non-Clinical Supplies	☒	
24.	Archival of study documents		☒

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Schedule B

I. **Budget for Clinical Trial – Break Up**

Visit 1/Screening	8,000
Visit 2/ Baseline/ Day 0	5,000
Visit3/ Day 3	5,000
Visit 4/Day 7	5,000
Visit 5/ Week 2	5,000
Visit 6/ Week 3	5,000
Visit 7/ Week 4	5,000
Visit 8/ Week 5	5,000
Visit 9/ Week 6	5,000
Visit 10/ Week 7	5,000
Visit 11/ Week 8	5,000
Visit 12/ Week 9	5,000
Visit 13/ Week 10	5,000
Visit 14/ Week 11	7,000
Visit 15/ Week 12	5,000
Visit 16/ Week 14	5,000
Visit 17/ Week 16	5,000
Visit 18/ Month 2	5,000
Visit 19/ Month 3	5,000
Visit 20/Week 52/53	5,000
Total	**105,000**

Total for 13 patients (a)	**1,365,000**
Miscellaneous (Phone & fax bills, stationery, Scan etc.) (b)	**60,000**
Administrative @ 25% of the total budget (c)	3,41,250
Total PI Grant (d)	**17,66,250**
Per patient Grant (e)	**1,35,865 INR**

PASS THROUGH	**Cost in INR**	Comments
EC Fee	**25,000 INR**	Excluding Tax
EC Fees for renewal of study approval	**NOT APPLICABLE**	
EC fees for protocol amendment	**NOT APPLICABLE**	
EC Fees of SAE review	**NOT APPLICABLE**	
All the Investigation Charges as mentioned in the Protocol	**On actuals**	

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will be on actual at various visits:-		(ABI, Neurological Assessment, X-ray, Doppler, CT/MRI, ECG)
Offloading Shoes & Wound Dressing Protector	-	Will be provided by the CRO
Temperature Logger 2/site	-	Will be provided by the CRO
Patient Travel reimbursement per visits	**1000 per visit*19 visits= 19000**	247000
CRC Salary	**25,000 INR per month for 2 CRC (1Blinded & 1 Unblinded)**	Study coordinator fee of INR 25,000/- per month will be paid from the day of site initiation to site closeout.
	Total	INR 2,72,000

Expenses for AE/SAE management will be billed on actuals. SAE Compensations for related SAEs including Trial related Injury/Deaths	Applicable Taxes Present GST rate (18%) are not included in the pass-through budget	INR 1000/- per year (Archival of document post study not included in the budget)	INR 1,00,000 Startup Fee (will be adjusted from the future invoices)

NOTE:

II. Payment Schedule

A. Ongoing Payments:

- Invoice will be raised monthly for the completed visits of the enrolled subjects, after confirmation of CRA about the EDC entries completion of these visits.
- The payment schedule should be as per the SCHEDULE D
- All the payments made to site under investigator grant will be subject to TDS deduction.
- Pass through cost (ECG & Subject reimbursement) shall be based upon actuals. Site has to submit separate invoice for pass-through charges accompanying ECG bills.
- CRC Fees of INR 25,000/- will be paid monthly (includes both Blinded & Unblinded CRC)

B. Last Payment: 20% of last invoice will be retained & will be released at the time of the Close Out visit. This payment will be made when all the subjects for Clinical Trial have been recruited, all data have been entered in the Case Report Form and all queries resolved. In addition, any additional expense pending to be paid will be paid at this time.
In the event of any excess payment from the Sponsor/CRO to the Trial Site, the Trial Site must promptly return the excess amount to the Sponsor.

SCHEDULE C

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Estimated Budget for Screen Failure

INR 8,000/- per Screen failed subject will be reimbursed. The cap for screen failure patient is 5.

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SCHEDULE D

Price and Payment Schedule

The payment to the sites shall be made as per below listed schedule:

Sr. No.	Item	Price	Payment
1	Total subject visits performed in a Month (V1-V20)	Refer per subject cost from Schedule B	*100%

*20% of last invoice will be retained and will be released at the time of the Close-Out Visit

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महाराष्ट्र MAHARASHTRA ◐ 2018 ◐ UH 585469

TREASURY OFFICE THANE

जिल्हा कोषागार कार्यालय, ठाणे
1 DEC 2018
मुद्रांक प्रमुख लिपीक / लिपीक

PRODUCT CODE:	Sotagliflozin/SAR439954
STUDY CODE:	EFC14875
STUDY NAME:	THE SCORED TRIAL

INVESTIGATOR/INSTITUTION CONTRACT

Site Name & City: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow

Study Code/ Name: EFC14875 / The SCORED Trial Effective Date: 30th January 2019

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

Lt Col Varun Baipai VSM
Executive Registrar
SGPGIMS,Lucknow

This Contract (hereinafter "the Contract") is made on 21st day of January 2019, by and among:

DOCTOR SUSHIL KUMAR GUPTA, Professor, having his address at Endocrinology Department, 02nd floor, C-Block, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh 226014, India

Hereinafter the "**INVESTIGATOR**",

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, having its address at Rae Bareli Road, Lucknow, Uttar Pradesh 226014, India represented for the purposes hereof by Prof. Rakesh Kapoor, Director

Hereinafter the "**INSTITUTION**"

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function" (hereinafter the « Study ») to evaluate Sanofi drug **Sotagliflozin/SAR439954** (hereafter the « Investigational Medicinal Product ») in accordance with a protocol entitled [The SCORED Trial, EFC14875] and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care, and

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Endocrinology, and

WHEREAS, the INSTITUTION and the INVESTIGATOR having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority

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(«CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh 226014, India** (hereafter the «Study Site»). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH– GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR and the INSTITUTION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

The INVESTIGATOR and the INSTITUTION agree that any and all equipments if provided to the INVESTIGATOR's Study Site and or to the INSTITUTION to complete eCRFs shall remain the sole property of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall promptly return any such equipment when all eCRFs for the Study have been completed by the INVESTIGATOR and/or the INSTITUTION.

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ARTICLE 4. TERM.

This Contract is being entered into force from 30th **January 2019** ("the Effective Date") and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately 51 (fifty one) months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR and/or the INSTITUTION with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.3 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/HA/CA.

5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR / INSTITUTION or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.6 The INVESTIGATOR/INSTITUTION agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION by or on behalf of the SPONSOR shall be returned to the SPONSOR.

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ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **30 (thirty) Subjects** (the «Subjects »), within **approximately 15 (fifteen) months**. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., __x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR and the INSTITUTION to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR and the INSTITUTION agrees to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR and/or the INSTITUTION shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

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SGPGIMS,Lucknow

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR and the INSTITUTION of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR and the INSTITUTION, agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR and the INSTITUTION, shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or the INSTITUTION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

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ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the

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SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR and the INSTITUTION shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR and the INSTITUTION shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

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(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(e) adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

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ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR and the INSTITUTION shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR or the INSTITUTION is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR and/or the INSTITUTION to the SPONSOR.

17.4 The INVESTIGATOR and the INSTITUTION shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR and/or the INSTITUTION for the audits and inspections and that the assistance and availability of the INVESTIGATOR or the INSTITUTION for the audits and inspections is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR and the INSTITUTION upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR and the INSTITUTION represent and warrant that neither the INVESTIGATOR/INSTITUTION nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or

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Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		**INVESTIGATOR**	
[Signature]		**[Signature]**	
[Name]	**Dr. Chirag Trivedi**	**[Name]**	**Dr. Sushil Gupta**
[Title]	**Clinical Study Unit Director**	**[Title]**	**Professor, Department of Endocrinology**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	**Y. J. Cama**	**[Name]**	

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (INSTITUTION)	
[Signature]	DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
[Name]	**Prof. Rakesh Kapoor**
[Title]	**Director**
In presence of	
[Signature]	
[Name]	

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Executive Registrar
SGPGIMS,Lucknow

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 30th January 2019

1) The SPONSOR will pay **Rs.4,51,700/- (Rupees Four Lakhs Fifty One Thousand Seven Hundred Only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

Such amount is divided as follows:

EFC14875 (Per Subject Cost Details)			
Visits	**Investigator Fees (in INR)**	**Site Coordinator Fees*(in INR)**	**Subject reimbursement (for travel, meals during site visit) (in INR)**
Screening (V1)	17,000	3,300	1,500
Week 0 Randomization (V2)	22,500	3,500	1,500
Week 4 (V3)	14,000	3,800	1,500
Week 8 (V4)	14,000	3,800	1,500
Week 26 (V5)	14,500	4,400	1,500
Week 35 (V6) Phone Visit	3,700	2,600	-
Week 44 (V7) Phone Visit	3,700	2,600	-
Week 52 (V8)	17,500	4,300	1,500
Week 61 (V9) phone visit	3,700	2,600	-
Week 70 (V10) Phone visit	3,700	2,600	-
Week 78 (V11)	17,200	4,400	1,500
Week 87 (V12) Phone Visit	3,700	2,600	-
Week 96 (V13) Phone visit	3,700	2,600	-
Week 104 (V14)	17,500	4,300	1,500
week 113 (V15) Phone Visit	3,700	2,600	-
week 122 (V16) phone visit	3,700	2,600	-
week 130 (V17)	17,200	4,400	1,500
week 139 (V18) phone visit	3,700	2,600	-
week 148 (V19) phone visit	3,700	2,600	-
week 156 (V20)	17,500	4,300	1,500
week 165 (V21) phone visit	3,700	2,600	-
week 174 (V22) phone visit	3,700	2,600	-
week 182 (V23)	17,200	4,400	1,500
week 191 (V24) phone visit	3,700	2,600	-
week 200 (V25) phone visit	3,700	2,600	-
week 208 (V26)	17,500	4,300	1,500
week 217 (V27) phone visit	3,700	2,600	-
week 226 (V28) phone visit	3,700	2,600	-
pEOT visit	14,900	3,100	1,500
Close-out visit	14,900	3,100	1,500

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SGPGIMS,Lucknow

EFC14875 (Per Subject Cost Details)			
Visits	**Investigator Fees (in INR)**	**Site Coordinator Fees*(in INR)**	**Subject reimbursement (for travel, meals during site visit) (in INR)**
Follow-up visit	11,800	4,600	1,500
Unscheduled Visit (if done)**	17,000	4,700	1,500
Total Per Subject Cost	**321,400**	**106,300**	**24,000**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.20,000/- (Rupees Twenty Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 25% Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) Sponsor will pay one time lump sum of Rs.50,000/- (Rupees Fifty Thousand only) after the Study Closure to PAYEE for archival and document storage for a period of 15 years from the date of site closure.

7) A close out fee of Rs.10,000/- (Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit has been conducted.

8) A onetime start-up fee of Rs.50,000/- (Rupees Fifty Thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

9) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

10) All the devices or instruments provided by the SPONSOR will be returned to SPONSOR at the time of closeout.

11) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

12) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the Sponsor to the Payee against presentation by the Payee of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to

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Executive Registrar
SGPGIMS,Lucknow

whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the Payee shall indemnify the Sponsor such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

•	Bank Name & Branch:	State Bank of India , SGPGIMS, Rai Bareilly Road
•	Bank IFSC	SBIN0007789
•	Account No.:	10095237491
•	PAYEE:	Director SGPGI-Research Scheme A/C
•	PAN No.:	AAAJS3913N
•	GST No.:	09AAAJS3913N2ZN

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Ref.

To,

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital,

Rae Bareli Road, Lucknow - 226014,

Uttar Pradesh, India

Attn: Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital

Attn: Dr. Soniya Nityanand, HOD, Department of Haematology

Subject: Terms of Donation by Cuddles Foundation.

Dear Sir / Madam,

1. Cuddles Foundation (Cuddles) is a non-government charitable organisation, registered under the Mumbai Public Trusts act, 1950 with its registered office at 17/17H, 1st Floor, Bahubali Building, Cawasji Patel Street, Fort, Mumbai – 400 001. Cuddles is primarily engaged in providing nutrition related aid for paediatric oncology patients and related activities. Cuddles currently provides such aid to hospitals across India. Ms. Purnota Bahl (Founder and Trustee) of Cuddles, is the authorised signatory on behalf of Cuddles.

2. Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital is a government medical hospital which provides treatment to paediatric oncology patients.

3. Pursuant to discussions with the Hospital, Cuddles undertakes to make reasonable efforts to provide aid to the Hospital on the terms and conditions set out in this Letter.

a. Cuddles shall bear the cost, not exceeding such amount as may be mutually agreed between Cuddles and the Hospital from time to time: (i) of the Hospital retaining minimum 1 full time trained nutritionists having the requisite qualifications mandated by law (including any guidelines applicable to the Hospital) (Nutritionist); (ii) in relation to meals and other perishable food items procured by the Hospital for out-patients (Meals), (collectively Donation). The Donation shall be paid by Cuddles directly to the Nutritionist and provider of Meals, for and on behalf of the Hospital; and

b. Cuddles shall donate the products set out in Annexure 1 to the Hospital in such quantities and per a schedule as may be mutually agreed between Cuddles and the Hospital from time to time (Products).

4. The Hospital understands that Cuddles mandate is to provide nutrition related aid for paediatric oncology patients and the Hospital undertakes that it shall utilize the Donation and Products only for the treatment of in-patient and out-patient oncology patients aged 18 years or less.

5. The Hospital acknowledges that Cuddles, the persons named as trustees under its trust deed dated 3 October 2013, as amended from time to time (**Trustees**) or its employees are not experts and do not

S. Nityanand

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Cuddles Foundation Mumbai

have any nutrition related experience and confirms that Cuddles is merely acting as a donor to the Hospital of the Donation and Products.

6. The Hospital confirms that it is the responsibility of the Hospital to verify the credentials of the Nutritionist(s). The Nutritionist shall operate under the control and supervision of the doctors at the Hospital and the Hospital acknowledges that Cuddles will not supervise or control the work of the Nutritionist(s).

7. The Hospital confirms to provide space to store Meals and Products appropriately and that it is its responsibility to check that the Meals and Products are in good condition prior to their usage and Cuddles will have no role to play in determining which, if any, of the Meals paid for or Products donated will be utilized by the Hospital.

8. This Letter and the arrangement set out herein shall be deemed to have come into effect from 1st March, 2019 and shall continue to be in force till 28th February, 2022. Either Party can terminate this Letter by providing 1 (one) month's prior written notice.

9. The terms set out herein, including the Annexures, shall be governed by Indian law and may be amended only with the prior written approval of the Trustees of Cuddles and the Hospital.

We request you to kindly execute this Letter in acceptance of the aforesaid terms.

With regards,

Cuddles Foundation

Cuddles Foundation Mumbai

Agreed and confirmed

26/2

Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital

S. Nityanand 26.2.19

Dr. Soniya Nityanand, HOD, Department of Haematology, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Memorandum of Understanding (MOU)

Agreement to Establish a

Canada-India Neonatal Centre of Excellence in Research & Education (CINCERE)

Between

The Department of Medical Education of Uttar Pradesh

And

आत्मना सर्गो जितः

Sanjay Gandhi Postgraduate Institute of Medical Sciences

And

Sinai Health System

Each a "Party" and together "Parties"

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

In Support of

Sinai Health Foundation

Sinai Health System

संजय गांधी स्नातकोत्तर आयुर्विज्ञान संस्थान

आत्मना सर्गो जितः

Sanjay Gandhi Postgraduate Institute of Medical Science Lucknow (India)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

उत्तर प्रदेश UTTAR PRADESH

ET 321593

Agreement to establish a

Canada-India Neonatal Centre of Excellence in Research & Education (CINCERE)

Between

The Department of Medical Education of Uttar Pradesh

And

The Sanjay Gandhi Postgraduate Institute of Medical Sciences

And

Sinai Health System

Each a "Party" and together "Parties".

1. Whereas the Department of Medical Education of Uttar Pradesh (hereafter known as "UP"), and the Sanjay Gandhi Postgraduate Institute of Medical Sciences (hereafter known as "SGPGIMS") and Sinai Health System (hereafter known as "Sinai") have common goals to improve the health of infants through clinical care, training and research, and
2. Whereas UP, SGPGIMS, and Sinai under the direction of Dr. Shoo Lee desire to strengthen their international relationship in clinical care, training and research, and
3. Whereas UP and SGPGIMS wish to establish a neonatal research and training center based on excellence to serve the needs of India, and

4. Whereas Sinai agrees to partner with UP and SGPGIMS in this endeavor.

The UP, SGPGIMS, Sinai agree to establish a Canada-India Neonatal Centre of Excellence in Research & Education (hereafter known as "CINCERE") at Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS).

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This Agreement is signed at SGPGIMS on 6th Mar 2019 in Lucknow, India. With the signing of this agreement, UP, SGPGIMS, and Sinai agree to the following:

1. This Agreement is non-binding and no other legally binding obligations will be created until definitive agreements are executed and delivered by all Parties.

2. CINCEREis national in scope and SGPGIMSwill undertake to accept trainees from all across India.

3. The Parties will develop a statement of work which will document the details of the training program and the responsibilities of all the Parties based on the following components of the CINCERE programs("Statement of Work"):

(a) Clinical collaboration

Sinai will adviseSGPGIMS colleagues in clinical care of patients to facilitate mutual learning and share experience about care of patients. This will include ward rounds, clinical case discussion, discussion about the published literature and use of evidence-based methods and teaching. The aim is to enable Sinai and SGPGIMS faculty to share their expertise and upgrade neonatal care at SGPGIMS. A continuous quality improvement program will be introduced, and SGPGIMS staff will be trained in Evidence-based Practice for Improving Quality (EPIQ) methods.

(b) Research collaboration

SGPGIMS researchers will explore opportunities for joint research in neonatal-perinatal research including training of new and young researchers.A clinical and outcomes database will be established to facilitate research, audit and quality improvement.Research initiatives will include quality improvement, simulation, developmental and family integrated care, point of care technologies and telemedicine. The ethical issues if any, shall be dealt in accordance with existing procedures.

(c) Joint neonatal training program

A neonatal training curriculumwill be developed for SGPGIMS and associated community health providers, including doctors, nurses and others as deemed appropriate. The curriculum will include objectives, course duration, course content, course methods and evaluation criteria and will be jointly developed and taught by SGPGIMS faculty at SGPGIMS. Training will be conducted in English.Trainees will learn the fundamentals of neonatal-perinatal medicine, participate in daily NICU ward rounds, and engage in discussions about clinical cases, published literature and evidence-based practice. They will develop critical thinking

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SGPGIMS,Lucknow

skills and learn about different neonatal care approaches and research.

(d) Facilitation for Canadian Fellowship programs

Sinai will facilitate applications of deserving doctors who have passed PDCC or DM Neonatology from SGPGIMS in future, in desired neonatal fellowship programs of Canada.

(e) Neonatal nurse training program

A joint needs assessment will be performed and a nurse training program will be established to upgrade the skills of SGPGIMS nurses to an appropriate level. Canadian nurse educators may participate in the training program as deemed appropriate by the needs assessment.SGPGIMS will nominate at least two nurse educators to be part of the instruction cadre that will sustain the training program going forward.

(f) Visiting Scholar Exchange

SGPGIMSmay arrange for Visiting Scholars from SGPGIMS faculty members to visit NICUs in Canada& SGPGIMS. Visiting Scholars may choose their desired location in Canadafor postings subject to availability. In most cases, Visiting Scholars will be observers but practical experience may be available on an individually arranged basis. Visiting scholars will be responsible for their own expenses.

(g) Neonatal Advanced Simulation Training and Research Center (NASTARC)

Sinai will assist SGPGIMS to establish an advanced simulation center at SGPGIMS, and provide advice and training to SGPGIMS staff. Sinai will provide core equipment(Appendix A) to establish NASTARC. SGPGIMS will provide the physical facilities necessary for NASTARC and provide infrastructureand staff for its continued operation.

(h) Telemedicine Program

A telemedicine program will be established to enable on-going teaching and collaboration between SGPGIMS and Canadian faculty, and between SGPGIMS, state medical colleges and community health institutions.SGPGIMS will provide the telemedicine infrastructure and services in Lucknow.

(i) Infant Transport System

Sinai will assist SGPGIMS to establish an infant transport system at SGPGIMS, including providing advice and training to SGPGIMS staff. SGPGIMS will source funding and provide the staff and equipment necessary for the transport system. SGPGIMS will decide on the appropriate time for establishing the infant transport system.

4 Establish a joint committee (hereafter called the "Joint Committee") to oversee CINCERE and its programs, including to establish the goals, standards,

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Executive Registrar
SGPGIMS,Lucknow

curriculum and other aspects of the training program, including establishing selection and graduating criteria, selection of trainees and approving graduation of trainees, and approving any fees necessary. The Joint Committee will have equal representation from SGPGIMS, to be selected by the SGPGIMS leadership Board respectively, and be co-chaired by representatives from both organizations. An evaluation and progress review system will be jointly established.

5. SGPGIMS will.
(a) provide logistical support to organize the programs, including establishing the clinical database, making classrooms and teaching aids available for teaching, arranging for course materials, collection of necessary fees etc.;
(b) agree that clinical work is not required of Canadian faculty,
(c) agree that SGPGIMS faculty will work together to upgrade skills of NICU staff at SGPGIMS;
(d) provide housing, food and program related ground travel within India for Sinai (and partners) in Lucknow;
(e) beyond the first three years, the joint committee will explore alternate mechanisms for funding Sinai faculty visiting SGPGIMS;
(g) provide physical facilities, staff; establish and operate NASTARC, the telemedicine facility andother agreed joint programs;
(h) will be responsible for operation & maintenance of the equipment supplied for NASTARC as per Appendix A,
(h) nominateat least two nurse educators to teach neonatal nurses in collaboration with a nurse educator from Canada:
(i) prepare and submit an annual report within 3 months of each calendar year end to the joint committee;
(j) provide support for all other activities as decided by the Joint Committee.

6. Sinaiwill:
(a) organize participation of Sinaifaculty at SGPGIMS.
(b) endeavor to provide6 qualified faculty members each year to teach in SGPGIMS. Each will stay for up to a month duration;
(c) provide faculty trainingpersonnel with the understanding that faculty may include neonatologists nurses, respiratory therapists, dieticians, physiotherapists, occupational therapists, neonatal follow-up experts and others as determined appropriate by the Joint Committee;
(d) ensure that SGPGIMS is not responsible for salaries of Canadianfaculty;
(e) facilitate the applications of SGPGIMS trainees and visiting faculty to Canadian programs;
(f) endeavor to establish scholarships for selected trainees in Canada;
(g) endeavor to provide a nurse educator to train counterparts in SGPGIMS to provide training for neonatal nurses in India;
(h) provide core simulation equipment (Appendix A) for establishing NASTARCand related research programs; and to fund air travel to Lucknow, visa, research, training and other related activities of participating Canadian faculty, as decided by the Joint Committee. for the first three years, up to C$256,000.

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SGPGIMS,Lucknow

7. This agreement will remain in effect for a period of three (3) years, or until it is terminated by mutual agreement or by either party with three (3) months' notice.

8. The Joint Committee will meet at least once a year, at a mutually agreed upon time, to review the progress of the partnership and agree on future directions.

9. The Joint Committee will review the program annually & will prepare report for perusal of apex authorities of respective institutions /organizations, and make recommendations for change.

Signed by xxxx
On behalf of the Department of Medical Education, UP
Dates:

(Dr. K. K. Gupta)
Director
Medical Education & Training
Lucknow

Signed by xxxx
On Behalf of SGPGIMS
Dated 6/3/2019

Prof. Rakesh Kapoor
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signed by xxxx
On Behalf of Sinai Health System
Dated:

Acknowledged by Shoo K. Lee
Dated: March 6, 2019

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Appendix A

1. PremieNatalie & Mamabreast x12
2. Neonate SimNewB Advanced trainer in neonatal resuscitation x1
3. Premature Anne x2
4. NeoNatalie (dark) x12
5. Pneumothorax Trainer x1
6. Baby Stap for lumbar puncture x1
7. Vetspeed Neonatal Echocardiography simulator x1
8. Ultrasound Neonatal Head Phantom GEORGE x1
9. Neonatal and Pediatric Multi-Venous IV Training Arm Kit x6
10. Arterial arm stick kit x3
11. Medtronic Video laryngoscope x1
12. HeartSim 200 x1
13. Newborn ANNIE x2
14. Neonatal Intubation Trainer x6

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

DD 348124

MEMORANDUM OF UNDERSTANDING

1. This MoU made on this.....day of ..... Two Thousand Seventeen between Council of Scientific and Industrial Research, a Society registered under the Societies Registration Act XXI of 1860 having its registered office at Anusandhan Bhawan, 2 Rafi Marg, New Delhi-110 001 (hereinafter called CSIR which expression shall where the context so admits, include its successors and permitted assigns) through its CSIR-Central Drug Research Institute having its office at B.S. 10/1, Sector 10, Jankipuram Extension, Sitapur Road, Lucknow-226031, India, (hereinafter called CSIR-CDRI) of the one part.

   Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh 226014 , India (hereinafter called SGPGIMS which expression shall where the context so admits, include its successors and permitted assigns) of the second part.

   Each CSIR-CDRI and SGPGIMS here under are also referred to separately as the ("Party"), or together as the ("Parties")

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(16)

2. Preamble

2.1 WHEREAS CSIR-CDRI is a Pioneer Drug Research Institute having all the infrastructure facilities for and development of new drug from conceptual to commercialization stage.

2.2 WHEREAS SGPGIMS is one of the Premier Medical Institute providing Medical education and health services in India.

3. Objective of the Program

The objectives of the Program are to promote institutional linkage between CSIR-CDRI and SGPGIMS and to explore other avenues for possible collaboration where expertise exists and can be mentored by either or both of them and also to provide higher education opportunities for faculty, support staff and students of CSIR-CDRI and SGPGIMS .

4. Scope of the Program

The Program is established to provide collaborative cooperation through:

i) **Collaborative Research Programs in specific fields of interest** - CSIR-CDRI and SGPGIMS will jointly identify specific fields to conduct collaborative research programs of mutual interest and benefit to both parties. It should also include technical inputs for development of protocols for collaborative projects.

ii) **Submission of Joint projects**- Project proposals may be jointly submitted to DBT, CSIR, DST, ICMR, or any other funding agencies for extramural funding for carrying out further studies of selected project/molecules.

iii) **Faculty Exchange Programs**- Exchange programs for faculty will be explored and conducted accordingly which will be mutually beneficial for both the parties.

iv) **Student Exchange Programs**- Exchange programs for students will be explored and conducted accordingly which will be mutually beneficial for both parties.

v) **Joint Programs**: Organizing joint scientific conferences, workshops symposia, meetings in the areas of mutual interest. Societal Health awareness programs, etc.

vi) **Sharing of Instrumentation Facility**: Sharing of Instrumentation facility for discovery of new biomarkers in various human diseases.

vii) Any other areas/programs of mutual interest.

5. General Provisions

(i) The MoU shall remain valid for a period of five (5) years from the last date of signing of the MoU.

(ii) The collaborators shall initiate the work after obtaining necessary approval of the research project from Institutional Animal Ethics Committee of CSIR-CDRI and SGPGIMS respectively.

M. Dixit

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(iii) The collaborators shall initiate the work after obtaining necessary approval of the research project from Institutional Human Ethics Committee of CSIR-CDRI and SGPGIMS respectively.

(iv) Both parties acknowledge the importance of protection of human and animal subjects in any research activity. Matters related to the transfer of biological material should receive prior approval on each side by the competent authority according to the existing rules and regulations of each party.

(v) The progress of implementation of the program shall be reviewed by SGPGIMS and CSIR-CDRI, as mutually decided and the benefits of the collaboration shall be shared mutually.

(vi) Both parties shall take necessary financial approvals from the competent authority for fulfilling the objectives of the program under clause 4 on case to case basis.

(vii) Incase, If any molecule shows promising activity, it may be considered for further development by CSIR-CDRI and SGPGIMS on mutually acceptable terms and conditions.

(viii) Both parties and their student can visit the collaborating institutes as per requirements of the project, and shall have adequate insurance coverage without any financial liability on each other.

(ix) During the tenure of the MoU and thereafter parties undertake on its behalf and on behalf of its affiliates, employees, associates, consultants, professional advisors (collectively referred to as "Permitted Users") to whom information under the scope of the MoU is disclosed shall maintain its confidentiality and shall also prevent any disclosure of the information to any third party. PARTY shall allow access to the information to only Permitted Users who are evaluating the data and information and they shall maintain the confidentiality of the same as their own data.

(x) The parties shall consult each other for any publication in respect of research work. These publications (papers, reports etc.) shall be in the names of actual research workers, wherein it will be duly acknowledged that the work has been carried out under the collaborative research program of CSIR-CDRI and SGPGIMS . As a part of collaboration, the outcomes of the research under this Agreement shall develop joint publication.

(xi) Any publication, document and/or paper arising out of joint work conducted by the participants pursuant to this MoU will be jointly owned. The use of the name, logo and/or official emblem of the participants on any publication, document and/or paper will require prior permission of both the participants. It may however be ensured that the official emblem and logo is not misused.

DIRECTOR
Sanjay Gandhi Post...
Institute of Medical Sciences
LUCKNOW-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(xii) Applications for joint Patents will be filed in the name of institutions namely CSIR-CDRI, Lucknow and SGPGIMS, Lucknow.

(xiii) Both parties agree to ensure appropriate protection of Intellectual Property Rights generated from such cooperation consistent with their respective laws, rules and regulations and other international agreements to which both parties are signatories.

(xiv) In case research is carried out solely and separately by the Party or the research results are obtained through the sole and separate effort of the Party the Party concerned alone will apply for grant of IPR and once granted the IPR will be solely owned by the concerned Party.

(xv) In case of research results obtained through joint activities, the grant of intellectual property rights will be sought by both the parties jointly and once granted these rights will jointly owned by the parties on mutually acceptable terms and conditions.

(xvi) In case of research results obtained through joint activities under this MoU both parties will apply as co-applicants for the protection of intellectual property rights subject to exclusive rights of both the Parties to commercialize the technology jointly on mutually acceptable terms and conditions.

(xvii) Any expenditure towards filing, maintaing and securing of IPR, development of the product and revenue towards license fee and royalty shall be shared on case to case basis in mutual consultation between Director, CSIR-CDRI and Director, SGPGIMS under a separate agreement.

(xviii) Any product generated under the program shall be licensed to any industry by CSIR-CDRI and/or SGPGIMS under a separate agreement after mutual consultation between Director, CSIR-CDRI and Director, SGPGIMS.

(xix) The annual maintenance of the facility including all the instruments shall be the responsibility of each party without any financial liability on each other.

(xx) Nothing contained herein shall constitute this a partnership or joint venture agreement or constitute either party as the partner, principal or agent of the other, this being a MoU between independent contracting entities.

(xxi) No amendment or modification of this MoU shall be valid unless the same is made in writing by all the parties or their authorized representatives and specifically stating the same to be an amendment of this MoU. The modifications shall be effective from the date on which they are made, unless otherwise agreed to.

(xxii) Both parties shall do their utmost to ensure the smooth and efficient implementation of the program.

M. Dikshit

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(13)

(xxiii) This MoU can be terminated by either party by providing thirty (30) days notice of termination however; no termination should adversely interrupt or impair a program or course of study or its participants, commenced prior to such termination.

(xxiv) The parties will use their best efforts to settle all matters in dispute amicably. All disputes and differences of any kind related to this MoU shall be jointly settled between Director, CSIR-CDRI and Director, SGPGIMS.

For & on behalf of CSIR-CDRI	**For & on behalf of SGPGIMS**
Signature M. Siddiqui	**Signature**
Name निदेशक Director	Name DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow-226 014 (INDIA)
Designation केन्द्रीय औषधि अनुसंधान संस्थान Central Drug Research Institute लखनऊ / Lucknow	Designation
Seal	Seal
Witnesses	**Witnesses**
1- Naseem Ahmed Siddiqui CSIR-CDRI, LKO	1- Surendra Srivastava. SGPGIMS LKO
2- Neelima (Neelima Srivastava) BD-IP Unit, CSIR-CDRI, LKO	2- Amita Aggarwal SGPGI Amita

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

18

उत्तर प्रदेश UTTAR PRADESH

DL 880879

MEMORANDUM OF UNDERSTANDING

BETWEEN

INDIAN INSTITUTE OF TECHNOLOGY KANPUR

AND

(SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES)

FOR IMPLEMENTATION OF SCHEME NATIONAL INITIATIVE FOR SETTING UP OF DESIGN INNOVATION CENTRES

THIS MEMORANDUM OF UNDERSTANDING is made on this 04 day of July 2016 between Prof. Indranil Manmathe Director, Indian Institute of Technology Kanpur (hereinafter called the 'THE FIRST PARTY') and Prof. Rakesh Kapoor, Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences) (here in after called the 'THE SECOND PARTY').

WHEREAS it has been the concern of the Government of India to establish Design Innovation Centers to promote a culture of innovation and creative problem solving, to promote knowledge sharing and to enhance interdisciplinary design-focused education, research & entrepreneurial activities.

AND WHEREAS in pursuance of this concern, the Project objectives are:

- To promote a culture of innovation and creative problem solving.
- To serve as a place that imparts design based education and practice systematic design through projects.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ION B:

E FIRST PARTY'agrees to:

- Release the Grant as described at Section C.
- Render or arrange to render such technical assistance and guidance as may be needed by 'THE SECOND PARTY', from time to time for an effective and efficient implementation of the Scheme.
- Supervise the Scheme in the concerned Institutions.
- Select and review the project proposals of the faculty as well as students of the Second Party through Project Review Body (PRB) consisting of design experts.
- Assist or arrange to assist such academic assistance as required in forming a curriculum on design innovation within the Spoke institute
- Review the findings of audits and maintain the policy reforms and conduct evaluation studies.

SECTION C:

THE FIRST PARTY'will release funds as mentioned in Annexure A towards the approved scheme of the Institution in instalments on the basis of

- Fund requirement of the selected project proposals submitted by the faculty and students of the Second party by the 'Project Review Body'set up by the First party and satisfactory progress and performance against eligible activities by the Second Party,
- Unspent balance lying with the Spoke.
- Submission of Fund Utilization Certificates by the Second Party and The financial as well as academic support is subject to receiving continuous grants for the same from the Ministry of Human Resource Development to meet expenditures to the First Party. The funding of DIC-Spoke Institutions will be limited to XII Five Year Plan.

SECTION D:

- Each DIC-Spoke Centre will have a Head or Director, who will be leader in the profession. He / She will be an eminent person in the field.
- IIT Kanpur: Prof. Nachiketa Tiwari
- Spoke: Director, SGPGIMS

SECTION E:

The Project implementation schedule:

- The Project became effective on 26th Aug 2016.
- The Project is expected to proceed at uniform rate over three years, extension and funding can be considered by the FIRST PARTY on the basis of outcome of the DIC and the approval of the same by the Ministry of Human Resource Development.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4-7-16

उत्तर प्रदेश UTTAR PRADESH

DZ 016386

30 JAN

This MoU is entered into and between CSIR-Indian Institute of Toxicology Research (CSIR-IITR), a constituent Laboratory of Council of Scientific and Industrial Research, New Delhi situated at Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow-226001, Uttar Pradesh, hereinafter called "CSIR-IITR".

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, situated at Rae Bareli Road, Lucknow-226014, Uttar Pradesh, hereinafter called "SGPGIMS".

Sharing a common desire to extend and strengthen the functional relationship between CSIR-IITR and SGPGIMS, we the undersigned, mutually agree to share existing facilities and available expertise at our respective institutions. CSIR-IITR and SGPGIMS signed to this effect a Memorandum of Understanding (MoU) on 23rd day of February, 2018 which reads as follows:

- The major objective is to establish a close linkage and functional coordination between CSIR-IITR and SGPGIMS for mutual

23.2.18

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

continuance will be subject to review after expiry of the agreed period of five years.

- Any disputes arising will be settled by mutual negotiation between the two parties.

In witness thereof the parties have jointly signed/executed this Memorandum of Understanding in two copies on the date and year written above.

For and on behalf of:

23.2.18

(प्रोफेसर आलोक धावन)
(Professor Alok Dhawan)
निदेशक/Director
सीएसआईआर–भारतीय विषविज्ञान अनुसंधान संस्थान
CSIR-Indian Institute of Toxicology Research
लखनऊ/Lucknow-226001

CSIR-Indian Institute of Toxicology Research, Vishvigyan Bhawan
31, Mahatma Gandhi Marg
Lucknow-226001, Uttar Pradesh

23/2/18

DIRECTOR
S.G.P.G.I.M.S., Lko

Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Rae Bareli Road, Lucknow-226014, Uttar Pradesh

Witness:

1. .....
.....

23/2/2018
डॉ० के० सी० खुलबे/Dr. KC Khulbe
प्रमुख, अनुसंधान योजना एवं व्यापार विकास विभाग
Head, Research Planning & Business Development Division
सी एस आई आर–भारतीय विषविज्ञान अनुसंधान संस्थान
CSIR-Indian Institute of Toxicology Research
विज्ञान भवन 31, महात्मा गांधी मार्ग, लखनऊ–226001 भारत
Vishvigyan Bhawan 31, Mahatma Gandhi Marg, Lucknow-226001 India

2. Prem Prakash
(PREM PRAKASH)

Witness:

1. .....
.....

Prof. Girish Gupta
Faculty Incharge (Research)
S.G.P.G.I.M.S.
Lucknow-226014

2. .....
.....

Dr. S. SRIVASTAVA
SCIENTIST-IV
Research Cell
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow - 226014

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Memorandum of Understanding

Between

सी.एस.आई.आर.-भारतीय विषविज्ञान अनुसंधान संस्थान

CSIR-Indian Institute of Toxicology Research, Lucknow

Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow-226001

And

संजय गांधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ

Sanjay Gandhi Post Graduate Institute of Medical Sciences

Rae Bareli Road, Lucknow-226014

On

23rd day of February, 2018

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

02 D16386

30 MAY

This MoU is entered into and between CSIR-Indian Institute of Toxicology Research (CSIR-IITR), a constituent Laboratory of Council of Scientific and Industrial Research, New Delhi situated at Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow-226001, Uttar Pradesh, hereinafter called "CSIR-IITR".

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, situated at Rae Bareli Road, Lucknow-226014, Uttar Pradesh, hereinafter called "SGPGIMS".

Sharing a common desire to extend and strengthen the functional relationship between CSIR-IITR and SGPGIMS, we the undersigned, mutually agree to share existing facilities and available expertise at our respective institutions. CSIR-IITR and SGPGIMS signed to this effect a Memorandum of Understanding (MoU) on 23rd day of February, 2018 which reads as follows:

- The major objective is to establish a close linkage and functional coordination between CSIR-IITR and SGPGIMS for mutual

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

cooperation towards the advancement of knowledge of the employees, faculty, scholars and students of both the institutions.

- CSIR-IITR and SGPGIMS will both provide intellectual and infrastructure support for carrying out collaborative /academic research in the areas of mutual interest. A prior approval of each research activity under such collaboration is required from the competent authorities of both the organizations. Mutually approved research projects will be executed without any financial liabilities on each other for recurring expenses after assessing the priority. The outcomes of the studies in terms of research papers, patents, products, etc will be jointly shared by the individuals from both the organizations.

- CSIR-IITR and SGPGIMS will encourage and provide facilities to explore and prepare joint proposals on thrust areas for funding. The technical activities and grant sharing between CSIR-IITR and SGPGIMS shall be mutually agreed while submitting such proposals to funding agencies. The outcomes of the joint research in terms of research papers, patents, products, etc will be jointly shared by both the organizations.

- The research orientation programme for the early and mid career faculty members of SGPGIMS may be conducted at CSIR-IITR and vice versa. The duration, frequency, adequacy and other modalities of such orientation programme can be decided on mutually agreeable basis.

- For ethically approved studies, SGPGIMS will provide the demographic data and biological materials including the tissues from human volunteers.

- CSIR-IITR and SGPGIMS may jointly organize Seminars/Workshops/ Conferences and short term training programme on the topics of mutual interest.

- SGPGIMS may offer honorary positions of Visiting Professors to the Scientists of CSIR-IITR as per the norms of SGPGIMS.

- These arrangements shall be valid for a period of five years commencing from the date of signing of this MoU and its

23/2/18

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

continuance will be subject to review after expiry of the agreed period of five years.

- Any disputes arising will be settled by mutual negotiation between the two parties.

In witness thereof the parties have jointly signed executed this Memorandum of Understanding in two copies on the date and year written above.

For and on behalf of:

(प्रोफेसर आलोक धवन)
(Professor Alok Dhawan)
Deputy Director
काउंसिल ऑफिस इंडियन टॉक्सिकोलॉजी अनुसंधान संस्थान
Council of Indian Institute of Toxicology Research

CSIR-Indian Institute of Toxicology Research, Vishvigyan Bhawan
31, Mahatma Gandhi Marg
Lucknow-226001, Uttar Pradesh

DIRECTOR
S.G.P.G.I.M.S., Lko.

Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Rae Bareli Road, Lucknow-226014, Uttar Pradesh

Witness:

1. ..... डॉ. के.सी. खुलबे/Dr. KC Khulbe
.....

2. .....
(PRAKASH)

Witness:

1. .....
.....

2. .....
Dr.S. SRIVASTAVA
SCIENTIST IV
Research Cell
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Lucknow - 226014

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

DT 962699

MEMORANDUM OF UNDERSTANDING

BETWEEN

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES

AND

WAYNE STATE UNIVERSITY

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, (hereinafter referred to as SGPGIMS"), an institution of higher learning, a tertiary care hospital established under the Government of Uttar Pradesh Act 30 year 1983 whose address is at SGPGIMS, Raebarelly Road, Lucknow 226014 India and shall include its lawful representatives and permitted assigns; **WAYNE STATE UNIVERSITY** (hereinafter referred to as "WSU"), a public institution of higher education established in 1868 whose address is at 4092 FACULTY/ADMINISTRATION BUILDING, ~~633~~ 56 W. KIRBY, DETROIT, MICHIGAN, 48202, UNITED STATES OF AMERICA and shall include its lawful representatives and permitted assigns; hereinafter referred to singularly as "the Party" and collectively as "the Parties"),

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

The Parties are desirous of entering into this Memorandum of Understanding to declare their respective intentions and to establish a basis of co-operation and collaboration between the Parties upon the terms as contained herein.

HAVE REACHED AN UNDERSTANDING as follows:

ARTICLE I
OBJECTIVE

The Parties, subject to the terms of this Memorandum of Understanding and the laws, rules, regulations and national policies from time to time in force in each Party's country, will endeavour to strengthen, promote and develop co-operation between the Parties on the basis of equality and mutual benefit.

ARTICLE II
AREAS OF CO-OPERATION

1. Each Party will, subject to the laws, rules, regulations and national policies from time to time in force, governing the subject matter in their respective countries, endeavour to take necessary steps to encourage and promote co-operation in the following areas:

   a) Exchange of students for the purposes of value-added study, learning and research;
   b) Exchange of academicians for the purposes of value-added study, training and research;
   c) Joint research and teaching activities; and
   d) any other areas of co-operation to be mutually agreed upon by the Parties.

   The lists of activities are not exhaustive and may be added from time to time with mutual agreement of the Parties.

2. For the purpose of implementing the co-operation in respect of any areas stated in paragraph 1 the Parties will enter into a legally binding agreement subject to terms and conditions as mutually agreed upon by the Parties including clauses on "confidentiality",

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Executive Registrar
SGPGIMS Lucknow

ment of dispute

renewed unless either institution informs the other in writing of its intention to terminate it at least six (6) months in advance.

2. This Memorandum of Understanding may be extended for a further period as may be agreed in writing by the Parties.

ARTICLE VII
NOTICES

Any communication under this Memorandum of Understanding will be in writing in the English language and delivered by registered mail to the address or sent to the electronic mail address or facsimile number of **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW** or WAYNE STATE UNIVERSITY, as the case may be, shown below or to such other address or electronic mail address of facsimile as either Party may have notified the sender and shall, unless other wise provided herein, be deemed to be duly given or made when delivered to the recipient at such address or electronic mail address or facsimile number which is duly acknowledged:

To : **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW**Raebarelly Road
Lucknow 2226014
India
(Attn: Director)
Tel : + 91 522 2668112
Fax : + 91 522 2668129
E-mail: director@sgpgi.ac.in

To : **WAYNE STATE UNIVERSITY (WSU)**
Ahmad Ezzeddine, PhD
Associate Vice President for Educational Outreach and International Programs
Office of the Provost
Wayne State University
656 W. Kirby, Detroit, MI 48202
UNITED STATES OF AMERICA
Tel: +1 (313) 577-8968

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Executive Registrar
SGPGIMS Lucknow

उत्तर प्रदेश UTTAR PRADESH

DH 041389

MEMORANDUM OF UNDERSTANDING

This MoU made on this Friday day July 7th of 2017 between National Institute of Pharmaceutical Education and Research (an autonomous institution under Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India), Shree Bhawani Paper Mill Road, ITI Compound, Raebareli-229010, India (hereinafter called NIPER, Raebareli) of the one part.

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014, India (hereinafter called SGPGIMS, Lucknow which expression shall where the context so admits, include its successors and permitted assigns) of the second part.

Each NIPER, Raebareli and SGPGIMS, Lucknow here under are also referred to separately as the ("Party") or together as ("Parties")

Background

i. NIPER, Raebareli and SGPGIMS, Lucknow will share interests in basic sciences and research in the areas of Cardiovascular, Drug Metabolism, Renal Physiology, Anticancer Research and Diabetes.

ii. The two Parties have identified that a stronger relationship between them is mutually beneficial and wish to establish a more formal relationship with each other.

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1. Commencement and Duration

1.1. This Memorandum of Understanding ("MoU") shall take effect on the date of signing and shall continue for a period of 5 years unless terminated earlier in accordance with the provisions of Clause 7.

2. Force of this MOU

2.1. The areas of agreement outlined in this MoU are described to facilitate more detailed and specific negotiations between the parties which may lead to the preparation and signing of one or more formal agreements between NIPER, Raebareli and SGPGI, Lucknow. Unless specifically noted herein, this MoU is not intended to be of legal force and effect in any manner whatsoever. This MoU shall not create a legal relationship between the parties.

3. Broad Areas for Cooperation

3.1. NIPER, Raebareli and SGPGIMS, Lucknow will discuss the possibility of cooperation in the following areas:

(a) Joint Research projects
(b) Training of Post Graduate students of NIPER at SGPGIMS as per the norms of the Institute.
(c) Organising joint seminars and conferences
(d) Joint publications as a result of collaborative research
(e) Faculty interaction between two organisations
(f) Any collaborative efforts that both may deem fit from time to time.

3.2. Representatives of the Parties may agree to review the operation of this MoU from time to time.

4. Joint Contributions

4.1. Potential areas for collaborative research will be identified and recorded in subsequent research specific agreement(s) that set out appropriate and relevant contributions by the Parties. This may include

(a) Access to its research laboratories and assist in development of projects involving the parties.

(b) Joint submission of research proposals to national and international organisations to obtain support for their common research objectives.

(c) NIPER, Raebareli and SGPGIMS, Lucknow shall work specifically in the areas defined in Para (i) and Para 3.1.

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Executive Registrar
SGPGIMS,Lucknow

4.2. The parties acknowledge that all specific financial arrangements proposed must be negotiated and will depend upon the availability of funds and organizational approvals.

5. **Confidentiality and Privacy**

5.1. NIPER, Raebareli and SGPGIMS, Lucknow recognize that they will come into possession of information which the other considers to be confidential, including Personal Information ("Personal Information" means information and opinions recorded in any form about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion). Each of NIPER, Raebareli and SGPGIMS, Lucknow covenants and agrees that it shall not, at any time, disclose to any third party, any confidential information of another party without first having obtained the prior written consent of the other party.

5.2. The provisions of this Clause 5 are intended to and shall be binding upon the parties upon the signing of this MoU and shall survive the termination or expiry of this MoU.

6. **Intellectual Property**

6.1. "Intellectual Property" means and includes all copyright, all rights in relation to inventions (including patent rights), plant varieties, register and unregistered trade marks, registered and unregistered designs and all other rights resulting from intellectual activity in the scientific, industrial, literary or artistic fields.

6.2. Each party shall retain all rights to existing intellectual property belonging to it and contributed by it ("Background IP") at the commencement of each Research Project arising under this agreement.

6.3. If any IPR issue emerges as a result of joint research, then a specific IPR addendum will be jointly agreed upon.

7. **Termination**

7.1. Either of NIPER, Raebareli and SGPGIMS, Lucknow may terminate this MoU by written notice to the other party. A minimum period of six months notice will be required from a party wishing to terminate the MoU, or such shorter period as the parties may agree upon in writing.

7.2. The termination of this MoU shall not affect the implementation of activities that have been undertaken prior to such termination,

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SGPGIMS,Lucknow

unless agreements pertaining to such activities explicitly provide for such termination.

8. Amendments and Supplementary Agreements

8.1. The parties may agree to amend this MoU at any time by further memoranda in writing executed by the duly authorized officer(s) of each party.

8.2. The parties shall wherever necessary enter into written agreements to facilitate collaborative activities arising from this MoU. Such agreements will specify the details of agreed activities and programs, including the contributions and responsibilities of the parties, funding, intellectual property provisions, confidentiality, risk allocation and indemnity obligations of each party.

9. Use of Name and Logo

9.1 No party shall use, nor permit any person or entity to use, the name or logo (or any variation thereof) of another party without first obtaining prior written consent from the other party. The parties intend that this provision shall be binding upon them and shall survive the termination or expiry of this MoU.

For and on behalf of NIPER, Raebareli

Signature

Name : **Dr. S. J. S. Flora**

Designation : **Director**

Seal **Dr. S.J.S. Flora Director NIPER, Raebareli**

Date

Witnesses

1. (KESHRI NATH TIWARI)
2. NIPER, RAEBARELI
   (ANUJ GARG)
   NIPER, RAEBARELI

For and on behalf of SGPGIMS, Lucknow

Signature

Name : **Prof. Rakesh Kapoor**

Designation : **Director**

Seal DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA

Date 2/7/2017

Witnesses

1. (DR. S. SRIVASTAVA) Scientist - IV, SGPGI
2. (DR. S.K. Agarwal)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

DZ 090167

Memorandum of understanding

By and between

Foundation of Primary Immunodeficiency Diseases, USA

AND

Sanjay Gandhi Postgraduate Institute of Medical Scientes, Lucknow.

The Memorandum of understanding ("MOU") describes the terms and conditions under which Foundation of Primary Immunodeficiency Diseases, USA ("FPID") will provide funding and assistance under its grant program to Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow (the "Recipient") in connection with the project described below (annexure).

Background regarding the Foundation of Primary Immunodeficiency Diseases, USA

This is a non-government organization co-founded by Dr Sudhir Gupta and Dr Abha Gupta and managed by board of directors comprising of luminaries in the field of immunology and primary immunodeficiencies. The aim is to support education, diagnosis, treatment, and research in primary immunodeficiency diseases (PIDs) in India and the U.S. The broad objectives among each head are:

Education:

1. Broaden public awareness of PID via lectures, seminars, and print, online, and broadcast media.
2. Educating general and specialty practicing clinicians about diagnosis and therapy for PID via lectures, seminars, and conferences.
3. Training of immunologists/hematologists in molecular diagnosis, hematopoietic stem cell transplantation, and gene therapy via an exchange program among various institutions.

Diagnosis:

1. **To support the establishment of centers/laboratories for the diagnosis of PID (in India).**
2. Routine immunology laboratory diagnosis
3. Molecular diagnosis

Contd....2..

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Treatment:

1. Treatment with immunoglobulin via different routes (e.g., subcutaneous and intravenous)
2. Hematopoietic stem cell transplantation (cord blood and bone marrow)
3. Gene therapy

Research:

Research projects to understand the pathogenesis of PID (Basic and Translational). Both fellowships and individual research projects may be funded.

More information on FPID is available at www.fpid.org

Terms and conditions:

Purpose: To set up an SGPGI-FPID Center for diagnosis of PID that will provide free of cost tests for patients with suspected PID

Support: Rs. 5,00,000/annually will be provided to run the laboratory for consumables and manpower . This amount may be increased based upon the need and satisfactory progress report.

Reports: The Recipient will provide 6 monthly report on the progress made

Confidentiality: FPID will protect the confidentiality of information and data provided by the recipient.

Payments: The payments will be made by electronic wire-transfer to SGPGI in the name of **Director, SGPGI (research account).**

Return of unused funds: Any grant that remains unutilized may be carried over for following year and adjusted into following year budget.

Compliance: The FPID reserves the right, in its sole discretion to discontinue the project grant program if the foundation is not satisfied with the progress of the grant or the information reported by the recipient.

Prohibited activities: The money provided by FPID will be used for the sole purpose for which it is to be used and in no circumstances will it be used for any other purpose.

Dispute Resolution: All disputes will be resolved by mutualdiscussion.

Duration of MOU: 5 years

Project commencement:
This MOU will become effective on the date that it is fully executed by both **FPID** and the **Recipient.** The FPID reserves the right, in its sole discretion to discontinue the project grant program if the foundation is not satisfied with the progress of the grant or the information reported by the recipient. In the event of such termination the FPID will provide recipient with written notice of termination documenting the reason for termination.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Other elements of this agreement

Any notice required by the MOU shall be sent in writing by certified mail addressed in the case of FPID to:
Dr Sudhir Gupta
2 Geneve, Newport Beach, CA 92660, USA

And in the case of recipient by courier mail to the address below:
The Director, SGPGI, Lucknow 226014, India

This MOU represents the complete agreement between the parties regarding its subject matter and supersedes all prior written or oral communications, representations and agreements regarding the same subject matter. This MOU may be amended or modified only in a written document signed by duly authorized representatives of FPID and recipient. This MOU may be executed in two or three counterparts, each of which will be deemed an original. If any provision of this MOU is held unenforceable for any reason, than unenforceability shall not affect the enforceability of any other provision of this MOU and the parties will negotiate in good faith to substitute an enforceable provision with similar aims.
Executed by the parties hereto as of the date set forth

FPID

Prof Sudhir Gupta
Co-founder and Chairman, Board of Directors
Date_____

Recipient

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW 226 014, INDIA

Date_____

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL751133608130 84Q
Certificate Issued Date	:	12-Jan-2018 12:11 PM
Account Reference	:	IMPACC (IV)/ dl982203/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL98220353284573996806Q
Purchased by	:	PHARMAZZ INDIA PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PHARMAZZ INDIA PRIVATE LIMITED
Second Party	:	SGPGI AND DR U K MISRA
Stamp Duty Paid By	:	PHARMAZZ INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Institution)

And

Dr. U.K. Misra (Principal Investigator)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

FOR THE STUDY

Title of Study:	A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke.
Protocol Number:	PMZ-01
Version Number:	02
Date of Protocol:	18 April 2016

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on **23 Mar 2018** ("**Effective Date**") at New Delhi **BY AND BETWEEN**:

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Office at B-4 Sarita Vihar New Delhi 110076, (hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institution having its office at Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014, (hereinafter referred to as "**Sanjay Gandhi Post Graduate Institute of Medical Sciences**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART**;

AND

Dr. U.K. Misra a registered medical practitioner holding MCI registration number-18599 , is the Professor at Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014 (hereinafter referred to as "**Principal Investigator**"), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART**;

Pharmazz, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(16)

RECITALS

1. WHERE **(Sanjay Gandhi Post Graduate Institute of Medical Sciences)** is a pioneering institution of world-class investigator sites in India. It is a chain of investigator sites having an exclusive set up for conducting Phase II to Phase IV clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related toPMZ-1620 is a lyophilized IRL-1620 Injection, proposed to act as a Treatment agent in Acute Ischemic Stroke.

3. Principal Investigator **Dr. U.K Misra, DM (Neurology)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement with **Dr. U.K. Misra** for conducting Clinical Trial Phase II study titled **"A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke"**."at Sanjay Gandhi Post Graduate Institute of Medical Sciences Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the proposed Study. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 Definitions

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

a) **"AGREEMENT"** shall mean this Clinical Trial Agreement;

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipments, samples, services, customer lists,

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marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) **"EFFECTIVE DATE"** shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled **"A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke"**As defined in the Protocol.

g) **"PROTOCOL"** shall mean: The description of the Study contained in the Study protocol number **PMZ 01** (a copy of which is attached as Exhibit A) and all amendments thereto as the Parties may from time to time agree in writing.

h) **"STUDY DRUG"** or **"Investigational Drug"** shall mean: IRL-1620 For Injection 30 µg/vial

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i) **"ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

j) **"DCGI"** Drug Controller Government of India.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

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Executive Registrar
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(13)

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator to complete the following -

Responsibility of the Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator

The **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees to provide full support to the Principal Investigator **at Sanjay Gandhi Post Graduate Institute of Medical Sciences Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014** to conduct the Clinical Trial in **Sanjay Gandhi Post Graduate Institute of Medical Sciences** premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the said hospital for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be jointly and severally responsible

a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**");

c) to fulfill all other terms and conditions stipulated herein and in the Exhibits hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

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2.2 The Principal Investigator shall personally review all case report forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/eCRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new

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principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethical committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** throughout the period of the Clinical Trial and **with third party vendor or sponsor** for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall obtain written approval from Pharmazz before destruction of such data.

2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

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Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz will provide the Study Drug to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the Safety and Efficacy of PMZ-1620 therapy along with standard supportive care in subjects of acute ischemic stroke.

3 VISIT AND INSEPECTION

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

a. examine and inspect the **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study, and audit all

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reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

c. Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 RECORDS AND REPORTING

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 PAYMENT, PRICING TERMS

5.1 Pharmazz agrees that in consideration of the Principal Investigator's and Sanjay Gandhi Post Graduate Institute of Medical Sciences carrying out the Clinical Trial in accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in Exhibit B, to the **Director SGPGI, Research Account** in accordance with the payment schedule set forth therein which shall include the remuneration and all other related cost.

5.2 The Parties agree that the payment of the amount set forth in Exhibit B will be paid by the Pharmazz to the **Director SGPGI, Research Account** to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the insurance program nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in Exhibit B is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in Exhibit B to be paid to **Director SGPGI, Research Account** shall be paid by Pharmazz. This amount is based on the estimated number of subjects in the time duration as agreed by Principal Investigator as per site feasibility report Exhibit D. Any change in the estimated number of subjects will proportionally affect the amount of payment.

5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to **Director SGPGI, Research Account** under this Agreement. The Budget as reflected in Exhibit B is exclusive of taxes.

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5.5 Site will raise GST invoices visit wise as mentioned in Exhibit B. All payments under this Agreement will be made within 15 days from the date of receipt of Invoice.

6 REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect)

The Second Party i.e. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be solely liable to pay all costs of such compliance. In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement.

Sanjay Gandhi Post Graduate Institute of Medical Sciences and PI are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

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The Second Party and PI will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of one year from the Effective date of this Agreement. This agreement can be extended with mutual understanding, if the trial is not complete.

8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90 day written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the Principal Investigator shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

9.1 Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for any of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI

b) **Sanjay Gandhi Post Graduate Institute of Medical Sciences** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters upon enrollment and as per his undertaking and site feasibility report provided **(Exhibit D);**

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the Principal Investigator **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to provide access by the Pharmazz's representatives all

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original medical records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and PI's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be effected by written notice to the Second Party and PI, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phase down costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and PI, whichever is later. The Second Party and PI shall be given reasonable opportunity to present to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and PI will be provided an additional period of time, specified and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party and PI to meet the deadline of (30) days for corrective measures then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

11.2 Upon termination or completion of the Study, the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were

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furnished to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees that it shall indemnify, defend and hold harmless the Principal Investigator, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

The indemnity granted in this Article shall apply separately to each Indemnity in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

12.2 It is a condition precedent to the Pharmazz's indemnification obligations under above mentioned clause 12.1 that:

a) Whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Pharmazz of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 12.1 above must (i) promptly notify the Pharmazz of the assertion of any such claims (ii) authorize and permit Pharmazz to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Pharmazz regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Pharmazz's obligations hereunder. Subject to the foregoing, Principal

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Investigator may also participate with prior consent of the Pharmazz in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Pharmazz to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Pharmazz.

The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** hereby irrevocably agree that they shall indemnify and hold harmless the Pharmazz, its present and future directors, officers and or employees against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Pharmazz by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences**; or (v) failure of the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines. The Institution and the Principal Investigator however shall in no event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof if the same is due to negligence and / or misconduct on the part of Pharmazz.

Sponsor warrant that they shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. Sponsor shall have the right to settle claims at its sole expense.

12.3 Sponsor shall provide the cost of medical management and compensation as per Rule 122-DAB-Compensation in case of injury or death due to study drug during the conduct of clinical trial.

a) In case of an injury occurring to the clinical trial subjects, he or she shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

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b) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expense incurred on the medical management of such subject.

c) The expense on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

12.4 **Insurance**

The Pharmazz undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the DCGI rules. This Insurance covers the Clinical Trial to be conducted for the Study at **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Insurance policy is attached at Exhibit E.

13. PUBLICATION OF RESULTS

It is the general policy of the Pharmazz to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Pharmazz for its perusal, comments and approval. The Pharmazz may at its discretion may either refuse the publication or forward it to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** along with its comments or modifications which shall be final and binding on the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences.**

14. PUBLICITY AND PRODUCT PROMOTING ACTIVITY

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Pharmazz shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Pharmazz and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Pharmazz.

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15. INTELLECTUAL PROPERTY RIGHTS

Sanjay Gandhi Post Graduate Institute of Medical Sciences agrees that all the Intellectual Property Rights with regard to **PMZ-1620** are and shall remain Pharmazz's exclusive property, and understands that **Sanjay Gandhi Post Graduate Institute of Medical Sciences** acquires no right, title, or interest in the Intellectual Property and the know-how used/created for the purpose of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees that all rights that may be created by the use of the Intellectual Property under this Agreement by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall inure to the sole benefit of Pharmazz and shall be the exclusive property of Pharmazz. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not at any time do or suffer to be done any act which would impair materially Pharmazz's proprietary rights in or to, or infringe, any Intellectual Property Rights of Pharmazz.

Pharmazz will be exclusively responsible if any dispute or claim arises regarding the ownership of the patent rights, copy rights & trade mark rights used by Pharmazz.

16. CONFIDENTIALITY

a) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree to keep confidential and secret all materials, documents and confidential information that the Pharmazz discloses to the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Pharmazz whether in written, electronic, oral, visual or other form ("**Confidential Information**").

b) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Pharmazz to any third party except as required by law provided that the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall:

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First give prompt notice of such disclosure requirement to the Pharmazz so as to seek any limitations on or exemptions from such disclosure requirement; and

Reasonably co-operate with the Pharmazz in any such efforts of defense in the confidential and proprietary information to be made before appropriate authority.

c) Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** can prove and produces credible written evidence to establish that such information or material:

i. at the time of disclosure or after disclosure to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** or their successors or assigns;

ii. by written records were in the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences**'s possession at the time of disclosure by the Pharmazz were not acquired directly or indirectly from the Pharmazz;

iii. subsequent to disclosure hereunder, the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** receives from a third party legally in a position to provide with information to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences,** provided, however, that such was not obtained by said third party directly or indirectly from the Pharmazz under an obligation of confidentiality.

d) All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property

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of the Pharmazz and will be treated as "Confidential Information" by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and may be used by the Pharmazz in any manner. Further, Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall assign to the Pharmazz all of their rights, title, and interest in such Inventions.

e) All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Pharmazz by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** forthwith upon written request or upon termination of this Agreement, whichever is earlier.

f) Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Pharmazz, and that if there is a breach (either actual or **threatened) by the Principal Investigator/ Sanjay Gandhi Post Graduate Institute of Medical Sciences** or co-investigator or a party in receipt of Confidential Information under this Agreement, the Pharmazz would have complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Pharmazz shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

g) Institution Information. During performance of this Agreement, Sponsor representatives may gain access through site visits or otherwise to information relating to Institution's business or research operations, policies, or procedures that Institution identifies to Sponsor as proprietary and confidential or that is reasonably apparent to Sponsor to be so. Unless Institution provides written consent, Sponsor will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by law.

17. SEVERABILITY & WAIVER AND ASSIGNMENT

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a) The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement. The parties agree that they negotiate in good faith or will permit a court/ Arbitration to replace any provision hereof so held invalid with a valid provision.

b) Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof but only by an instrument in writing..

c) This Agreement shall not be assigned as a whole or in part by any party without the prior written consent of the other parties except for the following types of general support services: communication, translation, photocopy of documents or similar services, failing which all actions taken will be null and void.

18. MISCELLANEOUS

a) It is agreed by the Parties that the Principal Investigator and Sanjay Gandhi Post Graduate Institute of Medical Sciences shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with any Parties including Pharmazz. Neither Principal Investigator nor **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall have any authority to represent, or bind the Pharmazz.

b) Principal Investigator shall comply with all the terms of the undertaking annexed hereto as **Exhibit C** and be read as part of this agreement, he has provided to the Pharmazz under this Agreement.

c) This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

d) If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

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e). The governing (applicable) language of this agreement shall be English, and all notices and other communications relating or pursuant to the provisions of the agreement (including, without limitation, those in connection with issues, disagreements and disputes) shall be in such language. This agreement, its formation and the facts and circumstances surrounding its making and performance, shall be interpreted in accordance with the following, and listed in order of precedence: (1) the express terms and conditions of the agreement; (2) the local laws of India

19. NOTICES

19.1. Unless otherwise provided herein, any communication, notice or notice of conditions interfering the performance of the agreement, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when received and acknowledged in case of electronic mode: Notifications shall be made to the following addresses:-

Pharmazz	**Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Mr. Sunil Gulati Chief Operating Officer	Dr. Rakesh Kapoor Director SGPGI	Dr. U.K Misra Principal Investigator
Pharmazz India Pvt. Ltd. B-4 Sarita Vihar New Delhi 110076 **Email:** sunil.gulati@pharmazz.com	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014 **Email:** director@sgpgi.ac.in	Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014 **Email:** ukmisra@rediffmail.com

19.2.1. Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration., which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed as per provisions of Arbitration and Conciliation Act, 1996 as amended from time to time. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto. Place of Arbitration shall be Delhi and both the parties shall bear the cost of arbitration in equal excluding counsel cost Parties agree that for claiming injunctive relief and for the enforcement of arbitral award only Delhi courts shall have exclusive jurisdiction

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SGPGIMS,Lucknow

in all matters arising out of or with this Agreement. This Agreement shall be governed by Laws of India.

20. RENEWAL CLAUSE

The agreement can be renewed by way of mutual consent of the parties in the event of requirement of further study of the protocol to complete the obligations enumerated herein above.

21. FORCE MAJEURE

Any delay or failure by the either party of required obligations shall be excused if and to the extent caused by acts of God, fire, storm, lockout, strike, terrorist act, flood, sabotage, Government Notification/ order, embargo, war (whether declared or not), riot, or other causes beyond the reasonable control of the said Party. If and when either party asserts Force Majeure as an excuse for failure to perform their obligations, then the said Party must notify the other Party in writing and upon the review of the said party's notice, the other Party shall determine whether the term of the agreement shall be extended for a reasonable time period to complete activities interrupted by the delays.

22. FURTHER ASSURANCES

Each party agrees that subsequent to the execution and delivery of this Agreement it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For **Pharmazz India Pvt. Ltd.**	For **Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Signature:	Signature:	Signature: .....
Name: Mr. Sunil Gulati	Name: Dr. Rakesh Kapoor	Name: Dr. U.K. Misra
Title: Chief Operating Officer	Title: Director, SGPGI	Title: Principal Investigator

DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow (U.P.) INDIA

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SGPGIMS,Lucknow

Exhibit-A

Clinical Trial Protocol

REFERENCE ENCLOSED

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(5)

Exhibit B

(Budget and Payment Schedule)

Budget

Total duration of Study	**9 months**		
Subject enrollment duration	**6 months**		
Total number of subjects	**15**		
Payment heads	**Total per subject**	**No. of Subjects**	**Amount per Head**
Investigator's Fees (In Rupees)	18000	15	270000
Study Coordinator Fees (In Rupees)	10000		150000
Protocol Procedures (Lab expenses) (In Rupees)	4425		66375
CT/ MRI cost (In Rupees)	4800		72000
Subject Travel (In Rupees)	2500		37500
Institutional Overhead on Investigator's & Coordinator's fees (In Rupees)			105000
Total Study Budget (In Rupees)			700875

- Protocol Procedures includes Lab expenses that is composed of cost of all the tests mentioned in protocol excluding Troponin T test, INR 55 shall be added to the Protocol procedures on Visit 1 (Baseline) for UPT if the subject is female.
- Recruitment of estimated number of trial subjects should be completed within 6 months.
- Archival fee will be paid on close out visit and it will be as per the institutional EC SOP.
- In addition to the above fee, Pharmazz shall pay for unscheduled visit (only if required) activities listed in Protocol.
- GST invoices required for release of payments visit wise.

Payee Details-

Payee Name	Director SGPGI, Research Account
Name of the Bank & Branch	State Bank Of India
A/C No:	10095237492
IFSC	SBIN0007789
MICR	226002034
PAN No./TAN No.	AAAJS3913N
GST No. (if applicable)	Not applicable

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Exhibit-C

Principal Investigator's Documents

REFERENCE ENCLOSED

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(3)

Exhibit-D

Site Feasibility Questionnaire Filled and Accepted by PI

REFERENCE ENCLOSED

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Exhibit-E

Insurance Policy for study

REFERENCE ENCLOSED

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Exhibit-F

Phase II Clinical Trial NOC

REFERENCE ENCLOSED

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Executive Registrar
SGPGIMS,Lucknow

GOVT. OF KARNATAKA
DEPT. OF STAMP & REGISTRATION
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CLINICAL TRIAL/STUDY AGREEMENT

This agreement is made on this 18 Sep 2018 by and between **"Norwich Clinical Services"** a company incorporated under Companies Act, 1956 and having its registered office at No.147/F, 8th main, 3rd block, Koramangala, Bangalore-560034, (hereinafter referred to as **CRO/Sponsor Representative**), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the One Part;

AND

"Dr. Raghunandan Prasad" working at **Sanjay Gandhi Post Graduate Institute of Medical Sciences(SGPGI), Rae Bareli Road, Lucknow-226014** (Hereinafter referred to as **"Principal Investigator"** or **"P.I."**), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the Second Part;

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI), Rae Bareli Road, Lucknow-226014 of the third part.

WHEREAS the purpose of this agreement is for conducting clinical study having Study Title:

"Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization- A Phase IV study." in accordance with applicable laws including but limited to Declaration of Helsinki, Schedule Y of Drugs and Cosmetics Act, 1940 and the rules framed there under, Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and ICMR Guideline 2017, on patients as stated in the protocol (hereinafter referred to as the subjects).

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1. The SPONSOR (GUERBET a company registered in France) is a pharmaceutical Company engaged inter alia in the business of manufacturing and/or marketing of various active pharmaceutical ingredients and pharmaceuticals in finished dosage forms;

1.1. **CRO/Sponsor representative** is a professional clinical research organization in India engaged in the business of undertaking bio studies, Clinical Trial Services and pharmacovigilance services in conformance to international standards.

1.2. The CRO has represented and warranted to sponsor that it has the necessary skill, experience, expertise and necessary facilities/infrastructure to provide the services contemplated under this agreement.

1.3. The CRO has also represented that all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement will be obtained and that all such licenses, authorizations and permissions will be in full force and effect at the time of executing the services outlined in this agreement.

1.4. Whereas the CRO desires to enter into agreement with **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Dr. Raghunandan Prasad to conduct the study in the Sanjay Gandhi Post Graduate Institute of Medical Sciences.

1.5. The CRO has agreed to engage Dr. **Raghunandan Prasad** who is a Specialist in the therapeutic area required for the study, be a Principal Investigator for the study mentioned above.

1.6. The CRO has agreed to engage Sanjay Gandhi Post Graduate Institute of Medical Sciences & the Principal Investigator for providing the services contemplated under this agreement, subject to the terms and conditions contained herein.

1.7. Whereas during the term of this Agreement, the terms and conditions herein contained shall govern the services to be provided by the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator to CRO under any subsequent individual agreement for specific services to be rendered, referred to as a Specific Protocol

1.8. The Project shall be conducted as per the CRO/sponsor's confidentiality requirements.

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Executive Registrar
SGPGIMS,Lucknow

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1.9. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator agree that the CRO/sponsor shall, subject to prior intimation to the Hospital and the P.I., have the right to enter their facility at reasonable times to inspect the facility, and the performance of the services hereunder. The CRO and the sponsor shall have the right to inspect and audit **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator records only to the extent they relate to services performed by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator hereunder for which the CRO is making payment to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator.

1.10. 1.10.1. Such rights shall, however, be only exercised by the CRO and the sponsor during **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator's normal business hours at a mutually agreed time and only following reasonable prior notice (48 hours prior notice being presumptively reasonable).

1.11. During the term of this Agreement, Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator agrees to diligently and conscientiously use its reasonable efforts to discharge its obligations in the Project as per the terms agreed hereunder, requested from time to time by the CRO/sponsor.

1.12. Responsibilities of **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator include providing such advice and information relating to the results of the studies subject matter of the Project as CRO/sponsor may reasonably request in writing from time to time to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator.

1.13. Notwithstanding the provisions of this clause, nothing in this Agreement shall preclude **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator from providing services to any other person or entity for such Project which is similar to the one undertaken in this Agreement.

1.14. The CRO expressly will have exclusive ownership interest in information, results; data developed or conceived under this Agreement and the studies covered by this agreement.

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Executive Registrar
SGPGIMS,Lucknow

Branch - SGPGIMS, Lucknow

PAN No. - AAAJS3913N

- Limited within 45 days after the receipt of invoice from the Hospital.
- Investigator payments will be made after the receipt of completed CRFs.
- In case of patients not completing the study, payment of investigator fee will be made on prorate basis, up to the stage of study completion for that patient as per the calculation above.
- For SAE's if any, 20% of the fee payable to the Investigator will be withheld and released only on completion of reporting, follow-up and relevant documentation.
- The above payments will be subject to TDS at the applicable rates.

Note:

"In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier." It is hereby clarified that the cost of the aforesaid medical management shall be borne by the Sponsor.

The following deductions will be made, if applicable:

- Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.
- Any capital expenses for the site incurred by the CRO on behalf of PI will be deducted from the fee payable to PI.

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SGPGIMS,Lucknow

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For NORWICH CLINICAL SERVICES

Signature:

Name: Dr. Saral Thangam

Title: Chief Executive Officer

Date:

NORWICH CLINICAL SERVICES PVT. LTD. BANGALORE

For Principal Investigator

Signature:

Name: Dr. Raghunandan Prasad

Title: Principal Investigator

Date: 25/09/18

For Sanjay Gandhi Post Graduate Institute of Medical Sciences.

Signature:

Name: PROF. RAKESH KAPOOR

Title: DIRECTOR

Date: 29.09.18

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

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Executive Registrar
SGPGIMS,Lucknow

Appendix E – Insurance

ICICI Lombard
GENERAL INSURANCE

CERTIFICATE OF INSURANCE (CLINICAL TRIALS LIABILITY INSURANCE)

Certificate Number:	4067/CT/GUERBET/16-17 – 001		Policy number: 406771018677223/01/002
Insured Company:	GUERBET		
Mailing Address:	15 Rue Des Vanessas, VillepinteSeine-Saint-Denis, 93420 FRANCE		
Policy Period:	June 1, 2016 (00.01 hrs)	to	May 31, 2018 (23.59 hrs)
Coverage for the below mentioned trial is effective from:	March 1, 2017		
Retroactive date:	June 1, 2016		

Coverage

The Policy of Insurance listed herein have been issued to the insured named above for the Policy period indicated. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this Certificate may be issued or may pertain, the insurance afforded by this Policy is subject to all the terms, exclusions and conditions of such Policy. Aggregate Limit shown may have been reduced by paid claims.

Territorial Scope / Jurisdiction:	India	
Aggregate Limit of Indemnity*:	₹ 74,389,500	
Any One Accident Limit*:	₹ 74,389,500	
Deductible:	₹ 111,584	any one claim including cost and expenses

* This is the total Limit applicable to the Policy and its shared by all the trials covered under this Policy
Limits and Deductibles if indicated in foreign currency are for the sake of convenience only. The policy will be issued in equivalent INR as on the date of inception of cover/ exchange rate agreed.

Study Protocol Number:	LUF-44-001
Study Title	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization - A Phase IV study
Clinical phase	as per the respective study protocol
Trial Start Date:	March 1, 2017
Estimated End:	June 30, 2018
Sponsor of the trial	GUERBET Address : 15 Rue Des Vanessas, Villepinte Seine-Saint-Denis, 93420 FRANCE

The Country in which the clinical trial take place: India **Number of Human Test Subjects:** 125

Certificate Holder: (optional)

☒ "To whom it may concern."
☐ If to be named on the certificate, state name and address of person/institution to whom the certificate will be handed out:

Requested Language of the Certificate: (tick) **Number of Certificates requested:** one

English: (default) ☒
Other: ☐

Date: February 6, 2017

Place: Mumbai

Authorised Signatory

Important Notes:(A) This Certificate is issued as a matter of information only and confers no rights upon the certificate holder (B) This Certificate does not amend, extend or alter the coverage afforded by the Policy (C) Should above described Policy be cancelled before the expiration date thereof, the Issuing Insurer will endeavor to mail 30days written notice to the Certificate Holder (if any name specified above), but failure to do so shall impose no obligation or liability of any kind upon the Insurer, its agents or representatives (D) Inception of the Policy is subject to fulfillment of all subjectivities communicated by us and 100% premium received by us (as per Insurance Act of India- Section 64 VB) and the Policy shall stand cancelled ab initio in the event of non-realization of the premium.

ICICI Lombard General Insurance Company Ltd.
Address: 414, Veer Savarkar Marg, Near Siddhi Vinayak Temple, Prabhadevi, Mumbai, 400 025

Prepared By:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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ICICI Lombard
GENERAL INSURANCE

CERTIFICATE OF INSURANCE (CLINICAL TRIALS LIABILITY INSURANCE)

Certificate Number:	4067-18-19- Guerbet -1	Policy number:	4067/148576020/00/000
Insured Company:	GUERBET		
Mailing Address:	15 RUE DES VANESSES, VILLEPINTE SEINE-SAINT- DENIS, 93420 FRANCE ILE DE FRANCE PARIS PIN - 92554		
Policy Period:	1-Jun-16 (00.01 hrs)	to	31-Dec-18 (23.59 hrs)
Retroactive date:	June 1, 2016		

Coverage

The Policy of insurance listed herein have been issued to the Insured named above for the Policy period indicated. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this Certificate may be issued or may pertain, the insurance afforded by this Policy is subject to all the terms, exclusions and conditions of such Policy. Aggregate Limit shown may have been reduced by paid claims.

Territorial Scope / Jurisdiction:	India	
Aggregate Limit of Indemnity*:	INR 74389500	Aggregate limit
Any One Accident Limit*:	INR 74389500	per occurrence limit
Deductible:	INR 111,584	

* this is the total Limit applicable to the Policy and is shared by all the trials covered under this Policy

Limits and Deductibles if indicated in foreign currency are for the sake of convenience only. The policy will be issued in INR and the exchange rate noted on the policy will be the prevailing rate as on the date of inception of cover. All claims will be paid to the Insured in India in INR.

Study Project Number:	LUF-44-001
Title of the Study:	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study
Trial Start Date:	June 1,2016
Estimated End:	31 Dec 18
Sponsor of the trial:	GUERBET
Additional Insured:	All Sites and Investigators are insured

The Country in which the clinical trial take place: India Number of Human Test Subjects: As per protocol

Certificate Holder: (optional)

- ■ "To whom it may concern."
- ☐ If to be named on the certificate, state name and address of person/institution to whom the certificate will be handed out:

Date: June 7, 2016

Authorised Signatory

Place: Mumbai Prepared by Shreya

Important Notes:(A) This Certificate is issued as a matter of information only and confers no rights upon the certificate holder (B) This Certificate does not ammend, extend or alter the coverage afforded by the Policy (C) Should above described Policy be cancelled before the expiration date thereof, the issuing insurer will endeavor to mail 30days written notice to the Certificate Holder (if any name specified above), but failure to do so shall impose no obligation or liability of any kind upon the insurer, its agents or representatives (D) Inception of the Policy is subject to full-filment of all subjectivities communicated by us and 100% premium received by us (as per Insurance Act of India - Section 64 VB) and the Policy shall stand cancelled ab initio in the event of non-realization of the premium.

ICICI Lombard General Insurance Company Ltd.
Address: # 414, Veer Savarkar Marg [Near Siddhi Vinayak Temple] Prabhadevi, Mumbai, India- 400 025

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Executive Registrar
SGPGIMS,Lucknow

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Appendix F – Indemnity

Guerbet

Confidential

February 1st, 2018

Guerbet

Boîte postale 57400
95943 Roissy CdG Cedex France
Tél. : 33 (0)1 45 91 50 00
www.guerbet.com

Société Anonyme
au capital de 12 50[illegible] 748 €
Siège social :
15, rue des Vanesses
93420 Villepinte
309 591 671 RCS Bobigny
Siret 309 591 671 00057

[illegible] 2920 Z

RE: Protocol No. LUF-44-001 "Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization - A Phase IV study" ("Protocol")

Dr. Raghunandan,

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI),
Rae Bareli Road, Lucknow-226014

Dear Dr. Raghunandan,

This letter outlines the indemnification obligations that Guerbet ("Sponsor") agrees to assume as sponsor of the Study. The terms of the Study are set forth in the Clinical Trial Agreement executed between Norwich Clinical Services (CRO) and Institution ("Agreement"). CRO is providing clinical research organization services to Sponsor under a separate contract.

Sponsor shall indemnify, defend, and hold harmless "Institution" involved in the Study and their respective trustees, directors and personnel, including Investigator (collectively, the "Indemnitees") from and against any and all liabilities, damages, losses, claims, and expenses, including court costs and reasonable attorneys' fees ("Losses") resulting from or arising out of any third-party claims, actions or proceedings arising out of (i) personal injury to or death of any Study subject enrolled in the Study, which injury or death is caused by treatment of such Study subject in accordance with the Protocol, or (ii) Sponsor's use or publication of Study Data (as defined in the Agreement), in each case solely to the extent that such Losses do not arise out of or in connection with any Institution Indemnitee's (A) failure to comply with this Agreement, the Protocol, any written instructions of Sponsor or CRO concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority or (B) negligence or willful misconduct.

An Indemnitee claiming a right of indemnification or defense under this letter shall provide Sponsor prompt written notice (in all events within thirty (30) days) of any such claim, including a copy thereof, served upon it, and shall cooperate fully with Sponsor and its legal representatives in the investigation of any matter regarding the subject of indemnification, at Sponsor's expense; provided, however, that failure by an Indemnitee to provide prompt notice shall not relieve Sponsor of its obligations hereunder except to the extent that Sponsor is prejudiced by such failure. Sponsor shall have the right to exercise sole control over the defense and settlement of any such complaint or claims for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; provided that Sponsor shall not enter into any settlement or admit fault or liability on behalf of any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld or delayed. An Indemnitee shall have the right to select and to obtain representation by separate legal counsel at the Indemnitee's sole expense.

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Executive Registrar
SGPGIMS,Lucknow

In addition to the above, Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study subject that is caused by treatment of the Study subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by (A) failure by Institution, Investigator or any of their respective personnel to comply with the Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority, or (B) negligence or willful misconduct by Institution, Investigator or any of their respective personnel.

Under no circumstances shall Sponsor be responsible to the Indemnitees for any lost profits, lost opportunities, or other incidental, consequential or special damages.

The Institution shall promptly notify CRO and Sponsor in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and cooperate with Sponsor in the handling of the adverse event.

Sincerely,

Pierre DESCHE
Senior VP, Development & Regulatory Affairs

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Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA70819968564369R
Certificate Issued Date	:	11-Mar-2019 01:15 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ VIJAYANAGAR2/ KA-BN
Unique Doc. Reference	:	SUBIN-KAKACRSFL08733275547610 34R
Purchased by	:	MYLIN BIOTECH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CTA AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	MYLIN BIOTECH INDIA PVT LTD
Second Party	:	SGPGI LUCKNOW
Stamp Duty Paid By	:	MYLIN BIOTECH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

MYLIN BIOTECH INDIA PVT LTD IN-KA70819968564369R RS. 100 11-MAR-2019 01:15 PM

Please write or type below this line

CLINICAL TRIAL AGREEMENT

Protocol # NIZY-BYT-MB-18

This Clinical Trial Agreement ("Agreement") is made as on 07.03.2019 between

Mylin Biotech India Pvt Ltd, incorporated under the laws of India with its registered office located at at #40/11-1 2nd floor, Govindraj Nagar, Magadi Road Bangalore -560040 and having PAN:AAICM3171B, including its successors, assigns and Affiliates (hereinafter "**Mylin**");

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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and

PROFESSOR Dr. ANITA SAXENA an Indian citizen/resident, with his address at Department of Nephology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow – 226014, Uttar Pradesh and having PAN : AAAJS3913N (hereinafter **"Principal Investigator"**);

and

Sanjay Gandhi Post Graduate Institute of Medical Sciences, with its address at Rae Bareli Road, Lucknow 226014, Uttar Pradesh (hereinafter **"Institution"**).

Mylin Biotech wishes to support a clinical trial entitled Protocol **#NIZY-BYT-MB-18 "A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients.**

The parties agree as follows:

1. **Definitions:**

1.1.1 **Affiliate:** means with respect to a Person, and other Person which, directly or indirectly through one or more intermediaries, Controls, is Controlled by or is under common Control with the first mentioned Person, "Control" shall mean with respect to any Party, the possession, directly or indirectly, of 50% or more of the voting securities and/or the power to direct or cause the direction of the board and/ or management and/or policies of that Person, whether through ownership of voting securities, contract or otherwise.

1.1.2 **Applicable Laws** means any statute, law, regulation, ordinance, rule, judgment, injunction, order, decree, ruling, license, permit, consent, approval, directive, agreement, guideline, policy or restriction, or any requirement or decision or interpretative, legislative or administrative action of, or determination by, any Authority having jurisdiction over the matter in question, or otherwise applicable to the Parties, whether in effect as of the date of this Agreement or at any time thereafter; and including all data protection, privacy, drug, anti-competitive, anti-corruption, anti-bribery as well as export and re-export laws and regulations, GCP and related United States Food Drug Administration ("FDA"), European Medicines Agency ("EMA") and India Food and Drugs Administration (or any other similar Authority), regulations and guidelines.

1.1.3 **Authority** means any constitutional, judicial, governmental, quasi-governmental, legislative, statutory, quasi-judicial, departmental, regulatory or public body constituted by any statute or ordinance or by a court of competent jurisdiction, or any authority having jurisdiction over the Parties or the subject matter of this Agreement.

1.1.4 **Intellectual Property Rights:** includes patents, trademarks, service marks, logos, trade names, internet domain names, copyright and moral rights, database rights, semi-conductor topography rights, rights in designs, rights in inventions, rights in know-how and other intellectual property rights, in each case whether registered or unregistered, and all rights or

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Executive Registrar
SGPGIMS,Lucknow

forms of protection having equivalent or similar effect anywhere in the world and the term "registered" includes registrations and applications for registration, rights to Study Results, economic copyrights and know-how therein conceived, generated or reduced to practice during the Study.

1.1.5 **Invention:** shall be understood in the widest sense of the word, in particular including but not limited to patentable and non-patentable technical inventions, discoveries, improvements, and innovations of any kind.

1.1.6 **Party:** means Mylin Biotech, Institution and Principal Investigator and "Parties" shall mean all of them.

1.1.7 **Person:** means any individual, corporation, company, partnership, trust, limited liability company, association or other entity.

1.1.8 **Study Site:** means the premises on which the Study will be carried out.

1.1.9 **Study:** means the investigation to be conducted at the Study Site in accordance with the Protocol.

1.10 **Study Team:** means the Principal Investigator, Sub-Investigator(s), Institution staff, employees Of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

1.11.1 **Regulatory Approval:** means any and all permits, consents, grants, approvals, authorizations, licenses, waivers, exemptions, concessions, sanctions, permissions, registrations, certificates, agreements, orders, declarations, filings, reports or notices of, with or to any Authority pursuant to Applicable Law.

1.11.2 **Research Staff:** Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

2. **Investigators and Research Staff.**

2.1 **Principal Investigator.** The Principal Investigator is an employee of the Institution who will be responsible for the direction of the Trial in accordance with applicable Institution policies. The Principal Investigator commits himself and his Research Staff to conduct the Trial as per the Protocol and the Applicable Laws, against fair compensation.

2.2 **Sub-investigators and Research Staff.** Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of that Trial as Sub-investigators or Research Staff.

2.3 **Obligations of Principal Investigator.** Principal Investigator shall be solely responsible for strict compliance by all Trial personnel, including the Sub-investigators and the Research Staff, with the terms of this Agreement. Principal Investigator shall ensure that any personnel who assist in the conduct of the Trial are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator will assume all those responsibilities assigned to all principal investigators under various Applicable Laws, rules, regulations, guidelines and standard including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards, and all Applicable Laws including those relating to the confidentiality, privacy and security of patient information.

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2.4 The Principal Investigator shall be solely responsible and liable for performance of the obligations under this Agreement by the Study Team. Any breach committed by the Sub-investigator or any other member of the Study Team shall be deemed to be a breach committed by the Principal Investigator. Nothing Contained herein shall discharge or relieve Principal Investigator from its obligations or liability hereunder.

2.5 **No Substitution.** Principal Investigator may not reassign the conduct of the Trial to a different principal investigator without prior written authorization from Mylin Biotech, In the event Mylin Biotech approves such replacement, such replacement principal investigator will be required to agree to the terms and conditions of this Agreement separately in writing. In the event Mylin Biotech does not approve a replacement principal investigator, Mylin Biotech will have the option to terminate this Agreement in accordance with the termination provisions below.

2.6 **Delegation of duties by Principal Investigator.** Principal Investigator may delegate duties and responsibilities to Sub-investigators or Research Staff only to the extent permitted by Applicable Law governing the Trial Conduct, as described below.

2.7 **Compliance with Institutional Policies.** Principal Investigator will comply with the policies and procedures of the Institution, with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Mylin Biotech promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the Parties will attempt to reach an appropriate accommodation.

3. **Protocol.** The Principal Investigator shall conduct the Trial in accordance with the Protocol.

3.1 **Amendments.** The Protocol may be modified only by a written Amendment, signed by both, Mylin Biotech and the Principal Investigator. The parties acknowledge that Protocol Amendments are also subject to approval by the responsible Institutional Ethics Committee ("IEC").

3.2 **Emergency Amendments.** If it is necessary to change the Protocol on an emergency basis for the safety of the Trial Subjects (hereinafter defined), Principal Investigator will notify Mylin Biotech and the responsible IEC as soon as practicable but, in any event, no later than three working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment duly executed by Mylin Biotech and the Principal Investigator.

3.3 **No Additional Research.** Principal Investigator represents and warrants that no additional research will be conducted on Trial Subjects during the conduct of the Trial, unless it is approved by Mylin Biotech in writing, and documented as a companion protocol or an Amendment to the original Protocol. Such prohibited research activities include analyses of biological samples from Trial Subjects for any non-therapeutic purpose.

4. **Institutional Ethics Committee.** Before the Trial is initiated, Principal Investigator will ensure that both the Trial and the informed consent form are approved by an IEC that complies with all applicable regulations. Principal Investigator will further ensure that the Trial is subject to continuing oversight by the IEC throughout its conduct.

4.1 **Trial Disapproval.** If, through no fault of Principal Investigator, the Trial is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Principal Investigator, as outlined below.

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5. **Trial Conduct.** Principal Investigator will conduct the Trial in accordance with the Protocol, Mylin's or its designee's written instructions and Applicable Law.

5.1 **Trial Initiation:** Prior to initiation of the Trial, Mylin Biotech shall organize an investigator meeting for all investigators who are taking part in the clinical trial for Mylin Biotech, at such place and time as finalized by Mylin Biotech (**"Investigator Meeting"**). The purpose of the investigator Meeting will including but not limited to, to make the investigators aware about – (i) scientific aspect of the clinical trial; (ii) standard operating procedures including documentation process and adverse event reporting; (iii) Protocol and various regulatory guidelines within which the investigator needs to conduct clinical trial for Mylin Biotech. The Principal Investigator agrees to attend the said Investigator Meeting along with such member of its Research Staff, as approved by Mylin Biotech (**"Attendees"**). Mylin Biotech agrees that it shall arrange for the travel and boarding and lodging of the Investigator Meeting Attendees.

6. **Mylin Biotech.** Mylin Biotech will provide the Principal Investigator with sufficient quantities of Mylin Biotech product that is being studied (**"Mylin Biotech"**) to conduct the Trial. If required by the Protocol and unless otherwise agreed in writing, Mylin Biotech will also provide placebo or comparator drug (**"Comparator Drug"**).

6.1 **Custody and Dispensing.** Principal Investigator will adhere to Applicable Law and industry standards requiring careful custody and dispensing of Mylin Biotech or Comparator Drug, as well as appropriate documentation of such activities.

6.2 **Control.** Principal Investigator will maintain appropriate control of supplies of Mylin Biotech or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Principal Investigator, Sub-investigators, or Research Staff.

6.3 **Use.** Principal Investigator will use Mylin Biotech or Comparator Drug only as specified in the Protocol. Any other use of Mylin Biotech or Comparator Drug constitutes a material breach of this Agreement.

6.4 **Ownership of Mylin Biotech.** Mylin Biotech is and remains the sole and exclusive property of Mylin. Mylin Biotech grants or assigns Principal Investigator no express or implied intellectual property rights in Mylin Biotech or in any methods of making or using Mylin Biotech.

6.5 **Payment for Mylin Biotech or Comparator Drug.** Principal Investigator will not charge a Trial Subject or third-party payer for Mylin Biotech or Comparator Drug or for any services reimbursed by Mylin Biotech under this Agreement.

7. **Representation and Warranties:**

7.1 The Principal Investigator and Institution hereby jointly and severally represent and warrant to Mylin Biotech the following:

a. The Principal Investigator is trained and qualified to conduct clinical trials at the Study Site, and the Study Team working on the Study shall be appropriately trained in ICH GCP and the Protocol;

b. The Principal Investigator and the Study Team shall perform the Study in an efficient and professional manner and shall complete the Study within the time period as informed by Mylin Biotech from time to time;

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c. The Principal Investigator and Institution shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective Authority(ies) under the applicable Regulatory Approval. It shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study in any manner;

d. The Principal Investigator and the Study Team shall conduct the Study under the review and direct supervision of Mylin Biotech, the EC, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to co-ordinate, review and safeguard the rights, safety and well-being of the Trial Subject;

e. The representation, warranties set or hereunder may be relied upon in any applications of any Authority(ies);

f. The Principal Investigator and/or the Institution shall not, at all times during the term hereof, neither appoint nor utilize the services nor assign the activities of the Study contemplated under the Protocol to any Sub-investigator(s), who is debarred under any regulatory requirements/ Law or statutes from undertaking or performing the Study or the obligations hereunder;

g. The Principal Investigator shall ensure the safe custody of the Study Drug in accordance with the Protocol and shall not use the Study Drug for any purpose other than the purpose of this Agreement;

h. The Principal Investigator and/or the Institution shall publish any data in connection with the Study only in accordance with the Protocol;

i. The Principal Investigator and the Institution shall promptly notify Mylin Biotech in writing of any change in the truth of any of the aforesaid representations;

j. The Principal Investigator shall take necessary and appropriate steps to inform its Study Team of the terms and conditions of this Agreement and to ensure that such persons comply with the terms and conditions of this Agreement;

k. The Principal Investigator and the Institution shall at all times be accountable to Mylin Biotech for any and all breach, action, inaction or omission, committed by the Study Team, support staff and personnel provided by it for conducting the Study;

l. In the event the Study Site is inspected and the Study data are audited / examined by any Authority(ies) having competent jurisdiction under the regulatory requirements or Applicable Laws, the Principal Investigator and/or the Institution shall forthwith notify Mylin Biotech in writing of such inspection, inquiry, audit or examination conducted by such Authority(ies);

m. The Principal Investigator shall co-ordinate, co-operate with and assist in conducting the Study and shall perform such obligations and duties, as may be assigned or imposed upon him/her, in a timely manner, in accordance with the regulatory requirements and Applicable Law;

n. The Principal Investigator and/or the Institution shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study / Study Agreement in any manner;

o. The Principal Investigator and the Institution shall apply for, and obtain, maintain, renew all the applicable approvals including Regulatory Approvals, if any, during the term of the

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Agreement, Further, the Principal Investigator and the Institution shall during the term of this Agreement abide by all Applicable Laws, as amended from time to time;

p. The Principal Investigator and the Institution shall perform such other roles, responsibilities and duties related to the Trial, as may be reasonable required by Mylin Biotech from time to time; and

q. The Principal Investigator shall maintain true and complete financial records relating to the Study performed under this Agreement including costs and expenses incurred in connection with the Study.

7.2 Each Party hereby represents, warrants and undertakes as follows:

a. it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement;

b. this Agreement constitutes a legal, valid and binding obligation of the Parties; and

c. Neither the execution nor the delivery of this Agreement nor its performance would violate any agreement nor constitute a default under any such agreements to which the Parties are a party.

7.3 Mylin Biotech hereby represents and warrants to the Institution that it will, during the term of this Agreement abide by all Applicable Laws Including provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, as amended from time to time.

8. Intellectual Property Rights

8.1 The Principal Investigator and/or the Institution shall duly notify Mylin Biotech, in a confidential written notification, of any Invention and/or Intellectual Property Rights arising as an incident to and/or during the conduct of the Study.

8.2 Principal Investigator and the Institution acknowledge and agree that any Intellectual Property Rights relating to the Study shall be deemed to be works for hire created for Mylin Biotech, who shall claim such Intellectual Property Rights through Mylin Biotech and shall hold sole title to such Intellectual Property Rights. All such Intellectual Property Rights shall be deemed assigned to Mylin Biotech, and the Principal Investigator and the Institution shall do or cause to be done all such things and deliver or cause to be delivered all such documents as are necessary to give effect to this provision. The Principal Investigator shall ensure that all members of the Study Team assign all Intellectual Property Rights to Mylin Biotech.

8.3 **Principal Investigator and the Institution hereby jointly undertake that:**

a. The Principal Investigator will unequivocally transfer to Mylin Biotech the right to obtain patent on Invention.

b. Principal Investigator shall take all steps necessary to secure Inventions and Intellectual Property Rights for the benefit of Mylin Biotech. To ensure the duties set forth in this Section are carried out, Mylin Biotech may, at its own cost, request that Principal Investigator prepares and signs appropriate documents and authorisations, as well as performs any other actions necessary for the rights to Inventions and Intellectual Property Rights to be vested fully and effectively in Mylin Biotech, Mylin Biotech has the exclusive right to choose the form of protection of intellectual property.

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c. Principal Investigator shall refrain from taking any actions that would prejudice the Intellectual Property Rights of Mylin Biotech in any way. Moreover, Principal Investigator agrees to inform Mylin Biotech of any known infringement of its Intellectual Property Rights, and to support Mylin, at Mylin's expense, in actions intended to protect Mylin's Intellectual Property Rights.

d. Mylin Biotech shall have exclusive and undisputed ownership of anything related to the Study, including without limitation, the Confidential Information, the Study Drug, the CRFs, the Protocol and the Study Results.

8.4 Any and all Intellectual Property Rights in relation to the foregoing in Section 8.3(d) shall vest exclusively in Mylin Biotech.

8.5 The provisions of this Section shall survive the expiration and/or termination of this Agreement indefinitely.

9. **Research Grant.** Funding will be made to the Principal Investigator by way of grant payments in accordance with **Attachment-B.** The grant represents Principal Investigator's costs of conducting the Trial. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the parties, The Principal Investigator will not directly or indirectly seek or receive compensation from patient(s) participating in the Trial ("Trial Subject(s)") or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Mylin Biotech including, but not limited to, Mylin Biotech, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Mylin Biotech and/or Comparator Drug administration.

10. **Trial Subject Enrolment.** Principal Investigator has agreed to enrol Trial Subjects in the Trial in accordance with the Protocol. Mylin Biotech reserves the right, on written notice, to limit the number of Subjects to be included in the Study, including, but not limited to instances where the recruitment target has been reached.

10.1 **Multi-Center Studies.** Mylin Biotech may discontinue patient enrolment if the total enrolment needed for a multi-center Trial has been achieved.

11. **Informed Consent.** Principal Investigator undertakes that it will obtain a written Informed Consent Form ("ICF") for each Trial Subject explaining the Trial Subject's rights in connection with its relationship with the Institution and Principal Investigator. Principal Investigator will maintain a signed original of that ICF in the Trial Subject's record. Principal Investigator will provide Mylin Biotech an opportunity to review and approve the content of the ICF, including any revisions made during the course of the Trial, before it is used. Principal Investigator will allow Mylin Biotech or its designee to inspect signed ICF's or photocopies thereof during monitoring visits or audits. Principal Investigator will submit any modifications it may propose to the ICF to Mylin Biotech for review and written approval by Mylin Biotech before submitting the ICF for IEC approval. The Principal Investigator will ensure that every Trial Subject signs and ICF approved by Mylin Biotech and the IEC before the Trial Subject begins participating in the Trial. When required, the approved ICF will be modified to reflect amendments to the Protocol.

12. **Adverse Events.** Principal Investigator will report adverse events experienced by Trial Subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone. If the Trial Subject is physically

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injured by Mylin Biotech or properly performed Trial procedures and the Institution, Principal Investigator and other individuals participating in the conduct of the Trial have followed the Protocol, all Applicable Laws and regulations and all directions of Mylin Biotech, Mylin Biotech will reimburse the reasonable costs of medical expenses necessary to treat the injury.

13. **Protected Health Information.** The Parties recognize a common goal of securing all individually identifiable health information and holding such information in confidence and protecting if from unauthorized disclosure. Principal Investigator represents and warrants that he/she will comply with the provisions of any Applicable Laws relating to the confidentiality, privacy and security of such information.

13.1 **Authorization to Use and Disclose Health Information.** Principal Investigator will obtain a written privacy authorization, complying with Applicable Law, for each Trial Subject which will enable Principal Investigator to provide Mylin Biotech and other persons and entities designated by Mylin Biotech with completed Case Report Forms (**"CRFs"**), source documents and all other information required by the Protocol. Mylin Biotech, though not a covered entity, recognizes that, pursuant to this Agreement, it has the responsibility to protect all individually identifiable patient information and to restrict the use of such information to those persons and entities, including consultants, contractors, subcontractors and agents, who must have access to such information in order to fulfil their assigned duties with respect to the Trial, Such use also will be restricted to those uses permitted in the authorization forms and neither Mylin Biotech nor any party to whom Mylin Biotech may disclose individually identifiable health information may use such information to recruit research subjects to additional studies, to advertise additional studies or products, or to perform marketing or marketing research. Principal Investigator will provide Mylin Biotech an opportunity to review and approve the content of the authorization (including any revisions made during the course of the Trial) before it is used.

14. **Confidential Information.** During the course of the Trial, Principal Investigator and/or the Institution may receive or generate information that is confidential to Mylin Biotech Affiliate.

14.1 **Definition.** Excepts as specified below, Confidential Information includes all information provided by Mylin Biotech, or developed for Mylin Biotech, Inventions (hereinafter defined), and all date collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with Mylin Biotech, commercialization and Trial strategies, trade secrets and know-how disclosed by Mylin Biotech to Principal Investigator and/or the Institution directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

14.2 **Exclusions.** Confidential Information does not include information that is in the public domain prior to disclosure by Mylin Biotech; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Principal Investigator; is already known to Principal Investigator and the Institution at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Principal Investigator and the Institution, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

14.3 **Obligations of Confidentiality.** Unless Mylin Biotech provides prior written consent, Principal Investigator may not use Confidential Information for any purpose other than the authorized in this Agreement, not may Principal Investigator and the Institution disclose Confidential Information to any third party except as authorized in this Agreement or as required by law. Required disclosure of Confidential Information to the IEC or to an applicable Authority is specifically authorized.

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14.4 **Disclosure Required by Law.** If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Principal Investigator and/or the Institution notifies Mylin Biotech or Mylin Biotech in writing as far as possible in advance of the disclosure so as to allow Mylin Biotech to take legal action to protect its Confidential Information, discloses only that Confidential Information required to comply with the legal requirement, and continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 **Survival of Obligations.** For Confidential Information other than Trial Data and Biological Sample Analysis Data, these obligations of nonuse and nondisclosure survive termination of this Agreement. Permitted uses and disclosures of Trial Date are described in Sections 18 (Publications) of this Agreement.

14.6 **Return of Confidential Information.** If requested by Mylin Biotech, Principal Investigator will return all Confidential Information, at Mylin's expense, except that required to be retained at the Study Site by Applicable Law. However, Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. **Trial Data, Biological Samples, and Records.**

15.1 **Trial Data.** During the course of the Trial, Principal Investigator will collect and submit data to Mylin Biotech or it agent, as specified in the Protocol. This includes CRFs (or their equivalent) or electronic data records, as well as any other documents or materials created for the Trial and required to be submitted to Mylin Biotech or its agent, such as X-ray, MRI, or other types of medical images, ECG, EEG, or other types of tracings or printouts, or data summaries (collectively, "Trial Data"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Trial Data.

a. **Ownership of the Trial Data** Subject to Principal Investigator's right to publish, with prior written intimation to Mylin Biotech, the results of the Trial and the non-exclusive license that permits certain uses, Mylin Biotech is the exclusive owner of all the Trial Data.

b. **Non-Exclusive License.** Mylin Biotech grants Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal research or educational purposes.

c. **Medical Records.** Medical records relating to Trial Subjects that are not submitted to Mylin Biotech may include some of the same information as is included in Trial Data; however, Mylin Biotech makes no claim of ownership of those documents or the information they contain.

d. **Personal Information Protection.** Each party represents and warrants that procedures compatible with relevant personal information and data protection laws and regulations will be employed so that processing and transfer of such information and data identifiers will not be impeded.

15.2 **Biological Samples.** If so specified in the Protocol, Principal Investigator may collect and provide to Mylin Biotech or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Trial Subjects for testing that is not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomics, or biomarker testing ("Biological Samples").

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a. Use. Principal Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Sample Date. Mylin Biotech or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, Mylin Biotech will not provide the results of such tests ("Sample Data") to the Principal Investigator or Trial Subject. Sample Data will be treated as Trial Data; therefore, if Mylin Biotech provides Sample Data to the Principal Investigator, that data will be subject to the permitted use of Trial Data as outlined in this Agreement.

15.3 **Records.** Principal Investigator will ensure that Trial Subject's Trial records, which include that Principal Investigator's copies of all Trial Data as well as relevant source documents (collectively, "Records"), are kept up to date and maintained in accordance with Applicable Law.

a. **Retention.** Principal Investigator will retain all records and documents pertaining to the Trial for a period in accordance with Applicable Law and the Protocol. Principal Investigator will retain Records, under storage conditions conducive to their stability and protection, for a period of fifteen (15) years after termination of the Trial unless Mylin Biotech authorizes, in writing, earlier destruction. At the end of such required retention period, Principal Investigator will not destroy any such records until it has obtained Mylin's prior written permission to do so; provided, however, that if Mylin Biotech does not give written permission to Principal Investigator to destroy such records within thirty (30) days of Principal Investigator's request to Mylin Biotech, then Principal Investigator may forward all such records to Mylin Biotech, at Mylin's expense, or continue to retain such records. Principal Investigator further agrees to permit Mylin Biotech to ensure that the records are retained for a longer period if necessary, at Mylin's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16. Inspections and Audits.

16.1 **Access.** Upon reasonable request by Mylin Biotech, authorized representatives of Mylin Biotech, and/or authorized representatives of the applicable Authority, may during regular business hours examine and copy; all CRFs and other Trial records (including Trial Subject records and medical charts; Trial Subject consent documents; drug receipt and disposition logs); examine and inspect the facilities and other activities relating to the Trial or the IEC; and observe that conduct of the Trial.

16.2 **Notice.** Principal Investigator and/or the Institution will inform Mylin Biotech within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Principal Investigator or research staff with regard to the Trial; will provide Mylin Biotech with a copy of any communications sent by such persons; and will provide Mylin Biotech or Mylin Biotech the opportunity to participate in any proposed or actual responses by Principal Investigator to such communications.

16.3 **Cooperation.** Principal Investigator and the Institution will ensure the full cooperation of the researchers and IEC members with any such inspection and will ensure timely access to applicable records and data. Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records. Principal Investigator will promptly forward to Mylin Biotech copies of any inspection findings that Principal Investigator received from a regulatory agency in relation to the Trial. Whenever feasible, Principal Investigator will also provide Mylin Biotech with an opportunity to

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prospectively review and comment on any responses to regulatory agency inspections in regard to the Trial.

17. **Inventions.** If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Principal Investigator and/or the Institution will promptly inform Mylin Biotech. Principal Investigator will assign all interest in any such Invention to Mylin, free of any obligation or consideration beyond that provided for in this Agreement. Principal Investigator will provide reasonable assistance to Mylin Biotech in filling and prosecuting any patent applications relating to Invention, at Mylin's expense.

18. **Publications.** Principal Investigator acknowledges that Mylin Biotech has the right to use the Study Results in any manner deemed appropriate to Mylin's business interests, both during, and following termination/expiry of , this Agreement. Mylin Biotech shall have to sole right to retain the ownership of any and all data arising out of the conduct of clinical trials in relation to the Study. Upon completion of the Study, Mylin Biotech shall publish the results of the authorized clinical trial, either positive or negative, in scientific journals and with mention of the EC of clinical research that approved the study. Where Principal Investigator requires the use of the Study Results for publication, the Principal Investigator shall seek Mylin's written approval 90 (ninety) days in advance; such consent shall not be unreasonably withheld. If part of a multi-center trial. Principal Investigator agrees that the first publication is to be a joint publication involving all centers. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of Trial at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Agreement.

19. **Publicity.** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, Mylin Biotech reserves the right to identify the Principal Investigator in association with the listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

20. **Indemnification.**

20.1 Mylin Biotech agrees to indemnify and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses arising out of a Trial Subject injury, the design of the Trial, or the specifications of the Trial protocol. Trial Subject injury means a physical injury or drug-related psychiatric event caused by administration or use of Mylin Biotech required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial. Mylin Biotech further agrees to reimburse Principal Investigator for the reasonable cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject injury. Principal Investigator agrees to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Principal Investigator further agrees to promptly notify Mylin in writing of any such medical injury.

a. **Exclusions.** Excluded from this agreement to Indemnify are any claims for damages resulting from (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Mylin Biotech (b) failure of an Indemnified Party to comply with any Applicable Law

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and governmental regulations, or (c) fraud, negligence or withful misconduct by an Indemnified Party.

b. **Notice and Cooperation.** Principal Investigator agrees to provide Mylin Biotech with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by Mylin Biotech, Principal Investigator agrees to authorize Mylin Biotech to carry out the sole management of defense of an indemnified claim.

c. **Settlement or Compromise.** No settlement or compromise of a claim subject to this indemnification provision will be binding on Mylin Biotech without Mylin's prior written consent. Mylin Biotech will not unreasonably withhold such consent of a settlement or compromise. Neither party will admit fault on behalf of the other party without the written approval of that party.

20.2 Principal Investigator and the Institution shall jointly and severally indemnify and hold harmless Mylin including its directors, employees; representatives, agents etc., and shall be fully liable for all claims, damages, losses, liabilities, costs or expenses (including reasonable legal fees) resulting or arising from:

a. failure by the Principal Investigator and the Study Team (Which shall include his/her employees, agents and representatives) to comply with the Applicable Law, the terms of this Agreement, ICH GCP and/or other nationally established guidelines, the approval of the IEC, Protocol or written instructions from Mylin Biotech;

b. any finding, requirement, determination or observation by any Authority (including but not limited to the FDA) which makes it necessary or desirable for Mylin Biotech to redo the Study;

c. failure by the Principal Investigator, the Study Team and/or the Institution to comply with Applicable Law;

d. any negligent act or omission or wilful misconduct or fraud by Principal Investigator, the Study Team and/or the Institution, fraud or misrepresentation.

20.3 Except in the case of fraud, willful misconduct, gross negligence or breach of any Applicable Law, neither Party shall be entitled to incidental, indirect, consequential nor special damages under any theory of Applicable Law arising in connection with such default or breach of the other Party's obligations under this Agreement, or any documents related thereto.

20.4 In the event of any act of Principal Investigator and/or the Institution, which renders the Study invalid, to the extent Principal Investigator and/or the Institution is liable, Mylin Biotech shall, in addition to any other right that Mylin Biotech may have under law or equity, have the option at its sole discretion to either (a) request Principal Investigator to repeat the Study at Principal Investigator's own cost, or (b) require Principal Investigator and/or the Institution to promptly refund Mylin Biotech the compensation received by Principal Investigator and/or the Institution under this Agreement and bear any additional costs that Mylin Biotech may incur for repeating the Study. Further without prejudice to any other rights that Mylin Biotech may have under law or equity, Mylin Biotech may, at its discretion, forthwith terminate this Agreement.

21. Termination.

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21.1 **Termination Conditions.** This Agreement terminates upon the earlier of any of the following events:

a. **Disapproval by IEC.** If, through no fault of Principal Investigator, the Trial is never initiated because of IEC disapproval, this Agreement will terminate immediately.

b. **Trail Completion.** For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subject; receipt by Mylin Biotech of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either party.

c. **Early Termination of Trial.** If the Trial is terminated early as described below, the Agreement will terminate after receipt by Mylin Biotech of all relevant Protocol-required data, Trial documents and Biological Samples and receipt of all payments due to either party.

(1) **Termination of Trial Upon Notice.** Mylin Biotech reserves the right to terminate the Trial for any reason upon thirty (30) days written notice to Principal Investigator.

(2) **Immediate Termination of Trial by Mylin Biotech.** Mylin Biotech further reserves that right to terminate the Trial immediately upon written notification to Principal Investigator and/or the Institution for causes that include – (i) failure to cure any breach within 15 days of written notice by Mylin Biotech notifying Principal Investigator of such breach; (ii) failure to enrol Trial Subjects at a rate sufficient to achieve Trial performance goals; (iii) material unauthorized deviations from the Protocol or reporting requirements; (iv) circumstances that in Mylin's opinion pose risks to the health or wellbeing of Trial Subjects; or (v) regulatory agency actions relating to the Trial or Mylin Biotech or Comparator Drug.

(3) **Immediate Termination of Trial by Principal Investigator.** Principal Investigator reserves the right to terminate the Trial immediately upon notification to Mylin Biotech or Mylin Biotech if requested to do so by the responsible IEC or if such termination is required to protect the health of Trial Subjects.

21.2 **Payment upon Termination.** If the Trial is terminated early in accordance with this Agreement, Mylin Biotech will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with **Attachment-B,** less payments already made. The termination payment will include any non-cancellable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by Mylin Biotech, and only to the extent such costs cannot reasonably be mitigated. If the Trial was never initiated because of disapproval by the IEC, Mylin Biotech will reimburse Principal Investigator for any other expenses that were prospectively approved, in writing, by Mylin Biotech.

21.3 **Return of Materials.** Unless Mylin Biotech instructs otherwise in writing, Principal Investigator will promptly return all materials supplied by Mylin Biotech, at Mylin's expense, for Trial conduct, and any Mylin-supplied Equipment. Principal Investigator will return and/or destroy, as required by Mylin Biotech, at Mylin's expense, unless otherwise specified by Mylin Biotech, any unused Mylin Biotech or Comparator Drug.

22. **Insurance.** The Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with local standards for all medical professionals conducting the Trial.

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23. **Debarment, Exclusion, Licensure and Response.** Principal Investigator and the Institution jointly and severally certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under Applicable Law with respect to services to be performed under this Agreement. Principal Investigator and the Institution also certifies that they are not excluded from any governmental health care program. Principal Investigator and the Institution further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and the Institution will notify Mylin Biotech promptly in writing to the extent possible, within two (2) business days if either of these certifications needs to be amended in light of new information or if Principal Investigator becomes aware of any material issues related to the medical licensure of any associated Trial researchers. Principal Investigator and the Institution will cooperate with Mylin Biotech regarding any responsive action necessary.

24. **Assignment and Delegation.** Mylin Biotech may at any time and upon written notice to Principal Investigator and/or the Institution assume the obligations and rights of Mylin Biotech or substitute Mylin Biotech with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Principal Investigator and/or the Institution to another without the prior written consent of Mylin Biotech, and the express agreement of Principal Investigator and/or the Institution, Mylin Biotech, and the requisite new assignee or subcontractor. Principal Investigator and the Institution must notify Mylin Biotech, at least 90 (ninety) days in advance, prior to moving to another location. This Agreement will bind and inure to the benefit of the successors and permitted assigns of Mylin Biotech.

25. **Equipment.** Mylin Biotech may provide, or arrange for a vendor to provide, certain equipment for use by Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C.

26. **Survival of Obligations.** Obligations relating to Research Grant, Confidential Information, Inventions, Records, Publications, Publicity, Debarment and Exclusion, and Indemnification survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

27. **Entire Agreement.** This Agreement contains the complete understanding of the parties and will, as of the Effective Date, supersede all other agreements between the parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the mutual consent of the parties. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

28. **Conflict with Attachments.** To the extent that terms or provisions of this Agreement conflict with terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in a writing between the parties.

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29. **Relationship of the Parties.** The relationship of Principal Investigator and/or the Institution to Mylin Biotech is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

30. **Force Majeure.** Neither party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) promptly notified to the other party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) days, then the parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

31. **Governing Law.** Subject to the terms of the Trial Conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions. The Parties agree to submit all their disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of Lucknow.

32. **Notices.** All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

TO MYLIN BIOTECH INDIA PVT LTD:
Attention. To:

TO PRINCIPAL INVESTIGATOR:
Attention. To:

TO INSTITUTION:
Attention. To:

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In the event that the parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence and binding Agreement with the expectation that original documents may later be exchanged in good faith.

[INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

ACCEPTED AND AGREED BY:
PRINCIPAL INVESTIGATOR

By:
Signature

Printed Name DR ANTI A SAIGAL

Title Professor

19/3/19
Date

ACCEPTED AND AGREED BY:
MYLIN BIOTECH

By: P. PRABHAKARAN
Signature

Printed Name

Title

Date

ACCEPTED AND AGREED BY:
INSTITUTION

By:
Signature

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Printed Name

Title

Date 14.05.2019

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Attachment A

Protocol

The clinical Trial to be performed pursuant to this Agreement shall be that set forth in the Protocol dated 28/August/2018. and incorporated into this Agreement attached hereto by reference in addition to all current and future amendments thereto, which is incorporated into this Agreement by reference and entitled:

Protocol Number: NIZY-BYT-MB-18 A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients.

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Attachment B

RESEARCH GRANT PAYMENT TERMS

B-1. **General Terms.** Principal Investigator ("Payee") will be paid the per patient grant amount as outlined on **Attachment-D** (Research Grant Worksheet) per Trial Subject properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled or continuing in the Trial in violation of the Protocol.

B-2. **Payment Terms.** Research grant payments for each Trial Subject will be made in Indian Rupees (INR) quarterly and based on approval of invoices submitted. Invoices will be issued by Payee upon notice delivered by Mylin Biotech. Payments will be made in accordance with eCRFs submitted and monitored, and in accordance with Attachment D "Research Grant Worksheet". Monitoring will occur based on site enrolment and completion of data entry. Payments will be made in quarterly instalments on a pro-rata basis. Undisputed invoices will be paid by Mylin Biotech within 60 (sixty) days of such invoice issue date.

B-3. **Non-Procedural Costs.** Payee will be paid for additional non-procedural costs that are pre-approved by Mylin Biotech, as set forth in Attachment D. To request payment for such costs, Payee will remit an itemized invoice to Mylin Biotech or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment D.

B-4. **Final Payment.** At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Mylin's review. The final payment will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Mylin Biotech is returned; and all close out issues are resolved and procedures completed, including final IEC notification. All queries must be resolved within five (5) days of receipt by Payee any time during the Trial. Mylin Biotech or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any Payee will promptly reimburse Mylin Biotech amounts overpaid within thirty (30) days of notification by Mylin Biotech or designee.

B-5. **Taxes.**

(1) All payments to Payee by Mylin Biotech will be subject to deduction of TDS.

(2) The Payee shall comply with all its obligations under applicable tax laws in force at the time, including all laws, rules and regulations under the Goods and Services Tax ("GST") Regime ("GST"). In particular, the Payee shall pay its taxes and make all filings necessary under GST Law, including the GSTR-1 form, within the prescribed timelines. The Payee shall defend, indemnify and hold Mylin Biotech harmless against all losses, claims and liabilities arising out of any failure by the Payee to meet its obligations under GST Law, including any failure or error that results in denial of any tax credit under GST law to Mylin Biotech, The Payee shall full co-operate with Mylin Biotech to respond to

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the relevant tax authorities' demands, and to resolve any mismatch of Mylin Biotech and the Payee's GST filings within the timelines prescribed under the GST Law.

(3) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable Authority with respect to or measured by compensation paid to Payee under this Agreement. Mylin Biotech will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

B-6. **Screen Failures.** A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrolment into the Trial. Screen Failures will be reimbursed, if at all, as outlined in Attachment D, based on work completed pursuant to the Protocol.

B-7. **Patient travel reimbursement.** Mylin Biotech, will reimburse reasonable patient travel related expenses per trial subject visit, up to the maximum amount listed in the Attachment D. Any reimbursement exceeding this limit will require prior written Mylin Biotech approval. Any payment will be based on the invoice together with supporting documentation (i.e. receipts) submitted to Mylin Biotech.

B-8. **Administrative Start-up Fees.** Within sixty (60) days of execution of this Agreement and receipt of a valid invoice, Mylin Biotech, will pay a non-refundable start-up payment in the amount listed in the Attachment D for the work performed to prepare for site activation and enrolment (including but not limited to, feasibility study, initial training of Protocol, briefings, advance talks, provisions of room for the monitoring, initiation of the Study at the Center, training of the future Members of the Study Team, participation in Investigator's meetings, contract review activities, the cost for purchasing small equipment, set-up costs for equipment and all other preparation).

B-9. **Necessary Procedures.** Payee will be reimbursed for valid necessary visits and procedures. Payment for any necessary procedure due to patient safety will be reimbursed at the agreed upon unit cost in the budget, or if there is no such unit cost in the budget, at the appropriate unit cost pre-approved by Mylin Biotech in writing, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Mylin's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Mylin Biotech will be notified as soon as practicable after the fact.

B-10. **Payee.**

The research grant payments will be made to the following payee and address:

Payee Name: Director, SGPGIMS Research Scheme Account, Lucknow
Payee Address: Raebareli Road, Lucknow, Uttar Pradesh 226014
Payee GST Number: 09AAAJS3913N2ZN
Payee PAN No: AAAJS3913N
Payee Bank Account Details: Saving account
Bank Name: State Bank of India
Bank Address: SGPGIMS Branch, Lucknow
Bank Account Number: 10095237491
IFSC Code: SBIN007789
Email address for remittance information: director@sgpgi.ac.in

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In cast of changes in the Payee's bank account details, Payee is obliged to inform Mylin Biotech in writing, but no amendment to this Agreement shall be required.

B-11. **Invoices.** All invoices must be issued and forwarded to the following as instructed:

MYLIN BIOTECH INDIA PVT LTD.
#40/11-1 2nd floor
Govindraj Nagar, Magadi Road
Bangalore - 560040

Each invoice must contain: (1) Mylin Biotech name, (2) Protocol Number, (3) Project Code, (4) a summary of the reimbursement to be made in compliance with the Research Grant Worksheet, and (5) the GST Registration number, (6) if GST reverse charges mechanism applies, the note "GST reverse charges applicable".

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation.

Any invoices submitted by the Payee more than 45 (forty five) days after the database lock will not be reimbursed.

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CLINICAL TRIAL AGREEMENT

Preamble:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow is a super specialty hospital, established by Government of Uttar Pradesh, as a center of excellence for providing medical care, education and research of high order and is chartered to function as a university under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, 1983. [Hereinafter referred to as "Act"]

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day 30/10/2018 **AMONG**

MYLIN BIOTECH INDIA PVT. LTD, a company originally incorporated in Bangalore and registered under section 592 of Companies act, 1956 as having place of Business and one of its office is located at #40/11-1 2nd floor, Govindraj Nagar, Magadi Road Bangalore -560040. through it **MYLIN BIOTECH INDIA PVT. LTD** "Sponsor"] of the First part.

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India, through its **"Director/Director's Nominee**..... [herein referred to as "Institute"] of the Second part.

AND

Professor Dr. Anitha Saxena a, **Department of Nephrology, Sanjay Gandhi Post Graduate institute of Medical Sciences** [hereinafter referred to as **"Principal Investigator"**] of the Third Part.

WHEREAS The Sponsor, Institute and, Principal Investigator are willing to jointly carry out the Study Number: **NIZY-BYT-MB-18** Entitled **A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients. [Hereafter referred to as "Study"]** described in Study Protocol;

AND WHEREAS Sponsor is desirous of engaging the said Principal Investigator and Institute for carrying out the Study through **CRO [if needed]**

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

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1.0 Statement of work

1.1 "Study" shall be deemed to be "Clinical Trial" as defined in rule-122 DAA of the Drugs and Cosmetics Rule, 1945.

1.2 Sponsor shall provide Principal Investigator with a sufficient quantity of Study Supplies to conduct the Study at investigational Site in timely manner. Institute and Principal Investigator shall use Study Supplies only to conduct the Study in accordance with the Protocol; All Study Supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of Sponsor, unless otherwise designated. The Institute and Principal Investigator will be responsible for the return of excess, unused Study Supplies to the Sponsor.

1.3 Study Timelines: Study Timelines for the purpose of this Agreement will be as per need of Protocol.

2. Obligations and Responsibilities of Principal Investigator

2.1 The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria.

2.2 The Principal Investigator will conduct the study in accordance with protocol, Schedule Y and ICMR Guidelines along with Helsinki and ICH Guidelines for international studies.

2.3 The Principal Investigator will make necessary arrangement for inspection of documents etc. by sponsor's monitor, official of regulatory agency or IEC nominee.

2.4 The Principal Investigator shall report all serious and unexpected adverse events and/ or death to the Licensing Authority, Sponsor, and IEC as per Appendix XI of Schedule-Y of Rules.

2.5 The Principal Investigator shall forward its report on Serious Adverse Event of Death after due analysis of all factors with his opinion to Chairman of IEC, Chairman of Expert Committee and Head of the Institute and the Licensing authority as per Appendix X of schedule Y.

2.6 The Principal Investigator shall forward its report on Serious Adverse Event other than Death after due analysis of all factors with his opinion to Licensing Authority, Chairman of IEC and Head of the Institute as per Appendix X of schedule Y.

2.7 The Principal Investigator will be responsible for proper and prompt filling of CRF, preservation of investigation reports and recordings.

2.8 During and following a Clinical Trial Subject's participation in Study, the Principal Investigator shall ensure that adequate medical care is provided to the participant (Clinical Trial Subject) for any adverse events.

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2.9 The Principal Investigator will ensure enrolment of trial participants after obtaining informed consent including audiovisual recording and also informing the provisions of adequate treatment and compensation for SAE as per schedule Y.

2.10 Principal Investigator shall complete the Clinical Trial under his supervision as per the agreement and the Statutory provisions, but if for any reason he/she is unable to carry over the study it shall be his/her responsibility to hand over the study to his/her Co-PI or to any of the Faculty members of the Institute, to be decided by the Head of Department of the PI or Director and obtain the approval of the Ethics Committee and the Sponsor.

2.11 The Principal Investigator will be responsible for proper account of receipt, utilization and return of unused sample of trial drug to sponsor and prevent its use for any other study.

2.12 The Principal Investigator will be responsible for providing non-compliance and progress report to Institutional Ethics Committee (IEC) within a week of occurrence or due date.

2.13 The Principal Investigator will be responsible for forwarding to IEC communications from sponsors within a week of receipt with comments for the need of any change in protocol or PIS.

2.14 The Principal Investigator will be responsible for obtaining IEC and sponsors permission for storage of blood or tissue samples for future use.

2.15 The Principal Investigator shall be responsible for obtaining sponsor's permission before publication or conference presentation of any data.

3.0 Obligation and Responsibilities of Institute:

3.1 Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory requirement.

3.2 Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.

3.3 Fulfillment of necessary obligations by IEC, PI and supporting staff.

3.4 Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.

3.5 Adequate treatment and compensation for SAE to trial participants.

3.6 Necessary infrastructure support to PI.

3.7 Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related Study documents.

3.8 Ensuring accuracy, completeness, legibility and timelines of the Data reported to the Sponsor in the Case Record Forms (CRFs) and in all required reports.

3.9 Study shall be terminated on the recommendation of IEC, when safety and benefit of Clinical Trial Subjects is doubtful.

3.10 Safety reporting as per schedule Y and/or Sponsor policy.

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3.11 Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records.

3.12 The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.

3.13 If Sponsor or CRO violates the terms of this Agreement or does not provide the claimed compensation to the subject then the Institute or Principal Investigator may not conduct any other further clinical trials of this sponsor.

3.14 Approval of study within 8 weeks of receipt of Investigator's brochure, protocol including PIS & CRF, regulatory approvals, draft CTA, Insurance policy and IEC fee from sponsor.

3.15 Approval of midterm changes within 8 weeks of receipt of documents.

3.16 Review of progress report DSMB report & SAE from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

3.17 Review of SAE at SGPGI and necessary action within the time frame decided by regulatory agencies.

3.18 Review of final report.

3.19 Approval of storage of blood or tissues for use in future studies.

3.20 Facilitate visit of sponsor's monitor or representative of regulatory agencies.

3.21 Institutional clearance for sample to be sent abroad for non-pharmacogenetic studies.

3.22 Archiving of data for 5 years (or longer if required by sponsor/regulatory agency).

3.23 Safeguarding IPR of sponsor and SGPGI.

3.24 Providing alternate PI if PI unable to continue.

3.25 Audited statement of utilization of Funds.

4.0 Obligation and Responsibilities of Sponsor

4.1 To provide investigator's brochure, Protocol, CRF draft CTA, Insurance policy from an Indian Insurance company and regulatory approvals.

4.2 To provide adequate supplies of trial drug, comparator and /or placebo prepared under proper quality control.

4.3 To provide Insurance cover for treatment and compensation of SAE and undertaking to supplement any amount not covered by the Insurance Company. Sponsor will also provide copy of Policy.

4.4 Undertaking to provide test drug free of cost to participants after termination of the trial if necessary till it become available in the country.

4.5 Not to send samples for Pharmacogenetic study abroad.

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4.6 To permit the storage of samples for future study if requested by Principle Investigator.

4.7 Provide a copy of final report at termination of the study.

4.8 Appropriate acknowledgement of contribution of SGPGI investigators in any resulting publication.

4.9 To define and follow procedure for premature termination.

4.10 To provide budget which should include cost of treatment, investigations and investigators charges, reimbursement of travel expenses to participants if necessary, Institute's overhead at the rate of 25% of the total budget and INR 25,000/- fee of IEC. Details of release of budget to be mutually settled.

5.0

5.1 Sponsor agrees that any injury or death of the Clinical Trial Subject occurring in Clinical Trial due to following reasons shall be considered as Clinical Trial related injury or death and the subject or his nominee as the case may be, will be entitled for financial compensation for such injury or death as per the notification of the DCGI & Gazette of India issued from time to time.

(a) Adverse effect of Investigational Product(s);

(b) Violation of the approved Protocol;

(c) Scientific misconduct or negligence by the Sponsor or his representative or CRO or Principal Investigator, Co-investigator or any member of his/her team

(d) Failure of Investigational Product to provide intended therapeutic effect;

(e) Use of placebo in a placebo-controlled Clinical Trial;

(f) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved Protocol;

(g) For injury to a child in utero because of the participation of parent in Clinical Trial;

(h) Any Clinical Trial procedures involved in the Study.

5.2 Sponsor should submit a status report on the Clinical Trial to the Licensing Authority at the prescribed Periodicity;

5.3 In case of studies permanently discontinued for any reason Sponsor shall submit a summary report to the Licensing Authority as per provisions of Schedule-Y of Rules.

6.0 Undertaking and Representation of Principal Investigator

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format given in Appendix VII of Schedule-Y of Rules.

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7.0 Undertaking and Representation of Institute

Institute hereby represents that:-

It has constituted the Institutional Ethics Committee as per the guidelines given in the Gazette of India & it has been registered with the DCGI vide letter No:……dated…..

(i) SOP is in compliance with GCP guidelines and applicable regulations;

(ii) It will ensure that IEC will discharge its responsibilities as per provisions of Schedule-Y

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that:-

It has furnished an undertaking along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of clinical trial related injury or death for which subjects will be entitled to compensation; as per provisions of rule 122 DAB (b) of Rules.

9.0 Administration

9.1 Overall responsibilities of the Study will rest with Principal Investigator, Institute and Sponsor to conduct the Study at Institute's premises.

9.2 The following Study plan will apply to the Study:

(a). Subject enrollment up to Institute's Enrollment Maximum (i.e.: Clinical Trial Subjects) shall be completed as stated in protocol. However, if the Institute and Principal Investigator are unable to enroll patients for the Study within 6 months of Investigation Site initiation Sponsor will be having the authority to change the Institute's Enrollment Maximum in a unilateral manner.

(b). Institute or Principal Investigator will not enroll more Study subjects than Institute's Enrollment Maximum Sponsor will not be obligated to make any payment with respect to any subject enrolled in excess of Institute's Enrollment Maximum.

(c). Subject to applicable law: Sponsor and Institute without any further obligation mutually may agree in writing to modify Institute's Enrollment Maximum.

(d). All subject visits will be conducted as proposed in the protocol. The sponsor will be informed is a visit is delayed by more than 2 weeks along with reason of delay.

(e). Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within 7 days after the subject's visit or, if applicable, receipt of the subject's test results.

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(f). All Data Queries from Sponsor must be completed and returned to Sponsor within a time frame mutually negotiated.

(g). any intentional changes of inclusion/exclusion criteria by the Principal Investigator or Study team will not be the liability of Sponsor.

10.0 Trial Drug; Materials Transfer; Records Retention; Inspection

10.1 Trial drug:

(i) Institute and Principal Investigator acknowledge that the trial drug/device is owned or controlled by Sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Institute or Investigator for the Trial, shall be construed to grant to either Institute or Principal Investigator any rights in or to the Compound.

(ii) Except as otherwise agreed by the Parties, Sponsor will provide the Compound and any control/placebo material to be administered to Trial subjects as part of the Trial (collectively, the **"Trial Drug"**) free of charge to Institute for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Trial subjects at the Trial Site in Strict compliance with the Protocol.

(iii) Institute and Principal Investigator shall use the Trial Drug solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial drug to any third parties. Institute and Principal Investigator shall handle, store, ship and dispose of the Trial drug as directed by Sponsor or its designee and in compliance with all applicable laws, rules and regulations.

(iv) Institute and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

(v) Neither support of the Trial, nor Institute participation in the Trial, impose any obligation, express or implied, on Institute or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's products.

(vi) Unless required by the Protocol, Institute will not modify the Trial Drug or its container. If the Institute policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Institute for use in a future study to be approved by IEC.

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10.2 Records Maintenance and Retention Investigator and Institute will maintain adequate and accurate records relating to the disposition of the Trial Drug and the performance of all required Protocol procedures on Trial subjects including but not limited to, written and audiovisual documents, medical records, charts pertaining to individual Trial subjects, "Case Report Forms **("CRF")** accounting records, notes, reports, and data. Institution will retain these documents for the longer period of at least 5 yrs. after completion or earlier termination of the Trial.

11.0 Representation and Warranties

11.1 Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the Trial in accordance with this Agreement and the Protocol.

11.2 Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

12.0 Confidentiality

12.1 Institute will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than patient medical records), including the Trial Results, Trial Inventions and information related thereto **(Confidential Information)**. Institute and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential Information will not include information that:

i. is or becomes publically available through no fault of Investigator or Institution.

ii. was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute form other source.

iii. is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

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iv. Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

12.2 Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

i. to comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Institute cooperate with Sponsor efforts to limit such disclosure by appropriate legal means:

ii. to protect any Trial subject's safety or provide appropriate medical care for any Trial subject, or to prevent a public health emergency with prompt notice to Sponsor

iii. for purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial subject related to the procedures included in the Protocol.

13.0 Return of Confidential Information

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

14.0 Trial Results and Inventions

14.1 Sponsor owns all data, Trial Results, Confidential Information, CRFs and all other information generated as a result of or in connection with the conduct of the Trial, excluding Institution's patient medical records and Principal Investigator's personal notes and hereby grants to the Institute a nonexclusive, non–transferable, non-sub licensable right to use the Trial Results solely for its own internal, non-commercial research, patient care, and educational purposes.

14.2 All inventions, ideas, methods works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institute, Principal Investigator or Trial Personnel: (i) as a result of or in connection with the conduct of the Trial (ii) that incorporate or use Confidential Information: or (iii) that are directly related to the Compound and in each case together will all intellectual property rights relating thereto (collectively, **Trial Inventions**"), will be the sole and exclusive property of Sponsor Or its designee. Institute and Principal Investigator will

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promptly disclose all Trial Investigations to sponsor in writing and interest in all Trial Investigations to sponsor or its designee. At sponsor's request and expense, Institute shall take and shall cause Principal Investigator and Trial Personnel to take, all additional actions as it deems necessary to perfect the interest of sponsor or its designee in Trial Investigations or to obtain patents or otherwise protect the interest of sponsor or its designee in Trial Investigations.

15.0 Payment

15.1 In consideration for conducting the Study Sponsor shall pay Institute and Principal Investigator as described in Annexure. All of Sponsor's payment obligations are conditioned upon Institute and Principal Investigator compliance with standards identified in this Agreement. Sponsor will not make payments, or, if payment has been made by Sponsor Institute and Principal Investigator will repay to Sponsor any payments, for Study visits, procedures, or other work associated with a Study subject if Sponsor determines that the Clinical Trial Subject's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

15.2 Sponsor shall pay on a Per Subject Cost for each Satisfactorily Completed Subject (as defined below) in accordance with Annexure as attached to this Agreement. If a subject is discontinued for reason stipulated in the Protocol, the Institute and Principal Investigator shall be paid a prorated rate for work completed.

(a). Per Subject Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Annexure-A. The estimated total amount per Clinical Trial Subject listed in Annexure-A is calculated for a Clinical Trial Subject that completes all the Study visits. Screening Visits are paid for consented Clinical Trial Subjects for whom all screening procedures are performed. All visit costs include Institutional overhead, staff fees and applicable taxes.

(b). the per subject costs is a fixed fee per patient which includes all costs and honoraria, including but not limited to:

-All Study related activities such as conduct of visit assessment and CRF completion -
Time and efforts of Principal Investigator/s and other Institute's Study personnel
-All manpower cost involved in the Study conduct
-All diagnostic test and other investigations
-Housing or hospital stay for patients including meals
-Patient reimbursement/ Compensation
-All over head costs
-Usage of Instruments/ equipments which during the Study should be having for proper

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(19)

-instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract

-Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of

-Institute infrastructure).

(c). A completed and evaluable patient means Patient:

(i). subjected to Study on whom all procedures have been performed and completed according to Protocol;

(ii). who is enrolled for the Study according to inclusion and exclusion criteria;

(iii). for whom all Data documented accurately and completely;

(iv). all Data queries resolved completely in mutually agreed timely manner; and

(v). for whom all source, CRF and other Study related documents completed as per protocol standard requirements as mentioned in Annexure.

15.3 **Screen Failures/ Drop-outs:** For drop-outs payment will be made by Sponsor on a pro rated basis for the number of completed visits and per screen failures (if applicable).

15.4 **Set-Up Fees:** Sponsor will pay the Institute an initial advance amount of **INR 25,000** (twenty five thousand only) within 15 days after obtaining the Ethics Committee and necessary regulatory approval. This up-front advance payment would be exclusive of Institutional overhead and service charges and shall be deducted/ adjusted on pro-rata basis from further subsequent payments.

15.5 **Hospitalization costs:** Apart from Study specific the in-house, treatment of the subject in the event of any SAE shall be paid by Sponsor to the Clinical Trial Subject.

15.6 **Institutional Ethics Committee Fees:** Institutional Ethics Committee review fees will be paid by sponsor as determined.

15.7 **Payments by Sponsor to Institute shall be directed as follows:**

Principal Investigator Fee/ Clinical Trial Subject Reimbursement and Hospitalization:

Payee Name (Account name)	**Director, SGPGIMS, Research a/c**
Account Number	**10095237491**
Bank Name	**State bank of India**
Branch Name	**SGPGI Branch, Lucknow**
Swift/IFSC Code	**SBIN0007789**
PAN Number*	**AAAJS3913N**
Send to	Dr. .....

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<<Cheque Delivery Address>>	....., **Department of .....Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014,U P, India**

15.8 Payments will be made **on monthly** basis according to actual work performed (CRF completion, source Data verification and CRF retrieval for completed visits). Advance payment will be adjusted against the 1st payment. Final payment will be made at the time of Investigation Site close-out visit or immediately after Investigation site close-out visit and payment will not be made until all queries are resolved.

15.9 Subject travel reimbursement is exclusive of Institutional overhead and will be done as mentioned in Annexure-A. However, Sponsor will release the funds to Institute and Principal Investigator for each Clinical Trial Subject, i.e., **Rs. .....**as per the Study schedule. However, it will be the obligation of Principal Investigator to pay the Clinical Trial Subject reimbursement on a pro rata basis **(Rs.....**- per visit). **Sponsor will provide an amount of .....N/A..... only for the future treatment Reimbursement to the Clinical Trial Subject who have completed the study.**

15.10 Payment will be made by Sponsor for Clinical Research coordinator salary per month **Rs. 20,000 (Twenty thousand rupees only)** for his/her efforts contribution to the Study. This payment would be inclusive of Institutional overhead and will be from the Investigation Site initiation visit to Investigation Site close out visit (until all the Data queries are resolved at the Institute's premises).

15.11 In the event there is a refund due to Sponsor at the time of premature termination of this Agreement by any party, the Institute agrees to remit the same to Sponsor within fifteen (15) days of the effective termination date.

15.12 **Tax deduction:** All fees and amounts listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the Institute for the Study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

16.0 Use of other parties' names

The Principal Investigator and Institute shall not use Sponsor's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ CRO/Institute.

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17.0 No joint venture etc.

This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18.0 Insurance and Indemnification

Insurance:

Institute shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

Indemnification:

Sponsor shall indemnify the Principal Investigator and Institute for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institute arising directly out of the performance of the Study pursuant to the Protocol and SOP; provided however

(i) Sponsor will not indemnify any Loss to the extent the Loss arises out of Indemnities' failure to conduct the Study in accordance with: (1) the Protocol except allowing for Protocol deviations which were medically necessary for a Clinical Trial Subject's safety or well-being and which were communicated to and accepted by Sponsor, (2) any other instructions by Sponsor, concerning the Study drug or device or a Study procedure, or (3) applicable local, state and central laws;

(ii) Sponsor will not indemnify any for Loss to the extent the Loss arose out of the negligence or wrongful acts or omissions of an Indemnity or any other person subject to an Indemnities' control;

(iii) The Sponsor will indemnify the subject suffering in any manner as a result of trial for any reason whatsoever including negligence or violation of the protocol by the Principal Investigator or any member of his team as per order of the incensing authority or the Institutional Ethics Committee.

19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

19.1 The Principal Investigator and Institute shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

19.2 The Principal Investigator and Institute shall notify to the Sponsor immediately by telephone

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or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute s facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the

Principal Investigator and Institute receives, obtains, or generates pursuant to any such study.

19.3 The Principal Investigator and Institute will permit the Sponsor to

a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.

b) Inspect and copy all Data, documents and records related to such work and the Study

19.4 The obligations of this Section shall survive termination of this Agreement.

20.0 Term; Waiver; Severability (The trial on its time extended)

20.1 This Agreement will be in force for a period of the trial or its time extended from the date of its signing. The term of this Agreement may be extended by consent of all parties to this Agreement.

20.2 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 12 months after the Effective Date. The Date of execution of this Agreement shall be the effective Date.

20.3 This Agreement will become effective after by the last signatory it is fully executed by all the parties hereto and shall continue in effect for the full duration of the Study according to the Protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

20.4 This Agreement may be terminated by any party upon giving at least a thirty (30) days written notice to that effect to the other parties. The day following the 30th day of such notice shall be "Effective Date of Termination". A reasonable adjustment will be made between the parties to ensure the Principal Investigator and Institute is reimbursed for project costs incurred to the date of termination of this Agreement for completing the study as per protocol or already enrolled subjects.

20.5 Sponsor may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institute subject to the discharge of their respective obligations under the terms of the agreement.

21.0 Effect of termination

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal

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Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(ii). Upon notice of termination of this Agreement by Institute or Sponsor or Principal Investigator, Institute shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institute shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails to repay such funds in a timely manner, Sponsor may deduct an equivalent amount from any payment then or later due from Sponsor to Institute under this or any other arrangement between the parties.

(iii). Upon termination of this Agreement, all unused Materials and all Sponsor Confidential Information (except for such records that Institute is required by law or regulation to retain) in Institute's possession shall be promptly delivered to Sponsor at Sponsor's expense, or, at Sponsor's option, destroyed with the destruction certified in writing.

22.0 Recordkeeping

The Institute and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, IEC requirements, and in accordance with all applicable local, state and Central laws and regulations. Institute or Principal Investigator shall cooperate with the Sponsor in making records, reports and Data developed under this Agreement.

Institute or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity, whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

23.0 Publication

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result

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from this Study. Data generated during the Clinical Trial Study is the sole property of the Sponsor. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but his name should to be included in any publication either author or as participant in the study.

24.0 Miscellaneous

24.1 Parties to this Agreement shall comply with the current provision of Drugs and Cosmetic Act 1940, Drugs and Cosmetic Rules 1945. For providing insurance to Clinical Trial Subjects in case of injuries or death, The parties to this Agreement have tied up with insurance company (The Oriental Insurance for 25,00000) which cover all patient enrolled in clinical trial. This insurance is valid from the period from 06.02.2019 to 05.09.2019. This insurance shall be extended from time to time till the expiry of Agreement.

24.2 The Study shall be started by Principal Investigator after this Agreement is executed by all the parties and required regulatory approvals/consent is available for the study.

24.3 The parties to this Agreement shall ensure that safety, welfare and right of the research participants (Clinical Trial Subject) are safeguard.

24.4 The Principal Investigator shall forward all Protocol deviation/non-compliance/violation/waiver reports to the IEC.

24.5 The safety completion Report shall be sent to IEC by Principal Investigator.

25.0 Governing Law

The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA as applicable in the State of Uttar Pradesh.

26.0 Jurisdiction

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be the site of trial, notwithstanding any other provision to the contrary in any law in this regard.

27.0 Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed by the Chairman of the Institutional Ethics Committee of the Institute at the trial site within 30 days of the receipt of a written request by the aggrieved. The

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Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

28.0 Amendment

This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the Study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed, in triplicate, by their officers, thereunto duly authorized to sign on behalf of their party.

1. Principal Investigator, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: _____

Dr. ANITA SAXENA

(Name)

Title/Designation: Professor Department of Nephrology

2. Director/his nominee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature and date: _____

Dr. .....

(Name)

Title/Designation: .....

(Director/his nominee)

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

12/3/2019

3. Sponsor

Signature and date: _____

Mr. P.PRABHAKARAN (Name)

Title/Designation: G.M – SALES & MARKETING.

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ANNEXURE

It was agreed that the Site will receive INR ...../- (.....) per Satisfactory Completed Subject for the Study according to the schedule indicated below. This Satisfactory Completed Subject amount is intended to cover the following Study- related costs incurred by the Investigation Site which includes (costs related to the Clinical Trial Subject visits, tests etc. Study related Communications, Institute service charges and Overheads).As this Study required inpatient hospitalization, hospitalization fees of INR ..... (..... only) per completed Clinical Trial Subject will be reimbursed by ..... to Institution. Clinical Trial Subject will be paid INR .....(.....rupees only) as a reimbursement for loss of daily wages due to participation in Study. In case of early withdrawal of Clinical Trial Subjects, the reimbursement can be provided on Pro-rata basis.

Apart from the Principal Investigator grant as listed below, on successful completion of all the visits, sponsor will provide the Patient Future treatment Reimbursement of .....- (Rupees ..... only) to the patients (who have completed the Study).

Investigator/ Hospitalization/ Patient reimbursement Grant (Inclusive of Institutional overhead)

Grant Distribution	
Coordinator Payment	INR 20,000 per month (From Investigation Site Initiation to Investigation Site Closeout)
Investigational Cost	Company will pay to SRL
Hospitalization Cost	N/A
Stationary and Miscellaneous	Mylin will provide
Patient Travel convenience	INR 200
Patient Future treatment Reimbursement	N/A Study

All the above mentioned amount is inclusive of 25% Institutional overhead

Maybe not applicable as Trial is on OPD level

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महाराष्ट्र MAHARASHTRA

15 FEB 2014

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प्रधान मुद्रांक कार्यालय, मुंबई
बनावट क्र ६०००१०
13 FEB 2014
बाजी अधिकारी

Amgen Technology Pvt. Ltd.
Dynasty Business Park
A Wing
Andheri - Kurla Road
Andheri (East)
Mumbai - 400059

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is made and entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India, and its parent or wholly owned subsidiaries of the parent ("**Company**") and Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Site**"). This Agreement shall be considered fully executed on the latest date that a party executes the same.

1. SCOPE OF SERVICES

1.1 Engagement. The execution of this Agreement alone, in the absence of any duly executed Order, as defined below, shall neither create any obligation of Site to perform hereunder nor create any obligation of Company to give Site any compensation. An "**Order**" is a document executed, at a minimum, by Company and Site, and issued pursuant to, and to be governed by, the terms of this Agreement. Unless otherwise specified, references to Agreement herein include all applicable Order(s).

1.2 Scope of Services. Company may engage Site through one or more Orders. An Order will be in a format similar to the document attached hereto and, among other things, shall set forth the particulars of the services to be performed ("**Study**"), including the clinical research and definition of the applicable Study drug ("**Study Drug**"). If engaged, Site agrees to and shall cause its employees, contractors, agents, representatives, including the principal investigator and sub-investigators (collectively, "**Site Representatives**") to perform the Study in accordance with this Agreement and Study protocol (as defined, including subsequent amendments) ("**Protocol**"). Site represents and warrants that it has the authority to require that Site Representatives comply with the applicable terms of this Agreement. Site shall notify Company of any material changes to Site Representatives, but in no event may Site change the principal investigator or any sub-investigator for a Study without Company's prior written consent. This Agreement,

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SGPGIMS,Lucknow

together with a duly executed Order, will be used by the parties for one Study only. Should the parties agree to use the Agreement for additional Study(ies), such agreement will be evidenced by an Order duly executed by all parties.

1.3 Biological Materials. All samples derived from Subjects enrolled in the Study, including blood, bone marrow, sera, platelets and other biological materials (the "**Biological Materials**") shall only be used in accordance with the Protocol and the EC approved informed consent.

1.4 Changes. In the event of a change to a Study that results in an increased cost, or if any increase in the compensation due for the conduct of a Study is necessary or appropriate, Company shall provide written notice in the form of a budget increase letter ("**Change**") to the Site to memorialize such increase in compensation. Unless the Site objects to such Change within ten (10) calendar days of the Change's date, said Change shall constitute an amendment to the applicable Order.

1.5 Protocol Deviations. If principles outlined in the ICH Harmonized Tripartite Guidelines for Good Clinical Practice ("**ICH GCP**") relating to the safety of Subjects (as defined herein) require a deviation from the Protocol, ICH GCP should be followed and the deviation shall immediately be reported to the other parties of this Agreement. Site shall also, within twenty-four (24) hours, notify Company of any Serious Breach of which Site becomes aware. For the purposes of this provision, a "**Serious Breach**" shall mean a breach of ICH GCP or Study Protocol, which is likely to affect (i) the safety of physical or mental integrity of the Subjects of any Study; or (ii) the scientific value of any Study. In addition, Site shall promptly inform the Institution Review Board or Independent Ethics Committee ("**IRB/IEC**") and any governmental authority as may be required by Applicable Law (as defined herein) of such deviation or breach.

2. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

2.1 Site shall use its best efforts to enroll evaluable subjects who meet all of the Protocol eligibility requirements ("**Subject(s)**").

3. COMPENSATION

3.1 Compensation. Compensation and payment terms for the applicable services shall be as set forth in the applicable Order. Site represents and warrants that the compensation provided under the terms of this Agreement as may be amended by subsequent Changes, represents fair market value and complies with Applicable Laws (as defined herein) and is consistent with fees charged for similar activities in Site's geographical area, has been negotiated at arms-length, and is unrelated to any procurement decision or promotion of Company's (or its affiliates') products, the volume or value of any referrals or other business otherwise generated between Company and Site.

3.2 Subject Withdrawal. Company shall have no obligation to compensate Site for a Subject who is determined to be ineligible for a Study, except for screen fails if provided for in the Schedule A, or for additional individuals who are enrolled in a Study without Company's prior written approval. In the event that a Subject (i) withdraws voluntarily; or (ii) is withdrawn from a Study for any reason other than the Subject failing to meet eligibility requirements, then Company shall compensate Site pursuant to the terms of the Schedule A for the procedures completed through the date of such withdrawal.

3.3 Payment Reconciliation. If, at the completion of a Study, Company has paid sums under the terms of this Agreement that exceed the total Study cost as provided in the Schedule A, Site shall, within 30 calendar days reimburse to Company any amount paid by Company that exceeds the adjusted Study cost. Site agrees to provide Company or its representative with all requests for payment under the terms set forth in the Schedule A within 30 calendar days after receipt of the adjusted Study/final payment. Where this is not possible, Site shall make all payment requests at the latest within 12 calendar months thereafter. Company shall not be obligated to make any payments after this period has expired.

3.4 Taxes, Customs, Fees, and Import/Export Duties. The pricing, fees, and compensation stated herein are inclusive of all applicable employment-related, consumer, use and other similar taxes (except Value Added Tax ("**VAT**")/sales tax), levies, duties, fees, and assessments which are legally enacted on or before the Effective Date (as defined herein), whether or not then in effect. VAT/sales tax, if applicable, will be paid by Company at the applicable rate and upon receipt of a valid VAT/sales tax invoice. Site, not Company, shall be responsible for any and all taxes on any and all income Site receives from Company under this Agreement.

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4. CONFIDENTIAL INFORMATION

4.1 Confidential Information. In view of Company's proprietary rights and interests, Site agrees to maintain as confidential all information received from or on behalf of Company or obtained as a result of the performance of this Agreement or developed under a Study (**"Confidential Information"**), and further agrees to limit access to any Confidential Information to only those persons who, under Site's direct control, will be engaged in employing such information for the purposes of fulfilling the obligations under this Agreement. At no time shall such information be employed for any purpose other than as described herein or disclosed to any third party without the prior written consent of Company.

4.2 Exclusions. The obligations set forth in this Article shall not apply to any portion of Confidential Information which (i) is or later becomes generally available to the public by use, publication or the like, through no act or omission of Site; (ii) Site possessed prior to the latest execution date of this Agreement without being subject to an obligation to keep such Confidential Information confidential; (iii) is lawfully obtained without restriction from a third party who had the legal right to disclose the same to Site; or (iv) is independently developed by the Site without the use or benefit of Confidential Information as evidenced by the Site's written records. In the event Site becomes legally compelled to disclose any Confidential Information, it shall immediately provide Company with notice thereof prior to any disclosure, shall use its best efforts to minimize the disclosure of any Confidential Information, and shall cooperate with Company should Company seek to obtain a protective order or other appropriate remedy.

4.3 Return of Company's Confidential Information. Site must return to Company all of Company's Confidential Information in tangible form, including without limitation all copies, translations, interpretations, derivative works and adaptations thereof, immediately upon request by Company. Notwithstanding the foregoing, if and to the extent required by Applicable Law (as defined herein), Site may retain 1 copy of applicable Confidential Information for record keeping purposes only.

5. PROPRIETARY RIGHTS

5.1 Ownership. Site agrees that all information, inventions, discoveries, know-how and improvements resulting from a Study conducted under this Agreement, including but not limited to material that may be subject to patent, trademark, or copyright protection (**"Intellectual Property"**) shall promptly be made known to Company and shall be the sole property of Amgen Inc. Site represents and warrants that it has secured from principal investigator and Site Representatives any and all transferable rights to Intellectual Property. Site hereby transfers and assigns to Amgen Inc. Site's full right and title to all Intellectual Property and agrees to undertake such actions reasonably requested by Company to give effect to such ownership. Amgen Inc. and its subsidiaries or affiliates including the Company shall be free to use the Intellectual Property. For each Study, Site shall furnish to Company all Study data, results, case report forms and an acceptable investigator's report. Any copyright in any such data, results, case report forms and investigator's report shall be the sole property of Company. Neither Company nor Site transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of any party, except as described in this Agreement.

5.2 Use of Study Drug. Site agrees that use of a Study Drug provided under this Agreement for any purpose outside of a Study is prohibited. If Site uses a Study Drug provided under this Agreement for any purpose outside of a Study, all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Intellectual Property in accordance with this Agreement and shall be the sole property of Company.

6. PUBLICATIONS

6.1 Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or

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oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

6.2 Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7. COMPANY-PROVIDED MATERIALS

7.1 Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order (**"Materials"**). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

8. REQUIRED EQUIPMENT AND SYSTEMS

8.1 Required Equipment. The parties acknowledge that certain equipment may be needed to properly conduct a Study. If Company and Site agree that Site does not have sufficient access to some or all of that certain equipment, then such equipment shall be identified in the Agreement and referred to as "Required Equipment." Unless otherwise specified, Company or its representative shall lend to Site for the duration of the Study such Required Equipment. As applicable, Company or its representative shall arrange for the delivery of such Required Equipment. At the completion or earlier termination of the Study, Company or its representative may retrieve any or all of the Required Equipment, title to which remains with Company or its representative.

8.2 Site's obligations. While the Required Equipment is on Site's premises, Required Equipment shall remain Company's or its representative's property at all times and shall be identified as such and can only be used to perform Studies. The Site shall ensure that the Required Equipment is stored, maintained and used properly. At all times after its delivery to Site and except for normal wear and tear, Required Equipment shall be at the sole risk of the Site as regards damage, loss, or destruction. While in Site's possession or control, Site shall be liable for the repair or replacement of any such Required Equipment that is damaged, destroyed, or lost.

8.3 Customized Required Equipment. If Company or its representative provides Site with Required Equipment that is specifically customized for use in a particular Study, then Site shall ensure that this Required Equipment is not used in any manner or for any purpose other than as set forth in the applicable Protocol. Additionally, at or before the conclusion of a Study, Company or its representative will provide instructions to Site regarding the destruction of or, at Company's expense, return to Company of such

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customized Required Equipment. Site agrees to destroy or return such Required Equipment pursuant to Company's or its representative's direction.

8.4 Required Systems. Site agrees to use any electronic system that Company may specify for use in the reporting and monitoring of clinical data and Study findings.

9. COMPLIANCE WITH APPLICABLE LAWS AND ACCEPTED PRACTICE

9.1 Accepted Practice. Site shall perform and shall cause Site Representatives to perform a Study in a professional and competent manner, using the degree of skill, diligence, prudence and foresight which would reasonably and ordinarily be expected from skilled and experienced professionals engaged in the provision of, and activities comprising, a Study.

9.2 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement before the Subject is allowed to participate in the Study. Site shall ensure that such consent permits Company's use of Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

9.3 Compliance with Applicable Laws. Site agrees to ensure that the Study is conducted in compliance with generally accepted standards of Good Clinical Practice, all laws, regulations, and guidance applicable to its performance hereunder, including the ICH GCP, Company's Protocol, written instructions and policies provided or referenced by Company and, applicable export control and economic sanctions regulations which prohibit the shipment of certain products and technology to certain restricted countries, entities and individuals, as well as applicable anti-bribery laws pertaining to interactions with government agents, officials and representatives ("**Applicable Law(s)**").

9.4 Data Protection. Site shall comply with the data protection provisions set forth by Applicable Law.

9.5 Records. Site shall maintain all records required under Applicable Law and the Protocol for 10 years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records.

9.6 Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors.

9.7 Governmental Contact by Site. Site shall not initiate any communications involving or relating to any Study with any governmental or regulatory authority (such as the United States Food and Drug Administration or the Drug Controller General of India) unless required by Applicable Law or requested to do so by Company and, then, only upon prior consultation with Company. However, if any governmental or regulatory authority initiates communications with, or gives notice to Site of its desire to meet with Site, conduct an inspection, or take any regulatory action regarding any subject matter relating to a Study, Site will promptly:

(i) Notify Company thereof;

(ii) Notify Company of any warning, violation or deficiency, including without limitation those noted by any governmental authority, with respect to a Study including without limitation facilities, equipment, or personnel supporting a Study;

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(iii) Provide Company with a copy of any correspondence or inspection reports issued with respect to a Study;

(iv) Provide Company with copies of and opportunities to comment on drafts of documents Site is required to submit to governmental authorities pursuant to its obligations hereunder; and

(v) Take action to correct any such violations or deficiencies or heed any such warnings.

Company acknowledges that it may not direct the manner in which Site fulfills its obligations to permit inspection by governmental authorities. Company representatives shall have the right to be on site during any such inspection by a governmental or regulatory authority, unless prohibited by Applicable Law.

9.8 For the purposes of this Agreement, Site shall ensure that the principal investigator for a Study and other Site Representative with applicable experience and knowledge are present during any inspections.

9.9 Debarment. Site represents and warrants that neither Site nor Site Representatives have been the subject of a debarment, disqualification or exclusion under any rules, in any jurisdiction where they have practiced, in particular in Europe or in the United States (where the main applicable texts are: Generic Drug Enforcement Act of 1992, Title 21 Code of Federal Regulations ("**C.F.R.**") Section 312.70 and 42 C.F.R. Part 1001 et seq.). Site shall notify Company immediately upon any inquiry concerning debarment, disqualification, or exclusion of Site or Site Representatives, or the commencement of any proceeding concerning the same. Notice of or failure to provide any such notice under this Section shall constitute a breach hereunder for which Company may terminate this Agreement immediately for default notwithstanding any right of Site to cure.

10. ANTI-CORRUPTION REPRESENTATION AND WARRANTY

10.1 Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site.

11. INDEMNIFICATION

11.1 Company's Indemnity. Company shall defend, indemnify, and hold harmless Site and Site Representatives (collectively, "**Site Indemnitees**") from any and all third party liabilities, claims, damages, losses, actions and suits ("**Claims**") for Personal injury or death arising out of, or in connection with the applicable Study. This includes medical management and financial compensation as may be required by Applicable Law.

11.2 Notwithstanding its obligations to the Subjects as defined per Applicable Law, Company's indemnification obligations towards the Indemnitees are contingent upon the following conditions:

(i) Site conducted the Study in accordance with, and otherwise complied with, this Agreement and Applicable Laws and such Claims do not arise out of or in connection with any of Site Indemnitees' failure to comply with the same;

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(ii) Such Claims do not arise out of the negligence or willful misconduct of any of the Site Indemnitees, or any other person on the Site Indemnitees' property who is not a Company employee;

(iii) Site timely provides written notice to Company of Claims such that Company is in no way prejudiced;

(iv) Site Indemnitees fully cooperate with Company and its legal representatives in the investigation and defense of Claims; and

(v) Company has sole control over the defense and settlement of Claims and Site Indemnitees do not settle or compromise Claims without Company's prior written consent (which consent shall not be unreasonably withheld).

11.3 Company's Indemnification Obligations. If Company is obligated pursuant to the terms of this Agreement to provide indemnity, Company shall do so diligently. Company shall not admit fault on behalf of any one or more of the Site Indemnitees without the relevant Site Indemnitees' written permission, such permission shall not be unreasonably withheld, conditioned, or delayed. Without limiting the Company's right to have sole control over the defense and settlement of Claims, Site Indemnitees shall have the right to retain separate legal counsel and representation at Site Indemnitees' sole cost.

11.4 Site's Insurance. Site shall maintain a policy or program of insurance at levels sufficient to support its obligations assumed under this Agreement and as required by Applicable Law, evidence of which shall be provided to Company upon written request, and Site shall provide prompt notice to Company of any cancellation in its coverage.

12. WAIVER OF CONSEQUENTIAL DAMAGES

12.1 IN NO CIRCUMSTANCES SHALL ANY PARTY BE LIABLE TO ANY OTHER PARTY IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR BREACH OF STATUTORY DUTY) OR OTHERWISE HOWSOEVER ARISING OR WHATEVER THE CAUSE THEREOF, FOR ANY LOSS OF PROFIT, BUSINESS, REPUTATION, CONTRACTS, REVENUES OR ANTICIPATED SAVINGS, OR FOR ANY OTHER SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGE OF ANY NATURE, WHICH ARISES DIRECTLY OR INDIRECTLY FROM ANY BREACH OF THIS AGREEMENT ON THE PART OF ANY OTHER PARTY. NOTHING IN THIS SECTION SHALL OPERATE SO AS TO RESTRICT OR EXCLUDE THE LIABILITY OF ANY PARTY IN RELATION TO DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OR INTENTIONAL MISCONDUCT OF SAID PARTY OR TO RESTRICT OR EXCLUDE ANY OTHER LIABILITY OF ANY PARTY THAT CANNOT BE SO RESTRICTED OR EXCLUDED BY APPLICABLE LAW.

13. SUBJECT INJURY

13.1 Subject Injury. In the event that a Subject suffers personal injury or death as a consequence of participation in the Study, Company shall bear such responsibilities as may apply to Company under Applicable Law. This does not prevent Company from filing an action against the Site or Site Representatives in case the adverse reactions described above are the result of the negligence or misconduct of the Investigator or any of the Site Representatives. Company does not authorize Site to offer compensation on behalf of Company, or to bind Company to any indemnity obligations in favor of any Subjects.

14. TERM AND TERMINATION

14.1 Effective Date. "**Effective Date**" shall be defined in each Order and such definition shall apply only to that Order.

14.2 Company's Right to Terminate. Company shall have the right, at any time, to suspend or terminate an Order, with or without cause and in whole or in part, by issuing a thirty (30) calendar day written notice to Site specifying the date and extent of termination. In the event of such termination, Site shall be entitled to compensation in accordance with the terms of the applicable Order up to the date of termination.

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Company shall also have the right to terminate immediately if it is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.3 Site's Right to Terminate. Site shall have the right to terminate any Order (i) if a principal investigator is identified in an Order and such principal investigator is unable to perform its obligations thereunder and a successor acceptable to Company is not available; (ii) if Company is in breach of any of its obligations hereunder and has failed to remedy such breach where it is capable of remedy within thirty (30) calendar days of a written notice from Site specifying the breach and requiring its remedy; or (iii) if Site is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.4 Obligations Upon Termination. Immediately upon receipt of notice of termination, Site shall stop enrolling Subjects into the relevant Study(ies) and shall cease conducting procedures on Subjects already enrolled in such Study(ies) as directed by Company, to the extent medically permissible and appropriate. Site shall return to Company within 30 calendar days of the effective date of termination any funds not expended or irrevocably obligated by Site prior to the effective date of the termination. Additionally, within 30 calendar days of the effective date of the termination, Site shall submit to Company a final invoice identifying any amounts Company may owe relative to the terminated Study(ies) and pursuant to the terms of this Agreement. Upon termination, Site shall, in accordance with Company's instructions, (i) preserve any data relating to the Study; (ii) turn over such data; and (iii) furnish Company an acceptable investigator's report for the Study.

15. MISCELLANEOUS

15.1 Amendments. Except as otherwise expressly provided herein, the terms of this Agreement may be amended only by the mutual written consent of the parties.

15.2 Use of Names. Company and Site shall not use each other's names (including the names of the other party's subsidiaries or parent, (if any)), symbols or marks, or any derivatives thereof in any form of publicity without the prior written consent of the owning party or parties, except that, without prior written consent of Site, Company may disclose on publicly-accessible clinical trial registries or through a Company-operated call center the general geographic location of Site (e.g., city, state, and/or country) and contact information of any party to this Agreement. In addition, and without prior written consent of Site, Company may identify the existence of this Agreement and/or, the name, and/or contact information of any party to this Agreement as required by applicable law. In addition, and without prior written consent of either party, Company and Site may disclose the other party's name in connection with publications hereunder.

15.3 Entire Agreement. This Agreement, any Order, and any amendments or Changes thereto, shall constitute the entire agreement between the parties hereto regarding the subject matter hereof and sets forth the entire terms and conditions under which this Agreement will be performed. There are no other agreements, oral or written, between the parties with respect to the subject matter of this Agreement, and all oral and written correspondence regarding the subject matter hereof is superseded by this Agreement. In the event of any inconsistency between this Agreement and any Order and the Protocol, if applicable, the terms of this Agreement shall govern, except as otherwise expressly agreed upon by the parties in a specific Order.

15.4 Counterparts. This Agreement and any Order, and any amendments or Changes may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on all parties notwithstanding that each of the parties may have signed different counterparts. Facsimiles or scanned copies of signatures or electronic images of signatures shall be considered original signatures unless prohibited by Applicable Law.

15.5 Severability. In the event any provision of this Agreement conflicts with the law under which this Agreement is to be construed or if any such provision is held illegal, invalid, or unenforceable, in whole or in part, by a competent authority, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with Applicable Laws. The legality, validity, and enforceability of the remaining provisions shall not be affected thereby, and shall remain in full force and effect.

15.6 Assignment and Sub-contracting. Neither the rights nor the obligations of Site under this Agreement may be assigned, transferred or otherwise disposed of, in whole or in part without the prior

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written consent of Company. In the event Company consents in writing to Site's use of a subcontractor or affiliate in the performance of Site's obligations hereunder, Site shall remain responsible for the proper performance of such Study, in accordance with this Agreement.

15.7 Waiver. No action or inaction by either party shall be construed as a waiver of such party's rights under this Agreement or as provided by Applicable Law. Except as expressly provided for in the Change Section, no other term of this Agreement may be waived except by an express notice in writing signed by the waiving party. The failure or delay of a party in enforcing any of its rights under this Agreement shall not be deemed a continuing waiver of such right. The waiver of one breach hereunder shall not constitute the waiver of any other or subsequent breach.

15.8 Equitable Relief. Each party understands and agrees that money damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching party shall be entitled to seek specific performance, injunctive, and other equitable relief as a remedy for any such breach. Such remedy shall not be deemed to be the exclusive remedy for breach of this Agreement but shall be in addition to any and all other remedies available at law or in equity.

15.9 Contractual Relationship. Site is engaged in an independent activity and not as an agent, employee, partner, or joint employer of Company. If applicable, Site represents and warrants that it is an employer subject to, and shall comply with, all Applicable Laws. Site shall be responsible for Site Representatives' and subcontractors' acts, errors, omissions, and conduct. Site acknowledges and agrees that Company shall have no responsibility or liability for treating Site Representatives as employees of Company for any purpose. Neither Site nor any Site Representative shall be eligible for coverage or to receive any benefit under any Company provided workers' compensation, employee plans or programs or employee compensation, bonus, incentives, retirement or other arrangements.

15.10 Governing Law. This Agreement shall be governed by the laws of the country where the services are performed, excluding conflict of law rules.

15.11 Survival. The parties' rights and obligations under any provisions set forth in this Agreement related to ownership of Intellectual Property, confidentiality, publications, use of names, Applicable Laws, governing law, Materials, subject injury, privacy, indemnification, and insurance, or which contemplate performance or observance subsequent to termination or expiration of this Agreement issued hereunder shall survive such expiration or termination.

15.12 Cooperation with Company Representatives. Site has been advised that, under separate agreements, Company may retain others (including without limitation contract research organizations) to perform certain services in connection with a Study. Site shall cooperate with, and to the extent appropriate, coordinate its performance hereunder with the services of such others so as to ensure successful completion of the Study.

15.13 Language. The official language of this Agreement is the English language. Should a party translate this Agreement into another language and a conflict in interpretation occur between versions, the original official language version shall prevail.

15.14 Notice. Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is: (i) delivered by hand; (ii) received by registered or certified mail, postage prepaid, return receipt requested; (iii) confirmed as received if by facsimile; or (iv) received by nationally recognized, overnight courier, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

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If to Company:

Amgen Technology Private Limited
Dynasty Business Park, 'A' Wing Level 4
Andheri-Kurla Road, Andheri (East)
Mumbai, India 400059

If to Site:

Sanjay Gandhi Post Graduate Institute
Rae Bareli Road
Lucknow, Uttar Pradesh-226014
India

With a Copy to:

International Legal Group
Amgen (Europe) GmbH
Dammstrasse 23
6301 Zug
Switzerland
Fax Number: +41 41 369 0411

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb '19

SANJAY GANDHI POST GRADUATE INSTITUTE

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences Rae Bareli Road, LUCKNOW-INDIA

(signature)

By: Rakesh Kapoor
(print or type name)

Title: _____

Date: 14.02.2019

05/03/2019
Dr. Amit Gupta
Professor & Head
Department of Nephrology
S.G.P.G.I.M.S., Lucknow

Amgen Technology Private Limited Mumbai

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SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Institution**"); and Dr. Amit Gupta, Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 285105) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Agreement shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20150238 entitled "A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double-dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for

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participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within 5 business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within 5 business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: AMG 416 ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will supply the Site with the Required Material(s). The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

3.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

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4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop, AV Camera. Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop, AV Camera.

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop, AV Camera.

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Director, SGPGIMS Research Scheme Account Lucknow "**Payee**"
Tax ID	AAAJS3913N

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

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7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all

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cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb' 19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rakesh Kapoor
(print or type name)

Title: DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences Lucknow-226014, U.P. INDIA

Date: 14.02.2019

DR. AMIT GUPTA

(signature) 05/03/2019

By: AMIT GUPTA
(print or type name)

Title:

Date: 05/03/2019

Dr. Amit Gupta
Professor & Head
Department of Nephrology
S.G.P.G.I.M.S., Lucknow

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Executive Registrar
SGPGIMS,Lucknow

Protocol Number	20150238
Site Number	30006
Investigator	Dr. Amit Gupta
Contract Number	
Maximum number of Subjects	10
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 4,86,390	10	Subject(s)	INR 48,63,900
SCREEN FAILURES	INR 12,005	1	per Subject	INR 1,20,050
ADMINISTRATIVE FEES				INR 50,000
MAXIMUM CONTRACT TOTAL*				**INR 50,33,950**

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs, laboratory costs. Amgen has provided thermohygrometer for temprature reading.*

SUBJECT FEES (Overheads 25%)

VISIT TABLE: STUDY	Schedule A
Screening	INR 12,005
Day 1	INR 20,690
Week 2	INR 17,160
Week 3	INR 16,700
Week 4	INR 17,620
Week 5	INR 17,300
Week 6	INR 17,160
Week 7	INR 16,700
Week 8	INR 17,160
Week 9	INR 17,300
Week 10	INR 17,160
Week 11	INR 16,700
Week 12	INR 17,550
Week 13	INR 17,300
Week 14	INR 17,160
Week 15	INR 16,700
Week 16	INR 17,160
Week 17	INR 17,300
Week 18	INR 17,160
Week 19	INR 16,700
Week 20	INR 17,160
Week 21	INR 17,300
Week 22	INR 17,160
Week 23	INR 16,700
Week 24	INR 17,160
Week 25	INR 17,300
Week 26	INR 17,160
Week 27	INR 12,915
Follow-Up	INR 12,850
Early Term	INR 13,855
SUBJECT VISIT TABLE SUBTOTAL(S)	Schedule A

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Completers, Screening to Week 27, Safety Follow-Up	INR 4,86,390
Early Termination	INR 13,855
MAXIMUM PER SUBJECT FEE	INR 4,86,390

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel reimbursement. Subject travel reimbursement is included at a rate of INR 900.00 per protocol required in-clinic visit

VISIT TABLE: SCREEN FAILURE	Schedule A
Screen Failure	INR 12,005
MAXIMUM SCREEN FAIL	INR 12,005

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
[1] Document storage/Archiving total 1	INR 0	1	per Site	INR 0
[2] Infrastructure Cost	INR 50,000	1	Total	INR 50,000
SUBTOTAL, ADMINISTRATIVE FEES				INR 50,000

1 Site has confirmed that archival fee is not applicable
2 Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastructure.

PAYMENT TERMS

Initial Payment	**50,000.00** *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

The EC for this study will be 'Bioethics Cee, IEC' and the payment of the EC fees will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."

2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

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GOVT. OF KARNATAKA
DEPT. OF STAMP & REGISTRATION
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CLINICAL TRIAL AGREEMENT – POISE-3

This **CLINICAL TRIAL AGREEMENT** ("**Agreement**"), effective as of the date of last signature ("**Effective Date**") is made between:

Hamilton Health Sciences Corporation ("**HHSC**"), through its **Population Health Research Institute** ("**PHRI**"), at 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada, represented by its Director

-and-

CBCI Society for Medical Education, ("**CBCI**") established and registered under the Karnataka Societies Registration Act, 1980, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Secretary (hereafter referred as the "**Society**")

-and-

St. John's Research Institute, ("**SJRI**") a unit of the Society, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Dean (hereafter referred as "**Institute**")

- and-

Division of Clinical Research and Training ("DCRT"), a Division of SJRI, with its administrative office at St. John's Research Institute, St. John's National Academy of Health Sciences, Bangalore-560 034 Karnataka; India, represented by, Dr. Denis Xavier, Vice Dean (PG), Professor, Dept. of Pharmacology, St. John's Medical College and Head DCRT (hereafter called "**National Leader**")

-and-

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, with its principal place of business at Department of Anaesthesiology, Raebareli Road, Lucknow, Uttar Pradesh, 226014, India (hereinafter the "**Institution**")

-and-

Dr. Sanjay Dhiraaj, as the principal investigator at the institution, with office at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Department of Anaesthesiology, Raebareli Road, Lucknow, Uttar Pradesh, 226014, India (hereinafter the "**Investigator**")

WHEREAS:

A. PHRI is coordinating and is the sponsor of a multi-centre clinical trial entitled PeriOperative ISchemic Evaluation-3 (**POISE-3**) ("**Project**"), the protocol including any amendments from time to time ("**Protocol**") is incorporated hereto by reference;

B. PHRI may also conduct substudies in conjunction with the Project ("**Substudy(ies)**"), and in the event that Site participates in any Substudies, all references to the Project shall include Substudy(ies), and the references to the Protocol shall include any protocols related to such Substudy(ies);

St. John's Research Institute Bangalore

Secretary

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Executive Registrar
SGPGIMS,Lucknow

C. PHRI has an agreement with SJRI to carry out national coordination activities in India for the Project;

D. DCRT, SJRI will be the National Leader Office ("**NLO**") Dr. Denis Xavier, Vice Dean (PG), Professor Dept. of Pharmacology, St. John's Medical College as its Head;

E. Investigator and Institution possess the resources and expertise to carry out a portion of the Project for a prescribed fee and wish to assist PHRI and NLO by acting as a site for the Project. The Investigators and Institution are hereinafter referred to jointly and severally as the "**Site**" and the activities carried out by the Site for the Project is referred to as the "**Study**";

F. The Study has been approved by the Institutional Ethics Committee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Luknow Ethics Committee (wherein such committee would approve the conducting of a clinical trial) at the Institution;

G. NLO obtained regulatory approval from Health Ministry Screen Committee (HMSC), Indian Council of Medical Research (ICMR) for conduct of a clinical trial in human subjects and has been registered on the Clinical Trials Registry of India (CTRI).

Each party is hereinafter referred to individually as a "**Party**" and collectively as the "**Parties**".

NOW THEREFORE, in consideration of the terms and conditions contained herein, the Parties agree as follows:

ARTICLE 1. PERFORMANCE OF THE STUDY

1.1 **Compliance:** The Parties agree to carry out the Study in conformance with the following: (a) all applicable requirements of any governmental, regulatory or other body that has authority with respect to the performance of the Study ("**Regulatory Authority(ies)**"); (b) generally accepted standards of good clinical practice, including but not limited to, to the extent adopted by the relevant Regulatory Authority, the Guidance for Good Clinical Practice of the International Conference on Harmonization, and all applicable laws, regulations and guidelines governing the conduct of human clinical research in the jurisdiction of the Institution (together with (a) as "**Applicable Laws**"); (c) the Protocol; and (d) this Agreement.

1.2 **Investigator:** The Study shall be carried out under the direction and supervision of the Investigator.

1.3 **Study Personnel:** Site represents that, during the course of the Study, all subinvestigators, employees, contractors, affiliates, agents and any other persons performing services for the Study (together as "**Personnel**") shall have the appropriate training, information, licenses, approvals, and certifications necessary to safely, adequately and lawfully perform the Study in accordance with this Agreement. Further, Site shall be responsible to ensure that the Personnel have read and understood the Protocol and shall perform their activities and fulfill their obligations in a timely and competent manner

1.4 **Informed Consent Form:** PHRI shall provide Site with a template informed consent form ("**ICF**") for the Study. Site shall, prior to initiation of the Study and during the conduct of the Study, obtain and maintain written approval from its/his/her institutional review board or ethics review board ("**IRB**") for the Study. Any changes to the ICF require the prior written approval of both the IRB, NLO and PHRI.

1.5 **Subjects:** Site shall obtain a completed and signed ICF from each subject participating in the Study ("**Subject**") prior to enrolling the Subject into the Study, and keep the Subjects informed throughout the Study.

1.6 **Recruitment:** Site may commence recruitment of Subjects upon receipt of an authorization to do so from PHRI/NLO. Site will use diligent efforts to recruit Subjects in accordance with the Protocol. The Parties acknowledge that the Project is a multi-centre study and that recruitment is

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on a competitive basis. Once the Project recruitment goal has been reached, PHRI reserves the right to notify Site to limit or cease further recruitment, and Site shall immediately comply upon receipt of any such notice.

1.7 **Conflict:** Site represents and warrants that it/he/she is not presently, and shall not be at any time during the performance of the Study under any obligation to a third party or subject to any impediments which would: (a) prevent, inhibit or negatively affect their performance of the Study, (b) create a conflict of interest or (c) otherwise impair the acceptance by a Regulatory Authority of the data or results collected by Site.

1.8 **Debarment:** Site represents that neither it/he/she nor any of the Personnel has been or is under investigation by a Regulatory Authority for debarment, disqualification, or any similar regulatory action, and that it/he/she has no notice or knowledge of debarment, disqualification, or any similar regulatory action by any Regulatory Authority in another jurisdiction. Furthermore, Site shall, during the term of this Agreement and for three (3) years following its expiration or early termination, promptly notify PHRI in the event of such debarment or threat of debarment, conviction, disqualification, or indictment of Site or Personnel.

1.9 **Subject Safety:** PHRI/NLO agrees to notify Site promptly upon receipt of Study information that would directly affect the health or safety of Subjects. Site shall without delay inform all Subjects and the IRB, as applicable. PHRI shall not be liable for the failure of Site to immediately inform Subjects or IRB of such new information. Site shall promptly report all safety data and information, including but not limited to any failure to comply with or deviations from the Protocols, to PHRI/NLO in accordance with the requirements of the Protocol.

1.10 **Records:** Site shall prepare, maintain and store accurate and complete written records and supporting documentation for each Subject ("**Source Documents**") in accordance with the instructions provided by PHRI/NLO and Applicable Laws. Site shall prepare and submit accurate and complete case report forms and all additional documentation ("**CRFs**") for each Subject to PHRI as required by the Protocol. Site shall reasonably cooperate with PHRI/NLO to promptly resolve all data queries from PHRI/NLO and provide such Source Documents as may be required. In accordance with the obligations in **ARTICLE 5 (Privacy)**, Site and the Personnel shall ensure that any data or Source Documents disclosed to PHRI/NLO does not include any information that would personally identify a subject and/or any personal health information ("**PHI**") unless permitted by signed ICFs and/or other authorizations.

1.11 **Audit and Monitoring:** Site shall cooperate with and permit Regulatory Authorities or PHRI/NLO to examine and inspect the facilities and equipment required for performance of the Study and to inspect and copy all data, reports, work products and results relating to the Study. In relation to visits by PHRI/NLO and/or its representative, the Parties will mutually and reasonably agree upon dates and times taking into account the reason for such visit. For clarity, access to records for monitoring or audit does not entitle PHRI/NLO to make or retain a copy of any Subject's personal identification information or PHI, as more particularly specified in **ARTICLE 5 (Privacy)**, unless such copying is permitted in accordance with the ICF or any other authorizations. Site understands that clinical trial monitoring is essential to good clinical practices and agrees to cooperate with PHRI/NLO to enable its monitoring activities without undue restriction. If Site is notified of an inspection by a Regulatory Authority, Site shall forthwith inform PHRI/NLO about the pending inspection and permit PHRI/NLO, or any person designated by PHRI/NLO, to attend the inspection unless prohibited by Applicable Laws or court order. Site shall forthwith communicate the information that arises from such inspections to PHRI/NLO, unless prohibited by Applicable Laws or court order. The Parties agree that any consideration payable for the assistance of Site for any audits and inspections is included in the consideration payable hereunder, whether or not itemized as such.

1.12 **Change of Investigator:** Should Investigator leave the Institution or otherwise become unavailable during the term of this Agreement, PHRI/NLO shall cooperate with Institution to find a replacement investigator who is acceptable to both Institution and PHRI/NLO. Institution shall require the replacement investigator to agree to comply with and be bound by all the terms and conditions hereof. Notwithstanding this, PHRI/NLO may elect not to approve any person

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proposed as a replacement investigator, in which event PHRI/NLO shall have the right to terminate this Agreement in accordance with **ARTICLE 10 (Termination)**.

1.13 **Study Product:** Site shall obtain the drug product required for use in the Study ("**Product**") from its local pharmacy, the cost of which is included in the Payment Schedule attached herein as **Exhibit 1**. Investigator shall: (a) use the Product solely for the purposes of conducting the Study, and (b) ensure the Product is stored in accordance with all instructions provided by the local pharmacy and the Product labels. Site shall control and/or limit access to the Product to the Personnel, and provide up-to-date records showing receipt and dispensing of the Product in accordance the Protocol and Applicable Laws.

ARTICLE 2. TERM

2.1 This Agreement shall commence on the Effective Date specified above, and continue until 31st December 2022, unless otherwise terminated earlier in accordance with **ARTICLE 10 (Termination)** ("**Term**").

ARTICLE 3. COMPENSATION AND PAYMENT

3.1 In consideration for the work performed pursuant to this Agreement, PHRI agrees to pay Site in accordance with the Payment Schedule attached herein as **Exhibit 1** and Payment Rule Form attached as **Exhibit 2**.

3.2 Site shall review the details accompanying each payment and inform PHRI in writing of any discrepancies between the payment received and the payment expected. Site shall inform PHRI of any final discrepancies no later than four (4) months after the Project database is locked. Should PHRI not receive written notice of any final discrepancies within such four (4) month period, all payments required to be made hereunder shall be deemed to have been made in full.

3.3 Site represents and warrants that it/he/she is not a resident or citizen of Canada for tax purposes.

ARTICLE 4. CONFIDENTIAL INFORMATION

4.1 Site agrees to maintain or cause to be maintained in confidence all information received, resulting from and related to the Project, including but not limited to, the Protocol and CRFs ("**Confidential Information**"). This obligation shall be binding for a period of ten (10) years from the termination or completion of the Project. Site will not disclose the Confidential Information without the prior written approval of PHRI/NLO. Site may disclose Confidential Information to Personnel and the IRB to the extent required for the proper conduct of the Study, provided that each person to whom disclosure is made is fully informed of the confidential nature of the information and agrees to keep it confidential in accordance with this Agreement.

4.2 The obligations in **Section 4.1** will not apply to Confidential Information if and to the extent only that it: (a) is or later becomes known to the public or is in the public domain, other than by an act or omission of Site; (b) is previously known to Site, before the Effective Date or prior to Site having signed a confidentiality agreement with PHRI in connection with the Project, as evidenced by written records; (c) is lawfully obtained from a third party and such third party has a legal right to disclose the information; or (d) is independently developed by Site without the use of the Confidential Information, as evidenced by written records.

ARTICLE 5. PRIVACY

5.1 All Parties shall comply with Applicable Laws regarding the Confidential Information, including but not limited to protected or personal information, PHI and all data received or obtained in the course of the Project. Access to PHI and/or personal information shall be provided only to the extent permitted by the Subject's ICF or other authorization and Applicable Laws. Site shall de-identify all information, data and documents prior to providing access to PHRI/NLO, however in the event PHRI/NLO receives or otherwise has access to a Subject's PHI and/or personal

Bangalore

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SGPGIMS,Lucknow

information PHRI/NLO shall hold the PHI and/or personal information in confidence in accordance with all Applicable Laws, the signed ICF or other authorization.

ARTICLE 6. INTELLECTUAL PROPERTY

6.1 PHRI shall own and have all rights, title and interest in: (a) all Project information, documents and data collected; (b) results derived from the performance of the Project in all forms and formats, and (c) any discovery or invention that may arise in the course of the Project by Site or the Personnel. Notwithstanding this, Site may use the data and results of the Study for its/his/her internal non-commercial research and educational purposes provided that until the Project results are public, as provided in **ARTICLE 7 (Publication)**, Site shall not make the results of the Study available to third parties without the prior written consent of PHRI. Subject medical charts shall remain the property of Site.

6.2 Site disclaims all rights, title and interest to the data and results, to any and all intellectual property arising out of or in connection with the Project, and to information and documents received by Site as a result of or in the course of performing the Study, except to the extent that such rights are expressly granted hereunder. Any discovery or invention shall be promptly communicated to PHRI. PHRI shall file and prosecute any patent applications, at its expense and in its sole discretion. Site and the Personnel agree to provide reasonable assistance with any patent applications. Any compensation payable for the assignment of the inventor rights is included in the consideration payable hereunder, whether or not itemized as such. Institution shall be responsible for payments to Investigator or Personnel according to Applicable Law or Institution policies for the assignment of inventor rights to PHRI.

ARTICLE 7. PUBLICATION

7.1 **Multi-Site Publication By Project Lead:** Site acknowledges that consolidated data from all sites will be analyzed collectively by a Project committee ("**Project Results**"). The Project committee will, regardless of the outcome, submit an initial publication to a peer reviewed, biomedical journal or otherwise make the Project Results public no later than twelve (12) months after the completion of the Project.

7.2 **Single Site Study Publication:** After the Project Results are public, or eighteen (18) months after the conclusion of the Project, Site shall have the right to publish the Study results from the data collected at its location in accordance with the terms of this **ARTICLE 7 (Publication)**. At least sixty (60) days prior to the date for submission of a publication, abstract, and/or presentation ("**Publication**"), Site shall provide copies of any proposed Publication to PHRI/NLO for review and comment by the Project committee. Site agrees to consider the comments, if any, of the Project committee.

7.3 If, in the course of review of the proposed Publication, PHRI/NLO and/or the Project committee identifies any Confidential Information that it or they may wish to protect, PHRI shall have the right to request amendments to the proposed Publication on reasonable grounds including without limitation to: (a) ensure that the proprietary information is not inadvertently divulged, (b) enable intellectual property rights to be secured, and/or (c) enable relevant supplementary information to be provided. Site shall comply with any reasonable request to amend or delete information in a proposed Publication, provided such request does not necessitate removal of Study data and/or results. In addition, on written notice, PHRI may require Site to postpone the Publication to enable PHRI to protect its intellectual property rights. Upon receipt of such written notice, Site shall delay the Publication for the period of time specified in the notice, provided that such period shall not exceed sixty (60) days.

7.4 Other than as agreed herein, no Party shall use the name(s) of another Party or its/his/her Personnel without the prior written consent of such Party. Site may acknowledge in general terms the existence of this Agreement and its receipt of financial support from PHRI in order to comply with Applicable Laws and for Publication of the Study Results, and with the prior written approval of PHRI/NLO in connection with advertising or promotional materials for the Project. PHRI may disclose the name(s) of Site in any Publication of the Project Results, and may use the

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names and the amount of funding provided to Site for registration of the Project on www.clinicaltrials.gov, www.ctri.in and to comply with Applicable Laws and general industry standards.

ARTICLE 8. DISCLAIMER

8.1 PHRI makes no warranties of any kind whatsoever concerning the efficacy or safety of the Project, the procedures, treatments and medical practices described in the Protocol, the Product, or the Protocol itself. Except as expressly provided herein, PHRI hereby specifically disclaims any and all warranties or conditions, which may be implied by law.

8.2 Site makes no warranties of any kind whatsoever concerning the success of the Study.

ARTICLE 9. INDEMNIFICATION AND INSURANCE

9.1 **PHRI:** PHRI/NLO agrees to defend, indemnify and hold harmless Site and its trustees, directors, officers and Personnel from and against any and all costs, losses, liabilities, damages, actions, proceedings, demands, claims and reasonable expenses including legal fees (**"Claims"**) made by a third party to the extent directly resulting from PHRI's/NLO negligence, wrongful acts and omissions in connection with its performance or non-performance of its obligations under this Agreement

9.2 **Site:** Site agrees to defend, indemnify and hold harmless PHRI/NLO, and its trustees, directors, officers, medical and professional staff, students, appointees, contractors, agents and sponsors (if any) from and against any and all Claims made by a third party to the extent directly resulting from Site's and the Personnel's negligence, wrongful acts and omissions in connection with its performance or non-performance of their obligations under this Agreement.

9.3 **Notification:** In connection with any Claim, each Party shall notify the other Parties promptly of any Claim and cooperate fully in the investigation and defense of any such Claims.

9.4 **Limitation of Liability:** Notwithstanding any other provision of this Agreement, under no circumstances will a Party be liable to another Party for any indirect, consequential or incidental damages that such other Party may have suffered, including without limitation damages for loss of profit or revenue and regardless of whether such other Party has been advised of the possibility of such damages arising, or for non-compensatory damages of any kind, including without limitation aggravated or punitive damages.

9.5 **Insurance:** During the Term and for the duration of their obligations surviving expiration or termination of this Agreement, PHRI and Institution will each obtain and maintain a policy or program of self-insurance at levels sufficient to support their obligations herein and in amounts appropriate to the conduct of their respective businesses, which at minimum, shall include comprehensive general liability coverage with limits of not less than the equivalent of two million dollars Canadian ($2,000,000) aggregate or amounts required by Applicable Laws.

9.6 **Investigator's License:** Investigator agrees to hold membership in the medical professional association in his/her jurisdiction for the duration of the Project and to provide evidence of such membership on PHRI's request.

9.7 NLO shall maintain in force a **clinical trial indemnity insurance** coverage for all Project Subjects recruited in India as required by Applicable Law. A copy of this will be provided to the Institution for reference and production to regulatory / Ethics office. NLO will provide payment to the Institution for reasonable unreimbursed medical expenses, including hospitalization, which the Institution may incur as a direct result of the treatment of a Subject's injuries that directly results from the Product or its administration during the Study, as determined by PHRI and the Investigator.

9.8 **Research Related Injury:** NLO shall be responsible for payment of the reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a Study

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Subject that results from the administration of the Product in accordance with the Protocol or the proper performance of any Protocol procedure.

9.9 A Party shall upon request provide the requesting Party with a copy of the relevant certificate of insurance coverage. As per Indian regulations, the expenses on medical management in case of any injury and financial compensation in case of clinical trial injury or death of the Project Subject shall be borne through the insurance cover undertaken by the NLO. Institution will consider building a contingency fund within the institution to meet the costs immediately and later get them reimbursed from NLO.

ARTICLE 10. TERMINATION

10.1 **For Default:** In the event either PHRI/NLO, on the one hand, or Site, on the other hand, fails to perform or performs improperly any of its material obligations under this Agreement, the non-defaulting Party shall provide the other Party or Parties with thirty (30) days' notice in writing to cure the default. In the event the default is not cured to the reasonable satisfaction of the non-defaulting Party, such Party may terminate this Agreement on notice to the other Parties. Either parties have equal rights to terminate this Agreement.

10.2 **For Safety or Other Reasons:** PHRI/NLO may terminate this Agreement at any time, on written notice to Site if: (a) the regulatory authorization or approval to perform the Project is withdrawn; (b) a decision is made to terminate the Project early due to safety or other reasons; (c) Site has not recruited a Subject into the Study within three (3) months of receipt of notice from PHRI to commence recruitment; or (d) Site is debarred or disqualified. Upon written notice to PHRI/NLO, Site may jointly terminate this Agreement if, in the reasonable judgement of Site, serious or life-threatening events raise issues of subject safety.

10.3 **For No Cause:** PHRI may also terminate this Agreement on thirty (30) days' prior written notice to Site for any reason.

10.4 **On-going Obligations:** Termination shall be subject to the on-going obligations of each of the Parties pursuant to **Section 10.5**. Immediately upon receipt of a notice of termination, Site shall cease recruitment of Subjects into the Study and cease conducting procedures as directed by PHRI and to the extent medically permissible.

10.5 **Closing Activities:** Regardless of the cause of termination, the Parties shall in all instances cooperate in closing-out of the Study and, if applicable, comply with all recommendations of the Project steering committee.

10.6 **Payment:** In the event of early termination of this Agreement, other than for a material breach by Site, PHRI shall pay all fees actually earned to the effective date of termination notice and for closing-out activities as determined by the Project steering committee. PHRI will consider payment of other reasonable non-cancellable expenses incurred by Site, but shall not be liable for such costs or expenses unless they have been pre-approved or subsequently agreed between the Parties.

10.7 **Survival:** The rights and obligations of Parties that by intent or meaning have validity beyond expiration or termination (including, without limitation, rights with respect to intellectual property, Publication, Confidential Information, privacy, and indemnification) shall survive the termination or expiration of this Agreement.

ARTICLE 11. NOTICE

11.1 Any notice required by this Agreement shall be in writing and delivered to the addresses or facsimile numbers specified below or to such other address as each party may from time to time designate to the other in writing. Delivery shall be deemed received as follows - if prior to 4:00 pm on a business day in the jurisdiction of the recipient and otherwise on the next business day by: (a) personal delivery, when delivered personally; (b) courier, upon courier's verification of

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delivery; (c) facsimile, successfully received transmission at recipient's location; or (d) electronic mail transmission successfully received by the recipient.

If to PHRI:
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Attention: POISE-3 Project Manager
Tel: 905-521-2100 x 40526
Fax: 905-297-3779
Email: shirley.pettit@phri.ca

If to NLO:
The Dean, St. John's Research Institute
a unit of CBCI Society for Medical Education
St. John's National Academy of Health Sciences
Johnnagar, Bangalore
560 034, India
Tel: +91 80 49467001
Fax. +91 80 25501088
Email: deansoffice@sjri.res.in

If to Site (Institution):
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow
Department of Anaesthesiology
Raebareli Road
Lucknow, Uttar Pradesh, 226014
India
Tel: 91-522-2495048
Fax: 05222668017
Email: sdhiraaj@gmail.com

If to Site (Investigator):
Dr. Sanjay Dhiraaj
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow
Department of Anaesthesiology
Raebareli Road
Lucknow, Uttar Pradesh, 226014
India
Tel: 91-522-2495048
Fax: 05222668129
Email: sdhiraaj@gmail.com

With copy marked to:
Dr. Denis Xavier
Head - Division of Clinical Research & Training
St. John's Research Institute
St. John's National Academy of Health Sciences
Johnnagar, Bangalore-560 034, India
Tel: +91 80 49466140, +91 80 4946010, +91 80 49467080
Fax: +91 80 49467090
Email: denis@sjri.res.in

11.2 Where any notice is given to PHRI under this Agreement in relation to any alleged breach or default of this Agreement by PHRI or any Claim against PHRI, Site shall also provide the notice to:

Research Counsel
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Fax: 905-296-2369
Email: phri.contracts@phri.ca

ARTICLE 12. CONCLUDING PROVISIONS

12.1 **Entire Agreement, Amendment and Assignment:** The Exhibits and the Protocol are incorporated herein by reference and form part of this Agreement. This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter herein. Any amendments or modifications to this Agreement shall be in writing and signed by authorized representatives of each Party. Institution and/or Investigator may not assign this Agreement or any obligation hereunder without the prior written consent of PHRI/NLO.

12.2 **Recitals:** The Parties acknowledge the foregoing recitals to be true and correct.

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12.3 **Conflict:** In the event of any conflict between this Agreement and the Protocol, this Agreement will govern for any non-clinical matters and the Protocol will govern for any scientific and clinical matters.

12.4 **Independent Contractors:** As between PHRI/NLO on the one hand, and Site and the Personnel on the other hand, the work performed pursuant to this Agreement shall be as independent contractors and not as partners, joint venturers, employees, subcontractors or agents. No Party has the power or authority to bind another Party.

12.5 **Force Majeure:** In the event that performance of a Party's obligations are prevented by events beyond its reasonable control, including but not limited to, acts of God, regulations or acts of any governmental authority, war, civil commotion, strikes, other labor disturbances, epidemics, fire, earthquakes, storms or other catastrophes of a similar nature, the affected Party will notify the other Parties as soon as reasonably possible and the affected Party shall be relieved of its obligations for the duration and to the extent the performance of an obligation is prevented thereby. During the existence of any such condition, the affected Party shall use diligent efforts to remove the cause and resume performance of its obligations.

12.6 **Governing Law & Jurisdiction:** The interpretation and construction of this Agreement shall be governed by the laws of India excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this agreement to the substantive law of another jurisdiction The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts where the cause of action arises for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts.

12.7 **Invalidity:** The invalidity or unenforceability of any provision of this Agreement shall not affect the validity of any other provision hereof. The Parties shall make commercially reasonable efforts to replace any invalid or unenforceable provision with one that is valid and enforceable, and reflects the originally intended commercial objectives of the Parties.

12.8 **Signing:** This Agreement may be signed in any number of counterparts, each of which so executed is deemed to be an original and when joined together constitute one and the same original agreement The Parties agree that fax or electronic copies have the same effect as original hardcopies.

- signature page to follow -

St. John's Research Institute Bangalore

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SGPGIMS,Lucknow

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Hamilton Health Sciences Corporation

Signature
Name: Tanya Chow
Position: Director of Contracts, Population Health Research Institute

Date: 2019-MAR-01
(YYYY-MMM-DD)

INVESTIGATOR

Signature
Name: Dr. Sanjay Dhiraaj

Date: 2019-01-29
(YYYY-MMM-DD)

INSTITUTION: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature
Name: _____
Title: _____

Date: _____
(YYYY-MMM-DD)

On Behalf of CBCI St. John's Research Institute

Signature
Name: Dr. TONY D.S. RAJ
Title: DEAN
St. John's Research Institute
St. John's National Academy of Health Sciences
Koramangala, Bangalore – 560 034, INDIA

Date: 2019 MAR 26
(YYYY-MMM-DD)

On behalf of St. John's Research Institute CBCI

Signature
Name: Rev. Dr. Paul Parathazham
Title: Secretary

SECRETARY
C.B.C.I. SOCIETY FOR MEDICAL EDUCATION
ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
SARJAPUR ROAD, BANGALORE - 560 034

Date: 2019 Mar 29
(YYYY-MMM-DD)

On behalf of NLO

Signature
Name: Dr. DENIS XAVIER, MD, M.Sc.
Title: Vice Dean (PG)
Professor of Pharmacology
St. John's Medical College
Bengaluru - 560 034. India.

Date: 2019 mar 16
(YYYY-MMM-DD)

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EXHIBIT 1 – PAYMENT SCHEDULE

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments will be processed on a quarterly basis with payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued within 25 days from the processing/run date (i.e., payment for run date March 31st is mailed on or prior to April 25th). Payments will be made for all CRFs received and validated to be clean prior to the run date, according to the payment schedule.

The fee per subject is inclusive of all costs (i.e. staff time, study lab investigations, event reporting costs, archiving costs, institutional overheads, cost to purchase TXA and any dispensation fees, participant expenses such as travel and parking, all applicable taxes including VAT or its equivalent).

Enrolment and Follow-up:

Visit Type	**Amount in CAD per Study Subject, per visit and receipt of all required CRFs for the visit**
Randomization Visit	75
Baseline	40
Hospital Discharge	50
1 Month	25
1 Year	40
Holdback fee *	20
Total Per Patient Fee (CAD) **	**250**

* Holdback fee will be paid after database lock if all required data for the participant has been collected and provided to PHRI prior to database lock.

** The actual fees paid will be based on completion of visits and collection of all required data.

Additional Payments for Product management at site:

Product management support fees will be provided in installments based on successful randomization of the first Study Subject and subsequent recruitment rate at Site towards various Study activities that will be required to be completed by the Site.

Subjects recruited	**Amount in CAD**
1st Subject recruited	200
20th Subject recruited	200
40th Subject recruited	200
50th Subject recruited	200

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EXHIBIT 2 – PAYMENT RULE FORM

COUNTRY:	**INDIA**
CENTRE #:	**464**
INSTITUTION:	**Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow**
INVESTIGATOR:	**Dr. Sanjay Dhiraaj**

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments will be processed on a quarterly basis with the payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued and sent out within 25 days from the processing/run date (i.e., payment for run date March 31st will be sent on or prior to April 25th) provided that a minimum of **500 CAD** has been earned within such payment period. Payments will be made for all CRFs received and validated to be clean prior to this date, according to the attached payment schedule.

Payments will be made to only one party. **(ALL INFORMATION BELOW MUST BE PRINTED)**

The following information is required in order to generate payment by wire transfer. Incomplete information could result in delay in payment.	
Bank Name:	STATE BANK OF INDIA
Bank Address:	STATE BANK OF INDIA, SANJAY GANDHI PGIMS, RAEBARELI ROAD, LUCKNOW, U.P.-226014
Bank SWIFT code:	SBININBB500
Beneficiary Name:	DIRECTOR SGPGIMS, RESEARCH ACCOUNT
Beneficiary Address:	DIRECTOR SGPGIMS, RESEARCH ACCOUNT, SANJAY GANDHI PGIMS, RAEBARELI ROAD, LUCKNOW, U.P.-226014
Beneficiary IBAN or Account number:	10095237491
IFSC Code (if applicable).	SBIN0007789
Reference (if applicable):	
Contact name and email of person generating the invoice (if applicable):	DR SANJAY DHIRAAJ

Institution Signature:	Date:
Name of the signatory:	
Investigator Signature:	Date
Name of the signatory: SANJAY DHIRAAJ	

The information below is required before PHRI can initiate any payment.

Are you an entity that has to submit value added tax? ___Yes ___ No Tax rate: ___%
If payment to the Investigator please provide following:
Social Security (US)/Social Insurance Number (Canada) or other applicable personal income tax identifier #:
Investigator First Name, Middle Initial and Last Name:
If payment to a business entity such as the Investigator's professional corporation or the Institution please provide the following:
Tax ID #/GST Registration:
PAN card no: #:
For HHSC use only – Vendor ID #:

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Executive Registrar
SGPGIMS,Lucknow

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उत्तर प्रदेश UTTAR PRADESH

BU 274405

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this ....., **Two thousand and Nineteen** BY AND BETWEEN President of India, acting through **Secretary,** Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

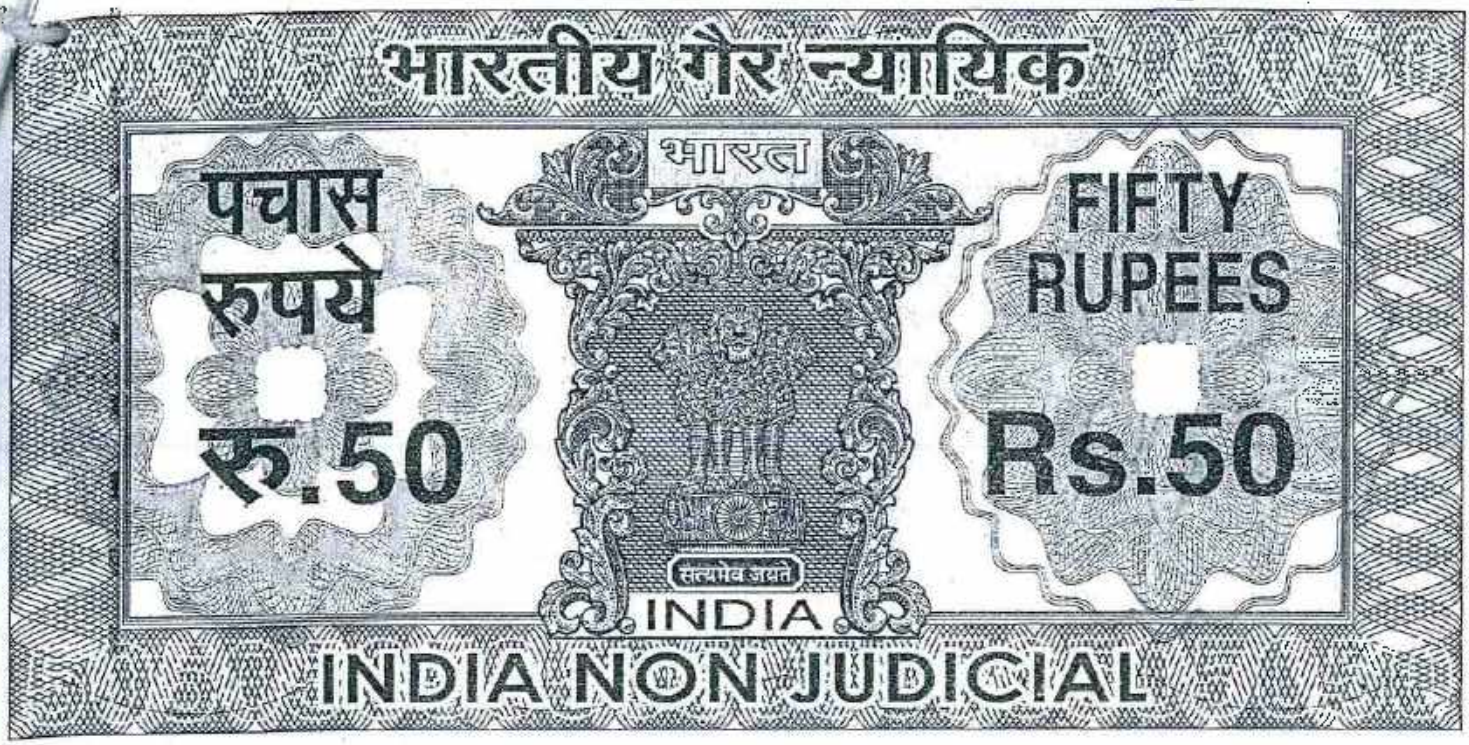
AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences an autonomous institution created by act of state legislature of UP (Act no 30 of 1983) having its registered office at Raebareli Road, Lucknow, 226014 hereinafter referred to as **SGPGI**. (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous **of Medical Biotechnology** decided to support a project submitted by Amita Aggarwal for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

Amita Aggarwal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



उत्तरप्रदेश UTTAR PRADESH BU 274406

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **Multi-institutional Network Program on Systemic lupus Ervthematosus Understanding the diversity of SLE**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs 33738828** over a period of **5** years from the date of sanction of the project, to **August 30, 2018** for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF SGPGI

2.1. To provide their contribution of none for 5 years from date of sanction of the project as detailed in Annexure – II. *(if a jointly supported project)*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

Lt Col Varun Bajpai VSM
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2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. **The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.**

3.0 DURATION OF PROJECT

3.1 Duration of project shall be 5 years from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by Dr Amita Aggarwal will be the joint property of SGPGI- and DBT, Government of India. It shall be the responsibility of SGPGI to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

Amita Aggarwal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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IN WITNESS WIEREOF the parties hereto have signed, scaled and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

Signed by ----------

1.

(Designation)

2.

For and on behalf of The President of India

Witnesses:

1. Dr. Sudhir Sinha

2. Mr. Arnnd Srivastava

Signed by ----------

(Designation)

For and on behalf of SGPGI, Lucknow

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras 1 to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Amit

Signature of Project Coordinator
(applicable only for multi-institutional projects)

Date :

Signature of Executive Authority of Institute/ University With seal

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Date : 31.10.2019

Amit

Signature and stamped of Principal Investigator :

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Date :

Signature and stamped of Co-Investigator **Signature and stamped of Co-Investigator**

Date :

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

No. BT/PR23111/MED/30/1852/2017
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: 31/08/18

ORDER

Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Powers Rules ,1978 , for the implementation of the project entitled: "**Multi-institutional Network Program on Systemic lupus Erythematosus Understanding the diversity of SLE**" for a period of 5 Year 0 Month at a total cost of Rs. **125958656** (Rupees Twelve Crores Fifty Nine Lakhs Fifty Eight Thousand Six Hundred and Fifty Six Only) on the terms and conditions detailed here under:-

2 The Project :

2.1 Title : **"Multi-institutional Network Program on Systemic lupus Erythematosus Understanding the diversity of SLE"**

2.2 **Details of the Investigators:**

Project Cordinator

Prof. Amita Aggarwal
Professor
Department of Clinical Immunology
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Department of Immunology
Rae Barielly Road PIN:226014, Rae Bareli, Uttar Pradesh, 226014

Prof. Amita Aggarwal
Professor
Department of Clinical Immunology
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Department of Immunology
Rae Barielly Road PIN:226014, Rae
Bareli,Uttar Pradesh, 226014

Dr. Ashish Jacob Mathew
Assistant Professor
Clinical Immunology and
Rheumatology
Christian Medical College, Vellore
Clinical Immunology and
Rheumatology
Christian Medical College, Vellore,
Vellore,Tamilnadu, 632004

nerated through eProMIS

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Dr. B Ravindran
PI
Professor Emeritus
INSTITUTE OF LIFE SCIENCES, Bhubaneswar
Institute of Life Sciences, Nalco Square,
Bhubaneshwar, Khorda,Orissa, 751023

Dr. Manish Rathi
Additional Professor
Nephrology
Postgraduate Instutite of Medical Education and Research
Department of Nephrology, PGIMER,
Chandigarh, Chandigarh,Chandigarh, 160012

Dr. Ranjan Gupta
Assistant Professor
Rheumatology
All India Institute of Medical sciences,New Delhi
Flat No. B-1/101, Varun Apartments, Sector No. 9, Plot No. 12, Rohini, New Delhi., Sri Ganganagar,Rajasthan, 110085

Prof. Bidyut Das
Professor
Medicine
S.C.B.Medical College, Cuttack
Department of Medicine, SCB Cuttack,
Orissa, Cuttack,Orissa, 753002

Prof. Liza Rajasekhar
Professor
Rheumatology
Nizam's Institute of Medical Sciences
Department of Rheumatology,
Hyderabad,Telangana, 5000082

Prof. Parasar Ghosh
Professor
Clinical Immunology and Rheumatology
INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH
Department, Kolkata,West Bengal, 700020

Prof. Vineeta Sobha
Professor
Clinical Immunology AND Rheumatology
St John's Medical College, St John's National Academy of Health Sciences
St John's hospital Bangalore, Bangalore,
Karnataka, 560034

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Prof. Vir singh Negi
Professor
Clinical Immunology
Jawaharlal Institute of P.G. Medical Education & Research
Department of Clinical Immunology JIPMER,
,Pondicherry, 605006

CO-PI:

Prof. Ramnath Misra
Professor
Clinical Immunology
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Department of Clinical Immunology, SGPGI,
Lucknow, Lucknow - 226014, Uttar Pradesh

2.3 Objectives:

Overall Objectives:

1. Development of an inception cohort from different parts of India for the assessment of clinical features, socio-demographic features, auto-antibodies, disease progression and outcome and evaluation of regional differences
2. Generation of a bio-repository to store samples that may be used in future for genetic studies and biomarker discovery
3. Assessment of soluble and cell-linked biomarkers in SLE patients with fever to determine if they can help differentiate infection from disease activity
4. To study the role of high dose vitamin D supplementation as an add on treatment in SLE patients

2.4 Time Schedule:

The duration of the project is 5 Year 0 Month from the date of this sanction order.

2.5 Project Cost:

The total cost of the project is Rs. 125958656/-(Rupees Twelve Crores Fifty Nine Lakhs Fifty Eight Thousand Six Hundred and Fifty Six Only) as per details given below :

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Institute	Year I	Year II	Year III	Year IV	Year V	Total Cost(Rs.)
1. All India Institute of Medical sciences,New Delhi	2477000	1952000	1952000	1802000	1802000	9985000
2. Christian Medical College, Vellore	5130448	3703276	3703276	1702000	1702000	15941000
3. INSTITUTE OF LIFE SCIENCES, Bhubaneswar	2488000	1919200	1953520	1791272	1833008	9985000
4. INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH	2477000	1952000	1952000	1802000	1802000	9985000
5. Jawaharlal Institute of P.G. Medical Education & Research	4688276	4163276	4163276	1802000	1802000	16618828
6. Nizam's Institute of Medical Sciences	2477000	1952000	1952000	1802000	1802000	9985000
7. Postgraduate Institute of Medical Education and Research	2477000	1952000	1952000	1802000	1802000	9985000
8. Sanjay Gandhi Post Graduate Institute of Medical Sciences	13720276	6485276	6285276	3624000	3624000	33738828
9. St John's Medical College, St John's National Academy of Health Sciences	2427000	1902000	1902000	1752000	1752000	9735000
Total (Rs.)	38362000	25981028	25815348	18299272	17921008	125958656

Institute wise details are:

Budget Head	Year I	Year II	Year III	Year IV	Year V	Total(Rs.)
1. Sanjay Gandhi Post Graduate Institute of Medical Sciences						

Prof. Amita
Head
Biochemistry & Experimental Medicine
SGPGIMS, Lucknow-226014

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Executive Registrar
SGPGIMS,Lucknow

SGPGIMS I^st year II^nd III^rd IV V

Equipment	6135000.00					6135000.00
Manpower	3435276.00	3435276.00	3435276.00	2274000.00	2274000.00	14853828.00
Consumables	3660000.00	2560000.00	2360000.00	950000.00	950000.00	10480000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	150000.00	150000.00	150000.00	100000.00	100000.00	650000.00
Contingency	240000.00	240000.00	240000.00	200000.00	200000.00	1120000.00
Total (Rs.)	13720276.00	6485276.00	6285276.00	3624000.00	3624000.00	33738828.00

2. Jawaharlal Institute of P.G. Medical Education & Research

Equipment	675000.00					675000.00
Manpower	2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9993828.00
Contingency	140000.00	140000.00	140000.00	100000.00	100000.00	620000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	150000.00	150000.00	150000.00	50000.00	50000.00	550000.00
Consumables	1160000.00	1310000.00	1310000.00	250000.00	250000.00	4280000.00
Total (Rs.)	4688276.00	4163276.00	4163276.00	1802000.00	1802000.00	16618828.00

3. Christian Medical College, Vellore

Equipment	1475000.00					1475000.00
Manpower	2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9993828.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Contingency	140000.00	140000.00	140000.00	100000.00	100000.00	620000.00
Consumables	952172.00	1000000.00	1000000.00	200000.00	200000.00	3352172.00
Total (Rs.)	5130448.00	3703276.00	3703276.00	1702000.00	1702000.00	15941000.00

4. All India Institute of Medical sciences,New Delhi

Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00

5. INSTITUTE OF LIFE SCIENCES, Bhubaneswar

Equipment	800000.00					800000.00
Manpower	720000.00	751200.00	785520.00	823272.00	864720.00	3944712.00
Contingency	200000.00	200000.00	200000.00	200000.00	200000.00	1000000.00
Travel	200000.00	200000.00	200000.00	200000.00	200000.00	1000000.00
Consumables	568000.00	768000.00	768000.00	568000.00	568288.00	3240288.00
Total (Rs.)	2488000.00	1919200.00	1953520.00	1791272.00	1833008.00	9985000.00

6. INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH

Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00

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Executive Registrar
SGPGIMS,Lucknow

7. Nizam's Institute of Medical Sciences						
Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00
8. Postgraduate Instutite of Medical Education and Research						
Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00
9. St John's Medical College, St John's National Academy of Health Sciences						
Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Total (Rs.)	2427000.00	1902000.00	1902000.00	1752000.00	1752000.00	9735000.00

Prof. Anita Aggarwal
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

2.6 Equipment:

The details of the equipment sanctioned for the implementation of the project at **Annexure-I**

2.7 Manpower:

The details of the manpower sanctioned for the implementation of the project at **Annexure-II**

3. Head of Account:

The **Non-Recurring** expenditure involved is debitable to:

Demand No. 85	**Department of Biotechnology**
3425	Other Scientific Research 2018-2019
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

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Executive Registrar
SGPGIMS,Lucknow

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2 Recurring expenditure involved is debitable to:

Demand No. 85	Department of Biotechnology
3425	Other Scientific Research 2018-2019
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.31	Grants-in-Aid General

4. **Terms & Conditions:**

In case the whole or a part of the amount of the grant-in-aid is being refunded. an interest rate at the rate of ten percent thereon shall be recovered.

The equipment sanctioned under the project should be purchased with in 18 months from the date of the release of the grant.

.1 The other terms and conditions governing this sanction are attached at Annexure- III.

.2 A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee institution on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/installment will be made only after signing of MoA by the grantee institutions and its acceptance by DBT. In case of NGO or Private Institution, MOA signed is mandatory for re-case. A format of the MoA is enclosed in Annexure-IV

1.3 The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the institute/Agency and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

5. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.

6. The Director, INSTITUTE OF LIFE SCIENCES, Bhubaneswar, Bhubaneswar, Orissa and The Director, INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH, Kolkata, West Bengal and The Director, Jawaharlal Institute of P.G. Medical Education & Research, Pondicherry, Pondicherry and The Director, Nizam's Institute of Medical Sciences, Hyderabad, Telangana and The Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh and The Dr. Paul Parathazham, St John's Medical College, St John's National Academy of Health Sciences, Bangalore, Karnataka and The Dr. Subhash Varma; Postgraduate Instutite of Medical Education and Research, Chandigarh, Chandigarh and The Principal, Christian Medical College, Vellore, Vellore, Tamilnadu and The Principal, S.C.B.Medical College, Cuttack, Cuttack, Orissa and The Prof. M.C. Misra, All India Institute of Medical sciences,New Delhi, New Delhi, Delhi would be responsible for submission of Statements of Expenditure (SoE), utilization certificates (UC), Assets Certificates, Manpower staffing & expenditure details in prescribed DBT formats to DBT in respect of grants released in this project from time to time.

7. PI's of DBT sponsored projects can consider appointment of JRF from Category-II merit list of DBT-BET exam so that candidates can be paid fellowships at par with NET/GATE/BET qualified candidates as per DST OM No. A.SR/S9/Z-09/2012 dated on 21 Oct 2014. However, there is no compulsion on PI's to select candidates for JRF in their projects from Category-II of DBT-BET.

8. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organisations shall be

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General ndia under the provision of CAG(DPC) Act 1971 and internal audit by the Principal Accounts Office the Ministry or Department, whenever the Institution or Organisation is called upon to do so.

the Research Project involves biological resource, the obligations under the Biological Diversity Act 2002 as applicable shall be complied with by the Project Investigator, the details of such obligations can be accessed at www.nbaindia.org

.This issues under the power delegated to this Department and with the concurrence of IFD vide their SAN No.102/IFD/SAN/1165/2018-2019 dated July, 18 2018.

11.This sanction order has been noted at serial no. 59 in the Register of Grants.

(Dr. Sandhya R Shenoy)
Scientist 'E'

To,
The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi - 110 002.
2 Amita Aggarwal(Project Co-ordinator), Department of Clinical Immunology, SGPGI Lucknow 226014
3 The Director, INSTITUTE OF LIFE SCIENCES, Bhubaneswar, Nalco Square, Chandrasekharpur, Bhubaneswar - 751023, Orissa
4 The Director, INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH, 244 A J C Bose Road, Kolkata - 700020, West Bengal
5 The Director, Jawaharlal Institute of P.G. Medical Education & Research, Dhanvantri Nagar, Pondicherry - 605006, Pondicherry
6 The Director, Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad - 500082, Telangana
7 The Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow - 226014, Uttar Pradesh
8 The Dr. Paul Parathazham, St John's Medical College, St John's National Academy of Health Sciences, St. John's Medical College, Sarjapur Road, Bangalore - 560 034, Bangalore - 560034, Karnataka.
9 The Dr. Subhash Varma, Postgraduate Instutite of Medical Education and Research PGIMER,Sector-12, Chandigarh,Pin- 160.012, India, Chandigarh - 160012, Chandigarh
10 The Principal, Christian Medical College, Vellore, Christian Medical College, Thorapadi P.O., Vellore , Vellore - 632004, Tamilnadu
11 The Principal, S.C.B.Medical College, Cuttack, CUTTACK,ORISSA, Cuttack - 753007, Orissa
12 The Prof. M.C. Misra, All India Institute of Medical sciences,New Delhi, Ansari Nagar East, New Delhi, New Delhi - 110029, Delhi
13 Dr. Ashish Jacob Mathew, Assistant Professor, Clinical Immunology and Rheumatology, Christian Medical College, Vellore- 632004, Tamilnadu
14 Dr. B Ravindran, PI, Professor Emeritus, INSTITUTE OF LIFE SCIENCES, Bhubaneswar, Institute of Life Sciences, Nalco Square, Bhubaneshwar, Khorda - 751023, Orissa
15 Dr. Manish Rathi, Additional Professor, Nephrology, Postgraduate Instutite of Medical

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Education and Research, Department of Nephrology, PGIMER, Chandigarh, Chandigarh - 160012, Chandigarh

16 Dr. Ranjan Gupta, Assistant Professor, Rheumatology, All India Institute of Medical sciences,New Delhi, Flat No. B-1/101, Varun Apartments, Sector No. 9, Plot No. 12, Rohini, New Delhi., Sri Ganganagar - 110085, Rajasthan

17 Prof. Amita Aggarwal, Professor, Department of Clinical Immunology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Immunology, Rae Barielly Road PIN:226014, Rae Bareli - 226014, Uttar Pradesh

18 Prof. Bidyut Das, Professor, Medicine, S.C.B.Medical College, Cuttack, Department of Medicine, SCB Cuttack, Orissa, Cuttack - 753002, Orissa

19 Prof. Liza Rajasekhar, Professor, Rheumatology, Nizam's Institute of Medical Sciences, Department of Rheumatology, Hyderabad - 5000082, Telangana

20 Prof. Parasar Ghosh, Professor, Clinical Immunology and Rheumatology, INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH, Department, Kolkata - 700020, West Bengal

21 Prof. Ramnath Misra, Professor, Clinical Immunology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Clinical Immunology, SGPGI, Lucknow, Lucknow - 226014, Uttar Pradesh

22 Prof. Vineeta Sobha, Professor, Clinical Immunology AND Rheumatology, St John's Medical College, St John's National Academy of Health Sciences, Department of Clinical Immunology and Rheumatology, St John's hospital Bangalore, Bangalore - 560034, Karnataka

23 Prof. Vir singh Negi, Professor, Clinical Immunology, Jawaharlal Institute of P.G. Medical Education & Research, Department of Clinical Immunology JIPMER, - 605006, Pondicherry

24 Cash Section, DBT (2 copies).

25 Sanction Folder.

26 File Copy.

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

(Dr. Sandhya R. Shenoy)
Scientist 'E'

Annexure -I

Details of the Equipment sanctioned for the implemention of the project titled "Multi-institutional Network Program on Systemic lupus Erythematosus Understanding the diversity of SLE":

Sanjay Gandhi Post Graduate Institute of Medical Sciences			
SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freezer	1	100000.00
2.	Centrifuge	1	45000.00
3.	Laptop/Computer	1	50000.00
4.	Server at Coordinating Centre	1	150000.00
5.	Pipettes	1	55000.00
6.	-80 degree freezer	3	3000000.00

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

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	Nanodrop	1	1400000.00
8.	Computer with Printer	1	50000.00
9.	Software for Biorepository	1	800000.00
10.	Barcode Reader & Printer	1	250000.00
11.	pippetes	1	500000.00
	Total		6135000.00

Jawaharlal Institute of P.G. Medical Education & Research

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 freezer	1	100000.00
2.	Centrifuge	1	450000.00
3.	Sample Label printer and reader	1	200000.00
4.	Pipettes	2	50000.00
5.	Laptop for data entry in OPD	1	50000.00
	Total		6750000.00

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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ristian Medical College, Vellore

No.	Name of Equipment	No.	Cost(Rs.)
1.	- 20 degree freezer	1	100000.00
2.	Pippete set	1	55000.00
3.	computer	1	50000.00
4.	sample label printer	1	20000.00
5.	centrifuge	1	450000.00
6.	-80 degree freezer	1	800000.00
		Total	1475000.00

Postgraduate Instutite of Medical Education and Research

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 freezer	1	100000.00
2.	Centrifuge	1	450000.00
3.	Sample Label printer and reader	1	20000.00
4.	Pipettes	1	55000.00
5.	Laptop for data entry in OPD	1	50000.00
		Total	675000.00

INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freer	1	100000.00
2.	centrifuge	1	450000.00
3.	sample label printer and reader	1	20000.00
4.	pipetteset	1	55000.00
5.	Laptop for data entry in OPD	1	50000.00
		Total	675000.00

Prof. Amita Aggarwal
Head
Dept. of Pathology (Microbiology Unit)
SGPGIMS, Lucknow

Nizam's Institute of Medical Sciences

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freezer	1	100000.00
2.	centrifuge	1	450000.00

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Executive Registrar
SGPGIMS,Lucknow

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	sample label printer and reader	1	20000.00
	Pipette set	1	55000.00
	laptop	1	50000.00
		Total	675000.00

All India Institute of Medical sciences,New Delhi

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freezer	1	100000.00
2.	centrifuge	1	450000.00
3.	sample label printer	1	20000.00
4.	pipette set	1	55000.00
5.	computer	1	50000.00
		Total	675000.00

INSTITUTE OF LIFE SCIENCES, Bhubaneswar

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-80 degree freezer	1	800000.00
		Total	800000.00

St John's Medical College, St John's National Academy of Health Sciences

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 freezer	1	100000.00
2.	centrifuge	1	450000.00
3.	Sample Label printer and reader	1	20000.00
4.	Pipettes	1	55000.00
5.	Laptop for data entry in OPD	1	50000.00
		Total	675000.00

Sandhya R. Shenoy
(Dr. Sandhya R. Shenoy)
Scientist 'E'

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Annexure -II

...tails of the manpower sanctioned for the implemention of the project titled "Multi-institutional ...twork Program on Systemic lupus Erythematosus ...nderstanding the diversity of SLE":

Head	No. of Position	Year I	Year II	Year III	Year IV	Year V	Total (Rs.)
1. All India Institute of Medical sciences,New Delhi							
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
2. Christian Medical College, Vellore							
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Lab Technician Lab Technician	2	432000.00	432000.00	432000.00			1296000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other1-SRO	1	729276.00	729276.00	729276.00			2187828.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9993828.00
3. INSTITUTE OF LIFE SCIENCES, Bhubaneswar							
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1	312000.00					312000.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1		343200.00				343200.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1			377520.00			377520.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1				415272.00		415272.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1					456720.00	456720.00
Lab Assistant Lab Assistant	2	408000.00	408000.00	408000.00	408000.00	408000.00	2040000.00
Total(Rs.)		720000.00	751200.00	785520.00	823272.00	864720.00	3944712.00

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4. INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

5. Jawaharlal Institute of P.G. Medical Education & Research

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Lab Technician Lab Technician	2	432000.00	432000.00	432000.00			1296000.00
Other1 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Other1 SRO	1	729276.00	729276.00	729276.00			2187828.00
Other2 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Total(Rs.)		2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9903828.00

6. Nizam's Institute of Medical Sciences

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

7. Postgraduate Instutite of Medical Education and Research

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

9. Sanjay Gandhi Post Graduate Institute of Medical Sciences

Data Manager DATA MANAGER	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Lab Technician Lab Technician	1	216000.00	216000.00	216000.00	216000.00	216000.00	1080000.00
Lab Technician Lab Technician (3 years sub project)	2	432000.00	432000.00	432000.00			1296000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other1 Senior Technical Assistant	1	384000.00	384000.00	384000.00	384000.00	384000.00	1920000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00

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Executive Registrar
SGPGIMS,Lucknow

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Other2 SRO	1	729276.00	729276.00	729276.00			2187828.00
Total(Rs.)		3435276.00	3435276.00	3435276.00	2274000.00	2274000.00	14853828.00
10. St John's Medical College, St John's National Academy of Health Sciences							
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

Emoluments detail of research personal(s) mentioned in table(s) of Annexure-II shall be applicable only if candidate(s) met educational qualification and eligibility criteria as per DST OM No.SR/S9/Z-09/2013 dated 21.10.2014.

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

(Dr. Sandhya R. Shenoy)
Scientist 'E'

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ TE 426392

प्रधान मुद्रांक कार्यालय, मुंबई
प.मू.वि.क्र. ८०००००३
- 3 APR 2018
सक्षम अधिकारी

श्री. प्र. ना. चिंचघरे

AGREEMENT
between

WBIO
Wockhardt BioAG
Grafenauweg 6, Ch-6300 Zug, Switzerland

And

WL
Wockhardt Limited
Registered office at D-4, MIDC, Chikalthana, Aurangabad-431006
and
Global headquarters at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051

And

INVESTIGATOR
Dr. Brijesh Singh
Dept of General Surgery, Sanjay Gandhi Post Graduate Institute of Medical Sciences,Lucknow 226014
Uttarpradesh

And

INSTITUTION
Sanjay Gandhi Post Graduate Institute of Medical Sciences,Lucknow 226014
Uttarpradesh

(WBIO, WL, the INSTITUTION, the INVESTIGATOR jointly referred to as "the Parties")

The Parties are pleased that the discussions between representatives of the WBIO on one hand and the INVESTIGATOR on the other hand, have resulted in the INVESTIGATOR's agreement to participate in the collaborative clinical research study: W-771/2349-301

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

Preamble:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow is a super specialty hospital, established by Government of Uttar Pradesh, as a center of excellence for providing medical care, education and research of high order and is chartered to function as a university under Sanjay Gandhi Post Graduate Institute of Medical SciencesAct, 1983. [Hereinafter referred to as "Act"]

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day **28 Jan 2018 AMONG**

Wockhardt Limited, a company originally incorporated in India having its registered office at D-4, MIDC, Chikalthana, Aurangabad- 431006, and Global headquarters at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051, (herein after referred to as ("WL")

AND

WOCKHARDT BIO AG, whose registered address is Grafenauweg 6, 6300 Zug, Switzerland hereinafter referred to as WBIO

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, **at Raebareli Road, Lucknow-226014, Uttar Pradesh,** India, through its **"Director/Director's Nominee** Prof RAKESH KAPOOR .[herein referred to as "Institute"] of the Third part.

AND

Dr.BRIJESH SINGH a **GENERAL AND LAPARASCOPIC SURGEON , Department of GENERAL SURGERY , Sanjay Gandhi Post Graduate Institute of Medical Sciences** [hereinafter referred to as **"Principal Investigator"**] of the Fourth Part.

WHEREAS The Sponsor, Institute and, Principal Investigator are willing to jointly carry out the Study Number: _____

Entitled....."..... ....." **[Hereafter referred to as "Study"]** described in StudyProtocol;

AND WHEREAS WBIO is desirous of engaging the said Principal Investigator and Institute for carrying out the Study through **Site Management Organization (SMO) [if needed]**

NOW, THEREFORE, in consideration of the premises and the covenants and Agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1.0 Statement of work

1.1 "Study" shall be deemed to be "Clinical Trial" as defined in rule-122 DAA of the Drugs and Cosmetics Rule, 1945.

1.2 WBIO shall provide Principal Investigator with a sufficient quantity of Study Supplies to conduct the Study at investigational Site in timely manner. Institute and Principal Investigator shall use Study Supplies only to conduct the Study in accordance with the Protocol; All Study Supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of WBIO, unless otherwise designated. The Institute and Principal Investigator will be responsible for the return of excess, unused Study Supplies to WBIO.

1.3 Study Timelines: Study Timelines for the purpose of this Agreement will be as provided in the Protocol.

2.0 Obligations and Responsibilities of the Principal Investigator

2.1 The Principal Investigator will recruit only qualified participants as per Inclusion and Exclusion criteria.

2.2 The Principal Investigator will conduct the Study in accordance with the protocol, Schedule Y (Drug and Cosmetics Rules, 1945) and Indian Council of Medical Research (ICMR) Guidelines along with Helsinki and The International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Guidelines for international studies and other applicable laws.

2.3 The Principal Investigator will make necessary arrangement for inspection of documents etc. by WBIO's monitor, official of regulatory agency or Institutional Ethics Committee (IEC) nominee.

2.4 The Principal Investigator shall report all serious and unexpected adverse events and/ or death to the Licensing Authority, WL,WBIO, and IEC as per Appendix XI of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

2.5 The Principal Investigator shall forward its report on Serious Adverse Event of Death after due analysis of all factors with his opinion to WL, Chairman of IEC, Chairman of Expert Committee and Head of the Institute and the Licensing authority as per Appendix X of schedule Y(Drug and Cosmetics Rules, 1945).

2.6 The Principal Investigator shall forward its report on Serious Adverse Event (SAE) after due analysis of all factors with his opinion to Licensing Authority, Chairman of IEC and Head of the Institute as per Appendix X of schedule Y (Drug and Cosmetics Rules, 1945).

2.7 The Principal Investigator will be responsible for proper and prompt filling of Case Report Form (CRF), preservation of investigation reports and recordings.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.8 During and following a Clinical Trial Subject's participation in Study, the Principal Investigator shall ensure that adequate medical care is provided to the participant (Clinical Trial Subject) for any adverse events.

2.9 The Principal Investigator will ensure enrolment of trial participants after obtaining informed consent including audiovisual recording and also informing the provisions of adequate treatment and compensation for Serious Adverse Event (SAE) as per schedule Y (Drug and Cosmetics Rules, 1945).

2.10 Principal Investigator (PI) shall complete the Clinical Trial under his supervision as per this Agreement and the Statutory provisions, but if for any reason he/she is unable to carry over the study it shall be his/her responsibility to hand over the study to his/her Co-Principal Investigator (Co-PI) or to any of the Faculty members of the Institute, to be decided by the Head of Department of the PI or Director and obtain the approval of the Ethics Committee and WBIO.

2.11 The Principal Investigator will be responsible for proper account of receipt, utilization and return of unused sample of trial drug to WBIO and prevent its use for any other study.

2.12 The Principal Investigator will be responsible for providing non-compliance and progress report to Institutional Ethics Committee (IEC) within a week of occurrence or due date.

2.13 The Principal Investigator will be responsible for forwarding to IEC communications from WBIO within a week of receipt with comments for the need of any change in protocol or Patient Information Sheet (PIS).

2.14 The Principal Investigator will be responsible for obtaining IEC and WBIO permission for storage of blood or tissue samples for future use.

2.15 The Principal Investigator shall be responsible for obtaining WBIO's written permission before publication or conference presentation of any data.

3.0 Obligation and Responsibilities of the Institute:

3.1 Study shall be conducted in compliance with the Protocol, Standard Operating Procedure (SOP) and applicable regulatory and legal requirements.

3.2 Ensuring that the rights, safety and well-being of Clinical Trials Subject are protected.

3.3 Fulfillment of necessary obligations by Institutional Ethics Committee (IEC), The Principal Investigator (PI) and supporting staff.

3.4 Protection of confidentiality, rights, safety and wellbeing of clinical trial participants.

3.5 Adequate treatment and compensation for Serious Adverse Event (SAE) to trial participants.

3.6 Necessary infrastructure support to PI.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

3.7 Communicating with IEC and obtaining approval for the Clinical Trial Protocol, written informed consent and other trial related Study documents.

3.8 Ensuring accuracy, completeness, legibility and timelines of the Data reported to WBIO in the Case Report Forms (CRFs) and in all required reports.

3.9 Study shall be terminated on the recommendation of IEC, when safety and benefit of Clinical Trial Subjects is doubtful.

3.10 Safety reporting as per schedule Y (Drug and Cosmetics Rules, 1945) and/or WBIO policy.

3.11 Upon request of the monitor, auditor, Institutional Ethics Committee or applicable regulatory authority, Institute should make available for direct access all requested trial related records provided WBIO shall be given prior intimation.

3.12 The confidentiality of record that could identify Clinical Trial subject should be protected and maintained.

3.13 If WBIO or Contract research organization (CRO) violates the terms of this Agreement or does not provide the claimed compensation to the subject then the Institute or Principal Investigator may not conduct any other further clinical trials of this sponsor.

3.14 Approval of study within 8 weeks of receipt of Investigator's brochure, protocol including Patient Information Sheet (PIS) & Case Report Form (CRF), regulatory approvals, draft Clinical Trial Agreement (CTA), Insurance policy and IEC fee from sponsor.

3.15 Approval of midterm changes within 8 weeks of receipt of documents.

3.16 Review of progress report Data and Safety Monitoring Board (DSMB) report & Serious Adverse Event (SAE) from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

3.17 Review of SAE at Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) and necessary action within the time frame decided by regulatory agencies.

3.18 Review of final report.

3.19 Approval of storage of blood or tissues for use in future studies.

3.20 Facilitate visit of sponsor's monitor or representative of regulatory agencies.

3.21 Institutional clearance for sample to be sent abroad for non-pharmacokinetic studies.

3.22 Archiving of data for 5 years (or longer if required by sponsor/regulatory agency).

3.23 Safeguarding Intellectual property rights (IPR) of sponsor and SGPGI.

3.24 Providing alternate Principal Investigator (PI) if PI unable to continue.

3.25 Audited statement of utilization of Funds.

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Executive Registrar
SGPGIMS,Lucknow

4.0 Obligation and Responsibilities of the Sponsor

4.1 To provide investigator's brochure, Protocol, Case Report Form (CRF) draft Clinical Trial Agreement (CTA), Insurance policy from an Indian Insurance company and regulatory approvals.

4.2 To provide adequate supplies of trial drug, comparator and /or placebo prepared under proper quality control.

4.3 To provide Insurance cover for treatment and compensation of Serious Adverse Event (SAE) and an undertaking to supplement any amount not covered by the Insurance Company. Sponsor will also provide copy of Policy to the Institute.

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4.5 Not to send samples for Pharmacogenetic study abroad.

4.7 Provide a copy of final report at termination of the study.

4.8 Appropriate acknowledgement of contribution of SGPGI investigators in any resulting publication.

4.9 To define and follow procedure for premature termination.

4.10 To provide budget which should include cost of treatment, investigations and investigators charges, reimbursement of travel expenses to participants if necessary, Institute's overhead at the rate of 25% of the total budget and INR 25,000/- fee of IEC. Details of release of budget to be mutually settle.

5.0

5.1 Sponsor agrees that any injury or death of the Clinical Trial Subject occurring in Clinical Trial due to following reasons shall be considered as Clinical Trial related injury or death and the subject or his nominee, as the case may be, will be entitled to receive from the sponsor financial compensation for such injury or death as per the notification of the Drug Controller General of India (DCGI) & Government of India issued from time to time.

(a) Adverse effect of Investigational Product(s);

(b) Violation of the approved Protocol;

(c) Scientific misconduct or negligence by the Sponsor or his representative or

Contract research organization (CRO) or Principal Investigator, Co-investigator or any member of his/her team

(d) Failure of Investigational Product to provide intended therapeutic effect;

(e) Use of placebo in a placebo-controlled Clinical Trial;

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Executive Registrar
SGPGIMS,Lucknow

(f) Adverse effects due to concomitant medication excluding standard care, necessitated as part of approved Protocol;

(g) For injury to a child in utero because of the participation of parent in Clinical Trial;

(h) Any Clinical Trial procedures involved in the Study.

5.2 Sponsor should submit a status report on the Clinical Trial to the Licensing Authority at the prescribed Periodicity;

5.3 In case of studies permanently discontinued for any reason Sponsor shall submit a summary report to the Licensing Authority as per provisions of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

6.0 Undertaking and Representation of Principal Investigator

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format given in Appendix VII of Schedule-Y of Rules (Drug and Cosmetics Rules, 1945).

7.0 Undertaking and Representation of Institute

Institute hereby represents that:-

It has constituted the Institutional Ethics Committee as per the guidelines given in the Gazette of India & it has been registered with the Drug Controller General of India (DCGI) vide letter No:.....dated.....

(i) SOP is in compliance with Good Clinical Practice (GCP) guidelines and applicable regulations;

(ii) It will ensure that IEC will discharge its responsibilities as per provisions of Schedule-Y (Drug and Cosmetics Rules, 1945)

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that:-

It has furnished an undertaking along with the application for Clinical Trial Permission to the Licensing Authority to provide compensation in the case of clinical trial related injury or death for which subjects will be entitled to compensation; as per provisions of rule 122 DAB (b) of Rules (Drug and Cosmetics Rules, 1945).

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Executive Registrar
SGPGIMS,Lucknow

9.0 Administration

9.1 Overall responsibilities of the Study will rest with Principal Investigator, Institute and Sponsor to conduct the Study at Institute's premises.

9.2 The following Study plan will apply to the Study:

(a). Subject enrollment up to Institute's Enrollment Maximum (i.e.: Clinical Trial Subjects) shall be completed as stated in protocol. However, if the Institute and Principal Investigator are unable to enroll patients for the Study within 6 months of Investigation Site initiation Sponsor will be having the authority to change the Institute's Enrollment Maximum in a unilateral manner.

(b). Institute or Principal Investigator will not enroll more Study subjects than Institute's Enrollment Maximum Sponsor will not be obligated to make any payment with respect to any subject enrolled in excess of Institute's Enrollment Maximum.

(c). Subject to applicable law: Sponsor and Institute without any further obligation mutually may agree in writing to modify Institute's Enrollment Maximum.

(d). All subject visits will be conducted as proposed in the protocol. The sponsor will be informed is a visit is delayed by more than 2 weeks along with reason of delay.

(e). Case Report Forms ("CRFs") information associated with a subject's visit must be satisfactorily completed within 7 days after the subject's visit or, if applicable, receipt of the subject's test results.

(f). All Data Queries from Sponsor must be completed and returned to Sponsor within a time frame mutually negotiated.

(g). Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or Study team will not be the liability of Sponsor.

10.0 Trial Drug; Materials Transfer; Records Retention; Inspection

10.1 Trial drug:

(i) Institute and Principal Investigator acknowledge that the trial drug/device is owned or controlled by Sponsor and that neither the terms of this Agreement nor the Protocol, nor any activities conducted by Institute or Investigator for the Trial, shall be construed to grant to either Institute or Principal Investigator any rights in or to the Compound.

(ii) Except as otherwise agreed by the Parties, Sponsor will provide the Compound and any control/placebo material to be administered to Trial subjects as part of the Trial (collectively, the "**Trial Drug**") free of charge to Institute for administering or dispensing solely by or under the supervision of Principal Investigator or sub-investigator to Trial subjects at the Trial Site in Strict compliance with the Protocol.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(iii) Institute and Principal Investigator shall use the Trial Drug solely to conduct the Trial in strict compliance with the Protocol and for no other purpose, and shall not transfer the Trial drug to any third parties. Institute and Principal Investigator shall handle, store, ship and dispose of the Trial drug as directed by Sponsor or its designee and in compliance with all applicable laws, rules and regulations.

(iv) Institute and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

(v) Neither support of the Trial, nor Institute participation in the Trial, impose any obligation, express or implied, on Institute or Principal Investigator to purchase, prescribe, provide favorable formulary status for or otherwise support Sponsor's products.

(vi) Unless required by the Protocol, Institute will not modify the Trial Drug or its container. If the Institute policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Institute for use in a future study to be approved by Institutional Ethics Committee (IEC).

10.2 Records Maintenance and Retention Investigator and Institute will maintain adequate and accurate records relating to the disposition of the Trial Drug and the performance of all required Protocol procedures on Trial subjects including but not limited to, written and audiovisual documents, medical records, charts pertaining to individual Trial subjects, "Case Report Forms (**"CRF"**) accounting records, notes, reports, and data. Institution will retain these documents for the longer period of at least 5 yrs. after completion or earlier termination of the Trial.

11.0 Representation and Warranties

11.1 Institute represents and warrants that it has the legal authority to enter into this Agreement and that the terms of this Agreement are not in conflict with any other agreements to which it is legally bound. Institute shall ensure that Investigator will not, enter into any agreement or engage in any activities that would materially impair its or his /her ability to complete the Trial in accordance with this Agreement and the Protocol.

11.2 Institute represents and warrants that the Principal Investigator is qualified as a medical practitioner under applicable laws and regulations.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

12.0 Confidentiality

12.1 Institute will (and will cause Principal Investigator and Trial Personnel to) keep strictly confidential and not disclose to third parties all information provided by or on behalf of subject or that is generated, discovered, or obtained by any of the above Party as a result of the Trial (other than patient medical records), including the Trial Results, Trial Inventions and information related thereto **(Confidential Information).** Institute and Investigator will use, and will cause Trial Personnel to use, Confidential Information only for purposes of the Trial. The obligations of this Section will survive expiration or termination of this Agreement. Confidential Information will not include information that:

(i) Is or becomes publically available through no fault of Investigator or Institution.

(ii) Was known to Principal Investigator or Institute without obligation of confidentiality prior to receiving it either directly or indirectly from other sources Under this Agreement, as demonstrated by written records predating the date it was learned by Investigator or Institute form other source.

(iii) Is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

(iv) Can be shown by written records of Principal Investigator or Institution to have been independently developed by Principal Investigator or Institution without reference to or reliance upon any Confidential Information.

12.2 Notwithstanding any other provision of this Agreement, Institute and Principal Investigator may disclose Confidential Information to the extent required.

(i) To comply with an applicable law, rule regulation or government order, after prompt notice to Sponsor provided that Investigator and Institute cooperate with Sponsor efforts to limit such disclosure by appropriate legal means:

(ii) To protect any Trial subject's safety or provide appropriate medical care for any Trial subject, or to prevent a public health emergency with prompt notice to Sponsor

(iii) For purposes of insurance or reimbursement by a third party or pay for medical treatment of Trial subject related to the procedures included in the Protocol.

13.0 Return of Confidential Information

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

14.0 Trial Results and Inventions

14.1 Sponsor owns all data, Trial Results, Confidential Information, Case Report Forms (CRFs) and all other information generated as a result of or in connection with the conduct of the Trial, excluding Institution's patient medical records and Principal Investigator's personal notes and hereby grants to the Institute a nonexclusive, non–transferable, non-sub licensable right to use the Trial Results solely for its own internal, non-commercial research, patient care, and educational purposes.

14.2 All inventions, ideas, methods works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institute, Principal Investigator or Trial Personnel: (i) as a result of or in connection with the conduct of the Trial (ii) that incorporate or use Confidential Information: or (iii) that are directly related to the Compound and in each case together will all intellectual property rights relating thereto (collectively, **Trial Inventions**"), will be the sole and exclusive property of Sponsor Or its designee. Institute and Principal Investigator will promptly disclose all Trial Investigations to sponsor in writing and interest in all Trial Investigations to sponsor or its designee. At sponsor's request and expense, Institute shall take and shall cause Principal Investigator and Trial Personnel to take, all additional actions as it deems necessary to perfect the interest of sponsor or its designee in Trial Investigations or to obtain patents or otherwise protect the interest of sponsor or its designee in Trial Investigations

15.12 **Tax deduction:** All fees and amounts listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the Institute for the Study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

Goods and Service Tax (GST)

The Institution, Investigator and SMO will issue GST invoice as per time specified under Section 31 (5) of the CGST Act, 2017, clearly mentioning its GSTIN and containing other details required under GST laws to WL for the services rendered. Further, WL will make the payment after deducting applicable taxes and records of such taxes deducted at sources will be made available to them by WL.

i) Obligation of Institution, Investigator and SMO

The Institution, Investigator and SMO shall comply with all applicable laws including GST and other indirect taxes, safety and health laws

ii) Compliance

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The Institution, Investigator and SMO confirm that they are duly registered under GST laws, labor laws and Professional Tax Act. Further, the provisions of all applicable laws captioned above are also applicable to employees employed by them.

iii) Anti Profiteering/ Passing Benefits

The Institution, Investigator and SMO shall pass on to WL all the benefits of either reduction in tax rates, exemptions, concessions, rebate, set off, credits, etc. or introduction of new tax rates exemptions, concessions, rebate, set off, credits etc. pertaining to all taxes, duties, imposts, fees and levies in respect of the supplies of goods or performance of obligations including reduction in procurement price, under the Agreement. This would specifically include reduction of tax rates as a result of statutory changes or judicial rulings and reduction in price where the Institution, Investigator and SMO are benefited due to reduction in taxes.

iv) Indemnity

The Institution, Investigator and SMO hereby represent that they are registered under GST and shall be compliant of GST provisions including issuance of proper tax invoice to enable WL avail entire input tax credit on timely basis. The Institution, Investigator and SMO further represent that they shall timely deposit GST amount due to the Government and file periodic statements / returns as per the provisions of GST Law and comply with all the requirements under GST law, to ensure timely receipt of input tax credit benefit of the taxes charged by them on their outward supplies to WL. In case of non-compliance of the GST provisions by the Institution, Investigator and SMO resulting in blockage or denial of any input tax credit benefit to WL, the Institution, Investigator and SMO shall hereby indemnify WL for input tax credits so denied along with interest, penalty and other costs.

v) Transition Clause

The Institution, Investigator and SMO should support WL on various aspects to comply with the transition provisions under GST. The Institution, Investigator and SMO should also take best of efforts to assist WL in identifying the tax benefits or refunds as the case may be, that may accrue on stocks, credits, taxes, etc on the GST Implementation appointed date and pass-on the same to WL.

vi) Change in law

Any statutory variation in duties, levies or taxes if applicable and specified in this Agreement, or the introduction of new duties, levies or taxes from the date of submission of bid/ quotation till the scheduled date for completion of work contemplated under the Agreement which include defect liability period if any, shall be communicated to WL prior to its levy. Institution, Investigator and SMO will not levy any such additional duties, levies or taxes without prior approval of WL. Further, any statutory variation in taxes will be levied after mutual agreement of all the parties.

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16.0 Use of other parties' names

The Principal Investigator and Institute shall not use Sponsor's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ CRO/Institute.

17.0 No joint venture etc.

This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18.0 Insurance and Indemnification

Insurance:

Institute shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance.

Indemnification:

Sponsor shall, at all times to come, indemnify the Principal Investigator and Institute for any direct damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institute arising directly or indirectly out of the performance of the Study pursuant to the Protocol and SOP only to the extent such claims are solely attributable to Sponsor.

Principal Investigator and Institute shall be responsible for all direct damages, losses and liabilities including reasonable attorney fees arising out of the negligence or intentional misconduct of its affiliates, employees, agents and contract personnel while providing services under this Agreement or claims arising from breach of any applicable laws or breach of any representations and warranties as mentioned herein the Agreement.

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19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

19.1 The Principal Investigator and Institute shall, permit authorized personnel of the Sponsor/ Sponsor designate and any Regulatory Authority including IEC to inspect the facilities of the Investigational Site before, during and after the Study.

19.2 The Principal Investigator and Institute shall notify to the Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute s facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the PrincipalInvestigator and Institute receives, obtains, or generates pursuant to any such study.

19.3 The Principal Investigator and Institute will permit the Sponsor to;

(a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.

(b) Inspect and copy all Data, documents and records related to such work and the Study

19.4 The obligations of this Section shall survive termination of this Agreement.

20.0 Term; Waiver; Severability (The trial on its time extended)

20.1 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 36 months after the Effective Date. The Date of execution of this Agreement shall be the effective Date. The term of this Agreement may be extended by consent of all parties to this Agreement.

20.2 This Agreement will become effective after by the last signatory it is fully executed by all the parties hereto and shall continue in effect for the full duration of the Study according to the Protocol unless extended or sooner terminated in accordance with the provisions of this Agreement.

20.4 This Agreement may be terminated by any party upon giving at least a thirty (30) days written notice to that effect to the other parties. The day following the 30th day of such notice shall be "Effective Date of Termination". A reasonable adjustment may be made (subject to mutual agreement) between the parties to ensure the Principal Investigator and Institute is reimbursed for project costs incurred to the date of termination of this Agreement for completing the study as per protocol or already enrolled subjects.

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20.5 Sponsor may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institute subject to the discharge of their respective obligations under the terms of the Agreement.

21.0 Effect of termination

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(ii). Upon notice of termination of this Agreement by Institute or Sponsor or Principal Investigator, Institute shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institute shall be compensated only for Study-related work actually performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which sponsor has agreed to pay as part of the Study under this Agreement. If, upon the Effective Date of Termination, sponsor has advanced funds which remain unutilized or surplus, Institute shall repay such funds within sixty (60) days of the Effective Date of Termination. In the event Institute fails to repay such funds in a timely manner, Sponsor may deduct an equivalent amount from any payment then or later due from Sponsor to Institute under this or any other arrangement between the parties.

(iii). Upon termination of this Agreement, all unused Materials and all Sponsor Confidential Information (except for such records that Institute is required by law or regulation to retain) in Institute's possession shall be promptly delivered to Sponsor at Sponsor's expense, or, at Sponsor's option, destroyed with the destruction certified in writing.

22.0 Recordkeeping

The Institute and Principal Investigator shall prepare and maintain records, reports and Data provided in the Protocol, Institutional Ethics Committee (IEC) requirements, and in accordance with all applicable local, state and Central laws and regulations. Institute or Principal Investigator shall cooperate with the Sponsor in making records, reports and Data developed under this Agreement.

Institute or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity,

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whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

23.0 Publication

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the Clinical Trial Study is the sole property of the Sponsor. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study but his name should to be included in any publication either author or as participant in the study.

24.0 Miscellaneous

24.1 Parties to this Agreement shall comply with the current provision of Drugs and Cosmetic Act 1940, Drugs and Cosmetic Rules 1945.

For providing insurance to Clinical Trial Subjects in case of injuries or death, The parties to this Agreement have tied up with insurance company (The.....Raheja. QBE General Insurance Co. Ltd..) which covers per patient amount (...2,00,000 only...per patient limit). This insurance is valid from the period from .....6/1/18.....) to (.....5/1/19.....). This insurance shall be extended from time to time till the expiry of Agreement.

24.2 The Study shall be started by Principal Investigator after this Agreement is executed by all the parties and required regulatory approvals/consent is available for the study.

24.3 The parties to this Agreement shall ensure that safety, welfare and right of the research participants (Clinical Trial Subject) are safeguard.

24.4 The Principal Investigator shall forward all Protocol deviation/non-compliance/violation/waiver reports to the IEC.

24.5 The safety completion Report shall be sent to IEC by Principal Investigator.

25.0 Governing Law

The validity, interpretation, and performance of this Agreement shall be governed and construed in accordance with the laws of INDIA.

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26.0 Jurisdiction

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be Mumbai, notwithstanding any other provision to the contrary in any law in this regard.

27.0 Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed in accordance with the sections of Indian Arbitration and conciliation Act 1996 ("the Act"), within 30 days of the receipt of a written request by the aggrieved. The Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

28.0 Amendment

This Agreement and Protocol may only be amended by the mutual written consent of the parties hereto. The parties agree that this Agreement constitutes the sole, full and complete Agreement by and between the parties and supersedes all other written and oral Agreements and representation between the parties with respect to the Study. No amendments, changes, additions, deletions, or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the parties. All changes and amendments to this Agreement shall be agreed in writing between the parties.

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Exhibit A
Payment Schedule for W-771/2349-301

(A)Per patient PI fee

Milestones	PI Fee in INR
Screening (Visit 1)	5,600
Randomization and Hospitalization (visit 2)	5,500
Early on Therapy (Visit 3)	5,000
Visit 4 (Late on Therapy)	5,000
PK Sampling (Levonadifloxacin IV and Oral arm)	3,000
Visit 5 (End of Study)	5,500
Visit 6 (Test of Cure)	5,500
All-cause mortality (Telephonic)	900
Per Patient Cost	36,000.00
25% Institutional Overhead Cost	9,000.00
Total Per Patient Cost	**45,000.00**

(B) Patient related cost: Patient travel reimbursement*
***INR 500 X 5 visits = 2,500/- per patient**

Total Site budget (A+B)

Description	Amount (INR)	No. of subjects	Total cost (INR)
Total Per patient cost	45,000.00	15.00	6,75,000.00
CRC Payments	10,000.00	12 months	1,20,000.00
Patient travel*	2,500.00	15.00	37,500.00
Start-Up Cost	15,000.00	-	15,000.00
Grand total			**847,500.00**

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- [1]The amount of INR 500 has been considered for calculation purpose. The travel reimbursements up to INR 1000 will be made as per actuals.
- [2]Budget is based on number of patients enrolled and visits completed. Budget can increase or decrease based on total number of subjects enrolled in the study.
- [3]Start-Up cost will be a one-time payment made to the Site.
- Archival cost for the Site will be not be applicable as documents will be archived by the WBIO.
- Exhibit A will be applicable for Site payments only after Site Initiation Visit.
- All payments will be done only after the completion of data entry for the specific visit for each subject.
- Screen failure cost will be INR 1500 provided screening procedures are conducted. Sites will be paid in the ratio of 1:4 (screen failure: randomized) for screen failure subjects.
- TDS will be deducted as per government of India regulations.
- Budget shared in Exhibit A is exclusive of Service taxes that may be applicable for services provided.
- Local laboratory charges and hospitalization charges would be paid as per actual invoices submitted in original which could vary from case to case basis.
- Payment for any additional visits conducted would be based on original invoices submitted by the Principal Investigator.
- The last payment to the Site would be released only after the data for this study has been locked.
- Sponsor will provide camera and laptop to the Investigator for use during the trial duration. If the Investigator randomizes 20 subjects with Gram-positive infection (as confirmed by the culture report from the Central Laboratory) in the stipulated trial duration as specified by the Sponsor, the camera and laptop will not be returned to the sponsor and will remain with the Investigator.
- In case the Investigator fails to enrol 20 subjects as specified above, the laptop and camera will be returned to the sponsor on completion of the trial without any further delay.
- .In addition to above, Ethics committee fees on actual basis would be borne by Wockhardt.
- Payment will be processed within 45 days from receipt of original invoice at Wockhard

- PI fee to be drawn in favour of:

Payee name	Director, SGPGIMS RESEARCH SCHEME ACCOUNT , LUCKNOW
PAN	AAAJS3913N
GSTN	09AAAJS3913N2ZN
Name of the Bank & Branch	State Bank of India, SGPGIMS Branch Lucknow
Bank account number	10095237491
IFSC Code	SBIN007789

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IN WITNESS WHEREOF THE PARTIES HERETO HAVE EXECUTED THE AGREEMENT AS OF THE DAY AND YEAR FIRST ABOVE WRITTEN.

For WBIO: Wockhardt BioAG Grafenauweg 6, Ch-6300 Zug, Switzerland **Signature:** _____ **Name:** Mr. Ajay Sahni **Role:** Director **Date:**	**For WL:** Wockhardt Limited Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051 **Signature:** Ashima Bhatia **Name:** Dr Ashima Bhatia **Role:** Sr. V. P., Global Clinical Development **Date:**
INVESTIGATOR Department of GENERAL SURGERY , Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh 226014 **Signature:** _____ **Name:** Dr.Brijesh Singh **Role:** Investigator **Date:** 02 May 2018	**For the INSTITUTION:** Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh 226014 DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA **Signature:** _____ **Name:** Prof Rakesh Kapoor **Role:** DIRECTOR, SGPGIMS, LKO **Date:**

Dr. BRIJESH SINGH
M.B.B.S., M.S. (Surgery)
Gen. & Laparoscopic Surgeon
S.G.P.G.I.M.S., Lucknow
Regn. No. - 42177

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SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2017 ◐ SR 500670

प्रधान मुद्रांक कार्यालय, मुंबई
प.मू.वि.क्र. ८०००००८
22 NOV 2017
सक्षम अधिकारी
श्री. दि. क. गवई

REGISTRY AGREEMENT

This **REGISTRY AGREEMENT** is made and entered into as of the 12th Day of December 2017 ("the Effective Date") by and between

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented by Dr. Chirag Trivedi duly authorized for the purposes hereof ("the Sponsor")

AND

DR. RAJ KUMAR SHARMA having his address at Sanjay Gandhi Postgraduate Institute of medical Sciences, Raebareli Road, Lucknow-226014, UP State, India ("the Investigator"),

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS) having its Raebareli Road, Lucknow-226014, UP State, India, represented by **PROF. RAKESH KAPOOR,** Director, duly authorised for the purposes hereof, ("the Institution"),

The Sponsor, Investigator and the Institution hereinafter referred to individually as the "Party" and collectively as the "Parties"

Site Name: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow
Study Code / Name: ANTHGL07849/RISE Study Effective Date: 12th December 2017

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

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SGPGIMS,Lucknow

PREAMBLE

WHEREAS, Sponsor wishes to perform A Registry to describe clinical experience with Thymoglobuline® used as induction immunosuppression in patients undergoing renal transplantation ("the Study") in accordance with Amended Protocol 01 bearing Study name: RISE Study, as amended from time to time during the term of this Agreement ("Term"), which is attached hereto as Appendix 1 ("the Protocol");

AND WHEREAS, the Investigator has reviewed the Protocol, desires to participate in the Study and assures that he has the necessary personnel, infrastructure and technical means to perform the Study;

AND WHEREAS, SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS) is a Government Hospital providing highest caliber faculty, high class education, research and patient care;

WHEREAS, the INVESTIGATOR is an acknowledged Nephrologist and is presently working in SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES College and Hospital; and

AND WHEREAS, SGPGIMS Research Scheme Account belong to the INSTITUTION for providing the services of managing the funds of the INSTITUTION;

AND WHEREAS, Institution is equipped to undertake the Study and Institution and Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

NOW, THEREFORE, the Parties agree to set out in this Agreement the terms and conditions governing their collaboration with respect to the performance of the Study.

1. OBLIGATIONS OF INVESTIGATOR

1.1 Conduct of the Study: The Study shall be performed in compliance with (i) this Agreement (ii) the Protocol, (iii) all applicable laws, regulations and directives, (iv) generally accepted practices relating to non-interventional studies and to investigators conducting such studies, and (v) guidelines, procedures and any reasonable instructions provided by Sponsor. Investigator shall comply with all the provisions of the Protocol, as may be amended from time to time during the Term. Investigator shall comply with the timelines in ***Appendix*** 2.

1.2 Investigator and Study Site: The Study will be carried out by the Investigator at Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebarell Road, Lucknow-226014, UP State, India (the "Study Site"). The Investigator shall obtain and maintain, during the Term, all necessary authorizations for the performance of the Study at the Study Site, under due observance and compliance with all applicable laws.

1.3 Recruitment of Patients: The Investigator shall be responsible for the recruitment of Patients for the Study (the "Patients"). The number of Patients to be recruited is estimated to be 20. The Investigator shall inform Patients in a language that could be understood by the Patients (i) the purpose of the Study; (ii) Patients' personal data will be used for the Study; and (iii) any other relevant aspect of the Study. The Investigator shall obtain consent from each Patient, or their respective legal representative, before the Patient's participation in the Study, using the informed consent form provided by Sponsor. Investigator shall ensure Patients' consent is given without any undue influence or coercion from any person involved in the Study.

1.4 Data collection: The Investigator shall use the Case Report Forms provided by Sponsor (the "CRF") for the data collection and will ensure that the contents of the CRF are accurate and precise, with reference to source document. If Sponsor requests Investigator to submit electronic CRF, Sponsor will provide Investigator with a computer and internet connection to be used solely for the completion and submission of the electronic CRF, and the necessary training. The Investigator shall take all reasonable precautions to avoid any damage or loss of Sponsor's computer, which will be returned to Sponsor promptly upon completion of the Study. The Investigator shall (i) report on the progress of the Study on such regular basis as requested by Sponsor; (ii) promptly submit the completed CRF to the Sponsor; and (iii) respond promptly to any query from the Sponsor on any CRF.

1.5 Sub-Investigator: The Investigator shall not delegate the performance of the Study (in whole or in part) to any third party except with the prior written consent of Sponsor. Any approved sub-

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investigator ("Sub-investigator") shall, at all time, work under the supervision and responsibility of the Investigator. Notwithstanding Sponsor's consent, the Investigator shall continue to be responsible for the proper performance of any activities delegated to Sub-Investigator and for the performance of his/her obligations under this Agreement.

1.6 **Pharmacovigilance:** The Investigator shall comply with all pharmacovigilance reporting requirements applicable to the Study in accordance with all applicable laws and regulations and Sponsor' procedures on pharmacovigilance reporting communicated by Sponsor to Investigator before or after the Effective Date, as may be amended from time to time during the Term.

1.7 **Declaration to relevant authorities:** The Investigator shall be responsible for the declaration(s) to all relevant authorities (including without limitation any medical association or health authority) required under applicable laws and regulations in relation to the payments received by the Investigator under this Agreement.

"Affiliates" shall mean, any corporation, partnership or other entity controlled by, controlling or under common control with sanofi-aventis (Trade Register : 395 030 844 RCS PARIS) and with the Sponsor, with "control" meaning the direct or indirect ownership of more than 50% of the capital stock or the voting rights in such corporation, partnership or other entity or the power to direct or cause the direction of the management or policies of such corporation, partnership or other entity through the ownership of securities or interests, by contract or otherwise.

1.8 **Legal standing:** The Investigator represents and warrants that (i) he/she has the legal right, authority and power to enter into and discharge his/her obligations under this Agreement and that (ii) he/she is not (and will ensure that any Sub-Investigator is not), disqualified or debarred from participating in the Study by any regulatory authority or under investigation that will lead to such consequence, and or otherwise prohibited or restricted in any way under any contractual obligation, and is fully and will remain fully authorized, qualified and free to perform the Study during the Term.

2. OBLIGATIONS OF SPONSOR

2.1 **Items supplied:** Sponsor shall provide the Investigator with all necessary information, documents and materials as it deems necessary for the performance of the Study.

2.2 **Financial compensation:** In consideration for the due and proper performance of the Study in accordance with the terms of this Agreement, Sponsor shall pay the Investigator the financial compensation set forth in the Financial Terms and Conditions attached in ***Appendix 2***.

3. OWNERSHIP AND USE OF DATA, RESULTS AND DOCUMENTS

3.1 All intellectual property rights owned by Sponsor and/or its Affiliates (as defined hereinafter) related to the Product and/or to any information provided by Sponsor and/or its Affiliates to Investigator for the purpose of this Agreement is the exclusive property of Sponsor and/or its Affiliates.

3.2 Nothing in this Agreement shall be construed as granting to the Investigator and/or any Sub-Investigator, any right, interest or licence to use any of such intellectual property rights, including with respect to any developments, improvements or variations thereof.

3.3 All the results, data, materials, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate, full and exclusive property of the Sponsor and or its Affiliates. For this purpose, Investigator presently assigns, and undertakes to procure the assignment by any Sub-Investigator to the Sponsor and or its Affiliates (or its designee) any and all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all materials created in relation to the Study. Investigator acknowledges that the compensation for any such assignment is included in the Financial Compensation paid by Sponsor under this Agreement.

4. CONFIDENTIALITY, RESTRICTED USE AND PUBLICATION

4.1 **Confidentiality and Restricted Use:** The Investigator agrees that during the Term and for a further period of five (5) years thereafter, he/she shall, and shall procure that any Sub-Investigator shall, hold

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and maintain in strict confidence all proprietary and confidential information of Sponsor, including without limitation financial, scientific, corporate, industrial, product and business information disclosed by Sponsor and or its Affiliates and any and all results, information, data and documents generated, produced or obtained in relation to this Agreement) (the "Confidential Information") and not use the Confidential Information for any purpose other than the performance of this Agreement. However, no provision of this Agreement shall be construed so as to preclude use or disclosure of information:

a) which was already known to the Investigator before Sponsor's disclosure, as evidenced by his/her written records;
b) which is disclosed in good faith to the Investigator after the Effective Date by a third party lawfully in possession of such information and not under an obligation of nondisclosure or restricted use towards the Sponsor;
c) which is or becomes public knowledge through no fault of the Investigator;
d) which is disclosed by the Investigator as a result of applicable laws and regulations provided Sponsor is notified before such disclosure to enable Sponsor to seek protective measures, if it deems appropriate, unless otherwise prohibited by law, in which case Sponsor will be notified as soon as reasonably practicable; or
e) which is developed by Investigator independently from the Confidential Information.

4.2 Publication: Investigator shall not make any publication or communication relating to the Study and or the results of the Study, without the prior written approval of Sponsor.

5. PERSONAL DATA PROTECTION

5.1 The Patient data and specific data regarding the Investigator and Collaborators which may be collected by the Sponsor and included in the Sponsor's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the Sponsor or its representative to Health Authorities or to a Sponsor's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

5.2 As data controller, when processing or archiving data pertaining to the Investigator, the Collaborators and/or the Patients, the Sponsor shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

5.3 The Investigator, the Collaborators and/or the Patients have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the Sponsor, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

6. AUDIT AND INSPECTIONS

The Investigator shall keep accurate, complete and up-to-date records of all activities under this Agreement (the "Record"). During the term of this Agreement and for a period of five (5) years thereafter, Investigator shall permit the Sponsor' auditors, and/or any regulatory authority to audit and inspect the Record and shall comply with the provisions on audit set forth in the Protocol.

7. DEBARMENT AND SENTENCING FOR MALPRACTICE

7.1 The Investigator represents and warrants that neither he/she nor any Collaborators involved in conducting the Study, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

7.2 The INVESTIGATOR shall immediately notify the Sponsor should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

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8. ANTI-BRIBERY

8.1 The Investigator represents and warrants that he/she nor any of his/her personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the Sponsor obtain or maintain business or obtain a business advantage.

8.2 The Investigator further represents and warrants that he/she has not made and agrees that he/she shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by "Anti-Bribery Provisions").

9. TERM AND TERMINATION

9.1 Term: This Agreement shall be effective on the Effective Date which shall be 12th December 2017 and shall remain in force until acceptance by Sponsor of all data generated from the Study and resolution of all queries arising there under unless earlier terminated under *Section 9.2*.

9.2 Early termination: Notwithstanding any other provisions of this Agreement, the Sponsor may, by notice to Investigator, terminate this Agreement at any time without any liability or compensation to the Investigator, which termination will take effect on the date specified in the notice. Either Party may terminate this Agreement, if the other Party breaches any terms of this Agreement and fail to rectify the breach within ten (10) days from the date of the notice from the non-defaulting Party.

9.3 Consequences of termination: Termination of this Agreement shall not affect any right which has accrued before the termination. Upon receipt of Sponsor's notice of termination, Investigator shall procure the Investigator and Sub-Investigator to cease all activities related to the Study and shall promptly return to Sponsor all data, results, reports or other materials disclosed by Sponsor and or its Affiliates for the performance of the Study and all data, results, reports or other materials arising out of, or conceived during the Study. Sponsor shall settle any amount due to the Institution within forty-five (45) days from the effective date of termination. The provisions of Articles 3, 4, and 6, and Sections 1.4, 1.6, 1.7, 9.3 and 10.6 shall survive termination or expiration of this Agreement.

10. GENERAL

10.1 Entire agreement : This Agreement and its appendices constitute the entire agreement between the Parties with regard to Patient matter and supersedes all previous agreement and or arrangement, oral or in writing. In case of any conflict between any provision of this Agreement and the Protocol, the terms and conditions of (a) the Protocol shall prevail with respect to scientific and medical matters; and (b) this Agreement shall prevail with respect to all other matters; to the extent of such inconsistency.

10.2 Independent Contractor: The relationship of the Parties under this Agreement is that of an independent contractor and no Party shall be considered an agent, employee or joint venture partner of the other party and shall have no right to bind the other party in any manner whatsoever.

10.3 Severability: If any provision of this Agreement shall be held to be invalid, illegal or unenforceable, such provision shall be deemed severed from this Agreement without affecting the validity, legality or enforceability of the remaining provisions.

10.4 Notice: Any notice to be given under this Agreement shall be in writing in English and shall be sent personally to the address provided in this Agreement or as may be notified in writing by one party to the other from time to time.

10.5 Assignment: Investigator shall not assign any of his/her rights and or obligations under this Agreement except with the prior written consent of Sponsor. Sponsor may assign this Agreement to any entity.

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10.6 **Governing law / Dispute resolution:** The validity, construction and performance of this Agreement will be governed by and construed for all purposes in accordance with the laws of India. Any disputes arising out of this Agreement shall firstly be resolved by the Parties amicably, failing agreement the Parties shall refer the dispute to the competent courts of Mumbai.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by them and/or on their behalf by their duly authorised representatives.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED		**SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES**	
[Signature]		[Signature]	
[Name]	DR. CHIRAG TRIVEDI	[Name]	PROF. RAKESH KAPOOR
[Title]	Clinical Study Unit-Director	[Title]	Director

The INVESTIGATOR	
[Signature]	
[Name]	DR. RAJ KUMAR SHARMA
[Title]	Investigator

Prof. R. K. Sharma
Senior Professor & Head
Deptt. of Nephrology &
Former Director & Dean
S.G.P.G.I.M.S., Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

APPENDIX 2

1. FINANCIAL TERMS AND CONDITIONS

- For:
  i. Investigator fees/ Co-investigator fees for all study related activities
  ii. Site coordinator fees for all study related activities

- Financial Compensation to the Investigator, per patient per completed CRF: Rs.25,000/- (Rupees Twenty Five Thousand only).

  Such amount is divided as follows:

Milestone	Investigator Payment per Patient (In INR)	Site Coordinator's Fees Per patient (In INR)	Total Amt (In INR)
Visit 1	4800	1200	6000
Visit 2	2600	650	3250
Visit 3	3000	750	3750
Visit 4	4000	1000	5000
Visit 5	2600	650	3250
Visit 6	3000	750	3750
TOTAL	**20000**	**5000**	**25000**

- The last payment will be done once all the Data is cleaned for database Lock.
- A DCF shall be considered "completed" when the DCF is fully completed and delivered to the Sponsor and any queries raised there-under by Sponsor are resolved.
- Total maximum Financial Compensation: **Rs.25,000/-** (Rupees Twenty Five Thousand only) for per patients recruited.
- 25% Institutional Overhead will be paid additionally.
- Note that, if coordinator is to be provided by Sanofi, the Study Coordinator Fees will not be applicable for the site.
- All payments made as per this Agreement are subject to tax deduction at source.
- No other charge or cost shall be borne by the Sponsor for performance the Study by Investigator unless otherwise provided herein.
- All payments under this Agreement will be made within forty-five (45) from the date of receipt by Sponsor of the relevant invoice(s) made out in the name of Sanofi Synthelabo (India) Private Limited and shall be sent to:

  Sanofi House, CTS No. 117-B,
  L&T Business Park, Saki Vihar Road,
  Powai, Mumbai – 400072
  Attention: Accounts Department

- Any out of pocket expenses approved in advance by Sponsor before incurring shall be reimbursed to Investigator subject to the receipt by Sponsor of an itemized invoice and relevant supporting documents, upon request.

- The Investigator will be responsible for any taxes and or other contributions applicable to Financial Compensation.

2. TIMELINES APPLICABLE TO THE STUDY

- Study start date:31-Jul-2017
- Cut off date, i.e. latest date before which Investigator shall have delivered the completed DCFs and responded to all queries: Jul-2019 (as applicable)
- All payments shall be made in favour of **"Director, SGPGIMS Research Scheme Account"**
- PAN No : - **AAAJS3913N**

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SGPGIMS,Lucknow

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અનુ.નં. ૨૪૩૨૬ તા. ૧૨/૦૨/૨૦૧૮ રૂ. ૧૦૦/-
અંકે રૂપિયા એકસો પુરાનો સ્ટેમ્પ જે સાંધણ સાથે
રૂ. — તે આજરોજ
શ્રી મેરીલ લાઈફ સાયન્સ પ્રા. લી.
રે. ચલા તા. વાપી ને વેચાણ આપ્યો

લેનારની સહી

સ્ટેમ્પ વેન્ડરનું નામ અને સહી લા.નં. ૧/૨૦૦૨
હીરેન જે. પટેલ, રતનવાડી, પારડી.

CLINICAL TRIAL AGREEMENT

This Agreement (Hereinafter "**Agreement**") is made and entered into on this 23rd day of Mar 2018 by and among:

Meril Life Sciences Pvt. Ltd.,with its principal office located at **Bilakhia House, Survey No.135/139, Muktanand Marg, Chala, Vapi-396191, Gujarat, India**represented by **Dr.Ashok Thakkar, Head-Clinical Research.** [hereinafter "the **SPONSOR**" **or** "**Meril**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns)] of the First Part.

And

Sanjay Gandhi Postgraduate Institute of Medical Sciences with his principal office located at **Rae Bareli Road, Lucknow-226014, Uttar Pradesh, India** (Hereinafter "**Institution or Centre** or **Study Site**") represented by **Prof. Rakesh Kapoor** having registered office at **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India** [Hereinafter referred to as the "**Institution**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns) of the Second Part.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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અનુ.નં. ૨૪૩૩૦ તા. ૨૧/૦૬/૨૦૧૮ રૂ. ૧૦૦/-
અંકે રૂપિયા એકસો પુરાનો સ્ટેમ્પ જે સાંધણ સાથે
રૂ. --- તે આજરોજ
શ્રી મેરીલ લાઈફ સાયન્સ પ્રા. લી.
રે. ચલા તા. વાપી ને વેચાણ આપ્યો

લેનારની સહી

સ્ટેમ્પ વેન્ડરનું નામ અને સહી લા.નં. ૧/૨૦૦૨
હીરેન જે. પટેલ, રતનવાડી, પારડી.

And

Dr. Nirmal Gupta with his principal office located at **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India** (hereinafter "**Investigator**") of the Third Part.

(Hereinafter individually "**Party**" or collectively "**Parties**")

WHEREAS the Sponsor is a Medical Devices company involved in research, development, manufacture and sale of medical devices for use in humans;

WHEREAS the Institute is recognized for its expertise and interest in multispecialty and have the facilities, infrastructure and expertise to conduct the clinical study entitled:

Dafodil™ 1 - A prospective, multi-center, single-arm clinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.

(Hereinafter referred to as the "**Clinical Trial**" or "**Study**")

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WHEREAS the Sponsor is desirous of conducting the Clinical Trial; and

NOW, THEREFORE, the Parties mutually agree as follows:

1 Definitions

1.1 **"Affiliate"** means a business entity which controls, is controlled by, or is under the common control with the Sponsor or the Institute. For the purpose of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

1.2 **"Agent(s)"** shall include, but shall not be limited to, any person (including the Investigator, any nurse or other health professional), any such person's principal employer in the event it is not the Centre and where such person is providing services to the Centre under a contract for services or otherwise, and/or any contracted third party providing services to the Centre under a contract for services or otherwise for the Study.

1.3 **"Agreement"** means this agreement, any signed amendment to it, as well as any documents which are signed consequently in relation to the study including Protocol, exhibits, schedules, or other addendums attached and/or referred to in this Agreement. In case of discrepancy between the numbered Clauses of this Agreement and any addition to this Agreement such as exhibit, Protocol, etc., the numbered Clausesof this Agreement shall prevail.

1.4 **"Confidential Information"** includes, but is not limited to,any knowledge and information pertaining to a Party's products and processes, ingredients, recipes, know-how, product plans , business plans, management reports, financial statements, internal memorandum, reports, patient information, inventions, designs, drawings, methods, processes, systems, technology, technical information relating to the disclosing Party's research, improvements, materials, data, trade secrets, marketing and regulatory strategy, customer lists, supplier lists, database and any other information pertaining to the business of a Party, which is not readily available to the public and does not constitute Results.

1.5 **"Effective Date"** means the date of the latest to occur of the following two conditions:
(i) Signature of this Agreement by the last Party to sign and
(ii) Approval of the Study by the competent ethics committee, institutional review board or equivalent body.

1.6 **"Fee"** shall mean the fee payable by the Sponsor for performing the Study.

1.7 **"ICH GCP"** shall meanE6(R1) guideline for Good Clinical Practise (GCP) issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use(ICH) in 1996 with applicable updates and amendments thereof.

1.8 **"Intellectual Property"** means any registered and unregistered intellectual property rights, such as, but not limited to, patents, designs, trademarks, trade names as well as copyrights, know-how, trade secrets and Confidential Information.

1.9 **"Lead Investigator"** means a physician chosen by Meril to provide scientific and medical supervision of the entire multi-centre Study.

1.10 **"Investigator"** means the person designated by the Centre and agreed upon by Meril who will take primary responsibility for the conduct of the Clinical Trial at the Centre, or any other person as may be agreed from time to time among the Parties as a replacement.

1.11 **"Protocol"** means the Study protocol no.MLS/MYV-1and all its amendments duly signed by the Investigator and the Sponsor.

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1.12 **"Research Subject"** means any person recruited to participate in the Study as a patient.

1.13 **"Results"** means the contents and results of all work and activities realized by the Centre including the Agents pursuant to this Agreement, limited to results, clinical data and medical conclusions related to the treatment of the Research Subjects with the Study Device in accordance with the Protocol.

1.14 **"Study Device"** means **Dafodil Pericardial Bioprosthesis** as defined in the Protocol.

1.15 **"Study"** means the **Dafodil™ 1 - A prospective, multi-center, single-armclinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.**

1.16 **"Study Deliverables"** shall mean the completed case report forms, any electronic databases required to be created under the Protocol, and any Study reports prepared by the Institute for the Sponsor (including, with respect to the data contained in such case report forms, electronic databases, and reports, only the compilation of data or any substantially similar compilation).

1.17 **"Trial Monitor"** mean one or more persons appointed by the Sponsor to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

2 Scope of the Agreement

2.1 Meril is sponsoring the Study entitled: **Dafodil™ 1 - A prospective, multi-center, single-arm clinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.**

2.2 Name of the study: **Dafodil™ – 1**

2.3 Meril shall act as the Sponsor of the Study, and the Centre shall act as one of the clinical sites at which the Study will be conducted. The Investigator has agreed to serve at the Centre as Principal Investigator in connection with the conduct of the Study. The Institute shall notify the Sponsor in advance if the Investigator is unable or unwilling to continue the Study or if the Investigator's affiliation with the Institute ceases, whereupon the Centre shall identify a successor whose appointment shall be subject to Meril's written approval.

2.4 The Investigator shall perform the Study in conformance with; (i) ICH-GCP guidelines, (ii) ISO 14155,(iii) Medical Device Directives of Global Harmonization Task Force and European Union,(iv) the Protocol, (v) all reasonable written instructions of the Sponsor and (v) all applicable laws, rules and regulations (including, but not limited to the Indian Drug and Cosmetic Act 1940, the Indian Drug and Cosmetic Rules, 1945, any other guidance and notification issued by Central Drug Standard Control Organization (as may be amended from time to time).

2.5 The Institute/the Investigator shall seek approvals which may be required to carry out the Study, including approval from Ethics Committee (EC) or Institutional Review Board (IRB) or equivalent body as required by the applicable laws and applicable standards before commencing the Study.

2.6 The Institute shall comply with applicable laws in the collection, storage, and transfer of any clinical samples or other human materials taken from Study Subjects, and shall obtain any consents required from Study Subjects for the use of such materials in accordance with the Protocol. The Institute shall ensure that any use of such materials, whether in the Study or otherwise, shall be consistent with such consents and applicable laws.

2.7 The Institute shall ensure that the clinical samples or other human materials taken from Study Subjects are tested in accordance with the Protocol and at a laboratory designated by the Sponsor.

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2.8 The Sponsor shall comply with applicable laws in the performance of its activities relating to the Study, and shall obtain all approvals and consents required in connection with such activities. The Sponsor shall conduct such Study-related activities in a manner consistent with the Informed Consents and all other applicable consents.

2.9 The Investigator shall ensure the study participation is voluntary and the participants have the right to withdraw at any time during the conduct of the study.

2.10 The Sponsor may amend the Protocol at any time. Any such amendment shall be in writing and sent to the Institute, and will not take effect until approved by the appropriate approving bodies such approval shall not be unreasonably withheld, conditioned or delayed.

2.11 The Centre shall enrol approximately 10-15 eligible Research Subjects for participation in the Study.

2.12 The Centre shall collect Research Subject specific data as per the prescribed study schedule in the Protocol on Case Report Form (paper or electronic) (hereinafter CRF) for the entire duration of the study. The Centre shall provide appropriate resources and facilities to enable the Investigator to conduct the Study in a timely and professional manner and according to the terms of this Agreement. The Centre shall ensure that only individuals who are appropriately trained and qualified will assist the conduct of the Study. The Centre is responsible for ensuring that all personnel of the Centre and Agents participating in the Study comply with the terms and conditions of this Agreement.

2.13 The Centre and the Investigator shall use their best endeavours to ensure that the recruitment of the Research Subjects is achieved in accordance with the timelines as specified. The Study being a multi-centre clinical trial, the Sponsor may amend the number of Research Subjects to be recruited at the Centre. If in the reasonable opinion of the Sponsor, recruitment at the Centre is proceeding at a rate below that required meeting the timeline, the Sponsor may, by a notice to the Centre, cease further recruitment. On the other hand, if the recruitment at the Centre is proceeding at a rate above that required meeting the timeline, the Sponsor may, with agreement of the Centre increase the number of the Research Subjects to be recruited.

2.14 Subject to the Centre's and the Investigator's overriding obligations in relation to the Research Subjects and individual patient care, neither the Centre nor the Investigator shall, during the term of this Agreement, conduct any other trial which might hinder the Centre's or Investigator's ability to recruit and study the required cohort of the Research Subjects.

2.15 Meril shall provide training to the personnel designated by the Centre for conducting the Study related activities. In addition, Meril shall conduct follow-up monitoring as it deems appropriate.

2.16 The details of activities of the Study (notably detailing scientific goals, methodology, and time schedule) are provided in the Protocol. The Centre and the Investigator shall not deviate from the Protocol except to the extent necessary for safety of the Research Subject/s and shall promptly notify the Sponsor and the EC/IRB in writing of any deviation from the Protocol with reasons.

2.17 The Institute shall refrain from, and shall cause the Investigator and the Agents to refrain from using the Study Device in any manner that is contrary to the provisions of, or outside the scope of, the Protocol or that is contrary to the written instructions of the Sponsor.

2.18 The decision to include any Research Subject in the Study shall occur only after the decision to use the Study Device on said Research Subject has been made exclusively on medical grounds by the Investigator. On enrolling the subjects in the study, the Centre shall complete the Electronic Case Report Forms (hereinafter "**eCRF**") for the Research Subject specific data as per the prescribed study schedule in the Protocol for the entire length of the Study. The Centre shall provide all necessary and sufficient facilities, equipment, resources and personnel to perform the services required hereunder.

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2.19 The Institute and the Investigator shall supervise Agents employed by the Institute for conduct of the Study (the Study Staff), and shall ensure (directly in the case of employees, and by contract in the case of contractors) that all Study Staff are appropriately trained, qualified, and certified, and are informed of and abide by the applicable terms of this Agreement.

2.20 The Institute shall keep and maintain, diligently and in sufficient detail to satisfy all applicable legal requirements, such Study data and records as are required by the Protocol and applicable laws, including any source data, clinical data of Research Subjects and Study Deliverables (the "Study Documents").At the Sponsor's request, the Institute shall retain the Study Documents beyond the period required by the applicable laws Study Documents in accordance with applicable laws. After the required retention period (including any additional period requested by the Sponsor) has expired, the Institute shall provide the Sponsor sixty (60) days' written notice before destroying any Study Documents.

2.21 In order for Meril to monitor the progress of the Study, a regular exchange of letters, emails and phone calls between Meril and the Investigator shall occur during the performance of the Study. Face-to-face meetings may also be held between Meril and the Investigator as often as reasonably necessary. The Institute and the Investigator will allow, with reasonable prior notice, Meril and /or the regulatory authorities to perform facility and site audit.

2.22 The Institute shall permit the Trial Monitor to access the Study Documents during regular business hours, upon reasonable advance notice to the Institute by the Sponsor. The Sponsor shall comply with applicable laws regarding the confidentiality of Study Subjects' medical records and other health information, shall hold the Study Subjects' personal identifying information in confidence, and shall act in accordance with the Informed Consents and the HIPAA Authorizations. Subject to the foregoing, the Trial Monitor may copy Institute records containing such information. The Institute may redact personal identifying information of Study Subjects before giving them to the Study Monitor for copying these records. The Sponsor shall not attempt to contact any Study Subject except to the extent expressly permitted by the IRB or as required to comply with applicable laws.

2.23 During monitoring as per Clause 2.19, the Trial Monitor has the right to inspect any facility being used for the Study and to examine any procedures or records relating to the Study. The Trial Monitor/Sponsor will alert the Centre and the Investigator to significant issues (in the opinion of the Trial Monitor/Sponsor) relating to the conduct of the Study.

2.24 The sponsor's monitor to send the post-monitoring visit report promptly to the site.

2.25 In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Centre and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor. The Sponsor shall, subject to any obligations of confidentiality, communicate the results of such investigation to the Centre. In the event that the Centre reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Centre, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor.

2.26 The Institute shall make available to the Sponsor or its designated agent the Study site, the Study Staff, and, subject to applicable laws relating to patient confidentiality, all Study Documents for purposes of review and audit upon reasonable advance notice during regular business hours. If the Investigator fails to correct any violations of the Protocol, this Agreement, or applicable laws found in such audit after receiving written notice thereof, the Sponsor may provide notice to the Institute of such violations, whereupon the Institute shall promptly take action to correct them.

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2.27 The Institute shall provide the Sponsor prompt, advance notification of any audit by a regulatory authority, which audit is directly related to the Study (or, when advance notification is impracticable, prompt notification of any completed audit). To the extent possible, the Institute shall permit the Sponsor to review and comment in advance on any written communication from the Institute to the regulatory authority in connection with such an audit; provided, however, that such review does not adversely impact the timeliness of the Institute's response to the regulatory authority. The Institute shall promptly provide the Sponsor with copies of all communications between the Institute and the regulatory authority related to such audit unless prohibited from so doing by the regulatory authority, and shall promptly take action to correct any deficiencies found by the regulatory authority during the audit. With respect to a pending audit directly related to the Study by any regulatory authority, the Institute shall permit the Sponsor's representatives to be present at such audit unless prohibited from so doing by regulatory authority. With respect to any audit by any regulatory authority, which audit is not directly related to the Study, the Institute shall promptly notify the Sponsor of any findings of such an audit that would be likely to have an adverse effect on the Institute's ability to conduct the Study.

2.28 The sponsor to send the DSMB report if applicable and its timely submission to Ethics Committee.

2.29 The Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a Study Subject that is directly related to the conduct of the Study in accordance with the Protocol and the Sponsor's written instructions to the Institute (or to the extent that the Sponsor's written instructions conflict with the Protocol, the Sponsor's written instructions to the Institute only). The Sponsor is not required under this Section 2.26 to provide compensation for (a) other injury- or illness-related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the Institute nor the Study Subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the Protocol or other misconduct or negligence, in each case by any Agent of the Institute (including the Study Staff and the Investigator), or (d) medical expenses for injury or illness unrelated to the Study Device and unrelated to the proper performance of any other procedure required by the Protocol or Sponsor's written instructions to the Institute. The Sponsor confirms that it has taken appropriate insurance policy for the conduct of the Study as per the applicable laws.

3 Confidentiality

3.1 The Centre and the Investigator agree that any Confidential Information (or any evaluation thereof including but not limited to analysis, deconstruction, disassembling or reverse engineering) received from Meril shall be held in strict confidence and centre shall not disclose or use (other than in connection with or expressly permitted by this Agreement). All Confidential Information shall remain the property of Meril. Such information shall be used by the Centre and its Agents including the Investigator only in the performance of their duties hereunder, and shall not be used or disclosed, directly or indirectly to any third party, except as necessary to accomplish the purposes of this Agreement and then only if such Agents, and third party/parties are bound by an obligation of confidentiality consistent with the terms of this Agreement or as required by the law. The Centre hereby assures that their Agents including, but not limited to, the Investigator shall comply the provisions of this Clause. Upon the request of Meril, the Centre shall promptly return to Meril all Confidential Information of Meril in the possession of the Centre, the Investigator or other personnel and Agents, together with any documents or notes containing such Confidential Information, except for one archival copy which may be retained by the Centre if required in order to monitor compliance with the terms of this Agreement and the applicable laws.

3.2 The Centre, the Investigator, or any other personnel of the Centre, or Agents shall not publicly or privately disclose or divulge any term or provision of this Agreement or the transactions contemplated hereby without the prior written consent of Meril, except as may be required by applicable law, rule, regulation or order and the internal reporting requirements of the Centre, and

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except for communications to employees or Agents in order to perform the work required under this Agreement.

3.3 In the event the Centre, the Investigator or any of their personnel including Agents are required to disclose Confidential Information of Meril under any applicable law, regulation, legal process, judicial order or by any applicable order or requirement of any governmental or regulatory authority, it may do so only to the extent required; provided, however, that the Centre and the Investigator shall:

(a) give prompt notice to Meril of the required disclosure of Confidential Information sufficiently in advance of making the required disclosure to allow Meril a reasonable opportunity to take steps to object to, prevent, and/or limit its disclosure or obtain a protective or other similar order with respect to the required disclosure; and

(b) Restrict the disclosure to only that portion of the Confidential Information which is required to be disclosed.

3.4 Subject to Clause 6 below, the Centre and the Investigator undertake to keep the Results confidential and not to disclose to any third party.

3.5 Meril agrees to keep confidential, the Confidential Information received from the Institute or Investigator related to the Study. Meril agrees that all such information will not be disclosed to any of its agents or affiliates, including the Contract Research Organization, which will be involved in execution of one or more processes of the Study, for any purpose other than execution and conduct of the Study.

4 Privacy and Data Protection:

The Parties agree that each will comply with their respective obligations as required under applicable privacy and data protection laws. The Institute and the Investigator will obtain the consent of each Research Subject for the use, processing, holding and transfer of their data to other countries that may not have same level of data protection as in India.

5 Publication of Results

5.1 Meril reserves all the rights of publication and presentations of all the aspects of the Study including the outcomes of the study; interim and final.

5.2 Meril shall follow publication guidelines related to such publications and presentations.

5.3 The Chief Investigator shall be first author of the main scientific publication (multi-Centre Results), while other investigators shall appear in accordance with generally accepted standards for authorship, followed by Sponsor's Study Head – Clinical Research, the Medical Writer and the statistician, and the relevant persons from the CRO. Study publication will be registered in a manner that meets the criteria of the International Committee of Medical Journal Editors. The publication of the Results from the Centre shall not be allowed until principal scientific publication of the main Study is published. The Centre shall be allowed to publish sub-studies of the whole Study only after written approval by the Sponsor. All publications will follow the uniform requirements for manuscripts submitted to biomedical journals by the International Committee of Medical Journal Editors.

5.4 Subject to and without prejudice to above, the Centre may publish or present the Results collected or produced as a result of its participation in the Study in appropriate scientific journals, meetings or other professional publications, only under the following conditions:

(a) The proposed publication or presentation is consistent with the rules and conventions governing similar studies in all relevant jurisdictions.

(b) A draft of the proposed publication or presentation has been provided to Meril at least thirty (30) working days prior to the first intended submission for publication or presentation. Meril

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will review and respond with its comments, if any, within (30) working days of receipt of such copy. If Meril believes that any proposed publication or presentation contains any Confidential Information of Meril, then Meril shall so notify the Centre and the Centre and Investigator shall delete such Confidential Information of Meril from the proposed publication or presentation. If Meril believes that any proposed publication or presentation contains any patentable Results, the disclosure of such proposed publication or presentation to any third party shall be delayed for an additional ninety (90) working days to permit the filing of a patent application by Meril. Should Meril request such a delay, Meril shall use its best efforts consistent with reasonable business and scientific practice to do all things which it believes would expedite the filing of such patent application.

(c) Meril retains the right of final review prior to publication.

(d) The Centre shall give credit to Sponsor for its sponsorship of the Study in all publications or presentations related to the Study.

6 Results and Intellectual Property

6.1 The Centre and its Agents (including employees, the Investigator, contractors, consultants and other personnel) shall promptly disclose in writing to Meril, all the Results and Intellectual Property pertaining to the Results. Meril shall own and retain all right, title and interest in and to any Results and Intellectual Property resulting from all work performed in connection with the Study. To the extent that such Intellectual Property pertaining to Results does not vest automatically in Meril, the Centre hereby irrevocably agrees to assign and does hereby assign to Meril all rights, title and interest in and to any Intellectual Property that may inure to its benefit in connection with work performed pursuant to this Agreement and will execute and will cause its Agents including the Investigator to execute all documents which may be necessary to give effect to the provision contained herein. The Centre shall not assign, transfer or waive any rights it may have as an employer to any Results or any Intellectual Property pertaining to Results that is conceived or developed by personnel at the Centre (including the Investigator) in the performance of this Agreement to any entity other than the Sponsor.

6.2 Meril shall own complete data sets and Results produced under this Agreement and shall own all right, title and interest in and to any and all copyrights or copyrightable material, including software programs, produced, composed, or fixed in any tangible medium of expression in the performance of work under this Agreement. Meril shall have sole right to determine the disposition of all or any part thereof.

6.3 Neither the Centre nor the Investigator shall use any name, trademark, logo, symbol, or other image of Sponsor in advertising, publicity or otherwise, without the prior written consent of Meril. Neither the Centre nor the Agents including the Investigator, and representatives, shall issue or disseminate any press release or statement, or initiate any communication of information regarding the Study, written or oral, to the communications media or to any third party without the prior written approval of Meril.

6.4 The Parties acknowledge and agree that certain pre-existing Intellectual Property owned by Meril, Institute and Investigator shall not be affected by this Agreement. Except as otherwise expressly provided herein, no right or interest in or to any patents, trade secrets or other Intellectual Property owned or otherwise held by Meril or the Institute or the Investigator is granted or implied hereunder.

7 Financial terms and conditions – Fee and taxation

7.1 Meril shall pay Fee as per the attached Exhibit-A.

7.2 In case of death of the Research Subject, all the balance remuneration till the last completed follow-up will be paid after submission of death form duly monitored for completeness, and report of the Ethics Committee to the Sponsor. In case of Research Subject lost to follow-up,

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terminated by the Investigator or Research Subject withdrawing consent, payment up to the last completed visit will be made.

7.3 If as a part of the Study and as directed by Meril, the Clinical examinations/investigations are conducted as per the Protocol; the payment for such Clinical examinations/investigations will be made as per Exhibit-A. Meril shall not be liable to pay any such charges if the Clinical examinations/investigations are not conducted in compliance with the Protocol.

7.4 The Fee will be paid by Meril every three months during the study duration. The final payment will be settled at the time of site close-out visit.

7.5 The payee will generate an invoice addressed to the Study Director/Head – Clinical Research of Meril. The invoice should include all details relevant to the milestone payment (as in Exhibit-A) during the period of the invoice with clear statement of amount of the Fee to be paid. The payment will be released by Meril within 30 working days of receipt of such invoice.

7.6 Meril will deduct tax on all payments as per the applicable law for which tax deduction certificates will be provided.

7.7 Invoicing address: Dr Ashok Thakkar, Head-Clinical Research,Meril Life Sciences Pvt. LtdBilakhia House, Muktanand Marg, Chala, Vapi 396191 Gujarat, India
Email: ashok.thakkar@merillife.com

Shipping address:

Dr. Ashok Thakkar
Head-Clinical Research
Meril Life Sciences Pvt. Ltd.
Survey No.135/139, Bilakhia House,
Muktanand Marg,
Chala, Vapi – 396 191
Gujarat, India.

The Invoices shall include details of enrolled, followed up and completed subjects during the period of the invoice with clear statement of amount of Fee to be paid. The due date of the invoices shall be 60 days from the date of receipt of invoices by Meril.

Bank details for payment:

Payee Name (Account Name): Director, SGPGIMS, Research a/c.

Account Number: 10095237491

Bank Name: State Bank of India

Branch Name: SGPGI Bank, Lucknow

Swift/IFSC Code: SBIN0007789

PAN Number: AAAJS3913N

Send to: Dr. Nirmal Gupta
Prof. & Head of Department of Cardiovascular and Thoracic Surgeon,
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India

All bank charges in India shall be borne by Meril. All bank charges outside India shall be borne by payee.

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8 Ownership:

All documents, protocols, data, know-how, methods, operations, formulas, Confidential Information and materials provided to the Centreby the Sponsor pursuant to this Agreement are and shall remain Sponsor's Property. The completed CRFs, the final reports and other Results of the study shall also be owned by the Sponsor. Sponsor shall not own patients' medical records.

9 Quality of performance - representation and warranties

9.1 The Centre and Investigator shall perform their obligations with care, skill and diligence, in accordance with the highest applicable professional standards recognized in the profession, and shall be responsible for the quality, accuracy and completeness of all medical treatments and procedures, and shall ensure the accuracy of the data obtained from the research and procedures conducted at the Centre. The Centre shall comply with all applicable legal and regulatory requirements. The Centre shall comply with Good Clinical Practice (GCP) guidelines during the course of the Study. The Centre and the Investigator shall comply with all provisions of this Agreement and the Centre shall be liable for any breach of the same by the Investigator.

9.2 The Centre and the Investigator hereby undertake:

(i) To comply with the Protocol and with the recommendations, suggestions and relevant literature provided by Meril;

(ii) To maintain proper written records concerning all matters in connection with the Study;

(iii) To submit to Meril any written report(s) as provided in the Protocol;

(iv) To report adverse and serious adverse events to Meril in writing within 24 hours after the occurrence thereof; and

(v) To obtain informed consent from the Research Subjects in the format and manner provided in the Protocol.

9.3 The Centre shall, in all respects and at all times, protect the personal rights of the Research Subjects, in particular regarding informed consent procedures and personal data. All information and data relating to the Research Subjects collected during the course of the procedures and research performed in connection with the Study by the Centre and its Agents including the Investigator will be treated as confidential and maintained in a safe and secured manner consistent with the Protocol. The Centre shall take all actions necessary to ensure compliance with this section by its Agents including, without limitation, the Investigator, the treating physicians, other participating investigators and all hospital personnel. All information and data delivered to Meril shall be stripped of all information that identifies the Research Subject as required by the applicable laws and regulations. For this reason, a Research Subject identification code shall be used for the transmission of data and other information of the Study.

9.4 Unless otherwise instructed by Meril, the Centre shall be permitted to distribute the data and other information to any data management company/CRO designated in writing by Meril.

9.5 The Centre and the Agents including the Investigator shall not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Study Device that are not consistent with Meril's documentation accompanying the Study Device or Meril's literature describing the Study Device, including the limited warranty and disclaimers. Neither the Centre, nor the Agents including the Investigator shall change, extend, or alter any warranty, representation or obligation which is binding upon Meril or its Affiliates.

9.6 The Centre and the Investigator shall cooperate with Meril's designated representatives and regulatory authorities regarding all matters related to the Study, including, but not limited to, auditing, monitoring and enabling full access to all documents, records, reports or other information related to the Study. Meril shall notify the Investigator in advance if and on what dates it intends to visit the Centre to inspect, monitor and/or audit the conduct of the activities related to the Study. The Centre and the Investigator will render whatever assistance is reasonably requested by Meril to enable it to conduct such activities, including, without

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limitation, providing access to requested information and documentation and correcting any matters that have been identified as items requiring attention or correction. All monitoring by Meril shall be conducted in accordance with applicable GCP Guidelines.

9.7 The Centre hereby represents and warrants that it has the physical facilities, equipment and personnel adequate to perform the Study in a proper manner in accordance with its obligations.

9.8 The Centre and the Investigator represent and warrant that the execution, delivery and performance of this Agreement will not, directly or indirectly, result in any violation or breach of any material contract, license, or permit to which they are a party or by which they are bound, or result in a violation of any law, rule, regulation, order, judgment or decree (including any rule or regulation of a medical professional society or similar group) to which the Centre or its personnel including the Investigator are subject. The Centre and the Investigator further represent and warrant that the execution, delivery and performance of this Agreement does not and shall not require any consent, approval, authorization or permit of, or filing or notification to, any governmental or professional entity which the Centre or the Investigator has not timely obtained.

10 Liability

10.1 Meril undertakes to indemnify, defend or cover costs for defence and release from liability ("Indemnify") the Investigator associated with the Study, Institute, their management staff, representatives (collectively referred to as the "Indemnified Parties") in relation to any claim of a third party regarding compensation for damages, costs, liabilities, expenses, including costs for legal representation of the Indemnified Parties, incurred as a result of a damage to the health of Research Subjects due to the failure of the Study Device provided, however, that to the extent that the claim is a direct result of (a) the failure of the Institute or one of its Agents (including the Investigator) to follow the Protocol or the Sponsor's written instructions (each when applicable), accepted medical practice, or applicable laws, or (b) any other negligence or wilful misconduct of the Institute or one of its Agents (including the Investigator), the Sponsor shall have no such obligation, and the Institute shall indemnify, defend, and hold harmless the Sponsor (and its officers, directors, employees, and agents, as applicable) from any loss, liability, damage or expense, but only to the extent arising from any such claim.

10.2 **Indemnification Procedure.** The Party seeking indemnification (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") of any claim, loss, or expense likely to lead to a claim for indemnification, along with all material related information. If such notice is not prompt, the Indemnitor's obligation under this Clause11 will be reduced to the extent that such delay prejudices the Indemnitor's defense of the claim. The Indemnitor shall have the right to manage the defense and settlement of any claim, except that the Indemnitor may not enter into any settlement admitting fault on behalf of the Indemnitee without the Indemnitee's prior written approval. The Indemnitee may not enter into any settlement of any such claim without the written permission of Indemnitor. The Indemnitee shall reasonably cooperate with the Indemnitor in the defense of the claim. The Indemnitee may hire its own counsel, at its own expense, to monitor the defense. In addition, the Indemnitee may elect to assume control of the defense of such claim, in which case the Indemnitor shall have no obligation to indemnify or further defend the Indemnitee with respect to such claim.

10.3 **Insurance.** During the term of this Agreement and for so long thereafter as may be necessary, the Institute and the Sponsor each shall carry liability insurance in the type and amount appropriate and customary for the conduct and sponsorship of the Clinical Trial, respectively as per applicable regulations to cover any claims that may arise in connection with its responsibilities under this Agreement. Upon request, each Party shall provide to the other Party a certificate of such insurance or evidence of such a self-insurance plan.

10.4 The Investigator will cooperate with Meril in collection of all requisite documents and completion of required process for insurance procedure for compensation claims towards Clinical Trial Liability Policy taken by Meril.

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10.5 For clarity, the general product liability of Meril for the Study Device remains unaffected by the Clause 11.3.

10.6 In no circumstances shall any Party be liable to another Party in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings for any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of any other Party.

11 Term and termination

11.1 **Term.** This Agreement shall come into effect upon the Effective Date and shall remain in force till the Study is completed and the Parties have discharged their obligations pursuant to this Agreement. The Parties expect this Agreement to expire after the day of "Site Close-out Visit"at the Institute by the Sponsor that is indicative of completion of participation of the Investigator and the Centre in the Study as well as finalization of the Study data base whichever is later; unless terminated earlier pursuant to this Clause 11.

11.2 **Sponsor Termination.** The Sponsor may terminate this Agreement (a) upon thirty (30) days' written notice to the Institute, in its sole discretion; (b) upon thirty (30) days' written notice to the Institute, for failure of the Sponsor and the Institute to agree upon a new Investigator pursuant to Clause2.3; (c) upon written notice to the Institute, if progress of enrolment at the Centre justifies such termination, in the sole discretion of the Sponsor; (d) upon written notice to the Institute, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Clause 2.9; (e) upon oral notice (promptly followed by written notice) to the Institute, if approval for the Study is not granted or is revoked by the relevant IRB; (f) upon oral notice (promptly followed by written notice) to the Institute, if any person performing activities under this Agreement is debarred, excluded or disqualified from participation in any federal health care program; or (g) upon oral notice (promptly followed by written notice) to the Institute, if the Sponsor determines that termination of the Study is necessary for the safety of the Study Subjects.

11.3 **Termination by Institute.** The Institute may terminate this Agreement (a) upon thirty (30) days' written notice to the Sponsor, for failure of the Sponsor and the Institute to agree upon a new Investigator pursuant to Section 2.3; (b) upon written notice to the Sponsor, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Section 2.9; or (c) upon oral notice (promptly followed by written notice) to the Sponsor if the Institute determines that termination of the Study is necessary for the safety of the Study Subjects.

11.4 **Termination for Material Breach.** Either Party may terminate this Agreement upon written notice to the other Party if the other Party materially breaches this Agreement and the breaching Party fails to cure the breach within thirty (30) days after receipt of written notice of the breach from the other Party.

11.5 **Procedures upon Early Termination.** If this Agreement is terminated before completion of the Study, the Institute shall cease enrolling Study Subjects immediately (or, in the case of termination by the Sponsor, as soon as the Institute has been notified of such termination), and shall cease conducting the procedures set out in the Protocol to the extent that doing so is medically permissible and appropriate. The Sponsor and the Institute shall negotiate in good faith on the subsequent treatment or transfer of the Study Subjects. In case of termination of the Study before completion, the Sponsor shall reimburse the Institute for (i) obligations incurred in accordance with the Study budget that cannot be cancelled or mitigated by the Institute using reasonable efforts, (ii) reasonable costs incurred in connection with the safe withdrawal of the Study Subjects from the Study, and (iii) mutually agreed post-termination expenses.

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11.6 **Return of Property.** Upon termination or expiration of this Agreement, the Institute shall, and shall cause the Investigator and Agents to, return to the Sponsor within thirty (30) days any unused Study Devices (is supplied by the Sponsor) except as required by law, any equipment on loan or lease from the Sponsor, and any copies of Confidential Information provided by the Sponsor that are in the possession or under the control of the Institute or the Investigator; provided, however, that the Institute may retain any copies of such Confidential Information to the extent required by applicable law. At the Sponsor's request and expense, the Institute shall dispose of the unused Study Devices and Control Devices (if supplied by the Sponsor) in accordance with Sponsor's instructions, subject to applicable law.

11.7 **Final Accounting.** The Institute shall deliver to the Sponsor, within ninety (90) days after expiration or early termination of this Agreement, a final accounting of amounts due (and reasonable supporting documentation, which requirement shall be satisfied by properly completed CRFs as to completed visits by Study Subjects), taking into account payments made and not yet made under the payment schedule, and expenses reimbursable pursuant to Clause8, from one Party to the other Party. Undisputed amounts due shall be paid within sixty (60) days thereafter.

11.8 Upon expiration or termination of this Agreement, all rights and obligations shall expire forthwith, except those rights and obligations which by their nature are intended to survive the expiration or termination of the Agreement, including Clause 3 (Confidentiality), Clause 4 (Privacy and Data protection), Clause 5 (Publication of Results), Clause 6 (Results and Intellectual Property), Clause 8 (Ownership), Clause 9 (Quality of performance - representation and warranties), Clause 10 (Liability) and Clause 12.8 (Governing Law/Jurisdiction), and each of their subparts.

12 Miscellaneous provisions

12.1 **Regulatory Approvals.** Each Party represents that it has and will maintain during the term of this Agreement all regulatory approvals required for the conduct of its respective activities in connection with the Study, and that all the Agents who perform activities under this Agreement on its behalf (including, in the case of the Institute, the Study Staff) have and will have the necessary expertise, training, qualifications, and certifications.

12.2 **Debarment.** The Institute certifies that it will not engage, directly or indirectly, any person (including the Investigator) to perform services under this Agreement if (a) that person is debarred by the applicable law or to the Institute's knowledge is threatened with debarment by a pending proceeding, action, or investigation, (b) that person is excluded from participation in any federal health care program or is the subject of an exclusion proceeding, or (c) that person is otherwise disqualified under federal or state law, or to the Institute's knowledge is threatened with such disqualification by a pending proceeding, action, or investigation, from participating in the Study. The Institute certifies that it will immediately notify the Sponsor in writing if any such debarment, exclusion, or disqualification occurs, or if any such debarment, exclusion, or disqualification proceeding, action, or investigation is commenced or, to the Institute's knowledge, is threatened, with respect to any such person.

12.3 **No Conflicting Obligations.** The Institute represents and covenants that none of the Institute or any member of the Study Staff or none of the Agents is or will become subject to any conflicting obligations that would materially interfere with the performance of the Study or any of the Institute's other obligations under this Agreement. The Parties agree that the conduct of other clinical trials targeting the same disease or patient population as the Study does not necessarily constitute such a conflicting obligation. The Institute represents that it has a system in place to manage, eliminate, or otherwise resolve conflicts of interest. The Sponsor shall not, and shall cause its agents and contractors to refrain from, making any payments directly to Study Staff for performing the activities set out in the Protocol.

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12.4 **Independent Contractors.** Nothing contained herein shall be construed as evidence of an employment relationship between Meril and the Centre (or any personnel of the Centre including the Investigator and Agents). In performing the services hereunder, the Centre shall be deemed as an independent contractor to Meril for all purposes. Neither the Centre nor the Investigator shall have any authority to incur any liability on Meril's behalf, or to bind Meril to any obligation without the express written authorization of Meril.

12.5 **Assignment.** Neither Party may assign this Agreement without the prior written consent of the other Party, except that (a) either Party may assign this Agreement to an Affiliate, or to a third party in connection with a merger or sale of all or substantially all of its assets relating to the Study or the Study Device; and (b) the Sponsor may delegate its obligations or assign its rights under this Agreement to a contractor, provided that the Sponsor remains liable for the performance of all delegated obligations. Any Party making an assignment pursuant to this Clause 13 (other than an assignment to an Affiliate) shall provide prompt written notification to the other Party. In the case of any assignment (but not a delegation), the assignee shall assume all of the obligations of the assignor under this Agreement.

12.6 **Integration and Modification/Waiver.** This Agreement together with any exhibits hereto, constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements, discussions and understandings between the Parties. No amendment, modification or waiver of any term or provision of this Agreement shall be effective except by written instrument duly executed by each Party. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

12.7 **Force Majeure.** Noncompliance by a Party with this Agreement due to any cause beyond the reasonable control of the Party, such as war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers (each, an event of "Force Majeure"), shall not constitute a breach of this Agreement. That Party shall be excused from performance under this Agreement to the extent and for the duration of such event of Force Majeure; provided, however, that it first notifies the other Party in writing thereof and that it uses reasonable efforts to cause such event of Force Majeure to abate.

12.8 **Governing Law/Jurisdiction.** This Agreement shall be construed and interpreted in accordance with the laws of India, without regard to its conflict of law's provisions. Any action brought to enforce or interpret this Agreement shall be brought in the courts of Mumbai, subject to appeal in the higher courts in India, and each Party hereby consents to the jurisdiction thereof.

12.9 **Severability.** If any term or provision of this Agreement is held to be invalid, unenforceable, or void by a court of competent jurisdiction, the remaining terms and provisions shall nevertheless be enforceable according to their terms.

12.10 **Counterparts.** This Agreement may be executed in one or more counterparts, which taken together, shall constitute one and the same instrument.

12.11 **Interpretation.** Unless the context of this Agreement requires otherwise, words of one gender include the other gender; words using the singular or plural number also include the plural or singular number, respectively; the terms "Clause" and "Section" refer to the specified Clause and Section of this Agreement; and the term "including" means "including, without limitation."

12.12 **Notices.** The Parties shall send notices in writing, referencing this Agreement. Notice shall be deemed given: (a) when delivered personally; (b) one (1) day after having been sent by facsimile, with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; (c) by e-mail with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) two (2) days after deposit with a

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nationally recognized overnight carrier, with written verification of receipt. Notice shall be given to the addressee below:

To the Institute:	**Sanjay Gandhi Postgraduate Institute of Medical Sciences** Attention: **Prof. Rakesh Kapoor** E-mail: director@sgpgi.ac.in
With a copy to:	**The Principal Investigator** Attention: **Dr. Nirmal Gupta** E-mail: drnirmalgupta@gmail.com
To the Sponsor:	**Meril Life Sciences Pvt. Ltd.** **Attention: Dr. Ashok Thakkar** E-mail: ashok.thakkar@merillife.com

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IN WITNESS WHEREOF, The Parties have duly executed this Agreement as of the date first written above.

Sponsor: Meril Life Sciences Pvt. Ltd.

Signature:

Date: 21/MAR/2018

Name: **Dr. Ashok Thakkar**

Title: **Head of Clinical Research**

Address for Notices: **Meril Life Sciences Pvt. Ltd., Bilakhia House, Muktanand Marg, Chala, Vapi-396191 Gujarat, India.**

Institute: Sanjay Gandhi Postgraduate Institute of Medical Sciences

Signature:

Date:

Name: **Prof. Rakesh Kapoor**

Director
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014 (U.P) INDIA

Title: **Director SGPGI**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

Investigator: Dr. Nirmal Gupta

Signature:

Date: 27/03/18

Name: **Dr. Nirmal Gupta**

Title: **Principal Investigator**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

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EXHIBIT-A

Fee Schedule

Meril shall pay to the Payee (as per Clause 7 of the Agreement) following Fee subject to and in compliance with the terms and conditions of this Agreement.

Total 30,000.00 INR (Thirty Thousand Indian National Rupees) for each enrolled Research Subject will be paid to **Director, SGPGIMS, Research a/c** based on submission of the data in compliance with the terms and conditions of this Agreement. The schedule of payment will be as given in the following table.

Visit type	Amount/per Research Subject in ₹
1. Screening, Enrolment and Follow Ups	
(A) On Research Subject Screening	5,000.00
(B) Submission of completed electronic Case Report Forms ("eCRFs") (Baseline, Post Implant-Discharge,30-days follow-up)	12,000.00
(C) Submission of completed e-CRFs till and including 180-day follow up	2,000.00
(D) Submission of completed e-CRFs till and including 1-year follow up	2,000.00
(E) Submission of completed e-CRFs till and including 2-year follow up	2,000.00
(F) Submission of completed e-CRFs till and including 3-year follow up	2,000.00
(G) Submission of completed e-CRFs till and including 4-yer follow up	2,000.00
(H) Submission of completed e-CRFs till and including 5-year follow up	2,000.00
(I) Site Close Out (After Final Data Base Lock)	1,000.00
Grand Total (A-I)	**30,000.00**

- All protocol specific Lab Investigations and diagnostic procedures cost will paid as pass-through cost post generating Invoice based on original supporting bills with applicable taxes.
- Patient travel reimbursement will be paid as per actual to subject, maximum up to INR 1500/- on return clinic follow up as per the protocol specific visits for each visit depending on your distance from the Hospital/Centre.
- All payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable.
- Reimbursement of any additional pass through cost including optional cost shall be subject to sponsor's prior approval and at actual.

Invoicing Instructions

Invoices in the name of "Meril Life Sciences Pvt. Ltd." shall be sent to:
Dr. Ashok Thakkar
Meril Life Sciences Pvt. Ltd.
Survey No.135/139, Bilakhia House,
Muktanand Marg ,
Chala ,Vapi – 396 191
Gujarat, India.

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Executive Registrar
SGPGIMS,Lucknow

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IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date first written above.

Sponsor: Meril Life Sciences Pvt. Ltd.

Signature:

Date: 26/MAR/2018

Name: **Dr. Ashok Thakkar**

Title: **Head of Clinical Research**

Address for Notices: **Meril Life Sciences Pvt. Ltd., Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala, Vapi-396191 Gujarat, India.**

Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences

Signature:

Date:

Name: **Prof. Rakesh Kapoor**

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Title: **Director SGPGI**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

Investigator: Dr. Nirmal Gupta

Signature:

Date: 27/03/18

Name: **Dr. Nirmal Gupta**

Title: **Principal Investigator**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

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पश्चिमबङ्ग पश्चिम बंगाल WEST BENGAL Z 793626

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("Agreement") is made as of 11-Sep-2018 (the "Effective Date") by and among

1 Dr. Piyali Bhattacharya, Consultant Paediatrician, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India ("Principal Investigator")

And

2 Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India (Institute)

And

3. Medelin Research Pvt Ltd, having its Registered Office at Acropolis , Unit No 10/5 , 10th floor, 1858/1, Rajdanga Main Road,Kolkata-107 ("CRO")

And

4. Wockhardt Ltd. having its Registered office address at D-4, M.I.D.C, Chikhalthana, Aurangabad – 431006 and its Global Headquarter at Wockhardt Towers Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051 ("Sponsor")

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WHEREAS,

a. The research contemplated by this Agreement is of mutual interest and benefit to the Sponsor, and will further the Sponsor's instructional and research objectives;

b. Sponsor based on the representation and warranties given by the CRO, desires to engage CRO on non-exclusive basis to initiate study of A Phase II / III, prospective, randomized, active-controlled, open label, Parallel group, 2-arm, Multi-centric trial for evaluation of Efficacy, Safety, and Tolerability of DTaP+Hib (Diphtheria, acellular Pertussis, Tetanus and Hemophilus influenza b) combination vaccine in Indian pediatric population in comparison with Pentaxim® (Diphtheria, acellular Pertussis, Tetanus, Hemophilus influenza b and IPV) combination vaccine of Sanofi Pasteur (WOC/DTH/CT-56/15) ."

c. The CRO has approached the Institution and Principal Investigators to perform the study in accordance with the Declaration of Helsinki (1996), the ICH Guidelines on Good Clinical Practice and Local Regulations and have accordingly finalized the Clinical Trial Protocol.

d. the Study contemplated by this Agreement will further the Sponsor's interest in advancing medicine and patient care and the said study contemplated by this Agreement;

e. the Institution is equipped to undertake the Study and the Institution, CRO and Principal Investigator have agreed to perform the Study for Sponsor according to the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants expressed herein, the parties agree as follows:

1. **REPRESENTATIONS AND WARRANTEES:**

a. Each party represents and warrants to and covenants with the other that:

i. It has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this agreement; , wherever applicable,

ii. It has the corporate power and authority to enter into and perform its obligations under this Agreement, whenever applicable,

iii. This Agreement has been duly authorized, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

iv. Neither the execution and delivery of this Agreement by either party, nor the performance by such party of its obligations hereunder nor compliance by such party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any indenture, mortgage, lease, agreement, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such party;

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b. **CRO represents and warrants that**

i. it has the facilities, professional, technical and clerical staff, experience, and expertise sufficient in quality and quantity to perform the Services and the Clinical Study pursuant to the Protocol within the time frame set forth herein and all appropriate permits and authorisations necessary to provide and perform, to the highest of professional standards, the services for the conduct of the clinical study in accordance with this agreement, the Protocol, ICH, GCP and all applicable standard operating procedures and has capability to perform or arrange for the performance of all services required by SPONOSR.

c. **Institution represent that**

i. The Institution represents that it is entitled to procure and the Institution will procure the services of Principal investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.

ii. The Institution shall notify the Sponsor if the Principal Investigator ceases to be employed by or associated with the Institution and shall use its best endeavors to find a replacement acceptable to both the SPONSOR and CRO. In order to ensure high standard of clinical trials, if no mutually acceptable replacement can be found the SPONSOR may terminate this agreement pursuant to clause 24(d). However in such an event CRO shall be eligible to receive money for the work successfully completed as certified by SPONSOR including the non-cancellable cost, if any, till the date of termination of this Agreement, within 60 days from the date on which both the parties mutually agreed.

d. **Principal Investigator represent that:**

i. The Principal Investigator hereby confirms that he is a competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub investigators and research staff and the Institution.

ii. he (the term "he" shall include "she") is free to participate in Clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his (the term "him" shall include "her") performance of the obligations detailed in this Agreement.

iii. he is not involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Evaluation Agency (EMEA), The Drug Controller general of India (DCGI) or other

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regulatory authorities. No data produced by him in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

iv. he has considered, and is satisfied that, facilities appropriate to the Clinical Trial are available to him at the Trial Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the CRO to perform the Clinical Trial efficiently and in accordance with the provisions of this Agreement.

2. Obligations/Responsibilities:

a. Principal Investigator

i. Principal Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub investigators or research staff.

ii. Principal Investigator will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is accountable to THE SPONSOR OR its representative for the compliance of Investigators to the terms of this Agreement.

iii. Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from THE SPONSOR or its representative.

iv. Principal Investigator may delegate duties and responsibilities to sub investigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.

v. Principal Investigator will comply with the policies and procedures of the organization / institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Sponsor or its representative promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

vi. The Principal Investigator shall be responsible for obtaining and maintaining all approvals from the relevant local research ethics committee for the conduct of the Clinical Trial and the principal investigator shall keep the SPONSOR fully apprised of the progress of ethics committee submissions and shall upon request provide the SPONSOR with all correspondence relating to such submissions. The Principal investigator shall not consent to any change in the Protocol

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requested by the relevant ethics committee without the proper written consent of the SPONSOR.

vii. The Study will be conducted by the Principal Investigator at the Institution with the prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the Sponsor and all applicable laws and regulations

viii. The Principal Investigator shall provide Sponsor with written evidence of review and approval of this Study by the institutional review board or such other committee that is responsible for reviewing and approving research (the "EC") prior to the initiation of the Study and with evidence of the EC's ongoing review and approval of the Study.

ix. The Principal Investigator agrees to perform the Study according to the Protocol, and in accordance with all applicable rules and regulations, including the ethical principles for medical research involving human subjects, World Medical Association, declaration of Helsinki, good clinical practices for clinical research in India, ethical guidelines for biomedical research on human participants by ICMR, Schedule Y and good clinical practice: ICH topic e6.

x. The Principal Investigator agrees not to implement any deviation from or changes to the Protocol without Sponsor's written consent and prior EC approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

xi. The Principal Investigator further agrees to use best efforts to provide Sponsor's with the data called for in the Protocol, including copies of each research subject's signed informed consent form, a signed authorization as required under any applicable India regulations/policies and properly completed case report forms, in a timely manner. The informed consent form shall comply with the requirements of GCP guidelines. The Institution will provide for (i) access to the research subject's medical records by Sponsor's and by the DCGI and other appropriate regulatory agencies and (ii) the use of Study data by Sponsor for any purpose that it deems appropriate provided that the research subject's personal identifying information has been removed. In the event of a conflict between terms of the Protocol and this Agreement, the terms of this Agreement shall govern.

xii. The Principal Investigator shall promptly report to Sponsor any significant developments that may occur during the Study, including but not limited to adverse clinical events as described in the Protocol.

xiii. The Principal Investigator and Institution agree to permit representatives of Sponsor and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Sponsor, the DCGI or other regulatory

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authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. The Principal Investigator shall notify Sponsor immediately if another regulatory authority schedules or, without scheduling, begins such an inspection.

xiv. The Principal Investigator agrees to maintain records and data related to the Study in compliance with all applicable requirements, and in any event, for at least a period of at least 3 years after the completion/termination of the study or submission of the data to the regulatory authority(ies) whichever is later. The Principal Investigator will insure that all Study data are promptly and accurately recorded on Sponsor's recording forms, whether electronic or paper.

xv. In the event that during the term of this Agreement, either the Institution or Principal Investigator becomes debarred or receives notice of an action or threat of an action with respect to its debarment, the Institution or Principal Investigator, as the case may be, shall notify Sponsor immediately. Institution hereby certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership or association that has been debarred. In the event that Institution becomes aware of the debarment or threatened debarment of any person or entity providing services to Institution which directly or indirectly relate to services provided under this Agreement, Institution shall notify Sponsor immediately and shall take appropriate measures to ensure that there is no delay in the Studies.

b. Institution:

i. The Institution shall ensure that all employees and agents of Institution who are assigned to perform services under the Agreement are made aware of the obligations contained in the Agreement and the Protocol and are bound by such obligations.

ii. The Institution and Principal Investigator shall all the time comply with all types of License, permission or certificates as required under laws, rules and regulations.

iii. The Institution shall bear all costs related to the performance of the Study except as expressly set forth in section 23.1 and attached budget.

iv. Institution shall apply its best efforts to retain the services of the Principal Investigator.

v. In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform the Sponsor/CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, who shall have a similar background and also knowledge of the Clinical Trial.

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vi. Any successor to the Principal Investigator must be approved, in writing, by the Sponsor/CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this agreement and to sign each such document as evidence of such agreement (although failure to sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

vii. The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India.

viii. The Institution agrees to immediately inform the Sponsor/CRO in writing if any person, including but not limited to the Principal Investigator, who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or to the best of the Institution's knowledge, is threatened, relating to the debarment of the Institution or any person performing services hereunder.

ix. The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with:

1. The Protocol and all other terms of this Agreement;

2. All laws and regulations pertaining to the transportation, storage, use, administration and disposal of drugs, vaccines/biologicals, and the conduct of clinical investigations among which the Helsinki Declaration but not limited to Schedule Y, Drug and Cosmetic Act of India, with the Good Clinical Practice approved by the Indian Regulatory Authorities.

3. Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs;

4. Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP;

5. All applicable laws and regulations.

x. The Institution agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

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xi. Such informed consent shall be obtained by the Principal Investigator using the informed consent form template developed for the Trial Site. The Privacy Rules shall be followed in order to obtain consent from Subjects as required throughout the Clinical Trial.

c. Sponsor / CRO

i. Sponsor / CRO agrees to provide to the Principal Investigator as designated by CRO all information concerning the Study Material that is necessary for safe and proper handling and storage of the Study Material and for performance of the Study.

ii. Sponsor / CRO agrees to provide the Study Material for use in the Study in accordance with the Protocol.

iii. The CRO shall be responsible for GCP, Protocol compliance, and Regulatory compliance.

3. **Sponsor Right:**

a. The Sponsor reserves the right to make any changes, amendments, addendum or supplements to the Protocol from time to time, as it may think fit and shall inform CRO and the Principal Investigator by giving a written notice to abide by the same.

b. Sponsor shall have the right to designate a different investigator or other supporting personnel so long as the choice is reasonably acceptable to CRO.

c. SPONSOR has a right but shall not be under any obligation to review all the investigators, supporting personnel and subcontracted vendors recommended by the CRO for performance of this agreement.

d. SPONSOR's representatives may visit CRO's premises / Site with a prior written notice at reasonable times and with reasonable frequency during normal business hours to obtain information regarding the progress of Study. CRO will assist SPONSOR in scheduling such visits. The costs of such visit shall be entirely borne by the SPONSOR. During such visits, SPONSOR'S representatives may examine the controls and procedures used by CRO in the performance of quality assurance inspections. SPONSOR shall also examine the completeness of the Services that CRO is providing to SPONSOR.

4. PAYMENT OF FEES:

a. As compensation for Institution / Investigator performance of the Services described in Protocol, SPONSOR / CRO shall pay Institution / Investigator fees for the services in the amounts and upon the terms specified in the Study Budget "Budget") attached to and made a part of this agreement.

b. Institution / Investigator shall not revise its prices for any reason unless mutually agreed in writing by all parties during the term of this Agreement. In any case,

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Institution / Investigator shall endure that the overall budget shall not exceed the total study budget as specified which shall form the part of this Agreement unless agreed by SPONSOR / CRO.

c. Institution / Investigator will not charge any amount to SPONSOR / CRO for their services which were not provided by the SPONSOR / CRO or agreed upon by and between the parties.

d. SPONSOR / CRO will reimburse Institution / Investigator for travel and other reasonable out-of pocket expenses incurred by Institution / Investigator personnel at the request of the SPONSOR / CRO. All pass through costs invoiced to SPONSOR / CRO will be at actual cost with no mark-up for administration or overhead. Travel and reasonable out-of-pocket expenses shall include the following:

i. Travel via commercial airlines, economy class; train or rental car;
ii. Local travel to places other than CRO's office by personal car at a rate to be agreed between the parties for each country
iii. Actual and reasonable lodging and meal expenses
iv. Actual and reasonable telephone expenses, mailing expense, express courier performance of services and photocopying expense incurred in the performance of the services under this agreements and
v. Other reasonable and necessary expenses as approved by SPONSOR.

e. Institution / Investigator shall submit a reasonable detailed invoice of services performed and completed, travel and out-of-pocket expenses to SPONSOR / CRO on a quarterly basis. A study startup fees of Rs. 40,000 will be given at site initiation visit.

f. The payments is excluding GST or similar taxes levied by state/central government on SPONSOR / CRO's fees. Any income tax, withholding tax or similar taxes deductible from the payment will be deducted by SPONSOR / CRO.

5. **Protocol**. Investigator will conduct the Study in accordance with the Protocol, ICMR GCP guidelines and applicable rules and regulations in India.

6. **Amendments.** The Protocol may be modified only by a written Amendment, signed by both THE SPONSOR and THE PRINCIPAL INVESTIGATOR.

7 **Emergency Amendments**. If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Investigator will notify THE SPONSOR and the responsible Independent Ethics Committee or Institutional Review Board (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment.

8 No Additional Research. The Institution & Principal Investigator ensures that no additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited

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research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.

9. **Subject Enrolment.** Investigator has agreed to enrol in Study a maximum of 20 subjects for phase II within one month and 50 subjects for phase III within three months unless THE SPONSOR extends this enrolment no. and period by written notification. A qualified subject is one who meets all Protocol criteria such as inclusion & exclusion criteria and agrees to participate in the study through informed consent in writing.

9.1 **Failure to Enroll.** If Investigator fails to enroll subjects at a rate adequate to meet the enrolment requirement, THE SPONSOR shall be free to terminate the Study early (see Section 24(d) Termination).

9.2 **Study Conduct.** Investigator will conduct Study in accordance with the Protocol, THE Sponsor's written instructions, ICMR, Good Clinical Practice (GCP) guidelines and all applicable governmental laws, rules, and regulations.

10 **Ethics Committee ("EC").** Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct.

11 **Study Disapproval.** If, through no fault of Investigator, the Study is disapproved by EC, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 24(a), Disapproval by EC, below.

12 **Data Protection:** Data collected in Study may include personal data and sensitive information which is subject to specific legislation relating to the processing, storage, transfer and use of such data or information. The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR / CRO will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Wockhardt Limited, to representatives and contractors working on behalf of THE SPONSOR group and to regulatory authorities across the world. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause (13).

13 Informed Consent and Authorization to Use and Disclose Health Information

13.1 **Informed Consent:** Investigator will provide THE SPONSOR / CRO an opportunity to review and approve the content of the informed consent form (including any revisions made during the course of the Study) before it is used. Investigator will obtain an audio-video and written informed consent from each study subject and will maintain a signed

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original of that consent in the subject's record. Investigator will allow THE SPONSOR / CRO to inspect signed informed consent forms or photocopies there during monitoring visits or audits (see Monitoring and Audits, Section 16).

13.2 **Adverse event:** Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone or facsimile. THE SPONSOR shall, so far as is lawful, have full responsibility for the reporting of all adverse events to local and international regulatory and/or health authorities.

14. **Confidential Information.** During the course of the Study, Investigator may receive or generate information that is confidential to THE SPONSOR. Any information marked by the sponsor as confidential and provided to the investigator 3 month before the execution of this agreement will also be treated as confidential information.

14.1 **Definition.** Except as specified in Section 14.2, Exclusions, below, "Confidential Information" includes

a. the Protocol,
b. the Investigator Brochure,
c. The informed consent of participants.
d. Study Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), subject to Investigator's right to publish the results of the Study (as described in Section 18, Publications, below),
e. Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), and
f. any other information related to the Study, THE SPONSOR'S DRUG, or THE SPONSOR technology, research, or business plans that THE SPONSOR provides to Investigator in writing or other tangible form and marks as CONFIDENTIAL or initially discloses orally and then summarizes and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure.

14.2 **Exclusions.** Confidential Information does not include information that

a. is known or open to the public or otherwise in the public domain at the time of disclosure,
b. becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Investigator,
c. is already known to Investigator at the time of disclosure and is free of any obligations of confidentiality, or
d. is obtained by Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

14.3 **Obligations of Confidentiality.** Unless THE SPONSOR provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

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a. Required disclosure of Confidential Information to the EC or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 18, Publications, of this Agreement.

14.4 **Disclosure Required by Law.** If disclosure of Confidential Information to any party other than the EC relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator

a. notifies THE SPONSOR in writing in 15 working days advance of the disclosure so as to allow THE SPONSOR to take legal action to protect its Confidential Information,

b. discloses only that Confidential Information required to comply with the legal requirement, and

c. continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 **Individually Identifiable Health Information.** If, in connection with this Study or performance of this Agreement, THE SPONSOR comes into contact with individuality identifiable health information relating to subjects who are not Study subjects, THE SPONSOR agrees to maintain the confidentiality of such information and not to use it for any purpose.

14.6 **Survival of Obligations.** These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the studies.

14.7 **Return of Confidential Information.** If requested by THE SPONSOR in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Study Data. Biological Samples and Study Records.

15.1 **Study Data.** During the course of the Study, Investigator will collect and submit certain data to THE SPONSOR or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical reports, subject diary, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data to THE SPONSOR or its agent within the time periods specified below.

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a. **Ownership of Study Data.** Subject to Investigator's right to publish the results of the Study (see Section 18, Publications), THE SPONSOR is the exclusive owner of all Study Data.

b. **Non-exclusive License.** THE SPONSOR grants Investigator no right to use study data for any purpose including research and/or education purpose.

c. **Data Management and statistical Analysis**: THE SPONSOR or its representative shall carry out the data management and statistical analysis. THE SPONSOR may consult and / or provide THE PRINCIPAL INVESTIGATOR for interpretation during report writing.

d. **THE SPONSOR** is the exclusive owner of study data.

15.2 **Biological Samples.** If so specified in the Protocol, Investigator may collect and provide to THE SPONSOR or its designee biological samples (e.g., blood,) obtained from Study subjects for testing that is directly related to subject care or safety monitoring.

a. **Use.** Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. **Analysis samples.** THE SPONSOR or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, THE SPONSOR will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator or Study subject.

c. **Ownership**. THE SPONSOR is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

15.3 **Study Records.** Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a. Retention. Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of at least 3 years after the completion/termination of the study or submission of the data to the regulatory authority (ies) whichever is later unless THE SPONSOR authorizes, in writing, earlier destruction. Investigator agrees to notify THE SPONSOR before destroying any Study Records after the required retention period. Investigator further agrees to permit THE SPONSOR to ensure that the records are retained for a longer period if necessary, at THE SPONSOR expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16 Monitoring, Inspections and Audits.

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16.1 **Monitoring.** THE SPONSOR / CRO or its representative shall be entitled at its absolute discretion (and in such form as THE SPONSOR / CRO sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit THE Sponsor's / CRO's representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by THE SPONSOR / CRO will relieve the Investigator of any of its obligations hereunder.

16.2 **Inspections and Audits.** The Study is subject to inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. THE SPONSOR / CRO or its representative may also choose to audit Study Records as part of its monitoring of Study conduct.

a. **Notification.** Investigator will notify THE SPONSOR / CRO or its representative as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.

b. **Cooperation.** Investigator will cooperate with regulatory agency or THE SPONSOR / CRO or its representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

c. **Resolution of Discrepancies.** Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

d. **Inspection Findings and Responses.** Investigator will promptly forward to THE SPONSOR / CRO or its representative copies of any inspection findings that Investigator receives from a regulatory, agency. Whenever feasible, Investigator will also provide THE SPONSOR / CRO or its representative with an opportunity to prospectively review and comment on any Investigator responses to regulatory agency inspections.

e. **Data Clarification Form:** THE SPONSOR / CRO or its representative may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which THE PRINCIPAL INVESTIGATOR or his/her nominee shall clarify within 7 working days.

f. **Study Conduct Evaluations.** THE SPONSOR / CRO or its external service providers may document and evaluate the performance of Investigator in the conduct of the Study. THE SPONSOR / CRO or its representative will use these evaluations solely for internal purposes.

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17. **Inventions.**

18.1 **Notification.** If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform THE SPONSOR or its representative.

18.2 **Assignment.** Investigator will assign all interest in any such Invention to THE SPONSOR, or its representative free of any obligation or consideration beyond that provided for in this Agreement.

18.3 **Assistance.** Investigator will provide reasonable assistance to THE SPONSOR or its representative in filing and prosecuting any patent applications relating to Invention, at THE Sponsor's expense.

18. **Publications.**

The findings of this study may be published in a scientific journal or presented at a scientific meeting with prior permission from SPONSOR The sponsor reserves the right to review all manuscripts prior to submission for publication or any paper before it is presented. In accordance with standard editorial and ethical practice, the sponsor will generally support publication of multicentric trials only in their entirety and not as individual center data. Authorship will be determined by mutual agreement between the sponsor in conjunction with the CRO and the Principal investigator(s).

19. **Debarment and Exclusion.** Principal Investigator and Investigator each certify that it/s/he is not debarred and that it/s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Investigator and Principal Investigator will notify THE SPONSOR promptly if either of these certifications needs to be amended in light of new information.

20. **Use of Name.** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, THE SPONSOR reserves the right to identify THE PRINCIPAL INVESTIGATOR and Investigator in association with a listing of the

Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

21. **Assignment and Delegation.**

21.1The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from THE SPONSOR / CRO any attempt to so assign, delegate, or subcontract is invalid. THE SPONSOR / CRO authorizes delegation or subcontracting any duties.

Lt Col Varun Bajpai VSM
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21.2 **Affiliates.** As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with THE SPONSOR / CRO.

21.3 **Successors and Assigns.** This Agreement will bind and inure to the benefit of the successors arid permitted assigns of each party.

22. **Conflict with Attachments.** If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

23. **Liability, Indemnification and insurance**

23.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject, he or she shall be given free medical management as long as required or until it is proved that the injury is not related to the IP (whichever is earlier)

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of study related injury or death of the subject shall be borne by the sponsor;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death:

(a) Adverse effect of the Investigational Medicinal Product;

(b) Violation of the Protocol, scientific misconduct or negligence by the Sponsor's Representative, CRO or the Investigator, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the Investigator, then the Investigator will be liable to reimburse to the Sponsor representative the expenses on such medical management and financial compensation that the sponsor's representative shall have paid to the subject or his/her nominee(s), as the case may be;

(c) Failure of the Investigational Medicinal Product to provide intended therapeutic effect where the standard care though available was not provided to the subject as pee trial protocol;

(d) Use of placebo in a placebo-controlled trial where the standard care though available was not provided to the subject as pee trial protocol;

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(e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) For injury to a child in-utero because of the participation of parent in the Study;

(g) Any clinical trial procedures involved in the Study."

(9) The Sponsor's representative shall indemnify, defend and hold harmless the Indemnitee, from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from the use of the Product in connection with the Clinical Trial.

23.2 In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the Sponsor's / CRO's representative and shall assist the Sponsor's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses. The Principal Investigator and the Institution agree to cooperate with and to authorize the Sponsor's representative to carry out the sole management and defense of such claim or action. Neither the Principal Investigator nor the Institution, its trustees, officers or Related Persons shall compromise or settle any claim or action without the prior written approval of the Sponsor.

23.3 Notwithstanding the foregoing, the Sponsor's representative shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless the Sponsor, officers, directors, agents and employees for loss or damage resulting from:

(i) failure of the Institution or the Principal Investigator or the Additional Personnel to adhere to the terms and provisions of the Protocol or any amendments thereto (including but not limited to the Principal Investigator's and the Institution's obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol (and any appendix or attachment to the Protocol), or the Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Clinical Trial, including but not limited to the Product, any comparative drug and any placebo;

(ii) Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable Health Authorities' requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

(iii) Failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

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(iv) Any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

23.4 The Institution shall secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:

(i) Medical professional and/or medical malpractice liability (including coverage for the Principal Investigator);
(ii) General liability (including coverage for the Clinical Trial site); and
(iii) Worker's compensation coverage,

in amounts required by applicable federal, provincial or state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Clinical Trial.

Upon request of the Sponsor, copies of certificates evidencing such insurance coverage will be made available to the Sponsor's representative and the Institution shall provide thirty (30) days' prior written notice to the Sponsor's representative in the event of cancellation or any material change in such insurance.

Term:

The term of this Agreement shall commence on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol unless sooner terminated as provided herein.

24. Termination.

24.1 **Termination Conditions**. This Agreement terminates upon the earlier of any of, the following events:

a. **Disapproval by EC.** If, through no fault of Investigator, the Study is never initiated because of EC disapproval, this Agreement will terminate immediately.

b. **Study Completion.** For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by THE SPONSOR / CRO of all Protocol-required data and Biological Samples; and receipt of all payments due to either party.

c. **Termination upon Notice:** THE SPONSOR reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

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d. **Immediate Termination by THE SPONSOR:** THE SPONSOR further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enrol subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in THE SPONSOR 's opinion pose risks to the health or all being of Study subjects; or regulatory agency actions relating to the Study or the Investigational Drug.

e. **Termination upon Notice by Investigator:** THE PRINCIPAL INVESTIGATOR may terminate the study, if THE SPONSOR / CRO does not comply with the agreement related to finance, supply of medication for the study and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to THE SPONSOR / CRO fifteen days prior to termination and THE SPONSOR / CRO shall have fifteen days to cure its default.

f. **Immediate Termination by Investigator**. Investigator reserves the right to terminate the Study immediately upon notification to THE SPONSOR / CRO if requested to do so by the responsible EC or if such termination is required to protect the health of Study subjects.

24.2 **Payment upon Termination.** If the Study is terminated early in accordance with Section 24 Termination Conditions, above, THE SPONSOR / CRO will provide a termination payment equal to the amount owed for work already performed, in accordance with Attachment A, less' payments already made. If the Study was never initiated because of disapproval by the EC (see Section 23.1.a, Disapproval by EC , above), THE SPONSOR / CRO will reimburse Investigator for EC fees and for any other expenses that were prospectively approved, in writing, by THE SPONSOR or its representative.

24.3 **Return of Materials.** Unless THE SPONSOR / CRO instructs otherwise in writing, Investigator will promptly return all materials supplied by THE SPONSOR / CRO for Study conduct, unused Case Report Forms, other study related material and any THE SPONSOR / CRO -supplied Equipment.

24.4 **Survival of Obligations**. Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification, and Debarment and Exclusion survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

15. Force majeure: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance cause a delay or failure in performance ('a Delay') and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator

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/ Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to SPONSOR / CRO. SPONSOR / CRO shall have the right to terminate a agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

16. Notice. Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to Sponsor:	Attn: Dr. Agam Shah Phone: 022- 26596762
If to Institution:	Attn: Prof Rakesh Kapoor Phone: 0522-2494001
If to CRO:	Attn: Dr. Monjori Mitra Phone: 9831075734
If to Principal Investigator:	Attn: Dr. Piyali Bhattacharya Phone: 9415104073

24 **Modification**. Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.

25. **Entire Agreement.** This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

26. To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial will be retained for a period of at least 3 years after the completion/termination of the study or submission of the data to the regulatory authority (ies) whichever is later. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform the Sponsor, the Parties shall discuss in good faith in order to find an alternative solution for the proper archiving of these elements in accordance with the applicable regulations. Subjects' files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of the Sponsor

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SGPGIMS,Lucknow

21. Governing Law: This agreement shall be interpreted and enforced under the laws of India and the Courts of Lucknow shall have exclusive jurisdiction to resolve any dispute under this Agreement.

Any dispute or difference which may at any time arise between the parties hereto as to the construction, meaning or effect hereof or as to any clause, matter or thing herein contained or as to the rights or liabilities of the parties hereunder then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within 90 days, then such a question or dispute shall be referred to the arbitration of a sole arbitrator to be mutually appointed by both the parties, under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996 and the rules thereunder, as amended from time to time. The venue of such Arbitration shall be in Lucknow and the arbitration proceedings shall be conducted in English. The decision of such arbitrator shall be final, binding and conclusive on the Parties. The parties hereto agree that the Courts in Lucknow, India alone shall have exclusive jurisdiction in respect of any matters pertaining to, arising out of or in connection with Agreement.

Executed by the parties

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SPONSOR

Wockhardt Ltd.
Mumbai.

11-9-18

Wockhardt Limited Mumbai

Name: Dr Rishi Jain, VP -- Medical Affairs, Wockhardt Ltd.
Date: _____

CLINICAL RESEARCH ORGANIZATION

Medclin Research
Kolkata.

MEDCLIN RESEARCH

Name: DR. MONJORI MITRA, RESEARCH DIRECTOR
Date: 03/09/2018

THE PRINCIPAL INVESTIGATOR

PI Name: DR. PIYALI BHATTACHARYA
Date- 19/11/2018.

INSTITUTION

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Name:
Date- 04.12.2018

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub-investigators and research staff are informed of their obligations under this Agreement.

Principal Investigator

Date- 19/11/2018.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

EXHIBIT A

Site Budget (Per Subject)					
Sl.No	**Budgetary Provision per completed subject**	**Rs.**	**No.**	**Units**	**Amount in Rs per subject**
1	Investigator fees	5800	1	Subject	5800
2	Phlebotomist	200	1	Subject	200
3	Total fees				6000
4	Reimbursements (travel)	300	4	visit	1200
					7200
Sl.No	**Budgetary Provision per incomplete subject**				**Amount in Rs per subject**
1	Investigator fees	2900	1	Subject	2900
2	Phlebotomist	100	1	Subject	100
3	Total fees				3000
5	Reimbursements (travel)	300	2	visit	600
					3600
Sl.No	**Other Expenses to be borne directly**				**Amount in Rs per subject**
1	EC fees				Actuals
2	CRC	15000	10	Months	150000
3	Institutional Overheads	25% of PI fees			Acttuals

a. The Principal Investigator hereby confirms that she has read and understood the clinical trial protocol entitled "A Phase II / III, prospective, randomized, active-controlled, open label, Parallel group, 2-arm, Multi-centric trial for evaluation of Efficacy, Safety, and Tolerability of DTaP+Hib (Diphtheria, acellular Pertussis, Tetanus and Hemophilus influenza b) combination vaccine in Indian pediatric population in comparison with Pentaxim® (Diphtheria, acellular Pertussis, Tetanus, Hemophilus influenza b and IPV) combination vaccine of Sanofi Pasteur". (WOC/DTH/CT-56/15, Version 02 / 20 May 2016, Amendment No. 03/ 03 Oct 2017).

b. All amendments and appendices have also been read and understood. The investigator agrees to the protocol of this trial and will perform the study in accordance with ICMR Good Clinical Practice, and applicable laws, rules and regulations.

c. The Sponsor had declared that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely Drugs & Cosmetics Act, 1940 and

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Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) are obtained by them for use of the same on children.

EXHIBIT B

Serial No.	Milestone
1.	Study Startup fee – Rs. 40,000
2.	Completion of 20 subjects (Phase II)
3.	Initiation of Phase III – Rs. 40,000
4.	Completion of 50% subjects
5.	Completion of Phase III (Excluding 10 % of the total budget of Phase III)
6.	Signing of clinical study reports (10% of total Budget)

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SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL07431673165790Q
Certificate Issued Date	:	30-Mar-2018 12:28 PM
Account Reference	:	IMPACC (IV)/ dl732103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL73210318441565745325Q
Purchased by	:	JSS Medical Research India Private Limited
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS Medical Research India Private Limited
Second Party	:	Not Applicable
Stamp Duty Paid By	:	JSS Medical Research India Private Limited
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

DATED 29 May 2018
JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Vatika Mindscapes (Tower B), Plot 12/2, Sector 27D,
Faridabad- 121003 (Haryana) India
(AS THE CRO)
Dr. Sudeep Kumar
Professor
Department of Cardiology
Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
(AS THE PRINCIPAL INVESTIGATOR)
AND
Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
(AS THE SITE/INSTITUTION)

CLINICAL TRIAL AGREEMENT

JSS Signatory

PI Signatory

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:
1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.

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This Clinical Trial Agreement (the "**Agreement**") is dated: 29 May 2018.

BETWEEN:

1. **JSS Medical Research India Private Limited.**, a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through Kishor Kumar, Financial Controller, India being authorized to sign this Clinical Trial Agreement on behalf of Sponsor, Abbott Healthcare Pvt. Ltd. (hereinafter referred to as "**JSS India**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

2. **Dr Sudeep Kumar**, working as [Professor, Department of Cardiology at [Sanjay Gandhi, PGIMS Hospital] having his residence at SGPGI Campus Raebareli Road Lucknow (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

3. **Sanjay Gandhi, PGIMS Hospital**, a *hospital/health care centre/company/nature of entity* registered under the provisions of Indian Companies Act, 1956 OR any other relevant law, having its registered office at Rae bareli road, Lucknow-226014 acting through its Dr Rakesh Kapoor, Director being authorized to sign this Agreement (hereinafter referred to as the "**Site**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. JSS India is a CRO and is in the business of providing Clinical Trial Site Management Services, Clinical Trial Monitoring Services and Clinical Data Management Services and certain other services related to any clinical study including site and principal investigator identification, regulatory, pharmacy services, identification and management of other agencies related to a clinical study translation of documents.

B. The Site is engaged in Clinical Trials and the PI is a *consultant* at the Site.

C. Abbott Healthcare Pvt. Ltd (hereinafter referred to as "**sponsor**") is Sponsor, desires to conduct a clinical trial in respect of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.

D. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof

JSS Signatory

PI Signatory

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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1. **Definitions and Interpretations**

1.1 In this Agreement:

"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordinance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by Sponsor.

"**Clinical Trial**" shall mean a clinical trial "A Prospective, Randomized, Double-blind, Double dummy, Multi Centre, Comparative Phase III Clinical Trial to Evaluate the Efficacy and Safety of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction". Conducted as per the Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as Sponsor may, from time to time, provide.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party's reasonable control.

"**Dispute Notice**" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean the chemical compound invented by Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and wellbeing of all such actual and potential research participants.

"**Feasibility Study**" shall mean shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

"Fee" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by Sponsor, or if so authorized by JSS India in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

"ICH GCP Guidelines" shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"Indian GCP" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research. **"Information Brochure"** shall mean the information brochure of Sponsor.

"Informed Consent Form" or **"ICF"** shall mean a written consent form provided by Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.

"Investigational Products" shall mean the chemical compound invented by Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by Sponsor.

"Invoice" shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

"Subject" shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"Payment Milestone" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"Protocol" shall mean Protocol Version 1.1 dated 30 June 2017, Protocol No. IVAP3001 as provided by Sponsor.

"Price" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'C' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"Screen Failure" shall mean the screen failure as defined in the Protocol.

"Serious Adverse Event" or an **"SAE"** includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

"Services" shall mean the services detailed in Schedule 'A'

"Site Indemnitee" shall mean the Site and its employees and its associated staff.

"Sponsor Property" shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India

JSS Signatory

PI Signatory

Institution head signatory

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Executive Registrar
SGPGIMS,Lucknow

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"**Standard Operating Procedures**" or "**SOP**" shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

1.2 In this Agreement:

1.2.1 words denoting the plural number include the singular and vice versa;

references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

references to this Agreement include the Recitals and the Schedules;

the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

references to any Party include its successors, transferees and permitted assignees.

2. Scope of the Agreement

The PI agrees to perform the Clinical Trial for and on behalf of the JSS India/sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by JSS India.

3. Term

3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. Clinical Trial

4.1 Clinical Trial Initiation: JSS India shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the JSS India may terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

4.2 Duration: The estimated duration for a Clinical Trial is defined in the Protocol including follow-ups. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions from JSS India.

4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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5. Responsibilities and Obligations of the Parties

5.1 JSS India shall be responsible for the following:

i. Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of sponsor.

ii. Other Duties: Site Monitoring, Medical Monitoring, Clinical Data Management, including electronic data capture Statistical Programming, Clinical Study Report preparation & IMP logistic management

5.2 The PI and/or the Site shall be responsible for the following:

a. The PI shall be responsible that the Trial should be conducted as per the Protocol, GCP Guidelines and Investigator's undertaking. For the tasks performed, Standard Operating procedures are to be documented.

b. PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

c. Upon request by JSS India, the PI will provide JSS India all information needed by JSS India and/or sponsor in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

d. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest as per timelines mentioned in the protocol. The PI will not postpone or cause delay in reporting any such information to JSS India and/or Sponsor irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

e. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

5.3 Regulatory Agency Audit: The PI and the Site will inform JSS India within twenty-four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India in any such investigation, and in the implementation of appropriate action plans for such observations.

6 Representations, Warranties and Covenants.

6.1 JSS India represents, warrants and covenants to Sponsor as follows:

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(a) Formation/Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times, and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of a Project.

(d) Freedom to Use: JSS India hereby represents and warrants that Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Site represents, warrants and covenants to JSS India and Sponsor as follows:

(a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Freedom to Use: The Site hereby represents and warrants that the JSS India/Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

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Institution head signatory

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i. The Site agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.3 The PI represents, warrants and covenants to JSS India as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

ii. Upon JSS India request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7 Use of Name

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

8 Ownership of Property and Data

Sponsor shall have sole ownership and rights to any inventions or discoveries relating to the Drug or study, whether patentable or not, made in the performance of this Agreement.

9 Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the

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appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (*any other applicable regulation*) (b) the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India / sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India/sponsor so elect, comprise: (a) inspection of the PI's and/or the Site's facilities and records relating to the rendering of services to or for a Clinical Trial; (b) review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

10 Publications

JSS India and Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information & approval from the Sponsor . The PI and the Site agrees to delete any information that may be confidential or proprietary.

11 Fees

11.1 Budget: The CRO, PI and/or the Site shall provide an estimate of the budget to the other Parties on or before site selection. The Parties shall negotiate and agree on the Budget The Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

11.1.1 The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the JSS India unless the PI and/or the Site have taken the written consent of JSS India before administration of such tests or services.

11.2 Payment of Fees and Expenses to the PI and/or the Site: The CRO- JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol, the consideration for their services will be prorated according to the actual number of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C

11.2.1 Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will issue its invoice for the Fees to the JSS India, on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

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(b) the JSS India, if so authorized, shall pay the invoiced amount within sixty (60) business days of the date of the invoice. The payment shall be made through crossed cheque/DD, as applicable:

PAYEE INFORMATION:

The Total study budget will be paid to below payee details (after TDS deduction)

Payee details:

PAYEE NAME	Director SGPGI Research Account
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAAJS3913N

11.2.2 Taxes: Any service tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to the PI's and/or Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

11.2.3 Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to JSS that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12 Insurance

a. JSS India shall maintain all adequate insurance coverage, including a (i) professional liability insurance, (ii) indemnity insurance covering JSS India, the PI and the Site, (iii) human clinical trial insurance covering JSS India, the PI and the Site during the Term.

b. The JSS shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4 to the Site and the PI.

13 Indemnification

13.1 Indemnity: JSS India on behalf of Sponsor shall indemnify, defend and hold harmless the Site, the PI, the Site Indemnitees, the Clinical Trial, and JSS India and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") incurred by or imposed on the Site Indemnitees or the Site, the PI, the Clinical Trial or JSS India or any of the associated staff in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Clinical Trial and/or JSS India to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure

13.2 Exclusions from Indemnification: The JSS India obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

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(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and JSS India or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 3 above, directly or due to a third-party claim shall give written notice to the JSS India, against whom such indemnification rights are claimed. Pursuant to Clause 3 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the JSS India/Sponsor shall not relieve the JSS India/Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the JSS India/Sponsor or its defences. With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 3 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from Sponsor; provided, however, that: (i) the Indemnified Party shall obtain the prior written consent of the JSS India/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if (A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against Sponsor, (B) such settlement does not expressly unconditionally release the JSS India/Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or (C) involves criminal or quasi-criminal allegations against the JSS India/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim; (ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified

Party or payable by Sponsor in connection with such claim or legal proceeding; (iii) the JSS India/Sponsor shall be entitled to participate in the defence of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and (iv) if the Indemnified Party abandons or fails to reasonably assume the defence of any such claim or legal proceeding, JSS India/Sponsor may assume control of the defence of such claim or legal proceeding at its own expense; provided, however, that if the JSS India/Sponsor shall control the defence of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the JSS India/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if (A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party, (B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or (C) involves criminal or quasi-criminal allegations.

13.4 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site, the Clinical Trial and JSS India as contained in the Clinical Trial Agreement.

13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of JSS India/Sponsor in relation to the Study.

13.6 The CRO shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement. The CRO shall not be liable for payments for a Subjects' lost wages.

14 **Confidentiality**

a. All of the information disclosed by JSS India or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

b. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 Termination

15.1 JSS India may terminate the Clinical Trial by written notice of at least one (1) month in advance.

15.2 The CRO may terminate for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or its representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India, to meet with JSS India or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI

g. Determination by JSS India in writing that business or scientific considerations require termination.

h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India or its representatives for use in the Study, are not completed and forwarded to JSS India or its designated representative, within the timelines prescribed by JSS India.

15.2 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India. However, JSS India shall have the sole right to determine the acceptability of a new PI.

15.3 In the event that JSS India exercise its right to terminate the Study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

15.4 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

16 Miscellaneous

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

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Institution head signatory Executive Registrar
SGPGIMS,Lucknow

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If to JSS India:

JSS Medical Research India Private Limited
Vatika Mindscapes (Tower B), 6th Floor,
Plot 12/2, Sector 27D, Faridabad-121003,
Haryana, India
Attention: Dr. Renu Razdan
Designation: Vice President, India Operations
Telephone: +91 129 6613 500
E-mail: renu.razdan@jssresearch.com

If to the PI:

Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
Attention: Dr. Sudeep Kumar
Designation: Associate Professor
Telephone: 9919002761
Email:sudeepkumar@yahoo.com

If to the Site:

Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
Attention: Dr. Rakesh kapoor
Designation: Director
Telephone: 9415410130
Email: rkapoor@sgpsi.ac.in

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written amendment/agreement signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by Sponsor, DCGI and Institutional Ethic Committee.

16.3 Independent Contractor Relationship: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India.

16.4 Assignment: This Agreement may be assigned by JSS India to any of its affiliates or to any third party without prior written confirmation of other parties. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India.

16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more

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than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

16.6 Survival: Sections 8, 9, 13, 14, 15, 16.2, 16.3 and 16.11 of the agreement shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.7 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.8 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.9 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Delhi alone shall have exclusive jurisdiction in respect thereof.

16.10 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be New Delhi, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.11 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

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IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

JSS India

By:
Print Name: Kishor Kumar

Title: Financial Controller-
JSS Medical Research India Private Limited

Date: 28 MAY 2018

The Principal Investigator

By:
Print Name: Dr Sudeep Kumar
Title: Professor
SGPGIMS, Lucknow

Date: 01 June 2018

The Site

By:
Print Name: Dr Rakesh Kapoor
Title: Director
SGPGIMS, Lucknow

Date: 18 JUNE 2018

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Executive Registrar
SGPGIMS,Lucknow

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Schedule A

[List of services to be provided by the PI and/or the Site]

Protocol Title: A Prospective, Randomized, Double-blind, Double dummy, Multi Centre, Comparative Phase III Clinical Trial to Evaluate the Efficacy and Safety of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction
Protocol ID: IVAP3001

List of services to be provided by the PI and/or the Site, but not limited to:

1. *Identification of protocol eligible patients for the study*
2. *Administration of informed consent process and AV recording*
3. *Recruiting patients as per protocol inclusion & exclusion criteria*
4. *Administration of patient diaries as per protocol*
5. Treat study participants as per randomization & adequate treatment follow-up
6. *Taking complete medical history of the patients*
7. *Responsibility for adverse events reporting*
8. *Writing the patient study summary-completion of source documentation*
9. Compliance to study subject visits as per Protocol
10. Transcription of data in to electronic case report form & resolution of data queries
11. Allow oversee of the study by CRO or their designee through regular monitoring visits
12. Site readiness for regulatory inspection & external/internal audits
13. IP management as per protocol and Archival of study documents & material
14. Regulatory document submission & management as applicable
15. Coordination with Ethics committee
16. Maintain Study site files

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Schedule B
Budget and Payment Schedules

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Payment shall be made against invoices sent every month according to table mentioned below.

The Parties understand and agree that the currency of the Agreement is and shall remain India Rupee (INR) and shall not be modified notwithstanding any exchange fluctuations that may occur.

All invoices shall be sent to the following address:

JSS Medical Research India Private Limited.
Plot No. 12/2, 6th Floor, Vatika Mindscapes Tower-B,
Near Sarai Khwaja Metro Station,
Sector-27D, Faridabad – 121003 (INDIA)

Each invoice must be an original copy (PDF or fax copies are not acceptable) and contain, as a minimum, the following information:

a) The Research Institution's Name and Address as it is written at the front of this Agreement
b) A description of the deliverable along with supporting attached (e.g. final written report) associated with the invoice
c) The total invoice amount in the currency specified in this Agreement, Payee Name, PAN
d) Signed & date by authorized signatory

Payment Schedule/Milestones per patient:

Visit Type	Amount INR	Approx. Percentage
V1(Including 2D Echo)	7750	25.8%
V2	3250	10.8%
V3	6250	20.8%
V4	3500	11.6%
V5	3500	11.6%
V6	5750	19.1%
Sub Total per subject	30000	NA
IOH @ 25%	7500	25%
Total for per protocol completed patient	37500	NA
Start up Amount	25000	NA

The cost for the trial will be as mentioned below:

a) The cost per protocol-correct and completed subject will be INR 30,000 (excluding Institutional overhead)
Note: Completed patient means once the subject has completed the final follow up and complete data entered and verified in the eCRF by the monitor.

This will include the following fees, as applicable, but not limiting to:

- The PI fees, study team fees, costs for unscheduled visits, site infrastructure maintenance for this study, stationery, courier and others study-related bills.

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b) If required/requested by site, A nonrefundable advance amount of INR 25000 would be issued to the site upon receipt of completely executed agreement and unconditional EC approval.

c) The following costs incurred by site, where applicable, would be reimbursed to site upon receipt by CRO of original receipts/ bills:

i. Fees related to local Ethics Committee reviews
ii. SAE management costs: The SAE management costs are applicable to all SAEs only related to the Clinical Trial/ protocol/ Investigational Product. The costs would be reimbursed to the site once the original bills/receipts are made available to CRO i.e. bills pertaining to hospitalization, investigations & procedures, medications for the SAE.
iii. This Clinical Trial will not involve any monetary expenses. Subjects will be reimbursed for all their expenses in connection with this Clinical Trial on actual basis (e.g. travel costs) by CRO. Subject travel re-imbursement will be paid on actuals upto Rs. 500 per visit upon producing the vouchers/ bills for the same to CRO.

d) The fees for a screen failure patient will be INR 5000. This screen failure payment includes all charges. The screen failure cost shall be applicable for every 3rd Screen failure.

e) Institutional overhead 25% of the total budget (if applicable)

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SCHEDULE C

JSS India on behalf of Abbott Healthcare Pvt.Ltd will make the payments as follows:

(i) Payments will be made once the CRFs for the patient visits have been verified by the CRO/ designee & query has been resolved. Invoices will be raised on monthly basis and sent to CRO for payment. Invoices will be raised on the basis work completed during previous month In the event that a subject withdraws or is withdrawn from the Trial for reasons beyond the Investigator's control (but after commencing the dosing regimen in accordance with the Protocol), payment shall be made pro rata (based on the number of visits completed) in respect of that subject provided all data in respect of that subject up to the time of that subject's withdrawal from the Trial have been completed and sent to and accepted by CRO.

(ii) Invoices will be paid within 60 days of receipts to the payee. Service tax as applicable will be levied on each invoice according to the guidelines of service tax rules of India.

(iii) From each invoice CRO will keep 15% retention money and the same will be paid once all queries are resolved and Clinical trial/Site is closed out in all respects.

(iv) There is no other amount payable to Institute/Investigator for the Clinical Trial (except) mentioned in this agreement.

(v) Above budget does not include any Related Adverse Event or Serious Adverse Event expenses. Any related Adverse Event or Serious Adverse Event expenses will be reimbursed on actual. Reimbursement of Adverse Event or Serious Adverse Event management will include but not limited to Investigations, Hospitalisation, Treatment costs. Site agrees to take approval for any special investigations in case of Adverse Events. Site agrees to give timely update on the plan of management in terms of cost, on the cost incurred in management of the above events.

vi) In case of early termination of Clinical Trial, final payment calculation will be based on actual work completed. In case extra payment has been made, payee will refund the extra money. In case there is any amount payable to payee the same will be paid by CRO.

vii) All payments are subject to TDS (other taxes as applicable) and all payments will be made once payment is received by CRO from Sponsor.

Summary of the items included in payment & items not to be reimbursed:

Items included in payment:

Items included in Professional fees of per patient cost:
• PI fees
• Clinical Trial team fees
• Administrative cost
• Payments for unscheduled visits
• Site infrastructure (including Telephone/ fax/ internet), IMP storage.
• Stationary and Couriers
Pass through costs to be paid on Actuals:
• Ethics Committee fees
• SAE management costs, if any
• Subject Compensation if any
• Travel reimbursements of patients

JSS Signatory

Institution head signatory

PI Signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Authorised Signatory

MUMBAI - 400 027

D-5/STP(V)/C.R.1093/02/10/710-14/10

10:28

Rs.0000200/- PB6515

INDIA STAMP DUTY MAHARASHTRA

FIRST ADDENDUM TO CLINICAL TRIAL AGREEMENT

This First Addendum is made at Mumbai and entered into on 9th day of March, 2021 by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at 7th floor, G Block, BKC Main Road, Bandra Kurla Complex, Bandra (East), Mumbai – 400051, Maharashtra, India (hereinafter referred to as "**Novartis**", which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the First Part;

AND

Dr. Sanjoy Kumar Sureka consulting at **Department of Urology and Renal Transplant, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh- 226014, India** (hereinafter referred to as "**the Investigator**", which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executors, administrators and successors) and the Second Part;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh- 226014, India represented by Prof. R. K. Dhiman whose designation is **Director**; hereinafter referred to as "**the Institution**", (which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the Third Part;

(Novartis, Investigator and Institution may hereinafter be individually referred to as '**Party**' and are collectively referred as '**Parties**').

WHEREAS

A. By a Affiliation Agreement for Researchers dated 23rd Feb 2018 entered into between the Parties hereto ("**Agreement**"), the Investigator and the institution have agreed to provide certain services to Novartis on the terms and conditions contained in the Agreement.

B. Now by this first Addendum, the Parties are desirous of amending the following clause 7 on the terms and conditions herein after appearing.

This Agreement shall be effective from 02-Jul-2020 and shall remain in force until 30-June-2021 (both days inclusive) unless earlier terminated in accordance with this Section.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOW THIS FIRST ADDENDUM WITNESSETH AND IT IS HERE BY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. This Addendum shall be effective from 02-Jul-2020 and shall be coterminous with the Agreement read with the Prior Addendums for all intents and purposes.

2. Save and except to the extent aforesaid, all other terms and conditions of the Agreement shall continue to remain unaltered, valid and binding upon the Parties.

IN WITNESS WHEREOF, the Parties to this Addendum have caused their duly authorized representatives to enter into and execute this Addendum.

Novartis Healthcare Private Limited

By: _____

Name: Murugantham K.

Title: Country Managing Head

Date: 17 Feb 2021

Sanjay Gandhi Postgraduate Institute of Medical Sciences

By: _____

Name: **Dr. Sanjoy Kumar Sureka**

Title: Investigator

Date:

By: _____

Name: **Prof. R. K. Dhiman**

Title: Institute

Date:

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules. You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.
2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.
The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.
In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.
You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent
I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.
I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

- ☐ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..
- ☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.
- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date: _____

Name: **Dr. Sanjoy Kumar Sureka**
Principal Investigator

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 3
Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:
- (i) securing any improper advantage; or
- (ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –
- (i) transactions are executed in accordance with management's general or specific authorization;
- (ii) transactions are recorded as necessary
  - (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and
  - (II) to maintain accountability for assets;
- (iii) access to assets is permitted only in accordance with management's general or specific authorization; and
- (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 4: NOVARTIS PROFESSIONAL PRACTICES POLICY

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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL922428828529 43Q
Certificate Issued Date	:	23-Feb-2018 10:53 AM
Account Reference	:	IMPACC (IV)/ dl982203/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL982203878080306754 96Q
Purchased by	:	PHARMAZZ INDIA PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	CLINICAL TRIAL AGREEMENT FOR ALZHEIMER PHASE II STUDY
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PHARMAZZ INDIA PRIVATE LIMITED
Second Party	:	SGPGI LUCKNOW AND PROF JAYANTEE KALITA
Stamp Duty Paid By	:	PHARMAZZ INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Institution)

And

Prof. Jayantee Kalita (Principal Investigator)

PHARMAZZ INDIA PVT. LTD.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(27)

FOR THE STUDY

Title of Study: A Prospective, Multicentric, Randomized, Double Blind, Placebo Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of mild to moderate Alzheimer's disease.

Protocol Number: PMZ-1620/CLINICAL-2.2/2017

Version Number: 01

Date of Protocol: 14 June 2017

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on 28 Mar 2018 ("**Effective Date**") at New Delhi **BY AND BETWEEN**:

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Office at B-4 Sarita Vihar New Delhi 110076 hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institution having its office Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014, (hereinafter referred to as "**Sanjay Gandhi Post Graduate Institute of Medical Sciences**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART**;

AND

Prof. Jayantee Kalita a registered medical practitioner holding MCI registration number-9795 , is the Professor, , Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014(hereinafter referred to as "**Principal Investigator**"), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART**;

PHARMAZZ INDIA PVT. LTD.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(24)

Pharmazz , **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

RECITALS

1. WHERE **(Sanjay Gandhi Post Graduate Institute of Medical Sciences)** is a pioneering institution of world-class investigator sites in India. It is a chain of investigator sites having an exclusive set up for conducting Phase II to Phase IV clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related to PMZ-1620 is a lyophilized IRL-1620 Injection, proposed to act as as a Treatment agent in Alzheimer's disease.

3. Principal Investigator **Prof. Jayantee Kalita, DM (Neurology)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement with **Prof. Jayantee Kalita** for conducting Clinical Trial Phase II study titled "A Prospective, Multicentric, Randomized, Double Blind, Placebo Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of mild to moderate Alzheimer's disease" **Sanjay Gandhi Post Graduate Institute of Medical Sciences** Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebarcli Road, Lucknow,-226014

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the proposed Study. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions**

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

a) "**AGREEMENT**" shall mean this Clinical Trial Agreement;

PHARMAZZ INDIA PVT. LTD.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipments, samples, services, customer lists, marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) **"EFFECTIVE DATE"** shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled "A Prospective, Multicentric, Randomized, Double Blind, Placebo Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of mild to moderate Alzheimer's disease. As defined in the Protocol.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

g) **"PROTOCOL"** shall mean: The description of the Study contained in the Study protocol number PMZ-1620/CLINICAL-2.2/2017 (a copy of which is attached as Exhibit A) and all amendments thereto as the Parties may from time to time agree in writing.

h) **"STUDY DRUG"** or **"Investigational Drug"** shall mean: IRL-1620 For Injection 30 µg/vial.

i) **"ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(23)

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as **'Services'**), under this Agreement includes **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator to complete the following -

Responsibility of the Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator

The **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees to provide full support to the Principal Investigator **at Sanjay Gandhi Post Graduate Institute of Medical Sciences** Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebarcli Road, Lucknow,-226014, to conduct the Clinical Trial in **Sanjay Gandhi Post Graduate Institute of Medical Sciences** premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the said hospital for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be jointly and severally responsible

a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research (**"Applicable Laws & Guidelines"**);

PHARMAZZ INDIA

Dr. J. KALITA
Professor
Deptt. of Neurology
SGPGIMS, Lucknow
Reg. No. 9705 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

c) to fulfill all other terms and conditions stipulated herein and in the Exhibits hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.2 The Principal Investigator shall personally review all case report forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/eCRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **Sanjay Gandhi Post Graduate**

Dr. J. KALITA
Professor
Deptt. of Neurology
SGPGIMS, Lucknow
Reg. No.- 9795 (AMC)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Institute of Medical Sciences shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethical committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** throughout the period of the Clinical Trial and **with third party vendor or sponsor** for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall obtain written approval from Pharmazz before destruction of such data.

Dr. MAMTA
Professor
Deptt. of Pharmacology
SGPGIMS, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz will provide the Study Drug to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the Safety and Efficacy of PMZ-1620 therapy along with standard supportive care in subjects of Alzheimer's Disease.

3 VISIT AND INSEPECTION

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

a. examine and inspect the **Sanjay Gandhi Post Graduate Institute of**

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Medical Sciences's facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study, and audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

c. Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 RECORDS AND REPORTING

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 PAYMENT, PRICING TERMS

5.1 Pharmazz agrees that in consideration of the Principal Investigator's and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** carrying out the Clinical Trial in accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in Exhibit B, to the **Director SGPGI, Research Account** in accordance with the payment schedule set forth therein which shall include the remuneration and all other related cost.

5.2 The Parties agree that the payment of the amount set forth in **Exhibit B** will be paid by the Pharmazz to the **Director SGPGI, Research Account** to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the insurance program nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in Exhibit B is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in Exhibit B to be paid to **Director SGPGI, Research Account** shall be paid by Pharmazz.

5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to **Director SGPGI, Research Account** under this Agreement. The Budget as reflected in **Exhibit B** is exclusive of taxes.

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5.5 Site will raise GST visit wise as mentioned in Exhibit B. All payments under this Agreement will be made within 15 days from the date of receipt of Invoice.

6 REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect)

The Second Party i.e. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be solely liable to pay all costs of such compliance. In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement.

Sanjay Gandhi Post Graduate Institute of Medical Sciences and PI are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

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The Second Party and PI will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of two year from the Effective date of this Agreement.

8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90 day written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the Principal Investigator shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

9.1 Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for any of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI

b) **Sanjay Gandhi Post Graduate Institute of Medical Sciences** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters upon enrollment and as per his undertaking and site feasibility report provided **(Exhibit D);**

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the Principal Investigator **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to provide access by the Pharmazz's representatives all

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original medical records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and PI's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be effected by written notice to the Second Party and PI, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phase down costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and PI, whichever is later. The Second Party and PI shall be given reasonable opportunity to present to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and PI will be provided an additional period of time, specified and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party and PI to meet the deadline of (30) days for corrective measures then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

11.2 Upon termination or completion of the Study, the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were

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furnished to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees that it shall indemnify, defend and hold harmless the Principal Investigator, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

The indemnity granted in this Article shall apply separately to each Indemnity in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

12.2 It is a condition precedent to the Pharmazz's indemnification obligations under above mentioned clause 12.1 that:

a) Whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Pharmazz of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 12.1 above must (i) promptly notify the Pharmazz of the assertion of any such claims (ii) authorize and permit Pharmazz to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Pharmazz regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Pharmazz's obligations hereunder. Subject to the foregoing, Principal

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Investigator may also participate with prior consent of the Pharmazz in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Pharmazz to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Pharmazz.

The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** hereby irrevocably agree that they shall indemnify and hold harmless the Pharmazz, its present and future directors, officers and or employees against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Pharmazz by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences**; or (v) failure of the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines. The Institution and the Principal Investigator however shall in no event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof if the same is due to negligence and / or misconduct on the part of Pharmazz.

Sponsor warrant that they shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. Sponsor shall have the right to settle claims at its sole expense.

12.3 Sponsor shall provide the cost of medical management and compensation as per Rule 122-DAB-Compensation in case of injury or death due to study drug during the conduct of clinical trial.

a) In case of an injury occurring to the clinical trial subjects, he or she shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

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Professor
Deptt. of

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b) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expense incurred on the medical management of such subject.

c) The expense on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

12.4 **Insurance**

The Pharmazz undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the DCGI rules. This Insurance covers the Clinical Trial to be conducted for the Study at **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Insurance policy is attached at Exhibit E.

13. PUBLICATION OF RESULTS

It is the general policy of the Pharmazz to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Pharmazz for its perusal, comments and approval. The Pharmazz may at its discretion may either refuse the publication or forward it to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** along with its comments or modifications which shall be final and binding on the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences.**

14. PUBLICITY AND PRODUCT PROMOTING ACTIVITY

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Pharmazz shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Pharmazz and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Pharmazz.

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15. INTELLECTUAL PROPERTY RIGHTS

Sanjay Gandhi Post Graduate Institute of Medical Sciences agrees that all the Intellectual Property Rights with regard to **PMZ-1620** are and shall remain Pharmazz's exclusive property, and understands that **Sanjay Gandhi Post Graduate Institute of Medical Sciences** acquires no right, title, or interest in the Intellectual Property and the know-how used/created for the purpose of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees that all rights that may be created by the use of the Intellectual Property under this Agreement by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall inure to the sole benefit of Pharmazz and shall be the exclusive property of Pharmazz. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not at any time do or suffer to be done any act which would impair materially Pharmazz's proprietary rights in or to, or infringe, any Intellectual Property Rights of Pharmazz.

Pharmazz will be exclusively responsible if any dispute or claim arises regarding the ownership of the patent rights, copy rights & trade mark rights used by Pharmazz.

16. CONFIDENTIALITY

a) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences, New Delhi** agree to keep confidential and secret all materials, documents and confidential information that the Pharmazz discloses to the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences, New Delhi** pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Pharmazz whether in written, electronic, oral, visual or other form (**"Confidential Information"**).

b) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Pharmazz to any third party except as required by law provided that the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall:

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First give prompt notice of such disclosure requirement to the Pharmazz so as to seek any limitations on or exemptions from such disclosure requirement; and

Reasonably co-operate with the Pharmazz in any such efforts of defense in the confidential and proprietary information to be made before appropriate authority.

c) Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** can prove and produces credible written evidence to establish that such information or material:

i. at the time of disclosure or after disclosure to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or their successors or assigns;

ii. by written records were in the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences**'s possession at the time of disclosure by the Pharmazz were not acquired directly or indirectly from the Pharmazz;

iii. subsequent to disclosure hereunder, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** receives from a third party legally in a position to provide with information to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences,** provided, however, that such was not obtained by said third party directly or indirectly from the Pharmazz under an obligation of confidentiality.

PHARMAZZ INDIA PVT. LTD.

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d) All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Pharmazz and will be treated as "Confidential Information" by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and may be used by the Pharmazz in any manner. Further, Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall assign to the Pharmazz all of their rights, title, and interest in such Inventions.

e) All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Pharmazz by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** forthwith upon written request or upon termination of this Agreement, whichever is earlier.

f) Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Pharmazz, and that if there is a breach (either actual or threatened) by the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or co-investigator or a party in receipt of Confidential Information under this Agreement, the Pharmazz would have complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Pharmazz shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

g) Institution Information. During performance of this Agreement, Sponsor representatives may gain access through site visits or otherwise to information relating to Institution's business or research operations, policies, or procedures that Institution identifies to Sponsor as proprietary and confidential or that is reasonably apparent to Sponsor to be so. Unless Institution provides written consent, Sponsor will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by law.

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17. SEVERABILITY & WAIVER AND ASSIGNMENT

a) The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement. The parties agree that they negotiate in good faith or will permit a court/ Arbitration to replace any provision hereof so held invalid with a valid provision.

b) Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof but only by an instrument in writing..

c) This Agreement shall not be assigned as a whole or in part by any party without the prior written consent of the other parties except for the following types of general support services: communication, translation, photocopy of documents or similar services, failing which all actions taken will be null and void.

18. MISCELLANEOUS

a) It is agreed by the Parties that the Principal Investigator and Sanjay Gandhi Post Graduate Institute of Medical Sciences shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with any Parties including Pharmazz. Neither Principal Investigator nor **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall have any authority to represent, or bind the Pharmazz.

b) Principal Investigator shall comply with all the terms of the undertaking annexed hereto as **Exhibit C** and be read as part of this agreement, he has provided to the Pharmazz under this Agreement.

c) This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

d) If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

e). The governing (applicable) language of this agreement shall be English, and all notices and other communications relating or pursuant to the provisions of

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the agreement (including, without limitation, those in connection with issues, disagreements and disputes) shall be in such language. This agreement, its formation and the facts and circumstances surrounding its making and performance, shall be interpreted in accordance with the following, and listed in order of precedence: (1) the express terms and conditions of the agreement; (2) the local laws of India

19. NOTICES

19.1. Unless otherwise provided herein, any communication, notice or notice of conditions interfering the performance of the agreement, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when received and acknowledged in case of electronic mode: Notifications shall be made to the following addresses:-

Pharmazz	**Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Mr. Sunil Gulati Chief Operating Officer	Dr. Rakesh Kapoor Director SGPGI	Prof. Jayantee Kalita Principal Investigator
Pharmazz India Pvt. Ltd. B-4 Sarita Vihar New Delhi 110076, **Email**: sunil.gulati@pharmazz.com	Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebareli Road, Lucknow,-226014,. **Email:** director@sgpgi.ac.in	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014 **Email:** jayanteek@yahoo.com

19.2.1. Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration., which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed as per provisions of Arbitration and Conciliation Act, 1996 as amended from time to time. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto. Place of Arbitration shall be Delhi and both the parties shall bear the cost of arbitration in equal excluding counsel cost Parties agree that for claiming injunctive relief and for the enforcement of arbitral award only Delhi courts shall have exclusive jurisdiction in all matters arising out of or with this Agreement. This Agreement shall be governed by Laws of India.

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20. RENEWAL CLAUSE

The agreement can be renewed by way of mutual consent of the parties in the event of requirement of further study of the protocol to complete the obligations enumerated herein above.

21. FORCE MAJEURE

Any delay or failure by the either party of required obligations shall be excused if and to the extent caused by acts of God, fire, storm, lockout, strike, terrorist act, flood, sabotage, Government Notification/ order, embargo, war (whether declared or not), riot, or other causes beyond the reasonable control of the said Party. If and when either party asserts Force Majeure as an excuse for failure to perform their obligations, then the said Party must notify the other Party in writing and upon the review of the said party's notice, the other Party shall determine whether the term of the agreement shall be extended for a reasonable time period to complete activities interrupted by the delays.

22. FURTHER ASSURANCES

Each party agrees that subsequent to the execution and delivery of this Agreement it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For **Pharmazz India Pvt. Ltd.**	For **Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Signature: ..... Name: Mr. Sunil Gulati Title: Chief Operating Officer	Signature: ..... Name: Dr. Rakesh Kapoor Title: Director SGPGI	Signature: ..... Name: Prof. Jayantee Kalita Title: Principal Investigator

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences

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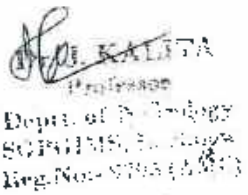
Executive Registrar
SGPGIMS,Lucknow

(4)

Exhibit-A

Clinical Trial Protocol

REFERENCE ENCLOSED



Dr. KALITA
Professor
Dept. of P[illegible]
SGPGIMS, [illegible]
Reg.No.- [illegible]

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SGPGIMS,Lucknow

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Exhibit B

(Budget and Payment Schedule)

Total duration of Study			12 months
Subject enrollment duration			6 months
Total number of subjects			15
Payment heads	**Total per subject**	**No. of Subjects**	**Amount per Head**
Investigator's Fees (In Rupees)	24000	15	360000
Study Coordinator Fees (In Rupees)	16000		240000
Protocol Procedures (Lab expenses) (In Rupees)	2940		44100
CT/ MRI cost (In Rupees)	9600		144000
Subject Travel (In Rupees)	4000		60000
Institutional Overhead on Investigator's & Coordinator's fees (In Rupees)	10000		150000
Total Study Budget (In Rupees)			998100

- Protocol Procedures includes Lab expenses that is composed of cost of all the tests mentioned in protocol. INR 55 shall be added to the Protocol procedures on Visit 1,3, 4,5,6,7 for UPT if the subject is female.
- Recruitment of estimated number of trial subjects should be completed within 6 months
- Archival fee will be paid on close out visit and it will be as per the institutional EC SOP
- In addition to the above fee, Pharmazz shall pay for unscheduled visit (only if required) activities listed in Protocol.

Payee Details

Payee Name	Director SGPGI, Research Account
Name of the Bank & Branch	State Bank Of India
A/C No:	10095237492
IFSC	SBIN0007789
MICR	226002034
PAN No./TAN No.	AAAJS3913N
GST No. (if applicable)	Not applicable

D. J. KALITA
Professor
Dept. of Neurology
SGPGIMS, Lucknow
Reg. No.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(4)

Exhibit-C

Principal Investigator's Documents

REFERENCE ENCLOSED

PHARMAZZ INDIA PVT. LTD.

D.J. KALITA
Professor
Deptt. of Neurology
SGPGIMS, Lucknow
Regn.No. [illegible] (AMC)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(3)

Exhibit-D

Site Feasibility Questionnaire

REFERENCE ENCLOSED

PHARMAZZ INDIA PVT. LTD. * Innovation in Science *

Dr. J. KALITA
Professor
Deptt. of Nephrology
SGPGIMS, Lucknow
Regd. No. [illegible]

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(2)

Exhibit-E

Insurance Policy for study

REFERENCE ENCLOSED

Dr. J. KALITA
Professor
Deptt. of Neurology
SGPGIMS, Lucknow
Reg. No.- 9795 (AMC)

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Executive Registrar
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Exhibit-F

Phase II Clinical Trial NOC

REFERENCE ENCLOSED

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Professor
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SGPGIMS, Lucknow
Reg.No- 9795 (MC)

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SGPGIMS,Lucknow

पश्चिमबङ्गा पश्चिम बंगाल WEST BENGAL Z 792508

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO BY AND BETWEEN:

Medclin Research Pvt. Ltd., a Company incorporated in accordance with the laws of India, under the Companies Act, 1956, having its office at Acropolis , unit 10/5 , 10th floor 1858/1,Rajdanga Main Road, Kolkata- 700107, hereafter referred to as **Clinical Research Organization(CRO)**

On the first part,

AND:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India

(Hereafter referred to as the "**Institution**")

AND:

Dr. Piyali Bhattacharya, Consultant Paediatrician, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India

(Hereafter referred to as the "**Principal Investigator)**

On the second part,

Initial here

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Executive Registrar
SGPGIMS,Lucknow

With each of the parties collectively or individually referred to as "Party" or "Parties"

THIS AGREEMENT RELATES TO THE FOLLOWING CLINICAL TRIAL:

A Multicentric, Randomized, Double Blind, Placebo Controlled Trial to assess the Efficacy and Safety of *Saccharomyces Boulardii CNCM-I 3799 and Bacillus Subtilis* CU – I *combination* For treatment of Acute Diarrhoea in Indian Children

PREAMBLE

WHEREAS, ALKEM Laboratories Ltd.is the Sponsor, as defined in the ICH GCP guidelines, of the above mentioned Clinical Trial and therefore wishes to perform this Clinical Trial;

WHEREAS, Medclin Research Pvt. Ltd. Is the CRO with Institution and the Principal Investigator are willing to organize, conduct and perform this Clinical Trial on behalf of the Sponsor;

WHEREAS, the Institution and the Principal Investigator have capable personnel and the necessary expertise to organize and perform clinical trials.

WHEREAS, the Principal Investigator is responsible for the scientific supervision and direction of the Clinical Trial and will conduct the Clinical Trial in the facilities of the Institution;

NOW THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), the Parties hereby agree as follows:

ARTICLE I – DEFINITIONS

For the purposes of this Agreement the following words and phrases shall have the following meanings:

- **"Additional Personnel"** means any co-investigator and/or any of Institution's contractors, employees, post-doctoral fellows, residents, demonstrators, students and/or technical staff, who may be involved in the Clinical Trial (as hereinafter defined), other than the Principal Investigator.

- **"CRO"** means Contract Research Organization; a person or an organization (commercial, academic, or other) contracted by the Sponsor, to perform one or more of a sponsor's trial-related duties and functions.

- **"Agreement"** means this Clinical Trial Agreement, all amendments and supplements to this Agreement and all schedules to this Agreement.

- **"Case Report Form"** means the form to be completed and returned to the Sponsor/CRO for each Subject participating in the Clinical Trial.

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- **"Clinical Trial"** means the clinical trial above-mentioned in the Preamble of the Agreement.

- **"Confidential Information"** means any and all information relating to the Sponsor, CRO which is of a confidential and proprietary nature, including but not limited to preclinical, clinical or formulation data, investigator's brochures, case reports, source documentation, study protocols and SOPs (as defined hereafter) as amended from time to time.

- **"Control"** means, whether used as a noun or verb, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

- **"Control Product"** means placebo to be used in the Clinical Trial in accordance with the Protocol.

- **"Enrollment Cap"** means that the Sponsor/CRO reserves the right to limit enrollment by giving written notice, or by giving notice by telephone followed by written notice, to the Institution and the Principal Investigator to cease further enrollment of Subjects in the Clinical Trial.

- **"GCP"** means:
  (i) The set of regulations established by Health Authority(ies) for conducting clinical studies including, without limitation, the set of regulations established by the CDSCO.
  (ii) The current international ethical and scientific quality standards for designing, conducting, recording and reporting clinical studies known as ICH Guidelines for Good Clinical Practice.

- **"Health Authorities"** means applicable health authorities, either governmental, regulatory or otherwise, including but not limited to the Drug Controller General of India (DCGI),

- **"ICH"** means the International Conference of Harmonization.

- **"IEC"** means the Institutional Ethics Committee responsible for review and approval of the Protocol.

- **"IND"** means an investigational new drug.

- **"Indemnitee"** means collectively the Institution, its Trustees, Officers, Directors, Agents, Additional Personnel and the Principal Investigator.

- **"Inventions"** means any inventions, discoveries, or innovations, products, processes, data, reports, results, formulations, technologies and compounds, whether patentable or not, arising directly or indirectly, in the performance of the Clinical Trial under this Agreement or using Clinical Trial funds or otherwise arising out of use of the Product.

- **"Investigational Product"** GUTGAIN ™ to be used in the Clinical Trial in accordance with the Protocol.

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- **"Person"** means an individual, partnership, joint venture, trustee, trust, corporation, unincorporated organization or other entity or a government, state or agency, or political subdivision thereof.

- **"Personal Data"** means any and all data concerning an individual participating in the Clinical Trial whether as a Subject or as an Investigator.

- **"Principal Investigator"** means the person who is named on the head of the Agreement and corresponds to the person who is named *"Investigator"* or *"Principal Investigator"* for either the entire study or a study site.

- **"Privacy Rules"** means any national and international standards of practice, establishing a category of information regarding the patients or Subjects, which may be used or disclosed to others in certain circumstances or under certain conditions.

- **"Processing"** means, in accordance with applicable rules and regulations, any operation or set of operations which is performed upon the Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

- **"Protocol"** means the last approved version of the protocol including any and all amendments, which will be considered as attached hereto upon completion, and is incorporated herein by reference.

  It is agreed that this Agreement shall be governed by the most recent version of the Protocol, and should this Agreement be executed prior to complete finalization of the Protocol, the last-dated version thereof will be considered to be incorporated by reference in place of any prior versions. In the event that there is a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement will govern with respect to contract terms and conditions but the Protocol will govern with respect to the conduct of the Clinical Trial and with respect to serving the best interests of patient welfare.

- "**Public Presentation**" means, collectively or individually, drafts of abstracts and/or manuscripts for publication (including slides and texts of oral or other public presentations).

- **"Recipient"** means, collectively and individually, the Institution and/or the Principal Investigator.

- **"Related Person(s)"** means any Person(s) having a relationship with a Party whether as an employee, Additional Personnel, agent or representative.

- **"Subject"** means an individual who is selected in accordance with the terms of the Protocol to participate in the Clinical Trial.

- **"SOPs"** means the Standard Operating Procedures as amended from time to time to be used for the purpose of the Clinical Trial

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- **"Trial Product"** means collectively the Investigational Product and the Control Product.

- **"Trial Site"** means the location(s) where the Clinical Trial activities are conducted by the Institution and/or the Principal Investigator.

ARTICLE 2 – SCOPE OF WORK

The Institution and the Principal Investigator shall conduct the Clinical Trial relating to the Product in accordance with the Protocol. Creation and modification of the Protocol shall be the sole responsibility of the Sponsor.

ARTICLE 3 - CLINICAL TRIAL APPROVALS

3.1 The Principal Investigator is responsible for ensuring that the Ethics Committee is registered before starting the Clinical Trial. The Investigator is responsible to follow up and ensure updating of serious adverse events causality opinion by the Ethics Committee to Appropriate Authority, Sponsor and CRO.

3.2 The Principal Investigator shall be responsible for having the Clinical Trial documents (such as Protocol, informed consent form and / or site inform consent form, any advertisement(s) pertaining to the recruitment of Subjects in the Clinical Trial) approved by the IEC prior to the beginning of the Clinical Trial.

3.2 In the event the IEC requests that changes be made to the Protocol such as the informed consent form template, the Institution shall immediately inform Sponsor/CRO of the IEC request in detail. Any modifications to the Protocol including the informed consent form template must be approved by the Sponsor's representative, CRO and/or appropriate regulatory authority, if applicable, before being implemented by Institution.

3.3 The Institution and the Principal Investigator shall not modify the Protocol without the prior written approval of the Sponsor.

3.4 The Sponsor's representative, shall be responsible for the submission of any IND application, if applicable resulting from the Clinical Trial, and the Parties agree to fully cooperate as necessary with the Sponsor's representative, and at Sponsor's expense, in the completion and filing of the IND.

ARTICLE 4 – ORGANIZATION OF THE CLINICAL TRIAL

4.1 The **estimated** time schedule of the Clinical Trial described in detail in the Protocol may be summarized as follows:

- Planned starting of the Subjects' recruiting process: May 2018
- Planned final report: 3 months post LSLV from all sites.

It is understood that the effective beginning of the Clinical Trial is dependent upon timely approval of key Clinical Trial documents and/or performance of preparatory

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activities by Sponsor's representative, CRO and/or third parties (e.g. IEC/IRB or Health Authority) and/or availability of the Trial Product. Thus, any delay in this approval and/or the performance of those preparatory activities and/or availability of the Trial Product may have a cascade effect on the Clinical Trial initiation. The Principal Investigator and the Institution agree that any such delay shall not entitle them to any compensation or remedy.

4.2 It is estimated that the Principal Investigator participating in this Clinical Trial will enroll a target number of Subjects of 45 Subjects in total, in approximately 50 to 180 days.

If not achieved, the Sponsor's representative/CRO might decide to reallocate the Subjects enrollment to another site and in this case, the rules set forth in section 4.2.1 of the Agreement will be applied.

For a multi-center Clinical Trial, the Sponsor's representative/CRO may amend the number of Subjects to be recruited by the Principal Investigator and in this case the rules set forth in sections 4.2.1 and/or 4.2.2 of the Agreement will be applied.

4.2.1 If in the reasonable opinion of the Sponsor/CRO, recruitment of Subjects is proceeding at the Trial Site at a rate below that required to enable the relevant timeline to be met, the Sponsor's representative/CRO may by notice to the Institution require recruitment at the Trial Site to cease and the terms of the Agreement shall relate thereafter to the number of Subjects who have been accepted for treatment in the Clinical Trial at the date of such notice; or

4.2.2 If recruitment of Subjects is proceeding at the Trial Site a rate above that required to meet the relevant timeline the Sponsor/CRO may with the agreement of the Institution increase the number of Subjects to be recruited by the Principal Investigator.

For a multi-center Clinical Trial having a competitive enrollment, the Sponsor/CRO reserves the right to request the Principal Investigator to limit recruitment of further Subjects or cease the recruitment, notably if the recruitment target for the Clinical Trial has been reached. In such event, the Sponsor's representative/CRO will inform the Principal Investigator on interrupting the recruitment of any Subject who has not yet signed the informed consent form.

The Principal Investigator shall upon receipt of a notice for stopping recruitment, stop immediately further recruitment of Subjects. Payment shall only be made according to the number of Subjects recruited up to the date of receipt of the said notice of stopping. The Sponsor's representative/CRO will neither take any responsibility, nor make any payment for the Subjects recruited after this date.

4.3 It is agreed among the Parties that the Principal Investigator and the Additional Personnel shall attend the mandatory training session(s) organized in relation with the Clinical Trial.

The Parties agree to inform each other of the Clinical Trial performance and therefore agree to organize and to participate in meetings related thereto.

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The Principal Investigator agrees to take the necessary time to meet with any person duly appointed by the Sponsor/CRO for monitoring the Clinical Trial.

4.4 If, at any time, Institution or Principal Investigator have reason to believe that the Clinical Trial will not be initiated or completed as per the schedule initially anticipated and agreed upon by the Parties, Sponsor's representative/CRO will be advised immediately, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by Sponsor's representative/CRO as provided in Article 14 hereafter.

ARTICLE 5 - OBLIGATIONS OF THE INSTITUTION AND/OR THE PRINCIPAL INVESTIGATOR

5.1 The Institution shall apply its best efforts to retain the services of the Principal Investigator.

In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform the Sponsor/CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, which replacement shall have a similar background and also knowledge of the Clinical Trial.

Any successor to the Principal Investigator must be approved, in writing, by the Sponsor/CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India.

The Institution agrees to immediately inform the Sponsor/CRO in writing if any person, including but not limited to the Principal Investigator, who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or to the best of the Institution's knowledge, is threatened, relating to the debarment of the Institution or any person performing services hereunder.

5.2 The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with:

(a) The Protocol and all other terms of this Agreement;

(b) All laws and regulations pertaining to the transportation, storage, use, administration and disposal of drugs, vaccines/biologicals, and the conduct of clinical investigations among which the Helsinki Declaration as amended in Edinburgh, Scotland (October 2000), including, but not limited to the Public

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Health Service Act, the Food, Drug and Cosmetic Act of India, with the Good Clinical Practice approved by the Indian Regulatory Authorities.

(c) Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs;

(d) Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP;

(e) All applicable laws and regulations.

5.3 The Institution agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

Such informed consent shall be obtained by the Principal Investigator using the informed consent form template developed for the Trial Site. The Privacy Rules shall be followed in order to obtain consent from Subjects as required throughout the Clinical Trial.

5.4 The Institution and the Principal Investigator shall have the following record keeping and reporting obligations:

(i) To prepare and maintain complete and accurate written records, accounts, notes, reports and data relating to the Clinical Trial under this Agreement.

(ii) To prepare and submit to the Sponsor's representative, CRO (in a periodic and timely manner during the term of this Agreement) all raw data and other material called for in the Protocol, in the form of properly completed Case Report Forms supplied by the Sponsor, for each Subject. All Case Report Forms and the information and data stored in any electronic database shall be the exclusive property of the Sponsor.

(iii) To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial during five (5) years. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform the Sponsor, the Parties shall discuss in good faith in order to find an alternative solution for the proper archiving of these elements in accordance with the applicable regulations. Subjects' files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of the Sponsor.

5.5 The Principal Investigator shall report any adverse experiences and adverse events observed in the Clinical Trial to the Sponsor/CRO. All adverse experience/event reports

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shall be prepared and collected by the Principal Investigator according to the procedures outlined in the Protocol.

5.6 The Institution and the Principal Investigator shall use their best efforts to complete expeditiously the Clinical Trial in accordance with the time-schedule provided for in the Protocol.

5.7 The Institution shall, on or before the signing date of this Agreement, supply the Sponsor/CRO with a complete list of its Additional Personnel who it anticipates will be involved in carrying out Institution's obligations under this Agreement, specifying the role each individual will play in carrying out these obligations. The Institution agrees to inform the Sponsor/CRO of any changes to such list and train new Additional Personnel to the specificities of the Clinical Trial.

5.8 The Institution and the Principal Investigator agree to inform the Sponsor's representative/CRO of any cooperation or collaboration they would like to undertake regarding a therapeutic/ prophylactic concept similar to the one studied according to the Protocol if such a project would compete with the Clinical Trial. The Sponsor's representative/CRO will be entitled to terminate this Agreement if such a cooperation or collaboration is deemed by the Sponsor's representative/CRO to be incompatible with its interests.

5.9 The Sponsor's representative/CRO registers all its clinical trial protocols on the web site http://ctri.nic.in. If local regulations require the Clinical Trial to be registered locally, the Institution and the Principal Investigator are in charge of doing it and informing the Sponsor. The Sponsor's representative/CRO shall support them by providing the required information.

ARTICLE 6 – TRIAL PRODUCT, EQUIPMENT AND DOCUMENT

6.1 The Trial Product, as well as the documents and the material necessary to conduct the Clinical Trial, as described in the Protocol, shall be supplied free of charge to the Institution by the Sponsor. In certain circumstances, the Sponsor's representative/CRO might instruct the Institution to purchase the Control Product and/or equipment. In such a case, the Sponsor's representative, will reimburse these expenses to the Institution at invoice value (all invoices are requested by the Sponsor's representative, CRO prior to reimbursement).

The Institution shall inform the Sponsor's representative/CRO on or before the signing date of this Agreement of the name and complete address to which the Product shall be shipped by the Sponsor.

6.2 All the Trial Product, the document, the equipment and the material supplied pursuant to this Agreement shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to the Agreement. It is understood that the Trial Product is provided by the Sponsor's for the sole purpose of conducting the Clinical Trial.

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THE SPONSOR'S REPRESENTATIVE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE TRIAL PRODUCT OR ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OTHER THAN FOR ITS USE IN THIS CLINICAL TRIAL.

All unused doses of Trial Product shall be promptly returned to the Sponsor's representative/CRO upon the completion of the Clinical Trial as directed by the Sponsor, or upon earlier termination of this Agreement, unless written authorization to destroy the Trial Product is given by Sponsor. If authorization to destroy unused Trial Product is previously given in writing, the Institution shall provide the Sponsor's representative/CRO with documentation as to the method of destruction. The Institution shall conform with all laws and regulations pertaining to the disposal of drugs, vaccines/biologicals during any destruction of unused quantities of the Product. Upon delivery, the Institution and the Principal Investigator shall be responsible for any improper administration, storage or handling of the Trial Product and for its use beyond its applicable expiration date.

6.3 If some products among the Investigational Product and/or Control Product were to be recalled, the Principal Investigator and the Institution commit to implement the Sponsor's instructions immediately and to quarantine the product(s) at stake.

ARTICLE 7 - AUDITS

7.1 During the Clinical Trial and for such additional period of time that the records are required to be retained by law or otherwise, it is agreed that representatives of the Sponsor/CRO may arrange with the Principal Investigator or her designee, after having duly informed the Institution respecting at least seven (7) days prior notice:

(i) To examine and audit, at regular business hours, the locations where the Clinical Trial is performed;

(ii) Subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Clinical Trial conducted under this Agreement and to inspect and make copies of all data necessary for the Sponsor's representative/CRO to confirm that the Clinical Trial is being conducted in conformance with the Protocol and in compliance with all applicable legal and/or regulatory requirements of any and all Health Authorities; and

(iii) To meet with any person involved in the Clinical Trial's performance.

7.2 The Institution agrees to assist the Sponsor/CRO, to the extent deemed reasonable by the Sponsor/CRO, in facilitating the Sponsor's representatives' examination, inspection, auditing and copying of materials relating to the Clinical Trial and in order to enforce the rights granted to the Sponsor's representative/CRO in this Article 7.

The Principal Investigator and the Institution agree to take any action, as reasonably requested by the Sponsor/CRO to properly correct or address any deficiencies noted

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during any audit and agree to cooperate with the Sponsor's representative/CRO with respect to any action taken to address any such deficiencies.

7.3 If the need arises (or if the need be), the Institution agrees to notify Sponsor/CRO within twenty-four (24) hours in the event that a Health Authority notifies the Institution of a pending inspection/audit. In addition, the Institution will forward to Sponsor/CRO any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to accept Sponsor's/CRO's assistance in responding to any citations. Such responses shall be made within ten (10) business days of issuance of any citations or within any earlier deadline set by the issuing Health Authority. The Institution shall also provide the Sponsor's representative/CRO with copies of any documents provided to any inspector or auditor. In the event any applicable Health Authority requests or requires any action to be taken to address any citations, the Principal Investigator and the Institution agree, after consultation with the Sponsor/CRO, to take such action as necessary to address such citations, and agree to cooperate with the Sponsor/CRO with respect to any such citation and/or action taken with respect thereto.

ARTICLE 8 - FINANCIAL PROVISIONS

The financial provisions applicable to the Agreement in consideration of the performance of the Clinical Trial are provided for in Schedule A attached hereto.

ARTICLE 9 - CONFIDENTIALITY

9.1 Before and during the course of the Clinical Trial, the Recipient may obtain, or have access to Confidential Information.

Except as expressly set forth in this Article, the Recipient shall each cause its Related Person(s) to keep the Confidential Information confidential, and the Recipient shall not disclose directly or indirectly, and shall cause its Related Persons not to disclose directly or indirectly, any Confidential Information to anyone, except that the foregoing restriction shall not apply to any information disclosed hereunder if such Confidential Information, as reasonably demonstrated by the Recipient:

(i) is generally available to the trade or public or becomes after the time of receipt by the Recipient part of the public domain, other than by reason of any breach or default by the Recipient or any of its Related Persons of a confidentiality obligation under this Agreement;

(ii) was already known to the Recipient at the time of disclosure by the Sponsor/CRO;

(iii) is disclosed to the Recipient or any of its Related Persons by a Third Party who has the right to disclose such information; or

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(iv) based on such person's good faith judgment with the advice of counsel, is otherwise required to be disclosed in compliance with applicable legal requirements to a Health Authority.

Whenever the Recipient becomes aware of any state of facts which would or might result in disclosure of Confidential Information pursuant to subparagraph (iv) above, it shall, if possible, promptly notify the Sponsor's representative/CRO prior to any such disclosure so that the Sponsor's representative/CRO may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement.

In any event, if the Recipient is unable to promptly notify the Sponsor's representative/ CRO or if such protective order or other remedy is not obtained, or if the Sponsor's representative/CRO waives compliance with the provisions of this Agreement, the Recipient will furnish only that portion of the information which its counsel directs is legally required and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded the Confidential Information.

The Sponsor's representative/CRO shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security except as required by the relevant laws, enjoining or restraining the Recipient and any of its Related Persons from any violation or threatened violation of this Article.

9.2 The Recipient agrees that no Confidential Information shall:

(i) Be used in its own business except as necessary to the fulfillment of the rights and obligations of the Recipient under this Agreement;

(ii) Be disclosed, assigned, licensed, sublicensed, marketed, transferred or loaned, directly or indirectly to any third party other than to an Affiliate or a representative of the Recipient in accordance with the provisions of this Agreement, except as necessary to the fulfillment of the rights and obligations of the Parties under this Agreement;

(iii) Be used or exploited by the Recipient or any of its Related Persons for its or their respective benefit or the benefit of any other relationships with customers of such Party and its Related Persons.

(iv) Be used by the Recipient for obtaining intellectual property rights.

Without limiting the generality of the foregoing, the Recipient agrees that, it shall not (and shall not permit any of its Related Persons) at any time to use any Confidential Information in the conduct of its business without the prior written consent of the Sponsor/CRO.

The obligations set forth in this Article shall extend to copies, if any, of Confidential Information made by the Recipient and/or its Related Persons and to documents prepared by such persons which embody or contain Confidential Information.

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9.3 The Recipient shall deal with Confidential Information so as to protect it from disclosure with a degree of care not less than that used by it in dealing with its own information intended to remain exclusively within its knowledge and shall take reasonable steps to minimize the risk of disclosure of Confidential Information which shall include, without limitation, ensuring that only their respective Related Persons who have a *bona fide* "need to know" such Confidential Information for purposes permitted or contemplated by this Agreement shall have access thereto.

The Recipient shall notify all of its Related Persons who have access to Confidential Information of its confidentiality and the care therefore required, and shall obtain from any such Related Person an agreement of confidentiality incorporating the restrictions set forth herein.

9.4 The obligations set forth in the present article shall survive the termination of this Agreement for a period of Five (5) years.

9.5 Except as otherwise agreed to by the Parties in writing, the Recipient shall (and shall cause its Related Persons to), within thirty (30) days after the termination of this Agreement, return to the Sponsor's representative/CRO or destroy all documents and tangible items then in its possession which it has received from the Sponsor's representative/CRO or its Related Persons pertaining, referring or relating to the Sponsor's Confidential Information, as well as all copies, summaries, records, descriptions, modifications, and duplications that it, or any of its Related Persons has made from the documents or tangible items received from the Sponsor's representative/CRO or Related Person; provided, however, that the Recipient may retain one copy of each document in its legal files solely to permit the Recipient to continue to comply with its obligations hereunder and, in addition, may upon notice to the Sponsor, retain in its legal files or in the office of outside legal counsel one copy of any document solely for use in any pending legal proceeding to which such document relates.

ARTICLE 10 – INVENTIONS AND PATENTS

The sole and exclusive right to any Inventions shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor's representative/CRO in writing of any such Inventions, and at Sponsor's request, and expense, Institution and Principal Investigator will cause to be assigned to Sponsor's representative/CRO all right, title, and interest in and to any such Inventions and provide reasonable assistance to obtain patents including causing the execution of any invention assignment or other documents.

ARTICLE 11 – DATA, PUBLICATIONS, OTHER RIGHTS

In recognition of the importance of disseminating information relating to any novel or important observations or results that may arise from the Clinical Trial, and understanding that such need must be balanced with the Sponsor's obligations to maintain control over Confidential Information as well as to comply with all appropriate Health Authorities' rules and regulations, the Parties hereby agree to the following:

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11.1 The Institution and the Principal Investigator agree that all research data and results generated during the course of or as a result of the Clinical Trial shall be the property of the Sponsor. The Principal Investigator and the Institution further agree to execute any documents or undertake any further actions requested by the Sponsor's representative/ CRO to evidence transfer of title to such data.

11.2 Subject to the terms and conditions of this Agreement, the Institution and the Principal Investigator have the right to publish or publicly present their results of the Clinical Trial. The Principal Investigator and the Institution agree not to publish or publicly present any interim results of the Clinical Trial without prior review by the Sponsor, as provided below. The Principal Investigator and the Institution further agree to provide ninety (90) days written notice to the Sponsor, including a complete copy of the intended Public Presentation, prior to submission for publication or presentation to permit the Sponsor to review a Public Presentation which reports any results arising out of the Clinical Trial. The Sponsor shall have editorial rights with respect to a Public Presentation and the right to review and comment on the data analysis and presentation to ensure that:

(i) Confidential Information is protected by the provisions contained in Article 11.4 below;
(ii) The information contained in the Public Presentation are accurate; and
(iii) The Public Presentation is fairly balanced and in compliance with applicable Health Authorities' regulations.

If the Parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of Sponsor's Confidential Information, the Institution agrees to meet with Sponsor, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

In the event that the Parties cannot resolve their dispute within a period of ninety (90) days, they may refer the matter to an independent adjudicator having expertise in the field of the Clinical Trial selected jointly by them who shall decide the matter. The Parties agree to abide by the adjudicator's decision. The Principal Investigator and Institution agree not to release a Public Presentation until such time as a resolution has been reached, whether by the Parties on their own, or by the adjudicator.

11.3 To the extent that the Institution's participation in the Protocol is a part of a multi-center clinical trial, the Institution and the Principal Investigator agree that an initial Public Presentation of their results shall occur only together with the other sites unless specific written permission is obtained in advance from the Sponsor for Public Presentation of separate results. The Sponsor shall advise as to the implications of timing of any Public Presentation in the event the Clinical Trial is still in progress at sites other than the Principal Investigator's one and any institution or investigator participating in a multi-center clinical trial shall follow the Public Presentation review procedures set forth in Article 11.2 above.

11.4 No Public Presentation shall contain any Confidential Information. Public Presentation shall be confined to new discoveries and interpretations of scientific fact. At the

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Sponsor's request, the Sponsor shall be acknowledged as one of many or as the sole financial Sponsor, as the case may be, of the Clinical Trial reported in the Public Presentation.

11.5 The Institution and the Principal Investigator shall be aware that a publication or presentation of patentable subject matter prior to filing respective patent application will jeopardize such patent rights. Therefore, if the Sponsor believes there is a patentable subject matter contained in any Public Presentation submitted for review, the Sponsor shall promptly identify such subject matter to the Institution. If the Sponsor requests and at the Sponsor's expense, the Institution and the Principal Investigator shall use their best efforts to assist the Sponsor in filing a patent application covering such subject matter prior to any publication.

Furthermore, in the event that the review of the proposed publications or other public disclosure results in a determination that potentially patentable subject matter would be disclosed, and that such disclosure would be prejudicial to perfecting Sponsor's intellectual property rights, the Principal Investigator or Institution shall delay the publication or public disclosure for an additional ninety (90) days, at Sponsor's request, to allow for filing the necessary patent applications.

ARTICLE 12 – LIABILITY, INDEMNIFICATION AND INSURANCE

12.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject, he or she shall be given free medical management as long as required or until it is proved that the injury is not related to the IP (whichever is earlier)

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the Sponsor;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death:

(a) Adverse effect of the Investigational Medicinal Product;

(b) Violation of the Protocol, scientific misconduct or negligence by the Sponsor's Representative, CRO or the Investigator, Provided that if such violation of the

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Protocol, scientific misconduct or negligence is by the Investigator, then the Investigator will be liable to reimburse to the Sponsor Representative the expenses on such medical management and financial compensation that the Sponsor's Representative shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) Failure of the Investigational Medicinal Product to provide intended therapeutic effect;

(d) Use of placebo in a placebo-controlled trial;

(e) Adverse effects due to concomitant medication excluding standard care, necessitated as part of the Protocol;

(f) For injury to a child in-utero because of the participation of parent in the Study;

(g) Any clinical trial procedures involved in the Study."

(6) The Sponsor's representative/CRO shall give an undertaking along with the application for clinical trial permission to the Licensing Authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled for compensation/

(7) The Sponsor's representative, CRO in case of injury or death occurring to the clinical trial subject, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII.

(8) However, the Sponsor's representative, CRO is liable to pay the medical management fee or compensation, only for those clinical trial related injury or death which happened by or before 28 day from the day of administering the product to the subject.

(9) The Sponsor's representative, CRO shall indemnify, defend and hold harmless the Indemnitee, from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from the use of the Product in connection with the Clinical Trial.

Therefore, the Sponsor's representative, CRO shall maintain, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this section 12 and shall also provide product liability and clinical trials liability coverage. The minimum amounts of insurance coverage required shall not be construed to create a limit of the Sponsor's liability with respect to its indemnification under this section 12. The Sponsor's representative/CRO shall maintain the aforementioned insurance during the Clinical Trial. This obligation to maintain insurance shall survive the termination of this Agreement. The Sponsor's representative/CRO shall provide the Institution with written evidence of such insurance upon the written request of the Indemnitee.

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12.2 In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the Sponsor's representative/CRO and shall assist the Sponsor's representative/CRO and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses. The Principal Investigator and the Institution agree to cooperate with and to authorize the Sponsor's representative/CRO to carry out the sole management and defense of such claim or action. Neither the Principal Investigator nor the Institution, its trustees, officers or Related Persons shall compromise or settle any claim or action without the prior written approval of the Sponsor.

12.3 Notwithstanding the foregoing, the Sponsor's representative/CRO shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless the Sponsor, CRO, officers, directors, agents and employees for loss or damage resulting from:

(i) failure of the Institution or the Principal Investigator or the Additional Personnel to adhere to the terms and provisions of the Protocol or any amendments thereto (including but not limited to the Principal Investigator's and the Institution's obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol (and any appendix or attachment to the Protocol), or the Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Clinical Trial, including but not limited to the Product, any comparative drug and any placebo;

(ii) Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable Health Authorities' requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

(iii) Failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

(iv) Any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

12.4 The Institution shall secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:

(i) Medical professional and/or medical malpractice liability (including coverage for the Principal Investigator);
(ii) General liability (including coverage for the Clinical Trial site); and
(iii) Worker's compensation coverage,

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in amounts required by applicable federal, provincial or state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Clinical Trial.

Upon request of the Sponsor, copies of certificates evidencing such insurance coverage will be made available to the Sponsor's representative/CRO and the Institution shall provide thirty (30) days' prior written notice to the Sponsor's representative/CRO in the event of cancellation or any material change in such insurance.

ARTICLE 13 - TERM

This Agreement shall become effective from the day of last signature and shall remain in full force and effect until completion of the final report of the Clinical Trial.

ARTICLE 14 – TERMINATION AND ENROLLMENT CAP

14.1 The Sponsor's representative/CRO may terminate this Agreement at any time by giving thirty (30) days written notice to the Institution. In the event thirty (30) days is determined by the Institution to be insufficient notice based upon evaluation of risks to enrolled Subject(s) then receiving the Product, the Parties will cooperate to safely withdraw Subjects from the Clinical Trial over a mutually agreeable period of time but in no event shall the Sponsor's obligation to supply the Product hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event the Sponsor's representative/CRO believes that immediate termination is necessary due to its evaluation of risks to enrolled Subject(s), the Sponsor's representative/CRO may terminate this Agreement immediately.

The Sponsor's representative/CRO reserves the right not to perform the Clinical Trial. In such a case, the Agreement shall be considered as automatically terminated upon the Sponsor's/CRO's formal notice to both the Institution and the Principal Investigator.

14.2 Notwithstanding any other provision hereof, the Sponsor's representative/CRO shall be entitled to terminate this Agreement for any Material Breach, which shall be defined as:

(i) The Institution and/or the Principal Investigator's failure to comply with their obligations, responsibilities and the terms and conditions of this Agreement including the Protocol;

(ii) The Institution and/or the Principal Investigator's failure to comply with: (a) their obligations for keeping the Sponsor's representative/CRO informed of all necessary and relevant information in connection with the Protocol; (b) any applicable law, rule or regulation relevant to the Clinical Trial; or (c) the work to be performed under this Agreement; or

(iii) A breach by the Institution, the Principal Investigator, or their Related Persons of the confidentiality provisions of this Agreement.

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14.3 Upon termination, for any reason:

(i) The Institution shall return to the Sponsor's representative/CRO all unused materials, including but not limited to, the Product and any clinical supplies (unless written authorization to destroy them is given by the Sponsor/CRO, in which case the Institution shall comply with the applicable provisions of Article 6 hereof);

(ii) Except in the event of termination because of a Material Breach by the Institution, and unless otherwise specified in writing between the Parties, the total sums payable by the Sponsor's representative/CRO pursuant to this Agreement shall be equitably pro-rated for actual work performed in accordance with the Protocol to date of notice of termination with any unexpended portion of funds previously paid by the Sponsor's representative/CRO to the Institution being refunded to the Sponsor/CRO;

(iii) In the event of termination as a result of a Material Breach, the Parties agree to make a good faith effort to reach agreement to compensate the Institution for actual work performed in accordance with the Protocol to date of notice of termination; and

(iv) The Principal Investigator shall return to Sponsor's representative/CRO all Confidential Information (as defined in Article 9 hereof) owned or controlled by the Sponsor's representative/CRO and in the possession of the Institution or its Related Persons;

(v) The Principal Investigator must submit to the Sponsor's representative/CRO the Case Report Forms for all the work in progress as of the effective date of termination.

14.4 The termination of this Agreement shall not relieve either Party of its obligations set out in Sections 5.3, 5.4, 5.5 and Articles 6, 7, 9, 10, 11 and 12 of this Agreement

14.5 Upon receipt of notice of Enrollment Cap, the Institution and the Principal Investigator agree to enroll no further Subjects in the Clinical Trial, and the funds payable pursuant to this Agreement shall be adjusted to reflect only the number of Subjects actually enrolled and the number of visits and technical procedures actually performed prior to receipt of such notice. The Institution and the Principal Investigator, as the case may be, shall refund to Sponsor's representative/CRO any funds received in advance from Sponsor's representative/CRO that are in excess of the adjusted funding.

ARTICLE 15 – DATA PROTECTION

15.1 It is understood among the Parties that Personal Data will be collected during the course of the Clinical Trial.

The Institution, the Principal Investigator and the Sponsor's representative/CRO agree to comply with all applicable Privacy Rules relating to such Personal Data including, if

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necessary, notification of their Processing activities under this Agreement to the supervisory authority.

The Principal Investigator and the Institution shall take any other steps requested by the Sponsor's representative/CRO in order to enable the Sponsor's representative/CRO to comply with any notification or other obligations applicable to it or its Affiliates under such laws.

Sponsor's representative/CRO represents and affirms to the Institution and the Principal Investigator that it has complied with, and will continue to comply with its obligations under the Privacy Rules applicable to the Clinical Trial.

15.2 The Principal Investigator and the Institution shall:

(a) Ensure that Personal Data collected for the purpose of the Clinical Trial will be processed only in accordance with this Agreement or as otherwise instructed in writing from time to time by the Sponsor.

(b) Ensure that Personal Data are not disclosed or transferred to any Third Party without the prior written consent of the Sponsor, except:

(i) As specifically stated in this Agreement, or

(ii) Where such disclosure or transfer is required by any applicable law, regulation or supervisory authority, in which case the Institution and Principal Investigator shall, wherever possible, notify promptly in writing (and in any event within five days of receipt) the Sponsor's representative/CRO prior to complying with any such request for disclosure or transfer and shall comply with all reasonable directions of the Sponsor's representative/CRO with respect to such disclosure or transfer.

(c) Ensure that Personal Data are accurate and, where necessary, kept updated and use best efforts to ensure that any Personal Data which are inaccurate or incomplete are erased or rectified where appropriate.

(d) Ensure that all appropriate technical and organizational measures are taken to protect Personal Data against accidental or unlawful destruction or accidental loss or alteration, or unauthorized disclosure or access and against all other unlawful forms of Processing.

(e) Notify the Sponsor's representative/CRO in a timely manner of any accidental, unlawful or unauthorized uses or disclosures of Personal Data; ensure that it refers any communication received from a Subject relating to the Subject's rights to access, modify or correct its Personal Data to the Sponsor's representative/CRO and to comply with all instructions of the Sponsor's representative/CRO before responding to such communications; comply with the provisions of this Agreement and the reasonable instructions of the Sponsor's representative/CRO to return, store or destroy the Personal Data.

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15.3 According to Privacy Rules, the Principal Investigator may request access to [his/her] Personal Data or to have [his/her] Personal Data rectified, blocked, erased or destroyed. In such case, the Principal Investigator shall send a written notice to:

Medclin Research Pvt. Ltd.
Acropolis , unit 10/5 , 10th floor
1858/1,Rajdanga Main Road,kol-107

ARTICLE 16 – NOTICES

All notices required or permitted to be given under this Agreement shall be in writing and may be effectively given if delivered personally or if sent by prepaid registered mail, or by facsimile addressed in the case of the Sponsor's representative/CRO to:

Dr. Monjori Mitra
Research Director
Medclin Research Pvt. Ltd.
Acropolis , unit 10/5 , 10th floor
1858/1,Rajdanga Main Road,kol-107

or in the case of the Institution to:

Prof. Rakesh Kapoor
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road, Lucknow 226014, Uttar Pradesh, India

For the Principal Investigator

Dr. Piyali Bhattacharya
Consultant Paediatrician
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road, Lucknow 226014, Uttar Pradesh, India

Any such notice shall be deemed to have been given and received when actually received. Either Party may change its address for service from time to time by notice given in accordance with the foregoing.

ARTICLE 17 - REPRESENTATION

17.1 Representations and Warranties by the Sponsor's representative/CRO: The Sponsor's representative/CRO represents and warrants to the Institution and the Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Institution and the Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) The Sponsor and CRO are Institutions duly organized and validly existing under the laws of India; and

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(b) The Sponsor and CRO has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of their obligations under this Agreement;

(c) The Sponsor and CRO has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Sponsor/CRO;

(d) This Agreement has been duly authorized, executed and delivered by the Sponsor's representative/CRO and constitutes a legal, valid and binding obligation of the Sponsor's representative/CRO enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) The Sponsor's representative/CRO shall hold harmless the Principal Investigator, the Institution, its employees and representatives against any and all liability arising out of any misrepresentation from its part.

17.2 Representations and Warranties by the Institution: The Institution represents and warrants to the Sponsor's representative/CRO and Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Sponsor's representative/CRO and Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) The Institution is a corporation duly incorporated and validly existing under the laws of Lucknow

(b) The Institution has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of its obligations under this Agreement;

(c) The Institution has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Institution;

(d) This Agreement has been duly authorized, executed and delivered by the Institution and constitutes a legal, valid and binding obligation of the Institution enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) The Principal Investigator is an employee of the Institution.

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17.3 Representations by the Principal Investigator: The Principal Investigator represents to the Sponsor's representative/CRO and the Institution, as of the signing date of the Agreement, and acknowledges that the Sponsor's representative/CRO and the Institution are relying on such representations in entering into this Agreement, that Principal Investigator has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of her obligations under this Agreement.

ARTICLE 18 – ETHICAL CONDUCT

The Parties will conduct themselves and undertake the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and all applicable anti-bribery legislation (national and foreign), including but not limited to the OECD Convention dated 17th December 1997 on combating bribery of public officials in international business.

In particular, the Parties will not offer, promise or give any improper pecuniary or other advantage, whether directly or through intermediaries to a public official, for the benefit of that official or of a third party, for the purpose of influencing decision or actions with respect to the subject matter of this Agreement.

Failure to comply with the provisions of this Article 18 will be deemed a material breach of a material provision of this Agreement.

ARTICLE 19 - BENEFIT, ASSIGNMENT & TRANSFER

This Agreement shall benefit and be binding upon all of the Parties hereto, and their respective successors and assigns. This Agreement is concluded by the Sponsor's representative/CRO intuitu personae. Hence the Agreement may not be assigned or transferred, whether directly or indirectly, by any Party without the prior written consent of the other Party, which consent may be reasonably withheld. However, the Sponsor's representative/CRO shall be entitled to assign and transfer to one or more of its Affiliates this Agreement, without the prior written consent of the other Party, with notice thereafter to the other Party.

The Institution and the Principal Investigator shall not be allowed to subcontract totally or partially the obligations the Sponsor's representative/CRO charged them with, without the prior written consent of the Sponsor. In this latter case, the Principal Investigator and the Institution shall be fully responsible for the part of the obligations so subcontracted and warrants to the Sponsor's representative/CRO that such part of the obligations shall be rendered under conditions consistent in all respect with the terms and conditions set forth herein. For sake of clarity, such consent from the Sponsor's representative/CRO will not relieve the Institution and the Principal Investigator from any liability or obligation under this Agreement and Institution and Principal Investigator will remain liable *vis-à-vis* the Sponsor's representative/CRO for the acts, omissions, defaults or negligence of its sub-contractors.

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ARTICLE 20 - LAW

This Agreement shall be governed by and construed in accordance with the laws of the Republic of India, exclusive of its conflicts of laws principles. All and any dispute arising in connection with the interpretation or execution of this Agreement shall be settled by the competent courts of Lucknow
- India.

ARTICLE 21 - PUBLICITY

No Party shall use the name of any other Party (or the name of any of the Sponsor's divisions or Affiliates) for promotional purposes without the prior written consent of the Party whose name is proposed to be used. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Clinical Trial, shall be made by the Institution or the Principal Investigator without the prior written approval of the Sponsor.

ARTICLE 22 - INDEPENDENT CONTRACTOR

Each Party acknowledges that it is an independent contractor. For greater certainty, the relationship between Sponsor, on the one hand, and Institution and Principal Investigator, on the other hand, shall not constitute a partnership, joint venture or agency. No Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior consent of the other Party to do so.

ARTICLE 23 – COUNTERPARTS

This Agreement may be executed in one or more counterparts, which, together, shall constitute one and the same Agreement.

ARTICLE 24 - AGREEMENT MODIFICATIONS

The provisions of this Agreement, may not be altered, amended or modified except by written agreement signed by both Parties.
The Parties acknowledge and agree that the schedule of the present clinical trial agreement may be subject to amendments and/or update and in such a case, the last-dated version approved in written by a representative of all Parties will be considered to be incorporated therein by reference in place of any prior versions.

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Executive Registrar
SGPGIMS,Lucknow

PGI/cardio/624 /18

Telegram : AYURVIGYAN
E-mail : pkgoel@sgpgi.ac.in
: golf_pgi@yahoo.co.in

Phone (O): + 91-(522) 2494227, 2494277, 2494231
(R): + 91-(522) 2494228, 2668071 (Direct)
Fax : + 91-(522)-2668078, 2668017

18

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
DEPARTMENT OF CARDIOLOGY

Dr. Pravin K. Goel
M.D. (Med), D.M. (Cardiology), FACC, FSCAI, FICC
Formerly Fellow Cardiac Radiology,
Greenlane Hospital, Auckland.
Professor & Head

RAEBARELI ROAD
LUCKNOW – 226 014 (INDIA)

Date: 08/10/2018

To,

Faculty Incharge,

Research, SGPGIMS,

Lucknow.

Sub:-Submission of CTA for Director's signature

Dear Sir,

Please find herewith the CTA of the study titled 'A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50-yrs.) with ACS undergoing PCI by optical Coherance Tomography (OCT) Imaging' for the final approval and signature. I have attached three sets of CTA, Ethics committee approval of the study. The referenced study is an academic study so insurance is not applicable, however sponsor would be covering the entire expenses if the participant has any adverse events or injury related to study as already been undertaken by me in the ethics submission.

Thanking you,

Dr PK Goel
Prof and Head,
Deptt of Cardiology,
SGPGIMS, Lucknow.

Returned on 12/10/18

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(17)

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL648607375799430
Certificate Issued Date	:	14-Aug-2018 11:52 AM
Account Reference	:	IMPACC (IV)/ di713403/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL71340333878650176618Q
Purchased by	:	ACADEMICS AND RESEARCH DEPARTMENT BATRA HOSPITAL
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	ACADEMICS AND RESEARCH DEPARTMENT BATRA HOSPITAL
Second Party	:	DR P K GOEL AND SANJAY GANDHI PGIMS LUCKNOW
Stamp Duty Paid By	:	ACADEMICS AND RESEARCH DEPARTMENT BATRA HOSPITAL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL STUDY AGREEMENT

This Agreement ("the Agreement") is made on this 10 /Aug/ 2018

By and between

Academics and Research Department, Batra Hospital & Medical Research Centre,1, Tughlakabad Institutional Area, Mehrauli Badarpur Road, New Delhi – 110062, India. (hereinafter referred to as **"Clinical Co-ordinating Center")** represented through its **Lead Investigator, Dr. Upendra Kaul.**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

AND

Sanjay Gandhi PGIMS, Lucknow India (hereinafter referred to as **"Site"**)

AND

Dr. P K Goel with his office address **Sanjay Gandhi PGIMS, Lucknow** at, India. (hereinafter referred to as **Principal Investigator or "PI"**)

The Clinical Co-ordinating Center, Principal Investigator and the Institution are henceforth referred to individually as **"Party"** and collectively as **"Parties".**

1. BACKGROUND

WHEREAS, Clinical Co-ordinating Center represented through its Lead Investigator has requested Institution and **Dr P K Goel** (Principal Investigator or "PI"), to conduct a clinical study: *"A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50 yrs.) with ACS undergoing PCI by optical Coherence Tomography (OCT) Imaging*

AND WHEREAS, Site is equipped to undertake the Study and Site has the experience and expertise to perform clinical studies of medical devices and Principal Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

Now, therefore, in consideration of the premises and the mutual promises and covenants expressed herein, Clinical Co-ordinating Center represented through its National Lead Investigator, Site and/or the PRINCIPAL INVESTIGATOR hereby agree to conduct the Study on the following terms and conditions and as described from time to time in the relevant statement of work (the "Statement of Work"):

2. RULES FOR INTERPRETING THIS AGREEMENT

Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this Agreement, except where the context makes it clear that a rule is not intended to apply.

(a) reference to any statute, regulation, proclamation, ordinance, by-law or guideline includes all statutes, regulations, proclamations, ordinances, by-laws or guidelines varying, consolidating or replacing them and a reference to a statute includes all regulations, proclamations, ordinances, by-laws or guidelines issued under that statute;

(b) Words importing the singular include the plural and vice versa and reference to one gender includes all genders;

(c) a reference to a document or agreement including this Agreement includes a reference to that document or agreement as amended, supplemented, varied or replaced from time to time;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.3 Each Party warrants that the person executing this Agreement on its behalf is duly authorized to do so and that nothing contained herein conflicts with any of the provisions of the Memorandum and Articles of Association or similar or other documents relating to the incorporation or of the rules and regulations governing the party.

4.4 None of the services provided by Clinical Co-ordinating Center, under or in connection with this Agreement can or shall be construed as an undertaking that the Study under or pursuant to this Agreement will lead to any particular results or that Clinical Co-ordinating Center has any interest, right or liability in the results of the Study. Clinical Co-ordinating Center confirms that it provides only management services for the Study under agreement with Dr.P. K Goel (Principal Investigator) and all liabilities, responsibilities of the Study, and its results or impact, is solely of the Clinical Co-ordinating Center and Clinical Co-ordinating Center shall have no liability of any manner whatsoever in this regard. Clinical Co-ordinating Center has performed no independent research or analysis regarding the safety or efficacy of any Investigational Product, the Protocol, or any other Trial Materials or treatment procedures involved in this Study and therefore Clinical Co-ordinating Center does not make any warranties, express or implied concerning the same.

4.5 The Site/PI warrant that they have obtained all consents and approvals to carry out the Study as per the Protocol.

4.6 The Site/PI ensure that in the event of a temporary absence of the PI, a nominated and authorized substitute Sub-Investigator shall perform the functions of the PI, though the PI will remain responsible for all his/her obligations under this Agreement. Such nomination/authorization will be done with prior written approval of Clinical Co-ordinating Center. If, however a permanent substitution is required it will be notified to Clinical Co-ordinating Center who shall send a written approval only after consulting with the Clinical Co-ordinating Center, otherwise the Study will be suspended, till a resolution is found.

4.7 No Party hereto shall use the name of another Party hereto or the Clinical Co-ordinating Center either expressly or by implication in any news or publicity release, policy recommendation or commercial purpose without the express written approval of that Party or the Clinical Co-ordinating Center, as the case may be. Nothing herein shall be construed as prohibiting the Clinical Co-ordinating Center from reporting on this Study to other investigators conducting the Study, or of exercising its publication rights.

5. MONITORING AND REPORTING

5.1 As per the Protocol, Site/PI shall report any SAE suffered by a Patient during the Study, whether or not causally related to the study or Patient's participation in the Study, immediately (and in any event within 7 days) to Clinical Co-ordinating Center describing the circumstances under which the SAE occurred and the remedies applied. Site/PI shall follow-up such immediate report by sending a written report to Clinical Co-ordinating Center.

5.2 If in the medical judgment of the PI alternatives on or deviations from the Protocol are required due to a medical emergency, the alternatives and / or deviations and reasons for their use, will be documented and be forwarded to Clinical Co-ordinating Center at the earliest possible occasion following the occurrence of any such event, within Seven (07) days.

5.3 The Site/PI shall notify Clinical Co-ordinating Center promptly if any Regulatory Authority requests permission to inspect the Site/PI facilities, records regarding the Study and shall permit such Regulatory Authority to conduct such inspection. If the inspection occurs than the Site/PI shall provide Clinical Co-ordinating Center with all materials, correspondence, statements, forms and records received from or exchanged with the Regulatory Authorities.

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7.2 Any information, inventions or discoveries (whether patentable, copyrightable or not), innovations, communications and reports (collectively, "Inventions") conceived, reduced to practice, made or developed by Site/PI as a result of conducting the Study shall be promptly disclosed to Clinical Co-ordinating Center and shall be the sole property of Clinical Co-ordinating Center.

7.3 All data supplied by Clinical Co-ordinating Center to the Site and PI, and all data generated in the performance of the Study, (collectively, "Data") shall be and remain the absolute and exclusive property of Clinical Co-ordinating Center. All copy rights and other rights of intellectual and industrial property with regard to the Data shall be vested in Clinical Co-ordinating Center.

7.4 Site/PI hereby assign to Clinical Co-ordinating Center all of their rights, title and interest in and to the Inventions and Data and further agree, upon request by Clinical Co-ordinating Center and at Clinical Co-ordinating Center's expense, to execute such documents and to take such other actions as Clinical Co-ordinating Center deems necessary or appropriate to effect such assignment and to obtain patent or other proprietary protection in Clinical Co-ordinating Center's name covering any of the foregoing.

8. FEE AND COMPENSATION

8.1 In consideration for the Study, the PI will be paid fee/compensation in accordance with the approved payment rates detailed in the budget proposal attached hereto as **Exhibit B** and in accordance with the payment milestones mentioned therein (the "Payment Schedule"). The consideration mentioned under Exhibit B is the total consideration and includes the consideration for purchase of any equipment, infrastructure, admin overheads or hiring of any manpower required, if any, in connection with the Study. The Payment Schedule may be modified only upon the prior written consent of Clinical Co-ordinating Center. Non-emergency additional tests or services (tests or services not required by the Protocol or performed in excess of Protocol requirements) shall not be compensated hereunder unless the written consent of Clinical Co-ordinating Center has been obtained prior to the administration of such tests or services. the clinical coordinating center agrees to pay 18 % GST on top of the agreed budget as per the exhibit B of the clinical study agreement.

8.2 In the event of PI recruiting more or less than minimum number of eligible patients, the consideration for the services will be pro-rated according to the actual number of Eligible Patients enrolled as per the agreed per patient fee.

8.3 Upon completion or termination of the study, the Site/PI agrees to provide written acknowledgement to the Clinical Co-ordinating Center and Clinical Co-ordinating Center that all work requested under this Agreement has been completed and all monies due have been received. In any event, acceptance of payments as "final" constitutes such acknowledgement.

8.4 Clinical Co-ordinating Center further agrees to reimburse Investigator for the actual cost of diagnostic procedures and medical treatment necessary to treat a Patient injury related to the study. Patient injury means a study related physical injury or related psychiatric event caused by administration or use of the Clinical Co-ordinating Center devise required by the protocol that the trial patient would likely not have received if the patient had not participated in the trial. In Case of study related injury or death, Clinical Co-ordinating Center will provide complete medical care as well as compensation for the injury or death as per IRB/IEC recommendation.

9. TERM AND TERMINATION

9.1 The Study shall be completed within the time period of 4 years.

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liability, loss, or damage resulting from (1) a failure to adhere to the terms of the protocol, or this Agreement or Clinical Co-ordinating Center's written instructions (2) failure to obtain the Patients' informed consent (3) failure to comply with any applicable governmental requirements; or (4) negligence or willful malfeasance by the Site, its trustees, the Principal Investigator or associated staff is excluded from this agreement to indemnify and hold harmless.

The Site and the Principal Investigator agree to notify Clinical Co-ordinating Center as soon as they become aware of a claim or action as to which Clinical Co-ordinating Center has indemnification obligations under this agreement and to cooperate with and to authorize Clinical Co-ordinating Center to carry out the sole management and defense of such claim or action. Clinical Co-ordinating Center agrees, at its own expense, to provide attorneys to defend against any such claim or action, whether or not such claim or action is rightfully brought or filed. Neither the SITE, its trustees, Principal Investigator nor associated staff shall compromise or settle any claim or action without the prior written approval of Clinical Co-ordinating Center.

Neither Clinical Co-ordinating Center nor Clinical Co-ordinating Center shall assume any liability for any direct or indirect damage incurred by any of the patients in the course of normal patient care and/or treatment by the Site/PI.

11. CONFIDENTIALITY

11.1 In handling a Patient's medical records, the Site/PI and associated staff shall hold in strict confidence the identity of the patient and shall comply fully with any and all Regulations regarding the confidentiality of such records and data protection.

11.2 The Site/PI shall be responsible for effecting and maintaining all registrations for the processing of personal data that are required by Regulations, including under the Drugs and Cosmetics Rules 1945. PI hereby consents for Clinical Co-ordinating Center and Clinical Co-ordinating Center's affiliates to collect and/or otherwise process personal data provided by or relating to PI for purposes of sharing such personal data with Regulatory Authorities and for any use by Clinical Co-ordinating Center and its affiliates. PI agrees that Clinical Co-ordinating Center and Clinical Co-ordinating Center's affiliates may transfer such personal data to Clinical Co-ordinating Center's facilities, and to Regulatory Authorities.

11.3 The Site/PI acknowledge and agree that all information disclosed to them by or on behalf of Clinical Co-ordinating Center or developed by the Site or PI in connection with the Study is the proprietary information of Clinical Co-ordinating Center and shall be deemed to be Clinical Co-ordinating Center's Confidential Information and each undertakes to Clinical Co-ordinating Center, for its own benefit and for the benefit of Clinical Co-ordinating Center, that it will ensure that such information is kept confidential, without limitation forever even after expiry or termination of this Agreement and is nor disclosed to any third party without prior written consent of Clinical Co-ordinating Center. The Site/PI will hold in strictest confidence and will not directly or indirectly, disclose, reveal, report, use, lecture, broadcast, transfer, disseminate in any form, upon or publish any Confidential Information of Clinical Co-ordinating Center or Clinical Co-ordinating Center.

11.4 The Site/PI shall limit access to the Confidential Information of Clinical Co-ordinating Center to their officers, directors and employees (collectively "Representatives") who require access to such Confidential Information in order to effectuate the purposes of this Agreement. The Site/PI agrees and shall obligate their Representatives to agree, that they will use the same degree of care and discretion as they use to protect their own Confidential Information.

11.5 The Site/PI shall use the Confidential Information of Clinical Co-ordinating Center only for the purpose of fulfilling their obligations under this Agreement. The Site/PI shall not be entitled to use any of the results or data, or any other information, resulting from or related to the Study for own

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SGPGIMS,Lucknow

13.4 **Entire Agreement**: This Agreement sets forth the entire Agreement and understanding of the Parties relating to the patient matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, between the Parties.

13.5 **Severability**: If any provision of this Agreement shall be held invalid, illegal or unenforceable, such provision shall be enforced to the maximum extent permitted by law and in compliance with the Parties' intent, and the remaining provisions shall not be affected or impaired.

13.6 **Amendments, Waivers**: This Agreement may be amended, modified, superseded, cancelled, renewed or extended, and the terms or covenants hereof may be waived, only by a written instrument (which identifies this Agreement and states the plan or intent to modify) executed by all Parties hereto, or in the case of a waiver, by the Party waiving compliance.

13.7 **Assignment**: Site/PI may not assign this Agreement to any party and may not subcontract any of their obligations under this Agreement, unless Clinical Co-ordinating Center have given prior written consent for the same.

13.8 **Survival**: Notwithstanding the termination of this Agreement, obligations which have accrued or have application beyond the term including without limitation those relating to confidentiality, intellectual property, publications, indemnification and enforcement of Parties' rights, shall survive the expiration or earlier termination of this Agreement.

13.9 **Relationship of the Parties**: The Parties agree that Site/PI shall perform services hereunder as an independent contractor, and not as an agent, retaining control over and responsibility for its own operations and personnel. Site/PI shall not, and will ensure that its Representatives shall not, represent themselves to be the agents, employees, partners or joint-ventures of Clinical Co-ordinating Center and shall not otherwise cause Clinical Co-ordinating Center to be liable under any contract or otherwise.

13.10 **Attachments**: Exhibits A& B form an integral and substantial part of this Agreement.

13.11 **Force Majeure**: No Party hereto shall be liable in damages or have the right to cancel this Agreement for any delay or default in performing its obligations hereunder if such delay or default is caused by conditions beyond its control, including but not limited to natural disasters, acts of God, government restrictions/policy, laws, wars, terrorist acts, or insurrections. Whichever of Site/PI and Clinical Co-ordinating Center is affected by such circumstances (the "Affected Party") shall promptly notify the other (the "Non-Affected Party") in writing when such circumstances cause a delay or failure in performance ("a Delay"). In the event of a Delay lasting for four (4) weeks or more the Non-Affected Party shall have the right to terminate this Agreement immediately by notice in writing to the Affected Party.

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Executive Registrar
SGPGIMS,Lucknow

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EXHIBIT – A

LIST OF SERVICES

1. *IDENTIFICATION OF ELIGIBLE PATIENTS FOR THE STUDY*
2. *ADMINISTRATION OF INFORMED CONSENT PROCESS*
3. *ENROLLING PATIENTS AS PER PROTOCOL INCLUSION EXCLUSION CRITERIA*
4. *TREAT STUDY PARTICIPANTS AS PER PROTOCOL & ADEQUATE FOLLOWUP*
5. *TAKING COMPLETE MEDICAL HISTORY OF THE PATIENTS*
6. *PHYSICAL EXAMINATION - SIGNS AND SYMPTOMS OF ALL THE PATIENTS*
7. *RESPONSIBILITY FOR ADVERSE EVENTS REPORTING*
8. *WRITING THE PATIENT STUDY SUMMARY-COMPLETION OF SOURCE DOCUMENTATION*

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SGPGIMS,Lucknow

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B. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

No payment will be made in the event of a failure to follow the study procedure as defined by the protocol, except where such failures are beyond the reasonable control of the Site. Reimbursement will not be provided for patients who enter the study but fail to meet all the inclusion and exclusion criteria. Reimbursement for discontinued or early termination patients will be prorated based on the number of confirmed completed visits.

C. PAYEE INFORMATION

The parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee (the "Payee").

Payments will be issued Quarterly by the Clinical Co-ordinating Center according to visits completed, as verified by the study monitor in the Electronic data captured tool –E-CRF records. Payments will be made by cheque in favor of this agreement payee details.

PAYEE NAME: Please note: This should be a business name and must match the business name used to file for your tax EIN or other tax ID number	Director SGPGIMS Research
PAYEE ADDRESS: Please Note: this should be street address, not a PO Box	Rae Bareli Road, Lucknow, 226014
PAYEE ACCOUNT NUMBER	10095237491
BRANCH ADDRESS	SBI (7789)
IFSC CODE	SBIN0007789
RTGS CODE	NA
SWIFT CODE	NA
MIRC NO	NA
TYPE OF ACCOUNT	Saving Account
PERMANENT ACCOUNT (PAN) OF PAYEE	AAAJS3913N
(GST NO)	09AAAJS3913N2ZN

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SGPGIMS,Lucknow

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संजय गाँधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
Raebareli Road, Lucknow-226014, India

Dr Nitin Agarwal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/** 346 **/2018**

Agenda Item No. 4 **Date:** 01-Aug-18

Title of project: "A prospective multi-centric study to investigate the plaque characteristics andnatural history of lesion in the non-culprit vessels in young Indian patients (<45 years) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging."

Principal Investigator: DrPK Goel **Department:** Cardiology

Name and Address of Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014

New/Re-review project: New

Date of IEC meeting: 18-Jul-18

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application to conduct the research study during the IEC meeting held on 18-Jul-18

List of documents reviewed:

1. Project Submission Form
2. Study Protocol
3. Case Report Form
4. Consent of Head of the PI's Department
5. Research Committee/Department committee /Doctoral Committee/Scientific Committee Approval
6. Undertaking by the PI
7. Conflict of Interest Statement by PI
8. CV of investigator outside SGPGI or of the student
9. Participant Information document (PID) consent forms CF) in English and Hindi

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(9)

संजय गाँधी स्नातकोत्तर आयुर्विज्ञान संस्थान लखनऊ
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road Lucknow 226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 PGI/BE/ 346/2018

Agenda Item No. 4 Date: 01-Aug-18

The following members of the Institutional Ethics committee (IEC) were present at the meeting held on 18-Jul-18

Dr. O. P. Asthana,Retd. Chief Scientist, Clinical and Exp. Med. Div.,CDRI, Lucknow- Chairman
Prof Rajan Saxena Dean SGPGI - Member
Prof Shally Awasthi Deptt of Pediatrics KGMU Lucknow - Member
Prof Vinita Das Deptt of Obst & Gynae KGMU Lucknow - Member
Justice Vishnu Sahai Former Judge Allahabad High Court - Member
Shri Vijai Varma, Chairman Upbhokta Forum Lucknow - Member
Dr Chandishwar Nath Retd Chief Scientist CSIR-CDRI Lucknow - Member
Shri Sharat Pradhan Senior Journalist Lucknow - Member
Shri. Yogesh Misra, Senior Journalist, Lucknow - Member
Dr. Mohan Gurjar, Deptt. Of CCM, SGPGI, Lucknow - Member
Dr. AK Srivastava, (Retd.) Dept. of Sociology, University of Lucknow (Spl. Invitee)- Member
Prof. Vinita Agrawal, Deptt. Of Pathology, SGPGI, Lucknow - Member Secretary

Scientific, ethical and legal issues and PID, CF were discussed.

The committee has given the following suggestions to the PI:

1. **The project has variation in age mentioned in the title submitted to IEC (mentions age <45 years) from that approved from Batra Hospital (mentions age ≤ 50years). Clarify.**
2. **Kindly clarify if FFR assessment is a non-invasive procedure or not.**
3. **Compensation clause needs clarification. Pg 42 mentions that 'any injury' will be taken care by 'clinical coordination center'. Clearly mention the name of the hospital and that the patient will not have to bear any cost of treatment for adverse event. Reimbursement of travel costs for follow up visits should be provided to the participants.**
4. **No insurance policy has been submitted. Insurance would be required to cover the cost of injury/adverse events.**
5. **CTA should be submitted to the Research Cell for approval and after approval, a copy should be submitted to the IEC for record.**

Decision - Minor Modification.

PI advised to submit within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.**Please reply by: 03-Sep-18**

Thanking you,

Your Sincerely,

Vinita Agrawal

(Dr. Vinita Agrawal)
Member Secretary
IEC, SGPGI, Lucknow.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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PGI/cardio/530/18

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(R): + 91-(522) 2494228, 2668071 (Direct)
Fax : + 91-(522) 2668078, 2668017

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
DEPARTMENT OF CARDIOLOGY

Dr. Pravin K. Goel
M.D. (Med), D.M. (Cardiology), FACC, FSCAI, FICC
Formerly Fellow Cardiac Radiology,
Greenlane Hospital, Auckland.
Professor & Head

RAEBARELI ROAD
LUCKNOW – 226 014 (INDIA)

Date:-20/08/2018

To,

Member Secretary,

IEC, SGPGI,

Lucknow.

Subject: Point wise clarification of the committee's comments on my submitted study.

IEC Code: 2018-103-EMP-104

Study title: A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50yrs.) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging

Dear Mam,

This is in response to your letter no PGI/BE/346/2018 dated 01/08/2018 please find the point wise clarification of the ethics committee's comments on my submitted study.

Thanking you,

Dr PK Goel,

Prof and Head,

Deptt. of Cardiology,

SGPGIMS, Lucknow.

OFFICE OF THE BIOETHICS CELL S.G.P.G.I. LUCKNOW
NO. 24-8

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(6)

To,

Date: 20.08.2018

Member Secretary,
IEC, SGPGIMS,
Lucknow.

Protocol Title: A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50yrs.) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging

Dear Dr P.K Goel,

This is in response to your institutional ethics committee letter dated 1st Aug 2018 in which the ethics committee raised few queries for the above referenced study.

The responses for each of the queries are given below:

1. The project has variation in age mentioned in the title submitted to IEC (mentions age < 45 years) from that approved from Batra Hospital (mentioned age ≤ 50 years). Clarify.

Response: It is a typographical error please considered it as ≤ 50 years.

2. Kindly clarify if FFR assessment isa non-invasive procedure or not.

Response: FFR assessment is an invasive procedure but diagnostic only.

3. Compensation clause needs clarification.pg. 42 mention that 'any injury will be taken care by 'clinical coordination center'. Clearly' mention the name of the hospital and that the patient will not have to bear any cost of treatment for adverse event. Reimbursement of travel cost for follow up visit should be provided to the participants.

Response: Any injury related to participation in the entire study will be treated at SGPGI and it will be reimburse (treatment cost) for the adverse event by the sponsor (Clinical coordination Centre of Batra hospital and Medical Research Centre New Delhi). Sponsor will be giving INR 500 as a travel reimbursement only for 1-year OCT follow up visit (the same has incorporated in ICF) because the rest visits will be of telephonic.

4. No insurance policy has been submitted. Insurance would be required to cover the cost of injury/adverse events.

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Executive Registrar
SGPGIMS,Lucknow

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Response: Since the referenced study is an academic study so "Insurance" is not applicable, however sponsor would be covering the entire expenses if the participant has any adverse events or injury related to study.

5. CTA should be submitted to the Research Cell for approval and after approval copy should be submitted the IEC for record.

Response: Once CTA is finalized, we will notify to the IEC for record.

20/2/18

Dr PK Goel,
Prof and Head,
Deptt. Of Cardiology,
SGPGIMS, Lucknow.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Ethics Approval

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SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road, Lucknow-226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/** 4444/2018

Agenda Item No. 4 **Date:** 29-Sep-18

Title of project: "A prospective multi-centric study to investigate the plaque characteristics and natural history of lesion in the non-culprit vessels in young Indian patients (<45 years) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging."

Principal Investigator: Dr PK Goel **Department:** Cardiology

Name and Address of Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014

New/Re-review project: New

Date, time and venue of meeting: 18-Jul-18 11.00 AM at Committee room of Guest house SGPGI

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application to conduct the research study during the IEC meeting held on 18-Jul-18

List of documents reviewed:

1. Project Submission Form
2. Study Protocol
3. Case Report Form
4. Consent of Head of the PI's Department
5. Research Committee/Department committee /Doctoral Committee/Scientific Committee Approval
6. Undertaking by the PI
7. Conflict of Interest Statement by PI
8. CV of investigator outside SGPGI or of the student
9. Participant Information document (PID) consent forms CF) in English and Hindi

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES
Raebareli Road, Lucknow-226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 PGI/BE/ 444/2018

Agenda Item No. 4 Date: 29-Sep-18

The following members of the Institutional Ethics committee (IEC) were present at the meeting held on 18-Jul-18

Dr. O. P. Asthana,Retd. Chief Scientist, Clinical and Exp. Med. Div.,CDRI, Lucknow- Chairman

Prof Rajan Saxena Dean SGPGI - Member

Prof Shally Awasthi Deptt of Pediatrics KGMU Lucknow - Member

Prof Vinita Das Deptt of Obst & Gynae KGMU Lucknow - Member

Justice Vishnu Sahai Former Judge Allahabad High Court - Member

Shri Vijai Varma, Chairman Upbhokta Forum Lucknow - Member

Dr Chandishwar Nath Retd Chief Scientist CSIR-CDRI Lucknow - Member

Shri Sharat Pradhan Senior Journalist Lucknow - Member

Shri. Yogesh Misra, Senior Journalist, Lucknow - Member

Dr. Mohan Gurjar, Deptt. Of CCM, SGPGI, Lucknow - Member

Dr. AK Srivastava, (Retd.) Dept. of Sociology, University of Lucknow (Spl. Invitee)- Member

Prof. Vinita Agrawal, Deptt. Of Pathology, SGPGI, Lucknow - Member Secretary

IEC has taken following decisions for the study/trial;

Scientific, ethical and legal issues and PID, CF were discussed.

The committee has given the following suggestions to the PI:

1. The project has variation in age mentioned in the title submitted to IEC (mentions age <45 years) from that approved from Batra Hospital (mentions age ≤ 50years). Clarify.
2. Kindly clarify if FFR assessment is a non-invasive procedure or not.
3. Compensation clause needs clarification. Pg 42 mentions that 'any injury' will be taken care by 'clinical coordination center'. Clearly mention the name of the hospital and that the patient will not have to bear any cost of treatment for adverse event. Reimbursement of travel costs for follow up visits should be provided to the participants.
4. No insurance policy has been submitted. Insurance would be required to cover the cost of

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road, Lucknow-226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/444/2018**

Agenda Item No. 4 **Date:** 29-Sep-18

injury/adverse events.

5. CTA should be submitted to the Research Cell for approval and after approval, a copy should be submitted to the IEC for record.

Decision Minor Modification.

As per above recommendations of IEC, the project/trial with documents has been reviewed by the Member Secretary and based on the documents submitted by PI following recommendation has been made.

'Decision: Approved.'

With the following condition:-

Copy of approved CTA should be provided to IEC.

The approval is valid until one year or duration of project whichever is later from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of annual status report.

Following points must be noted:

1. IEC should be informed of the date of commencement of study (AN5-V2/SGSOP 06/V3) and annual progress.
2. PI and other investigators should co-operate with IEC, which may monitor the trial from time to time.
3. The decision was arrived at through consensus. Neither PI nor any of proposed studyteam members was present during the decision making of the IEC.
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD and getting IEC concurrence and submitting status report, including accounts details should be submitted to HOD, IEC and extramural sponsors.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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संजय गांधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ
SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road, Lucknow- 226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/444/2018**

Agenda Item No. 4 **Date:** 29-Sep-18

5. New information or any SAE, which could affect any study, must be communicated to IEC and sponsors. The PI should report SAEs occurred for IEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the Bioethics cell should receive the SAE reporting form within 24 hours of the occurrence.

6. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms

7. Any deviation/violation/waiver in the protocol must be informed to the IEC as detailed in AN1-V3/SGSOP 09/V3.

8. If project/drug/device trial initiation not done in next 6 months from date of approval from IEC, further extension will not be granted and it will require resubmission to IEC.

We hereby confirm that the Institutional Ethics Committee is organized and operates as per amended schedule Y (20th Jan 2005), ICH GCP guidelines and applicable regulations.

Thanking You,

Your Sincerely,

Vinita Agrawal

(Dr. Vinita Agrawal)

Member Secretary

IEC, SGPGI, Lucknow.

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Executive Registrar
SGPGIMS,Lucknow

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Kapra, Medchal-Malkajgiri Distri
Pin-500062. Cell No:

CLINICAL TRIAL AGREEMENT

PROTOCOL APLICT/15/06

This Clinical Trial Agreement (the **"Agreement"**) is effective on 21 Feb 2018 fully executed by the parties (the **"Effective Date"**) and entered into by and between

CLINWAVE RESEARCH, a company incorporated under the Companies Act, 1956 having its Registered Office at A/221, 4-32-121, Phase-1, Allwyn colony, Kukatpally, Hyderabad-500072, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Dr. Vikas Kanaujia (Additional Professor), whose principal place of business is Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road Lucknow, Uttar Pradesh, India-226014

(hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

Sanjay Gandhi Post Graduate Institute of Medical Science, Raebareli Road Lucknow, Uttar Pradesh India-226014

(hereinafter referred to as the **"Institute"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

CRO, Principal Investigator and Institute is referred to herein individually as a "Party" and collectively as "Parties".

Whereas, Ajanta Pharma Limited, Plot number 43 AB, 44 BCD, Govt. Industrial Estate, Charkop, Kandivali (W), Mumbai-400067, India (Hereinafter referred to as the **"Sponsor"**) through its Agent CRO desires the Institution to study **"A Comparative, Randomized, Two Arm, Double Blind, Parallel group, Multicentric Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Ripasudil Hydrochloride Hydrate Eye Drops 0.4% w/v Vs Timolol Maleate Eye Drops 0.5% w/v in Subjects Suffering from Ocular Hypertension / Glaucoma.**- and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

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WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the qualified personnel and the facilities equipped according to Good Clinical Practices (GCP) to undertake the Study (defined herein below);

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. THE STUDY AND THE PROTOCOL

The study of shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No. **APL/CT/15/06** and entitled **"A Comparative, Randomized, Two Arm, Double Blind, Parallel group, Multicentric Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Ripasudil Hydrochloride Hydrate Eye Drops 0.4% w/v Vs Timolol Maleate Eye Drops 0.5% w/v in Subjects Suffering from Ocular Hypertension / Glaucoma"** a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of the Sponsor by the CRO.

Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Institutional Ethics Committee) or IRB (Institutional Review Board).

2. THE STUDY SCHEDULE

A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

B. **Enrollment.** Principal Investigator will enroll **minimum 30 Subjects** (as per the randomization schedule) and **not more than 50 Subjects** (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the Complete Study enrollment has been achieved; or

ii. the Sponsor has placed the Study on hold, for any reason; or

iii. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three (3) days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three (3) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.

D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals.

E. **Study Completion.** The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than three days after the last Subject visit.

3. PAYMENT

A. **Budget and Payment Schedule:** CRO shall on behalf of the Sponsor reimburse the Institution all direct and indirect costs incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the **"Budget and Payment Schedule"**). Payment shall be made by

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Cheque/NEFT/RTGS payable to (Institute) PAN No. AAAJS3913N. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study.

B. **Payment of Costs outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any subject who is not qualified to participate in the protocol based on the inclusion and exclusion criteria described in the protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the sponsor's clinical and/or medical monitor identified in the protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. "**Eligible and Evaluable Subjects**" are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

Address: **Dr. VIKAS KANAUJIA,**
Additional Professor, Department of Ophthalmology
Vth , Floor , New OPD Block , Department of Ophthalmology
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road Lucknow,Uttar Pradesh, India -226014

The further details for the payments should be provided as

1. **Cheque in the favor of: DIRECTOR, SGPGIMS RESEARCH SCHEME ACCOUNT, LUCKNOW**

2. **PAN No. - AAAJS3913N**

1.	**Name of Bank:**	State Bank Of India
2.	**Branch:**	SGPGIMS Campus, Raebareli Road, Lucknow **226014, UP**
3.	**Account No:**	10095237491
4.	**Branch Code:**	
5.	**IFS CODE :**	SBIN0007789

E. **Reimbursement.** Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. **Payments for Screen Failure:** Sponsor will not pay only for **Screen Failure subject**.

G. **Payment for Study Coordinator:** PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

4. **OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR**

A. **IEC/IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the Sponsor or Sponsor's designee with written confirmation of the IEC / IRB's

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approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notify the Sponsor and/or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. **Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC/IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the Sponsor.

C. **Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the Sponsor or Sponsor's designee and the Sponsor or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the Sponsor may terminate this Agreement as set forth in Clause 12(B) below.

D. **Sponsor Visits.** The Sponsor's representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

E. **Supplies.**

a. The Sponsor or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all

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rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug hereunder, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

F. **Study Records, Reports, and Data.**

i. *Study Records*. The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice (**"Study Records"**). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of **fifteen (15) years** after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than **sixty (60)** days prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data.

ii. *Case Report Forms*. The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement.

iii. *Annual Reports.* The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC/IRB.

iv. *Final Reports.* Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome (**"Final Report"**) to the IEC/IRB. In addition, any Serious Adverse Events will be reported to the IEC/IRB.

v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of study records.

G. **Reporting of Serious Adverse Event.** The Institution and Principal Investigator shall notify CRO/Sponsor of any Serious Adverse Event encountered in the Study **within twenty four (24) hours** of awareness of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given by fax / mail, whether or not notification was initially given by telephone. The SAE reporting and follow up would be as per the current local applicable regulatory requirements.

5. **CONFIDENTIALITY**

A. **Confidential Information.** The term "Confidential Information" shall mean any and all information, data or know-now, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds,

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procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

i. Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;

ii. Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;

iii. Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and

iv. Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

Disclosing Party: The term "Disclosing Party" shall mean the party disclosing Confidential Information to other party.

Receiving Party: The term "Receiving Party" shall mean the party receiving Confidential Information from the other Party.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. **Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of five (5) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. **Medical Confidentiality.** Notwithstanding any of the foregoing, Sponsor shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws.

6. **Protection.** Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care

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which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. **PUBLICATION**

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish his part, the prior written approval from Sponsor is required.

8. **OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES**

A. **Materials and Data.** The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA or other regulatory agencies.

B. **Patents and Inventions.** All right, title and interest in and to, whether domestic or foreign any inventions or discoveries (collectively, **"Inventions"**) first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in protocols, lab notebooks, or other written records, the know-how incidental thereto, and any patent applications and resulting patents derived there from shall be the exclusive property of that Party.

i. "New Invention or Discovery" shall mean any invention or discovery conceived and reduced to practice during and as a part of Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of the Sponsor.

ii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor.

iii. New Inventions or Discoveries arising out of the research performed under this Agreement solely by Institution, Principal Investigator, and/or any of their respective agents that is not covered by the provisions of Clause 7(B)(*iii*) (an **"Institution Invention"**) shall be the sole property of Institution (subject to any agreement between the Institution and Principal Investigator regarding the ownership of inventions).

iv. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the

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Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. **No Other Rights.** Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

9. **REPRESENTATIONS, WARRANTIES AND COVENANTS**

A. **Of the Principal Investigator.** The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the Sponsor (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable federal law relating to clinical studies that has not been disclosed to the Sponsor and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation (**"Notice of Intent to Disqualify"**). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the Sponsor immediately and the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability.

B. **Of the Sponsor.** The Sponsor represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the Sponsor's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

Sponsor represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) Sponsor has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular, Sponsor shall comply with all DCGI or FDA reporting rules that require it to inform Institution

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and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

C. **No Other Representations or Warranties.** Except for the limited representations and warranties given in this Clause 8, none of the Sponsor, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

D. **Of the Institution:** Institution will ensure that the Principal Investigator remits to the Sponsor all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

10. **GOVERNING LAW**

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Ahmedabad, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the courts of Ahmedabad, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Ahmedabad, India.

11. **INDEMNIFICATION**

A. **Sponsor Indemnification.** The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents (the "**Institution Indemnities**") from and against any liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments but only to the extent such claims, suits, actions, demands or judgments arise from or are caused by the Study Drug and are not covered by insurance or self-insurance as set forth in Clause 11 and provided that the Study is conducted in accordance with (i) this Agreement and the Protocol; (ii) all written instructions provided by the Sponsor concerning the Study; (iii) all applicable federal, state, or local laws, rules, regulations, requirements, and policies; and (iv) the manner required of reasonable and prudent clinical investigators and physicians; and such loss does not arise out of the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institution Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees; and the Sponsor is notified within ten (10) working days of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and Principal Investigator and the Institution and its directors, officers, and employees fully cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement.

B. **Institution Indemnification.** The Institution shall defend, indemnify, and hold harmless the Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("**Sponsor Indemnities**") from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the Sponsor concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees.

C. **Notification.** The Parties shall promptly notify each other of any such claims, suits, actions, demands, or judgments and the Parties shall reasonably cooperate with each other in the handling thereof.

D. **Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

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E. **Representation.** In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnity.

F. **Subject Injury.** Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the Sponsor in case of subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

12. **INSURANCE**

A. **Sponsor Insurance.** Sponsor shall maintain during the term of this Agreement and for a period of **One (1) year** thereafter, general liability insurance (with product liability endorsements) and professional clinical trial liability insurance coverage sufficient to meet its indemnification obligations. Sponsor will provide evidence of its insurance upon request and will provide to the Institution, **thirty (30) days** prior written notice of cancellation of its coverage. Sponsor further agrees to include Institution and Principal Investigator as additional insured on such policy.

B. **Institution Insurance.** Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 11 shall survive termination of this Agreement.

13. **TERM AND TERMINATION**

A. **Term.** This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F)(*iv*), above, unless earlier terminated in accordance with this Agreement.

B. **Termination.**

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i. Either Party may terminate this Agreement immediately upon written notice to the other if:

a. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;

b. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

c. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement..

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

iv. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, Sponsor will make payment to Institution for.

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. Reasonable non-cancelable obligations properly incurred for the Study by Institution prior to the effective date of termination.

v. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by Sponsor, to the extent medically permissible.

vi. **Immediate Termination by the Sponsor.** The Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.

vii. **Effect of Termination.** In the event this Agreement is terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the Sponsor to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the Sponsor's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes. The Sponsor shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement.

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viii. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11,and 12 shall survive any termination of this Agreement for any reason.

14. **MISCELLANEOUS**

A. **Use of Names; Publicity.** Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its employees in any advertisement, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Article 6). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. **Independent Contractors.** The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. **Limitation of Liability.** In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.

D. **Notices.** Any notices required or permitted to be given hereunder shall be in writing, shall be addressed to the Party to whom such notice is intended as follows, or such other address and/or number as such Party may substitute by written notice hereunder, and shall be effective on receipt.

E. **Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. The Sponsor may assign this Agreement to any successor to all or substantially all of the business of the Sponsor, or in connection with its merger, consolidation, change in control or similar transaction. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.

F. **Modification; Waiver.** This Agreement may not be altered, amended or modified in any way except in writing signed by the Sponsor, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right.

G. **Entire Agreement.** This Agreement and its Exhibits constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior discussions, negotiations, communications, understandings, agreements, representations and writings with respect to all matters covered by the Agreement. In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence except as otherwise specifically set forth in this Agreement.

H. **Severability.** In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

I. **Execution.** The Institution's IRB shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile signature.

J. **Changes to the Protocol.** If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement,

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however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

K. **Covenant Not to Hire**. Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

L. **Drug Safety and Reporting.** The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR and/or CRO's Medical Monitor concerning any AEs and also any follow-up queries from the regulatory authorities to the Sponsor. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.

Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR:

Name:	Dr. Rajasekhara Reddy
Cell number:	+91-7989233379
E-mail:	dr.sekhar@clinwave.in

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of the Study, or could alter the ECs / IRB's approval to continue the Study.

CRO will be responsible to notify on time the health authorities in India.

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IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

INSTITUTE

By: _____ DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA (Signature)

Prof. RAKESH KAPOOR
Director

_____

(Date)

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

PRINCIPAL INVESTIGATOR

By: _____

(Signature)

Dr. Vikas Kanaujia

_____

(Date)

CLINWAVE RESEARCH

By: _____ CLINWAVE RESEARCH HYDERABAD

(Signature)

Dr. Rajasekhar Reddy Tamma- Managing Director

21 Feb 2018

(Date)

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EXHIBIT A: PROTOCOL ALREADY SHARED WITH THE INVESTIGATOR

As Annexure 1

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EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : Dr. VikasKanaujla, Additional Professor, Ophthalmology
Site Address :Sanjay Gandhi Post Graduate Institute of Medical Science,
Raebareli Road Lucknow, Uttar Pradesh India-226014, UP INDIA

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for patients is as follows:

Overall per Patient Budget

Investigator Grant for completed subjects	INR 4000/Patient
Subject Travel Reimbursement	200/ Visit = Total 14,00/ Patient
Institution Overhead	25 % on Site Study Budget
Total	INR 4,200/- (Four thousand two hundred rupees only)/ Completed Patient)

The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within thirty (30) days after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have forty five (45) days after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices:
Send invoices to : Clinwave Research
Contact Person: Dr. KarthikaDadi
Address :A/221, 4-32-121, Phase-1, Allwyn colony, Kukatpally, Hyderabad-500072,

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

Final Payment

The final payment will be made after the close-out visit by the CRO CRA, after all CRFs for all subjects have been received and accepted by a CRO project leader, and all data queries for Institution have been resolved satisfactorily.

Budget notes, payment schedule, conditions of payment and payment directions

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1. All amounts above are in Indian Rupee (INR).

2. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.

3. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.

4. Service Tax will be deducted and applicable as per current government rules and regulations (i.e. on date of invoice).

5. A service tax (as applicable) will be considered on total grant subject to availability of service tax registration number with service provider. Service tax will be paid and applicable to service provider, provided to reflect the service tax registration number on Invoice / Bills."

6. In case recruitment is not initiated within a reasonable time period, unutilized amount (in keeping with the payment head above) would have to be returned to Sponsor.

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement is made by and between the following three parties:

1)ACCUTEST:

Accutest Research Lab. (I) Pvt. Ltd.
A-77, Khairne MIDC, TTC Industrial Area,
Khairne, Navi Mumbai, 400 709.
Tel.: +91 22- 2778 0718/19
Fax: +91 22- 2778 0720
Email ID: rajendra.telele@accutestgloabal.com

Hereinafter "ACCUTEST"

2) PRINCIPAL INVESTIGATOR:

Name: Dr Usha kant Misra
Address:. Sanjay Gandhi Post Graduate Institute of Medical sciences
Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India.
Tel.: +91-8004904627 /+91-9450653685
Fax: +91-05222668811
Email ID: drukmisra@rediffmail.com

Hereinafter "PRINCIPAL INVESTIGATOR"

CO-INVESTIGATOR
Name: Dr. Jayantee Kalita
Address: Sanjay Gandhi Post Graduate Institute of Medical sciences
Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India.
Tel. +91-9450411673 / +91-8004904630
Email ID: jayanteek@yahoo.com

Hereinafter "CO- INVESTIGATOR"

3) INSTITUTE:

Name of the Authorized Signatory: Dr. Rakesh Kapoor
Designation. Director
Name of the Institute: Sanjay Gandhi Post Graduate Institute of Medical sciences
Address: Sanjay Gandhi Post Graduate Institute of Medical sciences
Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India.

Hereinafter "INSTITUTE."

ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD. NAVI MUMBAI

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This Clinical Trial Agreement is effective from the date of last signature("**Effective Date**")

Accutest is engaged in the business of clinical trials management as a contract research organization and intends to carry out a clinical study ("the Study") with "**A prospective, multicenter, post-marketing surveillance to assess safety & efficacy of perampanel in Indian patients as an adjunctive treatment in partial onset seizures with or without secondary generalized seizures in patients with epilepsy aged 12 years or older.**"("the **Protocol E2007-M091-508**") for the purpose of obtaining data for the application of the Study Drug.

The Study Protocol Number: E2007-M091-508

Subject to the condition of obtaining the pertinent ethics committee approval and the regulatory authorities' authorization, the parties intend to participate in the Study by rendering their services and agree to the following:

Section 1: Study Protocol

The nature and scope of the Study are ensured from the Protocol. The Protocol precisely and exhaustively describes the clinical research activities and responsibilities for careful execution by the Principal Investigator. Any changes to the Protocol are subject to Accutest's prior written consent which the Principal Investigator shall obtain, and the approval/notification of the competent ethics committee and the Drug Controller General of India ("**DCGI**"). The Protocol, including any amendments, constitutes an integral part of this Agreement ("The **Agreement**") and shall be valid upon signature of this Agreement. In the case of any inconsistency between this Agreement and the Protocol, this Agreement shall prevail. The Principal Investigator warrant that they have received the Protocol.

Section 2: Rules for the Conduct of the Study

2.1 Legal framework

The parties agree that the duties and obligations of the provisions of the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments as set out in the Protocol of the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice", the applicable national legislation on public health and pharmaceuticals including the Central Drugs Standard Control Organization's Good Clinical Practice Guidelines ("**GCP Guidelines**")valid at the time of the performance of this Agreement; and all other pertinent rules and regulations shall be applicable including but not limited to Schedule Y to the Drugs and Cosmetics Rules, 1945 ("**Schedule Y**"), and that the Agreement shall be construed accordingly.

2.2 General Duties and Obligations

The Principal Investigator shall carry out the Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement.

The Principal Investigator hereby warrants that they have sufficient resources with regard to time, adequate personnel and facilities for the performance of the Study. Unless expressly agreed otherwise, the responsibility for services of third parties (including, but not limited to sub-investigators and satellite sites) remains with the Principal Investigator. The Principal Investigator shall ensure that all personnel and third parties are bound by and comply with the terms of the Protocol and this Agreement.

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SGPGIMS,Lucknow

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The Principal Investigator will inform Accutest, about all changes of personnel, facilities and clinical research methods at the Institute that may affect the Study.

In the event the Principal Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Principal Investigator will inform Accutest within 3 days of the Principal Investigator being unwilling or unable to perform the duties. The Principal Investigator shall continue to be bound by the provisions referred to in Section 5.2.

The Principal Investigator is an employee, of the Institute and Investigator guarantees the proper performance by him following all obligations hereunder.

2.3 Ethics Committee / Review Board / Regulatory Authority Approval / Notifications

Accutest shall undertake the necessary notifications to authorities in accordance with applicable laws. The Study shall not commence until the Principal Investigator is informed by Accutest that the authorities have given authorization.
Accutest will provide the Principal Investigator with all the documentation required for submission to the pertinent ethics committee. Institute/Principal Investigator will obtain the written approval of the appropriate ethics committee prior to the commencement of the Study and will furnish Accutest or its designate with the ethics committee's letter of approval and a list of all ethics committee meeting attendees.

The Study shall not commence until receipt of the ethics committee written approval and shall follow any conditions of approval imposed by the ethics committee, and the time interval has been observed and all regulatory documents that are necessary according to the ICH – GCP,Schedule Y, and other applicable pharmaceutical regulations are available.

Should the ethics committee express objections to the content or the performance of the Study, the parties will collectively develop modifications that accommodate the objections. Should the ethics committee approval be unobtainable nonetheless, the parties shall be entitled to mutually terminate this Agreement. Amendments to the Protocol must be submitted by the Principal Investigator to the pertinent ethics committee.

2.4 Subject Information and Informed Consent

The Principal Investigator shall ensure that during informed consent process, information to the subjects is provided individually and not in a group (in accordance with the provisions specified in Section 2.1 above) in a language that is best understood by the subject about the nature. significance and consequences of the Study, its expected duration, and the potential benefits and risks involved in Study participation.The explanation shall at least include all points listed in the ICH-GCP and Schedule Y.The Principal Investigator should obtain written Informed consent fromthepatient, record necessary source data (like IC-EC, ECG, Physical Examination, Vital,etc.) and submit verify the eligibility criteria prior to enrolling the patient in the study.The Principal Investigator shall conduct complete Informed Consent process as per current regulatory requirement and also document the written consent prior to the Study on a prepared Informed Consent Form (ICF) and shall hand out a copy of the ICF and subject information document to each subject. In accordance with the provisions specified in Section 2.1 above, Principal Investigator shall ensure that consent of the governing local health authorities and/or subject for the submission of ICF mentioned above anonymous data to and/or appropriate regulatory authorities, is obtained.

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All the study related documents should be preserved safely after the completion/termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently, if applicable.

Each subject will be informed accordingly, and his/her consent will be obtained

- that he/she is enrolled in the Study,
- that the subject's insurance has been effected and that each subject has obligations arising from the general insurance conditions; in particular these are:
- during the course of the Study the subject must immediately inform the Principal Investigator about any other medical treatment he/she undergoes;
- any health damage, which may be attributable to participation in the Study, must be immediately reported to the insurance company;
- that the necessary documentation of the subject's health and personal data and its distribution to Accutest, the competent health authorities, and other Institutes, as legally required, may take place.

In the event the patient or his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the Study informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the Study informed consent form

2.5 Enrolment Period

The recruitment phase may not commence until the written positive decision of the ethics committee has been obtained.

The Principal Investigator will recruit a maximum of **20 subjects** for the Study, as the enrollment is competitive amongst the investigative sites.

The Principal Investigator is aware that for this multicentre study, a competitive recruitment will apply. Should the total number of subjects enrolled in the study be met prior to the end of the anticipated enrollment period, Accutest shall have the right to end further enrolment of subjects; no payment will be made for any such additional subjects.

2.6 Study Documents and Drug Supplies

Accutest's designee shall ensure appropriate and timely supply of the documents and Study Drugs necessary for the performance of the Study. All supplies shall be returned to Accutest by the Principal Investigator/Institutein a timely manner throughout the performance of this Study, as outlined in the Protocol or when Accutest otherwise requests delivery of data, unused Drug, and clinical specimens.

The Principal Investigator hereby warrants that he/she shall:

a) account for all clinical supplies furnished by Accutest and keep a written inventory of any equipment supplied by Accutest according to guidelines provided by Accutest;

b) use the Study Drug solely for the Study, documenting each usage and to return all used and unused clinical or other supplies provided by Accutest upon conclusion of the Study;

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c) collect data properly and report to Accutest all relevant information and data obtained under the Protocol;

d) submit to Accutest signed CRFs/eCRFs resulting from the Study in a timely manner;

e) retain all necessary records and documents about the Study as required by applicable regulatory requirements, this Agreement, and/or the Protocol;

Moreover, the Principal Investigator shall update/maintain the investigator study file provided at the time of Site Initiation Visit (SIV) andas per ICH-GCP all relevant essential documents which are necessary for the conduct of the Study including but not limited to following:

a) Signed Protocol and amendments;

b) Investigator's Brochure and updates (If applicable);

c) Ethics Committee composition, approval(s)/opinion correspondence/reporting;

d) Notifications/Approval of regulatory authorities;

e) CVs and signature sheet for key study personnel (e.g. investigators);

f) Approved and signed informed consent forms;

g) CRFs/eCRFs (investigator's copy) (If applicable);

h) Serious adverse events documentation and related correspondence/reporting;

i) Instructions for handling of Study Drug;

j) Screening, enrollment, and monitoring logs and subject identification code list;

k) Study related correspondence with Accutest

2.7 Adverse Events

The Principal Investigator is obliged to document and manage all Adverse Events (AEs) in accordance with the Protocol and to notify Accutest of all Serious Adverse Events according to the study instructions ("Serious Adverse Event Reporting") within the timeline specified in the Protocolor as per current regulatory requirement

Section 3: Documentation and Monitoring

3.1 Documentation and CRF/eCRFs handling

The Principal Investigator shall keep all original medical files (paper and print-outs of electronic files) of every subject participating in the Study in addition to the Case Report Forms(CRFs)/electronic Case Report Forms (eCRFs). The medical file is the documentation containing all demographic and medical data of a subject. This medical file will clearly identify each Study subject and where the medical files are termed the source; entries on the CRFs/eCRFs must be traceable to entries in the medical file. In the course of the Study, the Principal Investigator undertakes to express medical data in writing using medical terminology where necessary, the status of the Study for the respective subject and be completed expeditiously following a subject visit. The Principal Investigator must sign all eCRFs/CRFs. The Principal Investigator should inform the general practitioner and, if applicable, any other physicians, treating the subject about his participation in this clinical Study. The Principal

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Investigator warrants that all eCRFs/CRFs submitted to Accutest are true, complete and correct and accurately reflect the results of the Study with respect to each person participating as a subject.

The Principal Investigator undertakes to cooperate with Accutest and acknowledges Accutest's right, upon a request, to be granted direct access to all requested trial-related records (including patient medical files).

3.2 Monitoring

The parties agree to frequent monitoring visits to the institute by Accutest. The monitor (CRA) will visit the Institute to discuss study progress with the Principal Investigator who will allow inspection of all study data including medical files requested by the monitor.

The CRAs will check the data entered in the eCRFs/CRFs. CRAs and possibly representatives of Accutest shall perform source data verification, comparing the CRFs/eCRFs with the medical records to validate the data. Despite the CRA's and other representatives' efforts, the Principal Investigator remain primarily responsible for the accurate and complete data entry in the CRFs/ eCRFs. All persons who obtain knowledge of medical records are subject to professional secrecy.

Such monitoring will be carried out during the study, but may also be demanded by the pertinent regulatory authorities after completion of the study. The Principal Investigator are obliged to inform Accutest immediately of any notification of an inspection by the pertinent regulatory authorities.

3.3 Audit and Regulatory Inspection

Audits or inspections may be carried out during the Study, but may also be demanded by the regulatory authorities after completion of the Study. In the event thatAccutest or authorities perform an audit, the Institute,Principal Investigator will allow access to the facilities, make documents available and if necessary provide information. Should a governmental or regulatory authority request or carry out an inspection of the Institute's or Principal Investigator's facilities, Principal Investigator has to immediately notify Accutestby telephone, mail or fax and allow Accutest to be present. The Principal Investigator shall provide to Accutest copies of all materials, correspondence, statements, forms and records that Principal Investigator receives, obtains, or generates pursuant to any such inspection.

Section 4: Confidentiality and Subject Data

4.1 Protection of Subject Data

On the CRFs/eCRFs, which will be used for evaluation of the Study, patient data will be documented in anonymous form only, i.e. without naming the subject, and passed on to Accutest and the DCGIand/or foreign regulatory authorities. The name of the subject, as well as other person-related data, will not be divulged by the Principal Investigator, or by Accutest. Accutest shall ensure that the protection of the data concerning subjects is safeguarded.

When, for reasons of the fulfilment of professional obligations or verification purposes, person-related data concerning the Principal Investigator or the subjectare stored or handled, reliable organizational measures must be employed to ensure that these data are not divulged to unauthorized third parties.

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Exception: When IEC or DCGI or any other regulatory authorities require the subject details then Principal investigator shall share photocopy and maintain the record in the file.

4.2 Confidentiality

Principal Investigator shall receive copies of the Study documents and the investigator site file. Principal Investigator/Institute is obliged to retain the documents facilitating identification of the Study patients, and all other Study Documentation disclosed by Accutest, for at least 15 years after the end or the premature termination of the Study or as communicated during site close-outvisit.Institute has no part to play in the closeout of the trial.Accutest is responsible for informing the Principal Investigator when it is no longer necessary to conserve all the Study documentation (ICH 4.9.5).

The Principal Investigator/Institute is obliged to maintain the secrecy of all information related to the Study and the Study Drug ("the **Information**"). The Principal Investigator shall procure that any co-workers assisting the Principal Investigator in the Study shall keep all such Information secure and strictly confidential as well. The Principal Investigator agrees not to use the Information for any purpose other than the performance of the Study.

The information shall not include:

- Information that enters the public domain and only then where this has occurred other than through unauthorized disclosure by the Principal Investigator or his co-workers.
- Information that is properly requested for by the ethics committee responsible for approving the Study may proceed or is requested by the pertinent regulatory authorities in accordance with prevailing legislation, provided that the Principal Investigator shall give prior written notice to Accutest of any such request for disclosure.

The above obligations of confidentiality shall remain in full force and effect.

4.3 Proprietary information

All documents, data, know-how, formulas and unused Study Drug provided to the Principal Investigator for purposes of the Study ("**Data**") are and will remain Accutest's property and will be returned to Accutestor their respective designates upon request. Notwithstanding the preceding, Accutest shall retain full ownership rights in and to all templates, programs and other materials developed or licensed by Accutest prior to or apart from the commencement of this Agreement, regardless of whether such materials are used in connection with this Agreement.The Principal Investigator hereby transfers and assigns to Accutest the Principal Investigator's worldwide right and title to all Data in perpetuity and agrees to undertake such actions reasonably requested by Accutest to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

4.4 Rights to results

Accutest shall have the right to use the results of the Study in any manner deemed appropriate to Accutest's business interests. All data attained during the performance of the Study are Accutest's property. The Principal Investigator assign worldwide rights and title to all data obtained in the Study in

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perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose. Principal Investigator shall notify Accutest of the results immediately, separately and in writing.

4.5 Intellectual Property

Neither the Principal Investigator nor his employees or agents shall acquire any rights of any kind whatsoever with respect to the Study Drug as a result of their performance under this Agreement. All inventions, discoveries, and technology relating to the Study Drug conceived by the Institute or its Principal Investigator, solely or jointly with others as a result of work done under this Agreement, shall be, and remain, at all times the sole and exclusive property of Accutest (subject to the right expressly reserved under Section 4.3).

The Principal Investigator hereby assign worldwide rights and title to the Intellectual Property in perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

The Principal Investigator warrant, by the execution of this Agreement, that they have not entered, and will not enter, into any contractual agreement or relationship which would in any way conflict with or compromise Accutest's rights to, any inventions, discoveries, or technology arising out of or related to their performance thereunder.

4.6 Publications

It is the general policy of the ARL & Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice, no interim data should be published by the Principal Investigator/ Institute unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institute request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the ARL & Sponsorfor its perusal, comments, and approval. The ARL or Sponsor may at its discretion either refuse the publication or forward it to the Principal Investigator/ Institute/ along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institute.

4.7 Publicity

No party to this Agreement shall use Accutest's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission of such party or Accutest, as appropriate.

Section 5: Term and Termination of the Agreement

5.1 This Agreement commences on the Effective Date provided that Accutest has received from the pertinent ethics committees and the DCGI, as required by law, approval to carry out the Study. This Agreement shall remain in force to the full conclusion of the Study according to the Study Protocol unless terminated prematurely. Accutest may terminate this Agreement immediately upon written notice to the Institute/Principal Investigator.

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5.2 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement.

Neither termination of this Agreement, however, effectuated, nor the end of the term shall cause the parties hereto to be released from their rights and obligations under Sections 3, 4, 6, 7 and 8, or under any other provisions of this Agreement that by their terms are understood to survive termination.

Upon completion of the Study, the Principal Investigator and the Institute shall return to Accutest, or its designee, all unused Study Drug, compounds, Comparator Drugs (when used), equipment as specified in Section 2.6 that were furnished to the Institute other than the investigator site file documents.

5.3 Should the Principal Investigator recognise within reasonable discretion that continuation of the Study is no longer possible, due to unexpected results medically not justifiable, due to severity of serious adverse events not justifiable or efficacy of the treatment with the Study Drug insufficient, he/she will immediately notify Accutest as well as the ethics committee. Should continuation not be justifiable, the Principal Investigator may arrange for immediate termination of the Study. In the event that the Study is terminated with the consent of Accutest,the Principal Investigator shall receive payment pro rata temporis basis for the efforts of the Study, in accordance with Appendix A.

5.4 Accutest may terminate its cooperation with the Principal Investigator prematurely, provided that:

a) one month after shipment of the Study material, no subjects have been enrolled or the Principal Investigator recruits no subjects or recruits such a low number of subjects that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase,

b) Accutest terminates the Study for the Study Drug or the indication is discontinued,

c) it is proved that the dosage used for the Study does not seem to be justified any more,

d) regulatory authorities or other pertinent institutions decide to terminate the Study in this center or as a whole,

e) the Principal Investigator fails to sufficiently adhere to the conditions of the Protocol and the need to exact and complete data documentation and the GCP Guidelines and Schedule Y.

5.5 Consequences of Termination: Upon the effective date of termination, the Principal Investigator shall:

a) terminate all services as efficiently and quickly as possible, except to the extent Institute/Principal Investigator is required to continue to follow the procedures and perform such services with respect to the ongoing Study, as may be necessary, until the appointment by Accutest of another Institute/Principal Investigator for the purpose of continuing the Study;

b) within 7 business days, provide copies of all information, data, documents (including but not limited to IPs, ICFs(blank copies), CRFs/eCRFs, Study related material & documents, and any clinical samples obtained with regard to the Study) prepared, conceived, generated or delivered by Principal Investigator as a result of or in connection with the conduct of the Study;

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c) Provide an accounting of all clinical supplies, which is subject to verification by Accutest. If Accutest objects to any charge, the parties shall use reasonable efforts to resolve expeditiously any disagreement.

Section 6: Payment Terms and Conditions

It shall be the Principal Investigator's/ Institute's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation, those which relate to the Principal Investigator, the Institute, and its employees and/or collaborators.

Payment of investigator grants on behalf of Accutest will be equatedwith respect to the number of subjects recruited and the services performed as set out in detail in the APPENDIX-I & II entitled "Investigator Grants."

In the case of any inconsistency between this Agreement and the APPENDIX, this Agreement shall prevail. For the avoidance of doubt, if any obligation is specified in one of these documents but not in the other, this shall not constitute an inconsistency.

In the event that Accutest or the Principal Investigator/Institute terminates the Agreement prematurely in accordance with Section 5.4, Accutest shall not pay grants for performance on subjects that do not conclude the Study provided that.

- where a subject has been recruited to the Study in violation of the Protocol, there shall be no obligation of payment;
- where failure by a subject to complete the Study is due to the omission of tests or assessments by the Principal Investigator, there shall be no obligation of payment;
- where failure by a subject to complete the Study is due to adverse effect, lack of effect, concomitant illness, non-compliance or non-attendance, provided that full data is available up to the time of the subject'sdropout and the event is satisfactorily recorded, payment shall be made in accordance with the above-referenced APPENDIX proportionately according to the amount of work carried out by the Principal Investigator pursuant to the Protocol;
- any sums advanced to the Principal Investigator prior to termination of this Agreement will be taken into account in calculating any sum due to the Institute or Principal Investigator and any balance outstanding and due to Accutest shall be paid to by the Principal Investigator;
- "Completed Patients" are subjectswho have completed the Study in accordance with the Protocol, and for whom full case report forms and any ancillary documentation required have been completed by the Principal Investigator to Accutest's satisfaction.

Section 7: Standard of Care, Insurance, Indemnity

7.1 Subject Insurance

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Thishas been obtained and will be provided to the site personnel before the initiation of the trial.

7.2 Product liability

Study Insurance will be provided to the site personnel before the initial of the trial.

7.3 Standard of care

In no event shall Accutest be held responsible for any controversy, demand or claim for the payment of damages deriving from Principal Investigator for-

(a) injuries or damages incurred if they are the result of or are alleged to be the result of negligence or willful misconduct on the part of the Instituteor agents or the Principal Investigator,

(b) activities contrary to the Protocol;

(c) unauthorized warranties made by the Principal Investigator concerning the product being tested;

(d) in any case, in which written, informed consent was not obtained for the subject involved in accordance with the Protocol.

The Principal Investigator hereby represent and warrant that they have obtained a professional liability insurance policy from a reputed and creditworthy insurance company, covering their liability for any damage, which may be caused as a result of fault or negligence, which they may commit in the performance of this Agreement. The Principal Investigator shall provide evidence of its insurance upon request by Accutest. The Principal Investigator shall be liable under this Agreement for direct damages resulting from negligence or wilful misconduct in the execution of the Study.

The Principal Investigator shall defend and hold harmless, and be responsible for losses suffered by Accutest and any agent and employees of Accutest from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the improper or negligent administration or use of the Study Drug during the course of the Study.

The Principal Investigator shall also indemnify, defend, and hold Accutest and its affiliates, directors, officers, employees and other representatives ("Accutest Indemnified Parties") harmless from and against any and all loss, costs, claims, actions, liability and/or suits, including without limitation, interest, penalties and reasonable attorneys' fees ("Accutest's Claims"), incurred by Accutest that arose from or was a result of following:

(a) any material breach by Principal Investigator under this Agreement;

(b) the failure, or act, error, deviation, omissions, negligence, gross negligence or intentional misconduct of the Principal Investigator in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(c) Principal Investigator's violation of any and all applicable laws rules and regulations of India.

(d) Principal Investigator's breach or default in performance of its obligations in connection with the Study:

(e) Principal Investigator's material deviation from the Protocol;

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(f) Principal Investigator's failure to complete the Study and any such delay attributable solely to Principal Investigator's willful misconduct, or failure to comply with its obligations under this Agreement.

Section 8: Parties

8.1 Conflict of Interests

The Principal Investigator warrant that they, as well as all their support personnel, are not presently under any agreement or obligation which conflicts with the duties and obligations owed to Accutest under this Agreement, and further agree not to undertake any such obligations or agreement during the course of the Study.

Where (if applicable) it is intended that the Study Drug will be the subject of a submission to the regulatory authorities for a New Drug Application, the Principal Investigator certifies that he/she shall, in any form or manner reasonably requested by Accutest, disclose, and shall use his/her reasonable best efforts to cause any sub-investigators for the Study to disclose, all of the following that they and their spouses, domestic partners and dependent children own or possess directly, indirectly, or equitably (all collectively "Financial Interests"):

(a) All compensation, payments (including other research grants, consulting or director's fees, honoraria, speaking and meeting travel fees and reimbursement) and items or services of value provided by or on behalf of Accutest (excluding compensation received under this Agreement);

(b) All licenses, assignments, or other conveyances of rights or interests in real, personal or intellectual property ofAccutest or relating to the Study Drug,

(c) All forms of interests in the equity (including stock, options, and warrants) or debt of Accutestor of other entities having a financial interest in the Study Drug; and

(d) All other financial interests, payments, and other compensation

During the conduct of the Study and for one (1) year after its completion, the Principal Investigator agrees to execute and update such forms, disclosures, and certifications now or subsequently required by Accutest related to the Financial Interests. The Principal Investigator hereby warrants that he/she has implemented a "Conflicts of Interests" disclosure and management policy and program that complies with the requirements and regulations issued or administered by the pertinent regulatory authorities, and the Principal Investigator warrants that he/she has and will continue to comply with such policies and programs.

8.2 Independent Contractor, Employees

The Institute and the Principal Investigator shall perform services under this Agreement only as independent contractors for Accutest, and nothing contained herein shall be construed to be inconsistent with that relationship or status. The Principal Investigator and his respective employees shall not be considered employees or agents of Accutest. This Agreement shall not create a business organization of any kind.

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The parties agree that they shall not directly or indirectly solicit for employment, employ or otherwise retain staff of the other party during the term of this Agreement or within the period of three (3) years following termination of this Agreement.

The Study is performed independently from any business transactions and decision on supply purchases with Accutest. The Instituteandthe Principal Investigator will not receive any benefits from the conduct of the Study beyond the remuneration agreed herein.

8.3 Assignment

Principal Investigator shall not assign his rights or obligations out of this Agreement to any third parties without Accutest's prior written consent. The Institute and the Principal Investigator understand and agree that this Agreement is being entered into to perform services forAccutest and that accordingly, Accutest may freely assign its rights and obligations out of this Agreement.

The Institute/Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Accutest. Any such consent shall not relieve the Institute and/or the Principal Investigator of its obligations hereunder.

Section 9: Communications

The Parties undertake to notify each other of all cases that influence the performance of this Agreement. Correspondences shall be made to the following addresses:

1)ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com	Name: Dr Usha kant Misra Address:. Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel.: +91-8004904627 /+91-9450653685 Fax: +91-05222668811 Email ID: drumisra@rediffmail.com
	CO-INVESTIGATOR Name: Dr. Jayantee Kalita Address: Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel: +91-9450411673 / +91-8004904630 Email ID: jayanteek@yahoo.com

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3) INSTITUTE:

Name: Dr Rakesh kapoor
Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raibareli road, Lucknow, Uttar Pradesh, Uttar Pradesh, India.
Tel.: +91-0522-2494001
Email ID: director@sgpgi.ac.in

Section 10: Contractual

10.1 Entire Agreement
This Agreement (including the Protocol and the APPENDIX) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by all parties and refers to this Agreement.

10.2 Applicable Law, Place of Venue

The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof.

The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, India will have sole jurisdiction over the litigation.

10.3 Severability

Should any of the provisions of this Agreement be declared entirely or in part invalid or unenforceable by the pertinent authorities according to the applicable laws, the remaining terms of this Agreement shall not be affected by such declaration. Such invalid provision shall be replaced by a valid provision reflecting - to the extent possible - the intent of the original provision.

10.4 Waiver

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

Section 11: Miscellaneous

Principal Investigator/Institute hereby confirms,

A. that he/she has never been subject to debarment proceedings indicted, convicted, or otherwise engaged in conduct for which a person can be debarred by law,

B. To have received a copy of the Investigator's Brochure and to be informed of its contents.

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

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The Investigator consents that his/her contact data, as well as information about the conduct of the Study, may be stored and processed for evaluation purposes during and after the completion of the Study by Accutest.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 20-Apr-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date **Dr. Usha kant Misra** **Co- Investigator:** Signature and Date **Dr. Jayantee Kalita**
3) INSTITUTE: For Signature and Date **Name & Designation: Dr. Rakesh Kapoor-Director**	

APPENDIX I

Financial Support for Investigator:

(a) **Total payment, compliance, completed patients, inclusion Criteria:**

Payment of remuneration will only be made under the condition that the Study is conducted in accordance with the Protocol, the Study documentation is complete and evaluable, can be verified from the subject medical files, and is submitted to Accutest at the stipulated points in time. Should these prerequisites not be fulfilled, the remunerations are forfeited, particularly for patients who are included in the Study despite non-compliance with the inclusion or exclusion criteria.

Unless expressly agreed otherwise in writing, total payment will not exceed the amount set out below.

For each evaluable patient who completes the study visits in accordance with the Protocol, GCP, and application regulatory requirement, Accutest will compensate the Investigator remuneration as specified in Appendix II.

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Payments for any costs not expressly specified herein, including but not limited to hospital overhead fees, staff costs, pharmacy fees, other tests,(if applicable) and travel costs, must come from the per patient enrolment fee.

(b) Payments will be made based upon the completed CRF/eCRFs collected by Accutest

(Please refer Appendix II for payment detail).

(c) Pro rata temporis payment

Should the Study be prematurely discontinued, the remuneration will be calculated on a pro rata temporis basis. For patients who do not complete the Study, remuneration may be paid on pro rata temporis basis. Payment will include only those patients participating in the Study whose date of joining the Study is not later than the date of the premature termination of the Study.

(d) Protocol violators, exclusion

For Protocol violators due to missed or delayed visits or in the event of a violation on the part of a patient of a Protocol resolution or the Regulations for Good Clinical Practice, no compensation will be paid for that patient /payment may be made at Accutest's sole discretion.

(e) Income tax

All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. Accutest will deduct the tax at the time of making payments unless a valid certificate (Form 15 AA -- for no TDS) from tax authority is made available in advance.

(f) Payment details

Accutest, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payees through A/C Payee Cheque as agreed by all signatories. Full of the grant shall be paid to the PI/ institute according to the payment milestones provided in APPENDIX II.

PI/ Institute payment
Payee Name: Director Research Account, SGPGIMS, Lucknow
PAN number: AAAJS3913N
GST Number: NA

Note:

1. Provide legible scan/photocopy of the PAN cards at the time of the signing of this agreement
2. All local investigations (local lab tests, CT scans,any diagnostic assessments etc.) would be done to the payee mentioned for "PI/ institute payment" without deducting TDS. (A separate bill for patient payment should submitted).

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

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Executive Registrar
SGPGIMS,Lucknow

PI Name: Dr. Usha Kant Misra Site Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Protocol Number: E2007-M091-508

1) ACCUTEST: For Accutest Research Laboratories (I) Pvt. Ltd: Signature and Date 20-Apr-2018 **Mr. Rajendra Talete, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date 17/18 **Dr. Usha kant Misra** **Co- Investigator:** Signature and Date 17/18 **Dr. Jayantee Kalita**
3) INSTITUTE: For Signature and Date **Name & Designation: Dr. Rakesh Kapoor- Director**	

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APPENDIX II

Visit	Amount(INR)
Screening	8000
Visit 1 (Enrollment)	3800
Visit 2 (Month 1)	3500
Visit 3 (Month 2)	3500
Visit 4 (Month 3)	3500
Visit 5 (Month 4)	3500
Visit 6 (Month 5)	3500
Visit 7 (Month 6)	3500
Total PI Grant (a)	32800
Institutional overhead (25%) (b)	8200
TOTAL (a+b)	41000
TDS 10% (c)	4100
Grand Total (a+b+c)	45100
TOTAL PI GRANT	45100

Payment Details & Milestone:

1. Principal Investigator Fees will be **INR 32800 /-** per completed patient (Including Clinical Research Coordinator payment and excluding institutional overhead and goods and service tax and/or other taxes if applicable). The taxes may be revised and shall be applicable as per the Government norms from time to time.

   All local investigations (local lab tests, CT scans,any diagnostic assessments etc.) will be paid to the payee mentioned for "PI/ institute payment"on Actuals on Production of the Bills/Invoice/Proof.

   CRC payment of INR 16000/- per month will be adjusted by the PI from the PI grant. The PI grant of INR 45100/- per patient is inclusive of CRC payment.

The above payment also includes following charges:

a) Investigator(s) and other team members fees

b) Stationary, cupboard, courier, telephone, fax, internet and electricity bills, etc.

c) Patient recruitment

d) Electronic Case Report Form/Case Report Forms (CRF/ eCRFs) completion and correction

e) Data Clarification Form (DCF) resolution

f) Consultation charges

g) Document archival

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2. Ethics Committee fee will be paid on actual on the production of Bill/proof/invoice.
3. Institutional Overhead will be paidon production of Bill/proof/invoice
4. Per patient cost will be paid as mentioned above upon confirmation by site monitor of receipt of legible and accurately completed CRF/eCRF for a properly qualified subject.
5. INR 2000/- for screen failure patient.
6. Expense towards the medical management of serious adverse events will be made as per actual.
7. INR 1000/- for unscheduled patient visit.

The following are the milestone for the payments:

1. Every month from SIV, site personnel is supposed to raise invoice.
2. Invoice should be 90% of the SDV completed at the site by the ARL monitor.
3. Rest 10% of study payment will be made after study close out visit once all documents and activities (related to site) are completed.

NOTE: *If above milestones are not achieved than proportionate amount will be paid based on patient randomized and visit completed by the patient.*

Principal Investigator agrees that before incurring any of the aforesaid expenses it shall obtain prior written approval from the Sponsor. Sponsor will generally provide procedural material required by the protocol for the study. However, in the event Sponsor requires Principal Investigator to procure aforesaid items, it shall reimburse the actual cost incurred by Principal Investigator in connection in addition to that.

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) Accutest will pay a sum for every complete and evaluable patient.

b) A complete and evaluable patient is defined as follows.

- All procedures must be performed according to the protocol
- A patient will only be included according to the inclusion/exclusion criteria
- All data are documented completely and accurately

c) All payments will be on a pro rata basis as mentioned in budget above. For patients who do not complete (early termination, drop-out. etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit, then an equivalent amount mentioned in the above budget will be deducted

d) An invoice will be generated/ requested for payment on a monthly basis according to the actual work performed (after source data verification and CRF/eCRFs review for completed visits). An invoice will be generated/ requested according to days completed by the patient as specified above.

e) If the patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without a waiver, if applicable), then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

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f) Patient conveyance/ compensation will be paid by Accutest on behalf of the Sponsor and is included in the budget as mentioned The TDS will not be deductedon payment released for patient compensation.

g) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

h) If the trial terminates prematurely, any payments made by Accutest exceeding the amount earned will be promptly refunded to Accutest (minus Ethics Committee fees, and patient conveyance/compensation).

i) Payment would be done on the basis of invoices generated by the site in consultation with site CRA on every monitoring after checking the CRF/eCRF completion.

NOTE: Site should generate a monthly invoice and should consider completed milestone from above at the time of invoicing.

1) ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date Rajendra Talele 20-Apr-2018 Mr. Rajendra Talele, Head- Clinical Development Services	Signature and Date 14/4/18 Dr. Usha kant Misra **Co- Investigator:** Signature and Date 27/4/18 Dr. Jayantee Kalita

3) INSTITUTE:

Signature and Date

20/4/2018

Name & Designation: Dr. Rakesh Kapoor-Director

Initial (ACCUTEST): Inital (PI) Initial (INSTITUTE):

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