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Unique Doc. Reference	:	SUBIN-UPUP1426760403130540109200V
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
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Stamp Duty Paid By	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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NOTARY VIJAY KUMAR DWIVEDI, Adv. Regn. No. 22366 Lucknow (U.P.) India GOVT OF (INDIA)

NOTARIAL NOTARIAL

Please write or type below this line

NOTARY VIJAY KUMAR DWIVEDI, Adv. Regn. No. 22366 Lucknow (U.P.) India GOVT OF (INDIA)

SWORN & VERIFIED BEFORE ME

9/5/2023

VIJAY KUMAR DWIVEDI

PN: .....Advocate & Notary

Regn. 22366 Expiry 24-8-2025

Mob. 9918733222

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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SADAR TEHSIL, LUCKNOW

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
P.N. .....Advocate & Notary
Regn. 22566 Expiry 24-8-2025
Mob. 9518733222

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
PMo... Advocate & Notary
Regn. ... Expiry 24-8-2025
Mob. No 18733...

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.

SWORN & VERIFIED BEFORE ME

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

Sign 9/5/2023
VIJAY KUMAR DWIVEDI
P.N. ..... Advocate & Notary
Regn. ..... Expiry 24-3-2023
Mob. ...

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 set .neir hand by their signature below.

S. Nityanand
29.04.2023

On behalf of Dr. RMLIMS, Lucknow

Signature

Name

26/5/23

On behalf of SGPGIMS, Lucknow

Director

Signature

Name

Signature of Witnesses

1.

2.

9/5/23

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Government of Uttar Pradesh

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Certificate No.	:	IN-UP47987547985288V
Certificate Issued Date	:	01-Mar-2023 11:34 AM
Account Reference	:	NEWIMPACC (SV)/ up14780704/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14780704899586717200004V
Purchased by	:	DR RAM MANOHAR LOHIA INSTITUTE OF MEDICAL SCIENCES
Description of Document	:	Article 5 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. 31/6/2000
UTTAR

worn and verified
efore me

R.C. VERMA
Adv. & NOTARY
Lucknow U.P. INDIA
Regd. No. 31/6/2000

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. 2
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

R. C. VERMA
Adv. & NOTARY
Lucknow U.P. India
Regd. No. 31/64/2000

NOTARY * GOVT. OF UTTAR PRADESH

A. Nityanand

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

Director
Dr. Ram Manohar Lohia
Institute of Medical Sciences
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. 31/64/2000

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 pm

F.I.R
Sd
11/4/23

To,
HOD Urology & Renal Trans.
Comment's plea
18/04/23

Bajpai
Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Not for Medico Legal Purpose

MAPI ACCREDITED
Certified
EGAC Accredited CAB # 916305

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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)

IN-UP80936710186269V

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

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

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:-

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

Signature and Stamp
Of HOI of Hospital 1

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 Director

Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow-226014

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. Radhya Krishan Dhiman
Director
Executive Registrar
SGPGIS Postgraduate Institute
Sanjay Gandhi Post Lucknow 226014

Lt. Col. Varun Bajpai VSM
Executive Registrar
SGPGIS Postgraduate Institute

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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Government of Uttar Pradesh

e-Stamp

Signature
Acc Name:- Mohit Kumar
Acc Code:- UP14014104
Acc Add.:- Sector 32, Noida Mob-9650885051
Lic No.151 Tehsil & Distt. Dadri G.B. Nagar U.P.

Certificate No.	:	IN-UP94250596846400U
Certificate Issued Date	:	19-May-2022 01:20 PM
Account Reference	:	NEWIMPACC (SV)/ up14014104/ GAUTAMBUDDH NAGAR 1/ UP-GBN
Unique Doc. Reference	:	SUBIN-UPUP14014104799410681171061U
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 Duty Paid By	:	POSTGRADUTE INSTITUTE OF CHILD HEALTH
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEMORANDUM OF UNDERSTANDING

This MoU made on this _____ of _____ between Postgraduate 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. 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 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.

3.2. 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 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

6.1. "Intellectual Property" means and includes all copyright, all rights in relation to inventions (including patent rights), plant varieties, register and unregistered trade-mark, 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, than 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.

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

For and on behalf of PGICH, Patna	For and on behalf of SGPGIMS, Lucknow
Signature	Signature
Name: Dr RK Dhiman	Name:
Designation: Director	Designation:
Seal:	Seal:
Date:	Date:
Witnesses	Witnesses
1.	1.
2.	2.

This proposal is to be sent to the following Institutes-

1. Era'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 (U.P.) Regd. No. 7167

ATTESTED
BALKRISHNA DIXIT
Advocate (Notary)
R. No. 7167
GAUTAM BUDH NAGAR (U.P.)

19 MAY 2022

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of Uttar Pradesh

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Certificate No.	:	IN-UP38860504821601V
Certificate Issued Date	:	20-Feb-2023 11:37 AM
Account Reference	:	NEWIMPACC (SV)/ up14756204/ BAKSHI KA TALAB/ UP-LKN
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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

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.

CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES CENTRAL COUNCIL FOR RESEARCH IN AYURVEDIC SCIENCES CENTRAL COUNCIL FOR RESEA

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 Regd. 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 Ka/14, Near Majar [illegible] 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 Adv. & Notary Govt. Lucknow Reg.No. 31(85) GOVT. OF U.P. INDIA

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.

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
117/175 Ka/14, Near Maj...
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.

5.2 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.

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.

NOTARY Suresh K... Adv. & Notary ... Reg. No. 31(...) GOVT. OF U.P. INDIA

SIGNATURE ATTESTED 20/2/23

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

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. GM 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 (AT.)

Address : RARI, INS-106, SECTOR-25 INDIRA NAGAR, LUCKNOW

Witness

1. Signature Mohit

Name : Mohit Kumar Rai

Address: Clinical Immunology department, SGPGIMS, Lucknow -226014, U.P.

2. Signature Anurag Kumar Srivastav

Name : ANURAG KUMAR SRIVAST

Address : 2/255, Rajini Khand, Sharda Nagar, Lucknow U.P. -226002

NOTARY
Suresh Kumar
GOVT. OF U.P. INDIA

SIGNATURE ATTESTED

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

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Government of Uttar Pradesh

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Certificate Issued Date	:	13-Jun-2022 03:38 PM
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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)

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Please write or type below this line

Sworn & Verified
Before Me

13/06/2022

AKHILESH KUMAR
Statutory Alert
ADVOCATE & NOTARY
Distt. Lucknow
Tehsil Mohanlalganj

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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.
The onus of checking the legitimacy is on the users of the certificate.
In case of any discrepancy please inform the Competent Authority.

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
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 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**

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.

NOTARY ... GOVT. OF U.P. (IN)

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SGPGIMS,Lucknow

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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SGPGIMS,Lucknow

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.

Lt Col Varun Bajpai VSM
Executive Registrar
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.

Lt Col Varun Bajpai VSM
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: 21/06/22

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
Tehsil Mohanlalganj, Lucknow

Identified the deponent/executant/surety 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 वि. / लिपीक

14/11/2022

मुद्रांक विक्री नोंदवही अनु.क्रमांक 09057 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 S.C.Shinkar

दुस-या पक्षकाराचे नाव .. Dr. Kausik 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 400 60...

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



जोडपत्र 2

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ WC 674426

जिल्हा कोषागार कार्यालय ठाणे

जिल्हा कोषागार कार्यालय, ठाणे
17 NOV 2022
मुद्रांक प्रमुख लिपीक / लिपीक

मुद्रांक विक्री नोंदवही अनु.क्रमांक 090508 दिनांक 23 NOV 2022

दस्ताचा प्रकार ..... Agg .....

दस्त नोंदणी करणार आहे का ? :- होय / नाही

मिळकतीचे थोडक्यात वर्णन ..... No .....

मुद्रांक विकत घेणा-याचे नांव.....

हस्ते असल्यास त्यांचे नाव, पत्ता.....

सही .....

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)

(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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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

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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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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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Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	IN-DL88688219854101U
Certificate Issued Date	:	11-Jul-2022 04:20 PM
Account Reference	:	IMPACC (IV)/ dl777003/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL77700399883435712145U
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/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;

GIGH Representative Initials _____ Institution Representative Initials _____ PI Initials _____

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Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:
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.

(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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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. Instittution 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;

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(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

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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Executive Registrar
SGPGIMS,Lucknow

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

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 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.

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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

Lt Col Varun Bajpai (SM)
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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(16)

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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SGPGIMS,Lucknow

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 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

भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

सत्यमेव जयते

INDIA NON JUDICIAL



महाराष्ट्र MAHARASHTRA ◐ 2021 ◐ BK 571462

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००९६
21 DEC 2021
सक्षम अधिकारी

श्री. सी. टि. आंबेकर

NOVARTIS HEALTHCARE PRIVATE LIMITED (First Part)

AND

Dr. Jayantee Kalita (Second Part)

AND

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

K. Mangamathi

Bajpai

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
Competent Authority
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: _____ 17 Jan 2022

Name: **Murugananthan K.**

Title: Country Monitoring Head

Date:

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____

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

Name: ***Dr. Jayantee Kalita***

Title: Principal Investigator

Date: 04 Feb 2022

By: _____ 10/2/22

Name: _____

Title: Institute Director

Date:

Prof. A.K. DHIMAN
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

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)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

FIRST AMENDMENT TO CLINICAL TRIAL AGREEMENT (43)

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

(71)

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

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

Title: Director

Date: 22/12/22

o/c
UCGd

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

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL



महाराष्ट्र MAHARASHTRA ◑ 2022 ◑ 30AA 420957

प्रधान मुद्रांक कार्यालय, मुंबई.
प.मु.वि.क्र. 6000099
3 NOV 2022
सक्षम अधिकारी

TITLE PAGE:

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

श्रीमती लता सांगळे

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		
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		

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS Lucknow

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.

APPENDIX

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CENTAUR PHARMACEUTICALS PVT. LTD. MUMBAI-56

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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-65

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Executive Registrar
SGPGIMS,Lucknow

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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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

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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 sire 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 muiticentric 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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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]

Lt Col Varun Bajpai VSM
Executive Registrar
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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 GO
Printed Name

ASSOCIATE DIRECTOR, CSU
Title

13 JAN 2023
Date

INSTITUTION

Signature 13/02/2023

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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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-KAKAGCSL0888967292774853V
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

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.

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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 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:

Lt Col Varun Bajpai VSM
Executive Registrar
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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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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: _____ 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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SGPGIMS,Lucknow

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

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

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-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...

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 Reg. 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 Ka/14 Near Main [illegible]

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. (India) Reg.No. 31(55)

SIGNATURE ATTESTED
SURESH KUMAR
Advocate & Notary Public
112/175 Ka/14, Near Mayur 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.

NOTARY Suresh Kumar OFU INDIA

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.

5.2 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.

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.

NOTARY Suresh K... Adv. & Notary Reg. No. 31(05)... GOVT. OF U.P.

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

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

NOTARY
Suresh Kumar
GOVT. OF U.P. (INDIA)

2. Signature

Name : DR. ANJALI BAIJNATH PRASAD
RESEARCH OFFICER (AT.)

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 SRIVASTAV

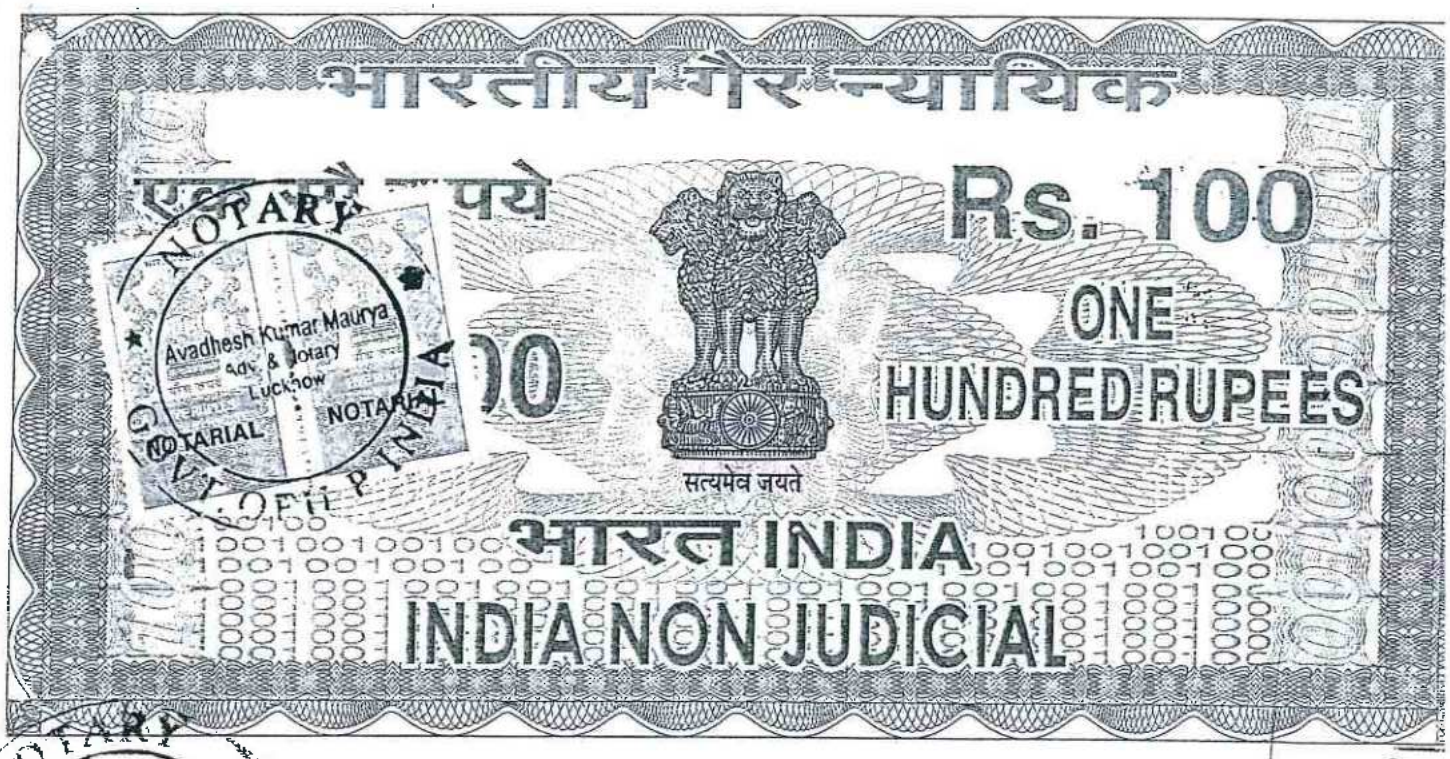
Address : 2/255, Rajini Khand, Sharda Nagar, Lucknow 226002

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

155



उत्तर प्रदेश UTTAR PRADESH

NOTARY Avadhesh Kumar Maurya Adv. & Notary Lucknow GOVT. OF U.P. INDIA

GH 142854

कोषागार लखनऊ से जारी

04 AUG 2023

कोष०/कोषा०/कोषाधिकारी आदेश कोषागार, लखनऊ

I identify the deponent who has signed before me

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;

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

24/8/23

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.

Avdhesh 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 Avadhesh 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.

NOTARY GOVT OF INDIA Avadhesh Kumar Maurya 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 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/

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 Avadhesh Kumar Maurya Adv. & Notary Lucknow GOVT. OF INDIA

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 U P INDIA

Signed by ----------

(Designation)

For and on behalf of The President of India

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

150

Signatures of two witnesses (from DBT):

Dr. Shubha R. Phadke
Professor & Head
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow-226014 INDIA

i.

Signed and stamped by:
(Dr. Shubha R Phadke)
Head of Department & Principal Investigator
SGPGIMS, Lucknow, UP (INDIA)

ii.

Signed and stamped by:
DEAN / DIRECTOR
For and on behalf of **SGPGIMS, Lucknow**

Lucknow (U.P.) India
S.G.P.G.I. Director

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. Moirangthem 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 1	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. 4,21,12,000.00

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.

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.

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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.

NOTARY Avadhesh Kumar Maurya Adv. & Notary Lucknow GOVT. OF INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Signature of Executive Authority of Institute/ University With seal:

S.G.P.G.I.M.S. Lucknow (U.P.) India Director

Date:

Signature and seal of Project Coordinator (If applicable) Not Applicable

Note:

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
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. 31/01/20

NOTARY
Avadhesh Kumar Maurya
Adv. & Notary
Lucknow
GOVT. OF U.P. INDIA

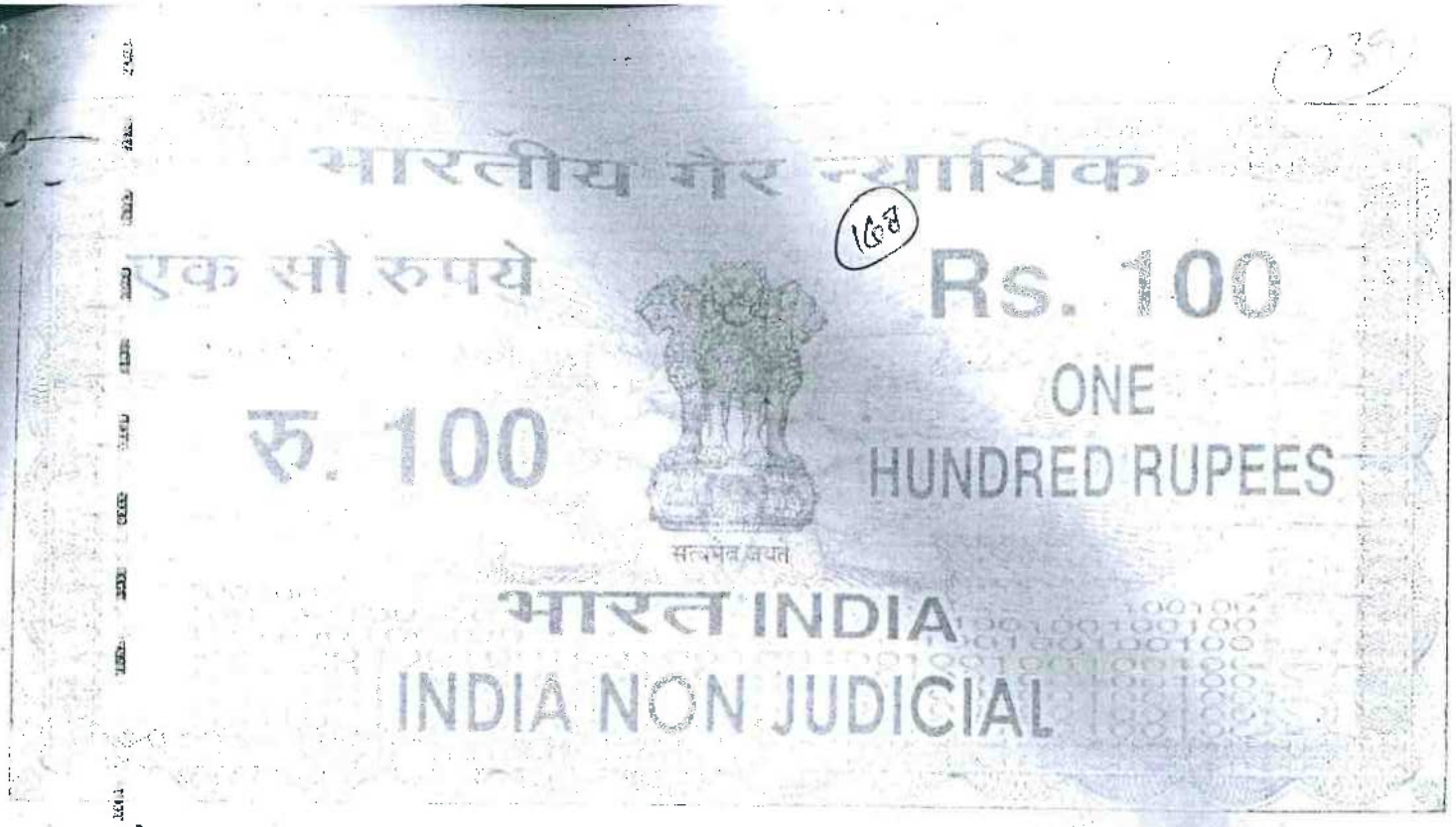
Dr. Moirangthem Amita
Associate Professor
Deptt. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
Lucknow-226014, INDIA

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*~~)----------, **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

क्रम संख्या 3829

स्टाम्प विक्रय की तिथि 22/05/2019

स्टाम्प क्रय करने का प्रयोजन Office work

स्टाम्प क्रेता का नाम व पूरा पता Director SGPGI Lucknow

Dr/ Shubha R. Phadke

स्टाम्प की धनराशि 100

राजा कुमार मिश्र

लाइसेन्स नं० 56

कलेक्ट्रेट कचेहरी, लखनऊ

लाइसेन्स की अवधि 31/03/2020 तक

167

Bajpai

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

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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.

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Received

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS, Lucknow

(159)

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(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.

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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

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,

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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

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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 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.

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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: 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

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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 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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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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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-KAKACRSFL0868120852930493U
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)

K.N.T.S.S.N. Branch, BDA Complex, Koramangala, Bangalore-34

Please write or type below this line

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**").

Bangalore

Statutory Alert

St John's Research Institute - Research Study Agreement Page 1 of 20

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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 access/excel). 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 or 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
Koramangala, Bangalore - 560 034, INDIA

For CBCI Society for Medical Education

Name: Rev. Dr. Paul Parathazham
Title: Secretary, CBCI - Society for Medical Education
Date:

SECRETARY
C.B.C.I. SOCIETY FOR MEDICAL EDUCATION
ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
SARJAPUR ROAD, 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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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.TMN20090000767KTK, T2031
SJMCH, Bengaluru - 560 034

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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)

सत्यमेव जयते

100

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 please inform the Competent Authority.

(23)

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.

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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:

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:

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Name: Asim Roy

Title: Director

Date: 01-03-2023

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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*

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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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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:-

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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-DLDL889803531579903464 42V
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.

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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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 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.

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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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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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 Parties.

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:

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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.

(Principal& Co-Investigator) (Institute/Hospital) (Sponsor)

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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** (B)

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 Pharmaceutical 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	21000
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	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 (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

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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 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	5500
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	33000
Institute Overheads (20%)	3110	3100	1800	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	10800	16800	16800	17400	16800	16800	49200	16800	16800	17400	16800	16800	16800	16872	360132
																Total grant per patient	300132

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SGPGIMS,Lucknow

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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SGPGIMS,Lucknow

(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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SGPGIMS,Lucknow

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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SGPGIMS,Lucknow

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

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INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Name of the Acc. HIMANSHU TIWARI
Acc Code UP14090604
Licence No. 518/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 write or type below this line

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 6A37C06CE12B44D...
Signature:	Amita Sharma
Name:	AGM-Legal
Designation:	18-Aug-23 | 10:59 AM IST
Date:	
For Dr. Amit Keshri	DocuSigned by: Dr. Amit Keshri 2611F0B4B0C446...
Signature:	
Name:	Dr. Amit Keshri
Designation:	Additional Professor, neuro-otology
Date:	17-Aug-23 | 10:11 PM IST

Bajpai

Lt Col Varun Bajpai VSM
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.

Lt Col Varun Bajpai VSM
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.

Lt Col Varun Bajpai VSM
Executive Registrar
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 2023

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.

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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:

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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(15)

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

(14)

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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(11)

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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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.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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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

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SGPGIMS,Lucknow

Novartis Healthcare Private Limited



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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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

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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 Protocol without Novartis' prior written consent;

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(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 identifications, medical notes, clinical observations, laboratory tests, and the receipt and

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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

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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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

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Executive Registrar
SGPGIMS,Lucknow

Name: **Dr. Narayan Prasad**

Principal Investigator

Novartis Healthcare Pvt. Ltd. Mumbai

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.

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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 Novartis regarding their financial interests in companies belonging to the Novartis group as well as those of their spouse and each dependent child

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

Healthcare

ANNEX 5: NOVARTIS PROFESSIONAL PRACTICES POLICY

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



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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Executive Registrar
SGPGIMS,Lucknow

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:

Lt Col Varun Bajpai VSM
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
58DDD4611A9C4FD481B9AF6EB0EE6756

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

Lt Col Varun Bajpai VSM
Executive Registrar
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		₹ 18,800.00	₹ 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	₹ 1,00,100.00
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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DocuSig

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

Record Tracking

Status: Original Holder: Srinidhi Shetty Location: DocuSign
7/27/2023 6:50:49 PM sshetty@biorasi.com

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
Electronic Record and Signature Disclosure: Accepted: 7/27/2023 10:55:47 PM 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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Executive Registrar
SGPGIMS,Lucknow

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.

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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, SALONI HEART FOUNDATION, between 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 successor) 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: MD, ACS IID
Contact No.: 7054444444
Email: psiid.up@gmail.com
Contact Address: 10B, C-Wing, Lok Bhawan, Lucknow

Witness:
Name: PANKAJ AGRAWAL
Designation: DIRECTOR (I-I)
Contact No.: 9839222050

For and on behalf of
M/s. SALONI HEART FOUNDATION

(AUTHORISED SIGNATORY)
Name: MRINALINI SETH
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Contact No.: +1-408-442-7163
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Witness:
Name: BRIJESH P. UPADHYAY
Designation: VOLUNTEER
Contact No.: 408.837.2725

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