To,
Dr. Sudeep Kumar
Professor
Department of Cardiology
SGPGI, Lucknow

Subject: Invitation for being a faculty in CCMH cycle 4

Dear Sir,

On behalf of Public Health Foundation of India (PHFI), Center for Chronic Disease Control (CCDC) and knowledge partners International Society of Hypertension (ISH) and British Hypertension Society (BHS), **a very warm welcome to the** Certificate Course in Management of Hypertension **(CCHQ) Cycle IV.** We would like to invite you to be a faculty to deliver this course and we thank you for agreeing to spare your valuable time to ensure its success. Your leadership, support and vision is of utmost importance to make this new initiative unique in the field of healthcare quality.

Brief overview of the course:

Certificate Course in Management of Hypertension (CCMH) is a joint certification program designed, implemented and delivered by Public Health Foundation of India in collaboration with academic partners Center for Chronic Disease Control (CCDC) and knowledge partners International Society of Hypertension (ISH) and British Hypertension Society (BHS). The educational grant for the same has been provided by ISH. This is an 8 modular course with the following objectives:

Primary objective
- To enhance knowledge, skills and core competencies of practicing Primary Care Physicians in management of Hypertension and its complications.

Secondary objectives
- To develop a standard teaching protocol and module for evidence-based learning on Management of Hypertension.
- To build a network of Primary Care Physicians and specialists in the field of Hypertension.
- To update practicing/primary care physicians with the latest advancements in the field of Hypertension.

Journey So far:
The CCMH initiative has been widely successful and over 2000 primary care physicians have been trained/enrolled till date. The first cycle of the course was launched on 24th of July 2016 across 25 centres in India in which 612 primary care physicians were trained. The second cycle of the course (Oct 2017 – July 2018) was implemented across 40 centres in India and a total of 658 primary care physicians were enrolled. A total of 175 primary care physicians were trained in the third cycle of the program (May-Dec 2019) across 10 centres in India.

State Government and Industry adoption
The state governments of Madhya Pradesh, Meghalaya, Manipur, Odisha and Tripura, and the Municipal Corporation of Kolkata to adopt the program for the capacity building of over 600 government medical officers. CCMH initiative implemented in Madhya Pradesh was selected as an innovative model at the

- 1 : 15 Class Ratio (Faculty and Participants)
- The candidate completing the certificate course successfully shall be awarded the certificate jointly issued by PHFI, ISH, BHS, CCDC and respective Regional Faculty.

The Minimum Eligibility for admission in course would be:
Medical graduate (MBBS) with minimum 3 years of clinical experience.
OR MD/DNB (Medicine or Internal Medicine or Family Medicine)
The course curriculum for the CCMH cycle-IV has been designed with inputs from the national expert members of the academic partners who are all eminent cardiologist and medicine specialists from across the world. Even though all efforts have been made to ensure that the information provided is accurate and up-to-date, you may occasionally come across instances where this is not so. We request you to point these errors and omissions to us so that we may rectify them in time for the next cycle.

Any curriculum is only good as the faculty that delivers it. We are fortunate to have the services of a panel of esteemed and experienced faculty, who represent the league of eminent cardiologists of this country. We feel that in your hands, the success of this course is assured.

With warm regards,

Dr. Arun P. Jose
Sr. Program Manager
Public Health Foundation of India

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

Certificate No.	:	IN-UP82270697794813T
Certificate Issued Date	:	10-Jun-2021 12:14 PM
Account Reference	:	NEWIMPACC (SV)/ up14238304/ MOHANLALGANJ/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP14238304523605231547 23T
Purchased by	:	DR UJJALA GHOSHAL WIFE OF DR UDAY CHAND GHOSHAL
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	DR UJJALA GHOSHAL WIFE OF DR UDAY CHAND GHOSHAL
Second Party	:	Not Applicable
Stamp Duty Paid By	:	DR UJJALA GHOSHAL WIFE OF DR UDAY CHAND GHOSHAL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF UNDERSTANDING

Between

JPN APEX TRAUMA CENTRE,
ALL INDIA INSTITUTE OF MEDICAL SCIENCES, NEW DELHI
(JPNATC, AIIMS)
And
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
UTTAR PRADESH

T s is the Memorandum of Understanding (MoU) entered **by JPN Apex Trauma Centre, AIIMS, New Delhi** (Prime Recipient) and **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Uttar Pradesh** ,Sub Recipient) **on 01-05-2021**, to specify the terms and conditions for the BMGF, USA funded project, titled ***"Infection Prevention and Control (IPC)- Capacity Building- Orientation Training for COVID-19 Preparedness and IPC for Healthcare Facilities"***, conducted by the JPN Apex Trauma Centre, AIIMS, New Delhi.

The terms of the Agreement are applicable to the project identified below conducted by the JPN Apex Trauma Centre, AIIMS, New Delhi.

Project covered under this Agreement

Name of the Project	**Infection Prevention and Control (IPC)- Capacity Building- Orientation Training for COVID-19 Preparedness and IPC for Healthcare Facilities**
Principal Investigator	Dr. Purva Mathur, Professor, Department of Laboratory Medicine, JPN Apex Trauma Centre, AIIMS, New Delhi.
ICMR Co-Ordinator	Dr. Kamini Walia, Scientist F, Division of Epidemiology and communicable Diseases, Indian Council of Medical Research, New Delhi
Collaborating Centre Principal Investigator	Dr. Ujjala Ghoshal, Professor, Depart nt of Microbiology, Sanjay Gandhi Postgraduate institute of Medical Sciences, Uttar Pradesh.
Funding Agency	Bill and Melinda Gates Foundation, [BMGF], USA.
Duration	2 years (1st of May 2021 to 30th of April 2023)

Background of the Project

COVID-19 caused by the novel coronavirus now known as SARS-CoV-2 (severe acute respiratory syndrome coronavirus-2), has spread worldwide with its first reported case in late December 2019 in Wuhan city of China. This rapidly growing pandemic has also affected many the healthcare workers. Presently, the clinical spectrum of disease is being defined including the potential for asymptomatic spread. So far, no specific treatment and prevention strategies like targeted antiviral drugs and vaccines, are available for COVID-19. Thus, we can only depend on the traditional public health outbreak response practices—isolation, quarantine, social distancing, and community containment.

On 30 January 2020, WHO declared the outbreak of COVID-19 as Public Health Emergency of International Concern and recommended that all countries should be prepared for containment, including active surveillance, early detection, isolation and case management, contact tracing and prevention of

On 30 January 2020, WHO declared the outbreak of COVID-19 as Public Health Emergency of International Concern and recommended that all countries should be prepared for containment, including active surveillance, early detection, isolation and case management, contact tracing and prevention of onward spread of COVID-19. On 28 February 2020, WHO raised the risk assessment for the COVID-19 outbreak internationally from "high" to "very high."

In order to protect our healthcare work force, such times call for appropriate training among healthcare workers, especially in populous countries like India. The World Health Organization (WHO) has defined four transmission scenarios for COVID-19:

1. Countries with no cases (No cases).
2. Countries with 1 or more cases, imported or locally detected (Sporadic cases).
3. Countries experiencing cases clusters in time, geographic location and/or common exposure (Clusters of cases).
4. Countries experiencing larger outbreaks of local transmission (Community transmission).

Technical guidance for government authorities, health workers, and other key stakeholders to guide response to community spread has been given by the WHO. Since, the number of cases in India as on 15th May 2021, has reached over 163 million, it becomes even more important to provide adequate training to the healthcare workers to deal with and contain the spread in case of future waves.

Thus, this project on COVID-19 preparedness and l. ' capacity building has been proposed. The aim of t proposed activities is to strengthen COVID-19 prevention across Indian health care facilities (HCF), with a focus on triage of symptomatic individuals, surveillance, infection prevention and control, and risk communication and community engagement, targeting high risk health care workers working directly with suspect and infected patients, many of whom will be severely ill, in healthcare facilities. These materials can also inform the general public. These efforts will support the maintenance of safe essential healthcare services by preventing healthcare-associated transmission of COVID-19 among healthcare workers (HCW) and patients.

All India Institute of Medical Sciences, New Delhi (AIIMS) will work with the ICMR, United States Centre for Disease Control (USCDC) and other AIIMS designated partners to develop and deliver these trainings. This work leverages the ICMR AMR network, and the AIIMS/USCDC supported IPC work within the AIIMS hospital acquired infection surveillance network and expands it to ensure appropriate IPC for COVID-19.

Responsibilities of Recipient (Sanjay Gandhi Postgraduate Institute of Medical Sciences, Uttar Pradesh)

- Nominate one person to liaise with AIIMS, New Delhi for workshop/training/review meetings related to the project and for feedbacks, reporting and troubleshooting as well as for financial matters.
- Should ensure trainings to maintain safe essential healthcare services by preventing healthcare associated transmission of COVID-19 among healthcare workers and patients.
- Identification and coordination of key leaders will be prioritized to optimize the use of all resources.
- Train staff of hospital to ensure that all they get prepared and ready to do fresher trainings in your region, in the future
- Provide sufficient IPC materials to training centers (in your region) tailored to COVID-19.
- Identify key staff needed to implement work and strengthen capacity and skills of key healthcare professionals.
- Would try to generate, apply and report accurate data of HAI and AMR to strengthen and expand the ability of healthcare systems.
- Recruitment of staff would be done as per the rules of Govt. of India. The positions and salaries would be as per ICMR guidelines.
- Provide technical and other assistance as and when required to the staff of hospital.
- Presentation of data in the annual/biannual meetings between various centres.
- The expenditure in each category (personnel salary/consumables) will not exceed the limit mentioned in the allotted budget.
- Ensure all procurements are done as per government of India's rules and regulations.
- All reports to be submitted to AIIMS in a timely manner.
- Financial audit as per requirement of BMGF will be conducted. Sites need to comply to audit requirements.

Responsibilities of JPN Apex Trauma Centre, AIIMS, New Delhi

- AIIMS will be responsible to work, implement and train for project related activities for staff of other networking sites.
- AIIMS will be responsible for development of training modules and SOPs as well as for conducting meetings.
- AIIMS would be responsible for data compilation, FAQ's and logs of the trainings conducted.
- AIIMS will be responsible to provide all IPC material tailored to COVID- 19.

- The existing HAI network will further receive the proposed orientation training for COVID -19 preparedness and IPC in two overlapping stages.
- Ensure the coordination of key leaders and partners to maximize the use of human resources and material resources.
- Primarily training in Bihar and U.P (7 to 8 Regional Trainers through TOT)
- Will identify additional centers for next phase as the network will expand and work closely with all centers.
- Targeted in person training as well as virtual IPC trainings will be conducted by AIIMS for regional hospitals focusing on triage and IPC
- The actual implementation of the training would be monitored through site-visits whenever possible. Till then, videoconferencing would be used at AIIMS for long distance trainings between site investigators and trainers.
- AIIMS would ensure timely collation of reports.
- AIIMS would be responsible for writing of manuscripts.
- AIIMS will provide all required technical and other assistance as and when required.

Financial responsibilities, Disbursement and Management of the Grant

Budget allocated to Sanjay Gandhi Postgraduate Institute of Medical Sciences, Uttar Pradesh

Budget Summary

Tentative Budget for two years:

Budget Statement
01.05.2021 to 30.04.2023

Head	Per Month	24 Months
Staff	In INR	In INR
JRF (31,000 + 24% HRA)	38,440.00	9,22,560.00
Junior Nurse	18,000.00	4,32,000.00
For Training Program/Stationary	50,000.00	
Overhead Charge (3%)	42,137.00	
Total Budget	**14,46,697.00/-**	

*(House Rent Allowance (HRA): JRF may be provided hostel accommodation wherever available and those residing in accommodation provided by the institute will not be eligible for drawing HRA. Wherever provision of hostel accommodation is not possible, HRA may be allowed as per Central Government norms applicable in the city/ location where they are working. The fellowship amount may be taken as basic for calculating the HRA)

Govt. of India Pay scales and Qualifications/ eligibility rules will apply. Each selected staff will work 100% of time for this project only.

Term and Termination

The initial term of this agreement has commenced on the 1st of May 2021 and shall continue till 30th April 2023, unless otherwise terminated in writing by either party as provided herein.

1. Either party may terminate the agreement upon 90 days written notice to the other party.
2. In the event of a material breach of any terms of this agreement, any party may terminate the agreement upon [illegible] written notice of any material breach of its terms with the other party and affording the breaching party 15 working days to rectify the breach to the noticing party's satisfaction.

Amendment

This agreement may be modified, cancelled, or renegotiated upon mutual consent, at any time, through an amendment signed by authorized representatives of the organizations.

This Agreement Document contains a total number of 9 pages.

In WITNESS WHEREOF, the parties have duly executed this Agreement, which shall become effective from May .

Authorized Signatories

Recipient Centre: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Uttar Pradesh	
Signature of PI Dr. Ujjala Ghoshal Professor & Head Dept. of Microbiology SGPGIMS., Lucknow-14	Signature of the Head of the Institute
Name: **Dr Ujjala Ghoshal** Designation: Professor & Head Address: Department of Microbiology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014 Uttar Pradesh Phone No: +91-7706997492 Email: ujjalaghoshal@yahoo.co.in	Name: **Prof. R.K. Dhiman** Designation: Director Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014, Uttar Pradesh Phone No: 91-522-668004-8, 668700, 668800, 668900 Ext: 2469/2009 Email: director@sgpgi.ac.in

Two Witnesses

Signature Dr. Chinmoy Sahu Associate Professor Dept of Microbiology SGPGIMS, Lucknow-14	Signature
Name: **Dr. Chinmoy Sahu** Designation: Associate Professor Address: Department of Microbiology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014 Uttar Pradesh Phone No: +91-8004904515 Email: sahu.chinmoy@gmail.com	Name: **Dr. Sangram Singh Patel** Designation: Assistant Professor Address: Department of Microbiology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow 226 014 Uttar Pradesh Phone No:+91-8005381619 Email: sangramsgpgi@gmail.com

उत्तर प्रदेश UTTAR PRADESH

EN 023759
5 JAN 2019

Memorandum of Understanding

Joint Research Project Agreement

This Joint Research Project Agreement ("Agreement") is made and entered on the date that appears on the signature page hereof ('Effective Date') between:

Sanjay Gandhi Postgraduate Institute of Medical Sciences, **Lucknow,** having its registered office at Raebareli Rd, Lucknow, Uttar Pradesh 226014 (herein after referred as SGPGIMS), which expression unless repugnant to the context or meaning hereof shall include its successors, administrators or permitted assignees.

and

Indian Institute Of Technology, Kharagpur ("IIT-KGP"), having its address at Kharagpur- 721302, India, which expression unless repugnant to the context or meaning hereof shall include its successors, administrators or permitted assignees.

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and IIT-KGP may be referred to herein individually as a "Party" and collectively as "Parties".

WHEREAS Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and

IIT-KGP had joined hands with each other by entering into a MoU dated 14th day of January 2020, to promote interaction and collaboration and carry out joint academic and research programme and also collaborative research projects.

AND WHEREAS Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow and IIT-KGP now propose to collaborate to form a nucleus for promoting research & development and creation of human capital in the fields of biomedical and clinical engineering and allied areas by exploiting the unique expertise, intellectual and infrastructural capabilities of both the parties, under the supervision of Dr. Sudipta Mukhopadhyay, Professor, Department of Electronics & Electrical Communication Engineering, Indian Institute of Technology Kharagpur, and project funded by external agencies. Dr. Sunil Kumar, Professor and HOD, Department of Radiodiagnosis, will be the contact person at SGPGIMS for this project and all other project initiated by him.

The project "Clinical Trial of the Content-based Image Retrieval-based Computer Aided Diagnosis (CBIR-CAD) for lung nodules and ILD patterns" was executed under the supervision of Dr. Sudipta Mukhopadhyay of Electronics & Electrical Communication Engineering Department, Indian Institute of Technology Kharagpur. This project was funded by DeitY. PGIMER was helping with critical data for the successful implementation of this project. In this project AIIMS Delhi has served as independent site to evaluate the tools developed in this project.

A new project proposal is under preparation and will be sent by Dr. Sudipta Mukhopadhyay on the continuation of the previous projects "Clinical Trial of the Content-based Image Retrieval-based Computer Aided Diagnosis (CBIR-CAD) for lung nodules and ILD patterns " to MeitY for funding. The project has been conceived with the expressed understanding that the medical data and interpretation of data, a critical inputs to the project, will be provided by experts of SGPGIMS who will also help the research in this area. This MOU will facilitate mutual cooperation and help us to make meaningful research and project proposals for funding.

1. **OBJECT OF THIS AGREEMENT.**

WHEREAS, SGPGIMS, and IITKGP are, now

- Recognizing the importance of research and development in the areas of biomedical science, engineering and technology,

- Appreciating the need for integrating the reservoir of highly qualified manpower in the fields of medical science and technology,

- Desiring to amalgamate their efforts by pooling their expertise and resources,

Now agree upon, to form a nucleus for promoting research & development and creation of human capital in the fields of biomedical and clinical engineering and allied areas by exploiting the unique expertise, intellectual and infrastructural capabilities of both the parties. General terms and activities are given as follows:

1. Exchange of research documents/findings on a case to case basis.

2. Visits of Faculty, Staff and Students to each other's campus (During visits, Faculty/ Staff/ Students would be provided appropriate accommodation in hostel/ guest houses).

3. Submission of joint projects seeking external support for collaboration in research & consultancy.

4. Sharing of laboratory, library and such other resources for the research teams on availability for bilateral applications without any financial burden on either party.

5. Agreement will be made for specific projects and activities separately.

6. Joint research project initiations and execution.

7. Any other activity may be included with mutual consent. Each organization will nominate one coordinator to oversee the functioning facilities under MOU.

2. CONFIDENTIALITY AND PUBLICITY.

a) During the TERM of the MOU, either party may provide to the other proprietary and confidential information that it considers essential for the conduct of any PROJECT at their sole discretion.

b) PROPRIETARY INFORMATION for the purposes of this AGREEMENT shall include all data, samples, discoveries, inventions, technical information, reports, know-how and other information related to and disclosed by either party to the other in any form of written materials and it shall be the duty of the receiving party to maintain its confidentiality.

c) The SGPGIMS and IITKGP agree to hold PROPRIETARY INFORMATION in confidence and to protect it against disclosure to the public and third parties. Accordingly SGPGIMS, and IITKGP shall employ protective measures fully commensurate with those used by them to protect their own trade secrets and other

confidential information from disclosure to the public and to third parties, but in no event less than the ordinary degree of care required by law to preserve the secrecy of information that under such law is deemed confidential. By way of example, such efforts will include the act of obtaining the execution of suitable confidentiality agreements from other parties and from other persons to whom such information is disclosed in the course of execution of the PROJECT and to retrieve the connected documents on completion of the project where given for the same.

d) The SGPGIMS, and IITKGP agree to use PROPRIETARY INFORMATION only for the specific project during the term of such project.

e) The SGPGIMS, and IITKGP agree not to copy, reproduce or otherwise reduce to writing any Part of PROPRIETARY INFORMATION except and only as may be reasonably necessary for the PROJECT.

f) INFORMATION disclosed by either party to the other in the form of results of the study / research originating from the projects under this agreement shall be treated as confidential and should not be shared with any third party, including any country, without the expressed permission of giving party.

g) Both SGPGIMS, and IITKGP will be free to publish research results out of projects under this agreement that does not contain proprietary information. In case it contains proprietary information decision to publish will be on a mutual consent basis so as to ensure protection of the related intellectual property.

h) The non-disclosure clause will survive three years from the date of expiry of this MOU.

3.**NON EXCLUSIVITY**: Nothing in this Agreement shall mean or shall be construed to mean that any of the Party is at any time precluded from having similar arrangements with any other person or third party, subject always to maintaining confidentiality obligations stated herein.

4.**LIMITATION OF LIABILITY**: IN NO EVENT SHALL EITHER PARTY HAVE ANY LIABILITY TO THE OTHER PARTY, END USERS OR ANY OTHER THIRD PARTY, FOR ANY INDIRECT, SPECULATIVE, SPECIAL OR CONSEQUENTIAL DAMAGES. NEITHER PARTY SHALL HAVE ANY LIABILITY UNDER THIS AGREEMENT BASED ON FAILURE TO ULTIMATELY COMPLETE THE ACTIVITIES ENVISIONED HEREIN. IN NO EVENT SHALL EITHER PARTY'S LIABILITY FOR MAINTAINING CONFIDENTIALITY UNDER THIS AGREEMENT EXCEED 70% OF THE TOTAL AMOUNT ACTUALLY PAID TO EITHER PARTY. The Parties also agree that this limitation of liability will only be in respect of this Agreement and will not in any event be applicable to any other specific agreement that may be executed between the Parties pursuant to this Agreement.

5.**INTELLECTUAL PROPERTY**: The Parties agree that all Intellectual Property, including but not limited to trade secret(s), copyrights, know how, or patents, owned or

possessed by either Party on the Date of signing of this Agreement shall remain the property of the said party. Intellectual Property, including but not limited to trade secret(s), copyrights, know how, or patents, created by either Party solely after the Date of signing of this agreement, as part of the performance under this Agreement shall remain the property of the said party exclusively. However, ownership and license rights in respect of joint intellectual property that may be developed or created jointly by the parties after signing of this Agreement as part of the delivery of services or performance under this Agreement, shall be jointly owned by the parties unless the sponsor suggest otherwise. The terms to exploit the joint intellectual property will be in accordance to the agreement with the sponsor.

The filing and maintenance of Joint IP generated shall be done jointly in the name of both the parties and the cost for the same shall also be borne jointly.

No license or any other right is granted or conferred under any Intellectual Property rights now or hereafter owned or controlled by either Party by implication, statute, inducement estoppel or otherwise, except of the basis of such agreements that may be specifically executed between the Parties.

6. **COSTS**:

There is no direct financial obligation on either Institute unless specifically agreed to. The financial requirement of individual institutions for joint project proposals will be separately mentioned in joint projects while submitting to funding agencies.

7.DURATION

This agreement shall come into effect on the day of the approval by both institutes with an initial duration of five years.

8.TERM, TERMINATION AND SURVIVAL: This Agreement shall commence on the Effective Date (the date of signing of this Agreement) and continue in full force and effect unless terminated by the Parties in writing. Either Party may terminate this Agreement at any time, with or without cause, by giving the other Party Thirty (30) days prior written notice. In such an event both Parties agree to fulfill their respective obligations which have accrued or arisen under the Annexure up to date of such termination. Within thirty (30) days after the termination of this Agreement, each Party shall prepare all items of the other Party in its possession for shipment and shall promptly deliver such material/ items to the other Party and shall erase all electronic copies of this or any other confidential information of the other Party. Effective upon the termination of this Agreement any permission as may have been granted to use the other Parties name, trademarks or trade names shall lapse. Termination of this Agreement by

either Party for any reason shall not affect the rights and obligations of the Parties accrued prior to the effective date of the termination.

9.CHOICE OF LAW: This Agreement shall be governed by and construed in accordance with the laws of India without reference to principles of conflict of laws and the parties irrevocably submit to the exclusive jurisdiction of the Courts in New Delhi for any action or proceeding regarding this Agreement.

10.**RELATIONSHIP**: The Parties agree that nothing in this Agreement should be construed as creating a partnership, employer-employee relationship, agency, franchise or joint venture, of any kind, between the Parties, and that neither Party will have the right power or authority to obligate or bind the other in any manner whatsoever, nor make any representations or warranties on behalf of the other, without the other Party's prior written consent in a separate writing.

11.**ENTIRE UNDERSTANDING, AMENDMENT ASSIGNMENT**: This Agreement sets forth the entire and final understanding of the Parties, and supersedes any and all oral or written agreements or understandings between the Parties, as to the subject matter hereof. No amendments or modifications shall be effective unless in writing and signed by authorized representatives of all the Parties. No right, duty or obligation under this Agreement may be assigned, delegated, factored or subcontracted in any manner by either Party without the prior written consent from the other Party.

12. **NOTICES**: All notices shall be directed in writing to the address aforesaid of the Parties.

The signature of the Parties below indicates their acceptance with the foregoing Agreement

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SIGNED FOR AND ON BEHALF OF IIT KHARAGPUR	SIGNED FOR AND ON BEHALF OF SGPGIMS Lucknow
Name:	Name: 05/02/21 Prof. R. K. DHIMAN Director Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
Designation: Dean (SRIC)	Designation: Director
(Authorized Signatory)	(Authorized Signatory)

WITNESSES

1) Signature	1) Signature
Name: Dr Sudipta Mukhopadhyay	Name: Dr. Sunil Kumar
Address: Dept. of E&ECE, IIT Kharagpur	Address: Department of Radiodiagnosis SGPGIMS Lucknow
2) Signature	2) Signature
Name: Dr. Debashis Sen	Name: Dr. Neeraj Jain
Address: Dept. of E&ECE, IIT Kharagpur	Address: Department of Radiodiagnosis SGPGIMS Lucknow

CONQUER CANCER®
THE ASCO FOUNDATION

2318 Mill Road, Suite 800
Alexandria, VA 22314
T: 571.483.1700
F: 571.366.9552
CONQUER.ORG

April 30, 2021

Sushma Agrawal, MD
Sanjay Ghandi Post Graduate Institute of Medical Sciences
SGPGIMS CAMPUS
Rae Bareily Road
Lucknow, 226014, India

Dear Dr. Agrawal:

On behalf of the Conquer Cancer Foundation of the American Society of Clinical Oncology ("Conquer Cancer") and the American Society of Clinical Oncology (ASCO), we congratulate you and your institution on being selected to receive a 2021 Conquer Cancer International Innovation Grant in the amount of $20,000 for your research titled, "A Randomized Study of Chemotherapy (CT) vs CT followed by Consolidation CTRT in Locally Advanced Gall bladder Cancers (LA-GBC) (RACE-GB Study)". The grant period commences July 1, 2021 and concludes June 30, 2022. Sanjay Ghandi Post Graduate Institute of Medical Sciences will receive the first year installment of the grant funds on or about July 1, 2021 by wire transfer.

Conquer Cancer will be distributing nationally a press release announcing all 2021 Conquer Cancer award recipients on May 28, 2021. We request that you and your institution refrain from making any public announcements regarding this honor until after this date so as to not precede Conquer Cancer's national announcement. Please share the release with the public affairs office at your institution to let them know you have received a grant from Conquer Cancer, and encourage them to share the release with local press and promote it in your institutional newsletter, website, and social media channels. We also request that your institution coordinate its own announcement with Vicki Kilpatrick at Vicki.Kilpatrick@asco.org

Please read and submit the attached Terms and Conditions with appropriate signatures by **May 17, 2021** through your account at Conquer Cancer's application portal (http://awards.asco.org) to confirm your acceptance of this award. If you are unable to accept this award for any reason, please contact Conquer Cancer as soon as possible at (571) 483-1700 or grants@conquer.org.

Congratulations again for being selected to receive this award. Best of luck in your research!

Sincerely,

Nancy R. Daly, MS, MPH
Chief Executive Officer, Conquer Cancer

Howard A. Burris, III, MD, FACP, FASCO
Chair, Conquer Cancer

Clifford A. Hudis, MD, FACP, FASCO
Executive Vice Chair, Conquer Cancer
Chief Executive Officer, ASCO

Lori J. Pierce, MD, FASTRO, FASCO
President, ASCO

(25)

CONQUER CANCER®
THE ASCO FOUNDATION

Terms and Conditions of the
2021 Conquer Cancer International Innovation Grant

The lead Principal Investigator set forth on the signature line below ("**Principal Investigator**") and the Grantee Organization ("**Recipient**") set forth on the signature line below agree to comply with these terms and conditions applicable to the 2021 Conquer Cancer International Innovation Grant (the "**Award**") as set forth herein ("**Terms and Conditions**"). These Terms and Conditions include the 2021 Conquer Cancer International Innovation Grant Request for Proposals dated September 9, 2020 and all forms and instructions of the Conquer Cancer Foundation of the American Society of Clinical Oncology ("**Conquer Cancer**") relating to the Award, which are incorporated into these Terms and Conditions by reference. Principal Investigator and Recipient agree to comply with these Terms and Conditions throughout the Award Period.

Definitions

A. The "**Research Project**" is the clinical research project described in the Recipient's grant proposal and approved by Conquer Cancer: A Randomized Study of Chemotherapy (CT) vs CT followed by Consolidation CTRT in Locally Advanced Gall bladder Cancers (LA-GBC) (RACE-GB Study).

B. The "**Award Period**" starts on July 1, 2021 and ends on June 30, 2022.

C. The "**Award Total**" shall be up to 20,000 United States Dollars, paid in two installments of up to $10,000, on or about July 1 2021 and January 1, 2022, subject to compliance by Principal Investigator and Recipient with these Terms and Conditions. Payment of the second installment is dependent on Recipient's satisfactory submission of the six-month progress report and financial report, and satisfactory research progress during the first reporting period.

D. The "**Announcement Date**" is May 28, 2021, the date on which Conquer Cancer will announce the Award and other recipients of Conquer Cancer awards.

E. The "**Required Acknowledgement**", to be used as described in paragraph 52 of these Terms and Conditions, is "This work was funded by a Conquer Cancer International Innovation Grant. Any opinions, findings, and conclusions expressed in this material are those of the author(s) and do not necessarily reflect those of the American Society of Clinical Oncology® or Conquer Cancer®."

Certifications, Representations, Warranties, and Covenants

(1) Recipient and Principal Investigator each certify that to the best of their or its knowledge, the information provided in its Award grant proposal (including the Letter of Intent) is complete and true. Recipient and Principal Investigator each agree to promptly notify Conquer Cancer of any changes to the information provided in the grant proposal.

(2) Recipient and Principal Investigator agree to comply with all applicable laws and regulations, including human subjects research, privacy, tax, humane care and use of laboratory animals, and laboratory safety laws. Award funds must be expended in accordance with United States laws and regulations addressing foreign corrupt practices and economic and trade sanctions, including those administered by the U.S. Treasury Department's Office of Foreign Assets Control (OFAC). By way of illustration but not of limitation, Recipient and Principal Investigator shall ensure that no Award funds are paid to any person included on the OFAC list of Specially Designated Nationals and Blocked Persons (available on the OFAC web site at http://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx). Award funds will be expended in accordance with all applicable anti-terrorist laws and executive orders, including financing and asset control laws.

(3) The Recipient and Principal Investigator agree that the Award is for scientific and educational purposes. Award funds will not be used for lobbying or political activities and will be used consistent with the purpose of the Award as stated in 2021 Conquer Cancer International Innovation Grant Request for Proposals.

General Requirements

(4) The Principal Investigator will be an active-status member of the American Society of Clinical Oncology (ASCO) throughout the Award period.

(5) The Principal Investigator will be a citizen or permanent resident of a country defined by the World Bank as low-income or middle-income, and currently residing in that country.

(6) The Principal Investigator will be affiliated with the Recipient.

(7) The Award will fund only the Research Project.

(8) The Recipient will be an organization with a charitable purpose registered as a not-for-profit with the relevant national authority or is a government agency. The Recipient will administer the grant funds for the sole purpose of the Research Project.

(9) The Recipient will be located in a country categorized by the World Bank as Low-Income, Lower-Middle Income or Upper-Middle Income.

(10) The Recipient has been operating for at least one full year, has an acceptable management structure and processes in place, and will be solvent with or without the support of the Award.

(11) The Recipient has experience in carrying out activities with tangible outcomes.

(12) The Principal Investigator and Recipient will require and ensure that all members of the research team relating to the Research Project will comply with these Terms and Conditions.

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Award Period

(13)The Principal Investigator will not be absent from participation in the Research Project or from the Recipient for extended periods of time during the Award Period, such as for a sabbatical leave or leave of absence, without prior written approval from Conquer Cancer. The Principal Investigator may request that the Award Period be delayed with a start date that begins up to six months after the published start date indicated in the Request for Proposals, which request will be approved or disapproved by Conquer Cancer in its sole discretion.

Responsible Conduct of Research

(14)The Research Project will be conducted according to the highest scientific and ethical standards and in compliance with all applicable laws and regulations and with the policies of the Recipient, including with respect to Recipient's conflict of interest policies and procedures. To the extent policies of the Recipient conflict with these Terms and Conditions, these Terms and Conditions will prevail.

(15)The Principal Investigator will provide evidence of permission to conduct human subjects research in the host country to Conquer Cancer prior to commencing research on human subjects, if applicable.

(16)The Principal Investigator will provide evidence of approval for the use animals in research in the host country to Conquer Cancer prior to commencing research on animal subjects, if applicable.

Funds: Payment and Use

(17)The Award funds will be paid to the Recipient in United States Dollars by wire transfer.

(18) The Award will be used solely as detailed in the Research Project (including the grant proposal and budget).

(19) Award funds must be maintained in a separate fund dedicated to the charitable purpose of the Award. Such a separate fund may be either 1) a physically separate bank account restricted to the described charitable purpose, or 2) a separate bookkeeping account (limited to the described charitable purpose) maintained as part of Recipient's financial records.

(20) No more than 5% of total costs will be applied to overhead or indirect costs of the Recipient in administering the Research Project.

(21) Award funds may not be used to pay for: ASCO Membership Fees; fees for courses or classes; costs for proposal development for additional funding; travel to the ASCO Annual Meeting or other international congresses or conferences; political campaigns; direct donations, grants, or scholarships to individuals; lobbying; bribery; illegal activity; or any costs that are not directly

related to the Research Project. No funds should be allocated to travel unless it is directly related to the Research Project itself.

(22) Award funds will not be used for expenditures incurred prior to the first day of the Award Period or after the last day of the Award Period. No additional expenses may be paid from Award funds after Conquer Cancer has received the Principal Investigator's final expenditure report or after any unexpended funds have been returned to Conquer Cancer, which must be provided in accordance with paragraphs 56 and 57.

(23) At the end of the Award Period, any unexpended funds and any funds expended inconsistent with the Research Project will be returned to Conquer Cancer.

(24)If the Research Project included budgeted subcontracts to other institutions, Principal Investigator will be responsible for obtaining expenditure reports and progress information annually, in concordance with the reporting schedule set forth herein. All consortium and contractual agreements must be pre-approved by Conquer Cancer and will be subject to and will comply with these Terms and Conditions. Principal Investigator will ensure that the Research Project is conducted in compliance with these Terms and Conditions.

(25)Principal Investigator may not subcontract with a new third party without written approval from Conquer Cancer. A request to reallocate the budget will be submitted to Conquer Cancer through its application portal (see Submission of Change Requests) for approval and will include a description of the work to be performed by the third party, reason for contracting with the third party, and a complete budget for the third party including revisions to the original budget categories. All contractual agreements will be subject to and will comply with these Terms and Conditions.

Submission of Change Requests

(26) All change requests related to the Award must be made through Conquer Cancer's application portal (awards.asco.org).

Requests for Budget Changes or Extensions

(27)The Principal Investigator may not move funds between budget categories or into new budget categories without prior written approval of Conquer Cancer. Budget changes must be consistent with the budget guidelines. The budget limit on indirect costs will be strictly followed and cannot be adjusted.

(28)Budget changes will be approved in writing by Conquer Cancer before expenditure of funds. The Principal Investigator will submit a re-budget request with a detailed justification of the proposed change through the application portal. The re-budget request must be made during the Award Period.

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(29)Any request for a no-cost extension must be made through the application portal at least 90 days prior to the expiration of the Award Period. Requests received after the last day of the Award Period will not be accepted and will automatically be disapproved. No cost-extensions of up to six months may be approved by Conquer Cancer in its sole discretion. Conquer Cancer may approve up to a maximum of three no-cost extensions.

(30)Requests for a six month no-cost extension require a no-cost-extension request submission through the application portal, an updated expenditure report and progress report, and a detailed explanation of why the request is being made. Requests will only be approved if they pertain to the Research Project. Conquer Cancer will approve or disapprove the request at its discretion.

(31)If a no-cost extension is granted by Conquer Cancer, the Principal Investigator will submit additional progress reports and financial expenditure reports every six months during the extension term.

Change of Personnel

(32)If the Principal Investigator desires to take a leave of absence from the Research Project for any reason during the Award Period, the Principal Investigator will submit a request in writing to Conquer Cancer to allow one of the co-investigators on the Research Project, who must be affiliated with the Recipient, to lead the Research Project. Subject to Conquer Cancer's written approval and in Conquer Cancer's sole discretion, the Award may be transferred to a co-investigator of the Research Project provided arrangements satisfactory to Conquer Cancer are implemented to continue the Research Project. Among other things, the co-investigator will be an active-status ASCO member throughout the remaining Award Period and will agree to comply with these Terms and Conditions. Conquer Cancer will approve or disapprove the request at its discretion.

(33) If the Principal Investigator is unable or not permitted to transfer the Award to a co-investigator, the Principal Investigator and the Recipient will relinquish the Award and any unexpended funds and funds expended inconsistent with the Research Project will immediately be returned to Conquer Cancer.

(34) Changes in co-investigators listed on the Research Project require prior written approval from Conquer Cancer. A written request, including justification for the change and the biosketch of the proposed new co-investigator, must be submitted prior to the investigator joining the Research Project team.

Changes in Research Focus

(35)Changes in the specific aims of the Research Project will not be allowed without prior written consent from Conquer Cancer. Any request for changes in the specific aims of the Research Project must be made through the application portal prior to performing any changes to the Research Project. Conquer Cancer will approve or disapprove the request at its discretion.

(36) Major changes in research design require prior written approval from Conquer Cancer. A request must be submitted by the Principal Investigator through the application portal prior to performing any aspects of any newly designed study. Examples of a major change include, but are not limited to, studying a different patient population than originally proposed or studying a different therapeutic than originally proposed.

(37) Minor changes in research methodology are not subject to prior approval by Conquer Cancer, but must be explained and justified by the Principal Investigator in the progress report.

Change in Recipient

(38) If the Principal Investigator accepts an appointment or new employment at another institution or organization during the Award Period, the Principal Investigator is not permitted to transfer the Award to a new Recipient. If the Principal Investigator and the Recipient are unable to fulfill the requirements of the Award, they must relinquish the Award and any unexpended funds and funds expended inconsistent with the Research Project will be returned to Conquer Cancer.

Program Reporting

(39) Throughout the Award Period, the Principal Investigator will submit expenditure reports and progress reports, including information about all subcontractors, regarding the Research Project through the application portal as directed in Exhibit A. It is the responsibility of the Principal Investigator to submit the reports in a timely manner. Conquer Cancer may contact appropriate persons connected to the Research Project to ensure the progress reports and expenditure reports are received as required. Principal Investigator and Recipient will comply with the then-current procedures of Conquer Cancer regarding submission of progress and expenditure reports.

(40) Noncompliance with any of these Terms and Conditions, including failure to submit progress or expenditure reports, may result in the withholding of payment on this Award or other awards of Conquer Cancer in effect at the Recipient, or on Conquer Cancer awards that may be awarded in the future, or such other action deemed appropriate by Conquer Cancer.

(41) Any unobligated balance remaining at the end of the Award Period or any extension term must be returned in full to Conquer Cancer along with the Final Expenditure Report by wire transfer. Wire transfer details are as follows:

Conquer Cancer, the ASCO Foundation
Bank – BB & T
ABA / Routing Number (WIRES) – 051404260
Swift Code: BRBTUS33
Account Number – 0000159760723
Reference Information: (Principal Investigator Name, 2021 International Innovation Grant)
BANK ADDRESS:

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BB & T
8200 GREENSBORO DR
MCLEAN, VA 22102
TEL: 703-442-5562

Post-Award Reporting Obligation

(42)The Principal Investigator is required to submit a post-Award report through the application portal one year after the Award end date as directed in Exhibit A. It is the responsibility of the Principal Investigator to submit the report in a timely manner.

(43) The Principal Investigator will respond to Conquer Cancer's requests for information following the Award Period and may be requested to update their information on the application portal. The Principal Investigator understands that this obligation survives the Award Period and that they have an ongoing obligation to provide this information.

(44) Conquer Cancer reserves the right to include information relating to the Award in its periodic reports, annual reports, awardee directory, publicly accessible databases of privately funded grant awards, or in any other materials issued by or on behalf of Conquer Cancer or Conquer Cancer's affiliates.

Recordkeeping and Audit

(45)The Recipient will record receipt of the Award funds and any Award Research Project expenditures in such a form as to enable Conquer Cancer to verify that the Award funds were expended for the stated purpose of the Award. All pertinent records, including invoices, purchase orders, worksheets supporting allocations, and copies of reports submitted to Conquer Cancer will be retained by Recipient for at least three (3) years after either the end of the Award Period or the expenditure of all Award funds, whichever is later.

(46)Conquer Cancer or its designated agent will have the right to request and receive from the Recipient or Principal Investigator copies of any and all documents, files, or records related to the Award at any time during or after the Award Period. This right includes, but is not limited to the right to audit such documents, files, and records or have them audited during or after the Award Period. If as a result of an audit, Conquer Cancer reasonably concludes that Award funds were utilized for purposes other than the Research Project, Conquer Cancer will be entitled to a refund of such funds.

Publications and Other Public Release of Results

(47) Conquer Cancer strongly encourages Principal Investigator to submit the results of Research Project for publication or other public release. In the event the Principal Investigator's results are published or otherwise publicly released either during or after the Award Period, the

Principal Investigator will provide Conquer Cancer with a copy of such publication or public release. All publications and public releases will include an acknowledgment of Conquer Cancer (see Public Announcements and Acknowledgments).

(48) Conquer Cancer supports the widest possible dissemination of funded research results. Principal Investigator is highly encouraged to publish in scientific journals that will provide public access to the research findings no later than twelve months after the date of publication.

Fee Waivers for ASCO Journals

(49) Principal Investigator will receive a full waiver of the flat submission fee to the *Journal of Clinical Oncology* (JCO) for submission of an article on the results of the Research Project for publication in the JCO. Principal Investigator shall clearly state, in the cover letter and on the title page, that the Research Project was supported by the Award and funded by Conquer Cancer. Any submission from Principal Investigator to the JCO shall be reviewed using the JCO's then-current established review process. Principal Investigator and Recipient acknowledge and understand that there is no guarantee that any submission will be accepted for publication in the JCO. Principal Investigator is not eligible for waiver of submission fees for submission of an article that does not directly focus on the results of the Research Project.

(50) Principal Investigator will receive a full waiver of the Open Access Article Publishing Charge to the *Journal of Global Oncology* (JGO) if the manuscript is accepted for publication in the JGO. Principal Investigator shall clearly state, in the cover letter and on the title page, that the Research Project was supported by the Award and funded by Conquer Cancer. Any manuscript submitted by Principal Investigator will be reviewed using the JGO's then-current established review process. Principal Investigator and Recipient acknowledge and understand that there is no guarantee that any submission will be accepted for publication in the JGO. Principal Investigator is not eligible for waiver of the Open Access Article Publishing Charge for submission of an article that does not directly focus on the results of the Research Project.

Public Announcements and Acknowledgments

(51) Conquer Cancer anticipates that the Recipient may wish to make a public announcement of this Award. The Recipient will submit to Conquer Cancer any proposed announcement, press release, or other public statement by the Recipient relating to the Award, prior to release, and will coordinate the release of such public announcement, press release, or statement with Conquer Cancer. A copy of any press release, announcement, or public statement must be provided to Conquer Cancer.

(52) The Principal Investigator and the Recipient will acknowledge the support of Conquer Cancer in all publications and presentations of the research funded by the Award. The Principal Investigator understands that all abstracts, publications, and presentations resulting from research supported by the Award will contain the Required Acknowledgment.

(53)The Principal Investigator is encouraged to use an emblem for the Conquer Cancer International Innovation Grant on posters, presentations, and similar items produced for scientific meetings and conferences. The emblem may be used with the acknowledgment language. The Principal Investigator can request this emblem by sending an email to grants@conquer.org

Intellectual Property Rights

(54) Conquer Cancer will have no intellectual property rights or other rights in or to data collected or scientific discoveries made through the Research Project funded by the Award. Conquer Cancer encourages its principal investigators and their grantee organizations to report to Conquer Cancer any inventions, discoveries, or intellectual properties that result from the support of the research.

Award Conclusion and Termination

(55) The Principal Investigator and Recipient will communicate immediately in writing to Conquer Cancer any intent to terminate the Award.

(56) Upon the earlier of the conclusion of the Award Term or the termination of the Award, all unexpended funds and any funds expended inconsistent with the Research Project will be returned to Conquer Cancer within 30 days. A final progress report and final expenditure report are also due within 30 days of the earlier of the conclusion of Award Term or the Award termination.

(57) Conquer Cancer reserves the right to terminate the Award, and these Terms and Conditions, if the Principal Investigator or Recipient: (i) does not comply with these Terms and Conditions (including the submission of progress and financial reports, as described under "Program Reporting"); (ii) does not make satisfactory progress towards the aims of the Research Project; (iii) requests a change to the Award as set forth in these Terms and Conditions and such request is not approved by Conquer Cancer; (iv) engages in gross negligence or willful misconduct in connection with the Research Project; or (v) in Conquer Cancer's sole judgment, becomes unable to carry out the purposes of the Research Project. If Conquer Cancer terminates the Award, the Recipient will repay Conquer Cancer within 30 days all grants funds unexpended as of the effective date of termination and all grant funds expended inconsistent with the Research Project.

Liability and Insurance

(58)Neither Conquer Cancer nor any of its affiliates assumes responsibility for activities supported by the Award. Principal Investigator and Recipient acknowledge complete responsibility for all aspects of the research, investigation, funding, and administration of and in connection with the Research Project. To the extent permitted by law, the Recipient will indemnify and hold

Conquer Cancer and its affiliates and all of their respective officers, directors, employees, contractors, members, and assigns harmless from and against any and all costs, losses, or expenses, including reasonable attorneys' fees, that the indemnified parties may incur by reason of the negligence or misconduct of the Recipient, the Principal Investigator, or any part of the research team related to the Research Project or any third party claim arising out of or in connection with the Research Project. If this indemnification is prohibited by the laws that govern the Recipient, then this provision will be deemed to be unenforceable and will have no force and effect.

(59) Recipient will maintain adequate liability and other insurance comparable to coverage held by institutions of similar size and nature, covering the Principal Investigator, employees, officers, and agents of Recipient during the Award Period. Upon request, Recipient will provide certificates evidencing its insurance coverage to Conquer Cancer.

Miscellaneous

(60) The provisions of these Terms and Conditions that, by their sense and context, are intended to survive the termination of this Award shall survive termination, including sections on Post-Award Reporting, Publications and Other Public Release of Results, Recordkeeping and Audit, Public Announcements and Acknowledgments, Intellectual Property Rights, and Liability.

(61) Recipient and Principal Investigator each agree that any personal data provided by them to Conquer Cancer pursuant to these Terms and Conditions will be provided in compliance with all applicable laws. With respect to any reports and other information provided to Conquer Cancer, Recipient and Principal Investigator each agree to seek consent or other lawful basis to provide such information to Conquer Cancer.

(62) No delay or omission by a party to exercise any right or remedy under these Terms and Conditions will be construed to be either acquiescence or the waiver of the ability to exercise any right or remedy in the future. Any waiver of any terms and conditions hereof must be in writing, and signed by the parties hereto. A waiver of any term or condition hereof shall not be construed as a future waiver of the same or any other term or condition hereof. In the event any part or provision of these Terms and Conditions is deemed unenforceable, void, or voidable, the remainder of the Terms and Conditions will remain in effect.

(63) These Terms and Conditions, including all exhibits and all materials incorporated by reference into these Terms and Conditions, constitute the entire agreement between the parties concerning the subject matter hereof, and supersede any prior oral or written agreements concerning the subject matter hereof. This Agreement may only be amended by a written agreement signed by the parties hereto. E-mail communication from Conquer Cancer, with or without a name and/or signature block, shall be considered a "written agreement" and shall constitute an amendment of this Agreement, except as specifically provided for in this Agreement.

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IN WITNESS WHEREOF, each party, by their signature or by signature of its duly authorized officer, has agreed to and accepted these Terms and Conditions.

Agreed and accepted by
Principal Investigator:

Signature

SUSHMA AGRAWAL
Principal Investigator
(Printed Name)

3/5/21
Date:

Agreed and accepted by
Recipient[1]:

Signature

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

Recipient Authorized Signing Official
(Printed Name and Title)
Sanjay Ghandi Post Graduate Institute of Medical Sciences

16/07/21
Date:

[1] *Must be signed by the Director or member of the Board of Trustees of the Grantee Organization*

Upload signed Terms and Conditions to your account at awards.asco.org by **May 17, 2021.**

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Exhibit A.
Reporting Deadlines and Requirements for the
2021 Conquer Cancer International Innovation Grant

Report Covers the Period of:	Required Report	Report Due Date
July 1, 2021 – November 30, 2021	Mid-Year Progress Update	December 15, 2021
	Mid-Year Expenditure Report	
July 1, 2021 – June 30, 2022	Final Progress Report	July 31, 2022
	Final Expenditure Report	August 31, 2022
July 1, 2022 – June 30, 2023	Post-award Progress Report	July 31, 2023

The Oriental Insurance Company Limited

(12)

This Document is Digitally Signed
Signer: arti mathur
Date & Time: Mr 21 4:32 AM
Location: INDIA

PROFFESSIONAL INDEMNITY -DOCTORS POLICY SCHEDULE

Policy No.	: 221113/48/2022/1074	**Prev. Policy No.**	: -
Cover Note No.	: -	Cover Note Date	: -
Insured's Code	: 131998106	Issue Office Code	: 221113
Insured's Name	: Dr. Sushma Agrawal (GSTIN:)	Issue Office Name	: CBO 4 LUCKNOW (GSTIN: 09AAACT0627R4ZU)
Address	: Type V/B-1, SGPGIMS Campus, Rae Bareilly Road, Lucknow LUCKNOW UTTAR PRADESH 226014	Address	: 134/135, SAHU PLAZA ALAMBAGH LUCKNOW UTTAR PRADESH 226005
Tel. /Fax /Email	: [redacted] noreply@doclandservices.com	Tel ./Fax /Email	: 0522 2450167 2450114 / 0 / gspal@orientalinsurance.co.in

Agent/Broker Details

Dev.Off.Code :
Agent/Broker :
Address :
Tel/Fax/Email :

Period of Insurance : FROM 18:14 ON 29/05/2021 TO MIDNIGHT OF 28/05/2022

Collection No. & Dt. : CC 1024900449 - 29/05/2021 GST INVOICE NO :092062123 UIN :0

Gross Premium : 160 GST : 28 Stamp Duty : .5 Total : 188

Co-insurance Details : NIL

RISK DETAILS

Name of the Doctor : **Dr. Sushma Agrawal**
Description of Profession : **MBBS MD Cancer Physician**
Indemnity Limit : **ONCOLOGISTS**

Any One Accident Rs . 1,00,000
Aggregate during the policy period Rs . 2,00,000

Location ID	Location Description
1	Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Rae Bareilly Road, Lucknow

Retroactive Date :

Add on Covers :

Total Sum Insured in words : Indian Rupees Two Lakhs Only
Total Premium in words : Indian Rupees One Hundred Eighty-Eight Only

The Insurance under this policy is subject to Warranties & Clauses :

Territorial Limits : Any where in India

In the event of a claim under the policy exceeding Rs. 1 lac or a claim for refund of premium exceeding Rs. 1 lac,the

Place : LUCKNOW
Date : 29/05/2021

IRDA-REGNO-556

For and on behalf of
The Oriental Insurance Company Limited

This is an electronically generated document (Policy Schedule).The Policy document duly stamped will be sent by post.

In case of any query regarding the Policy please call Toll Free No. 1800 11 8485 and 011 33208485.

Authorised Signatory

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ ZB 052583

प्रधान मुद्रांक कार्यालय, मुंबई.
प.मु.वि.क. ८०००००७
- 7 SEP 2021
सक्षम अधिकारी

CLINICAL STUDY AGREEMENT

This clinical study agreement ("Agreement"), effective as of 22-Sep-2021 (the "Effective Date"), is entered into by and among Medpace Clinical Research, LLC, with its principal office and place of business at 5375 Medpace Way, Cincinnati, Ohio 45227 and Medpace Clinical Research India Private Limited, 8th floor,office no.817,Rupa solitaire building, Millennium business park, Maharashtra, Thane-400710, India ("Medpace") , and Sanjay Gandhi Postgraduate Institute of Medical Sciences, a clinical research site with its principal office and place of business at Department of Medical Genetics, Main Hospital, Raebareli Road, Uttar Pradesh, Lucknow, 226014, India., ("Institution") and Dr. Shubha Phadke, having an address at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Department of Medical Genetics, Main Hospital, Raebareli Road, Uttar Pradesh, Lucknow, 226014, India ("Principal Investigator"). Medpace, Institution and Principal Investigator are sometimes collectively referred to herein as parties (the "Parties").

WHEREAS, Catalyst Biosciences, Inc., 611 Gateway Blvd., Suite 710, South San Francisco, CA 94080 ("Sponsor") is sponsoring a clinical study on the compound Factor VIIa, marzeptacog alfa (activated) [MarzAA] (the "Study Drug"), in accordance with Protocol No. MAA-304, titled "Phase 3 Study to Evaluate the Efficacy and Safety of Subcutaneous Marzeptacog Alfa (Activated) For On demand Treatment and Control of Bleeding Episodes in Subjects with Hemophilia A or Hemophilia B, with Inhibitors: The Crimson 1 Study" (the "Protocol"), and Institution possesses expertise in the conduct and performance of clinical studies. The performance of the Protocol shall be referred to herein as the "Study"; and

WHEREAS, Medpace is a contract research organization which has been contracted by Sponsor to manage and administer the Study; and

WHEREAS, Medpace desires that Institution and Principal Investigator participate in the conduct of the Study in accordance with the Protocol and the terms and conditions of this Agreement, and Institution and Principal Investigator desire to participate in the conduct of the Study in accordance with the Protocol and the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the foregoing and the mutual covenants and promises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1 SCOPE OF WORK AND COMPLIANCE WITH APPLICABLE LAWS.

Institution and Principal Investigator (as defined in the Principal Investigator section) shall perform the Study in strict compliance with the terms and conditions of this Agreement, any written instructions from Sponsor and/or Medpace, all generally accepted standards of Good Clinical Practice ("GCP"), the Protocol, and with all applicable local laws, Indian GCP and regulations governing the performance of clinical investigations. A copy of the Protocol has been provided to Institution and Principal Investigator and is hereby incorporated by reference, together with any and all amendments thereto, into this Agreement.

2 PRINCIPAL INVESTIGATOR

Principal Investigator will be responsible for the direction of the Study in accordance with applicable Institution policies, which Institution warrants and represents are not inconsistent with the terms of this Agreement and the Protocol. If, for any reason, he/she is unable to continue to serve as Principal Investigator and a successor acceptable to Institution, Medpace, and Sponsor is not available, this Agreement shall be terminated as provided in the Term and Termination section. Institution and Principal Investigator warrant and represent that Principal Investigator is fully qualified to conduct the Study and to serve in the capacity of Principal Investigator. Principal Investigator and all persons or entities who perform any portion of the Study ("Study Personnel") shall be employees or subcontractors of Institution and Institution shall be responsible for their compliance with the terms of this Agreement. Institution and Principal Investigator represent that neither Principal Investigator nor Institution are a citizen or resident of the United States, or a corporation or partnership that is and has been treated as a U.S. corporation or U.S. partnership, and that all payments received under this Agreement will be for services rendered outside the United States.

3 CONFIDENTIAL INFORMATION

3.1 "Confidential Information" means all information that is (a) provided by or on behalf of Sponsor or Medpace to Institution or Principal Investigator in connection with this Agreement or the Study, or (b) developed, obtained, or generated by Institution, Principal Investigator, or Study Personnel as a result of performing the Study under this Agreement (except for a Study subject's medical records), including, but not limited to, the Protocol, Study data, results, and reports from all sites conducting the Study. Confidential Information and all tangible expressions, in any media, of Confidential Information are the sole property of Sponsor or Medpace, as applicable.

3.2 Institution and Principal Investigator agree not to use Confidential Information for any purposes other than to conduct the Study. Institution and Principal Investigator agree not to disclose Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this section. Institution and Principal Investigator shall safeguard Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

3.3 The term Confidential Information shall not be deemed to include information that:

3.3.1 Is or becomes publicly available through no fault of Institution or Principal Investigator;

3.3.2 Institution and Principal Investigator can demonstrate they possessed prior to, or developed independently from, disclosure or development under this Agreement;

3.3.3 Institution or Principal Investigator receives from a third party which is not legally prohibited from disclosing such information;

3.3.4 Is appropriate to include in a publication pursuant to the Publications and Publicity section.

3.4 Unless Sponsor provides prior written consent, Institution and Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Institution or Principal Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by Applicable Law. Required disclosure of Confidential Information to the independent ethics committee ("IEC") and/or regulatory authority ("RA") is specifically authorized.

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

3.5 Is appropriate to include in a publication pursuant to the Publications and Publicity section.

Institution and Principal Investigator agree that Medpace may compile a database of information from Principal Investigator, Institution and Institution's personnel, for use in connection with the Study (including but not limited to feasibility questionnaires, CVs,

licenses, medical specialties, participation in clinical trials, financial disclosure forms) and/or may use this information for purposes related to its business. Institution shall have secured any necessary consents from its personnel to allow for this sharing of information and Principal Investigator hereby consents to such sharing of his/her information. Such information is used solely in connection with the initiation of studies and feasibility studies and is accessible only to the Sponsor of the respective study and personnel assigned to study management and for whom the information is needed in the performance of their duties (further described as "Authorized Personnel"). As some Medpace studies are being conducted worldwide, the personal information collected is available to Authorized Personnel who may be located in countries outside the country of origin. In order to provide for the protection of personal data, Medpace has established policies and procedures governing the security of and limited access to this data that are uniform throughout Medpace and its affiliates and comply with the applicable standards of personal data protection. When applicable, Medpace enters into data processing agreements with Sponsors in line with applicable data protection laws. The individuals' whose data is collected have a right to access, to modify, to rectify and to suppress their personal data, simply by requesting it to the attention of the Medpace Privacy Officer at privacy@Medpace.com, or to the following address: Medpace Privacy Officer, Medpace, Inc., 5375 Medpace Way, Cincinnati, Ohio 45227.

4 RECORDKEEPING

4.1 Instititution and/or Principal Investigator shall maintain all records, data, documents or information related to the performance of the Study until the later of:

4.1.1 Two (2) years following the date a New Drug Application is approved for the Study Drug that is the subject of the Study;

4.1.2 Two (2) years after the Investigational New Drug Application for such Study Drug is terminated or withdrawn; or

4.1.3 As defined by local laws and regulations.

4.2 At the end of such required retention period, neither Institution nor Principal Investigator shall destroy any such records until they have obtained Medpace's prior written permission to do so. Medpace will respond promptly to Institution's or Principal Investigator's requests to dispose of records.

4.3 Subject to the requirements of the Confidential Information section, following the end of the required retention period, Institution may retain in its possession an archival copy of Confidential Information that consists of any and all data, documents or information related to the performance of this Agreement solely as required for regulatory, legal, or insurance purposes.

5 ACCESS TO RECORDS AND AUDITS

5.1 Medpace and/or Sponsor shall have the right to inspect progress of the Study on the premises of Institution at reasonable times during the term of this Agreement. Medpace and/or Sponsor will notify Institution prior to any inspection of the date and time of the inspection. The representatives of Medpace and/or Sponsor may review and/or request copies of data derived from the Study, and Principal Investigator or Institution shall promptly provide such data. Principal Investigator and/or Institution will notify Medpace and/or Sponsor by telephone and

subsequently in written form, of any significant changes, including, but not limited to, changes in Study Personnel, Principal Investigator, or physical location, that occur during the Study.

5.1.1 Within twenty-four (24) hours after learning of any FDA, Drug Controller General Of India (DCGI) or other governmental or regulatory body (e.g., Institutional Review Board, Drug Enforcement Agency), regulatory inspections of which they become aware relating to the Study, Principal Investigator and/or Institution shall provide written notification to Medpace and Sponsor. Principal Investigator and/or Institution shall also provide a copy of any communications with the RA during and after inspection. Medpace and Sponsor shall have the right to be present at any such inspections and shall have the opportunity to provide, review, and comment on any responses that may be required. Further, Principal Investigator and/or Institution will provide in writing to Medpace and Sponsor copies of all materials, correspondence, statements, forms and records which Principal Investigator or Institution receives or obtains pursuant to this inspection.

6 COSTS AND PAYMENT SCHEDULE

In consideration of the proper performance of the Study by the Institution and the Principal Investigator under the terms of this Agreement and upon approval of Sponsor, payment will be made by Medpace or its designee to the payee ("Payee") designated in Schedule A appended hereto and incorporated herein by reference. Institution and Principal Investigator will accept payment from Medpace, or its designee, to the Payee as full consideration for services rendered. Once the designated Payees have been paid for the performance of the Study, neither Medpace nor Sponsor shall have any further obligation or liability whatsoever to pay Principal Investigator or Institution. All costs outlined on Schedule A shall remain firm for the duration of the Study, unless otherwise agreed to in writing by the Institution and Medpace. It is understood and agreed that no reimbursement will be provided by Medpace or Sponsor for subjects who are randomized into the Study in violation of the Protocol, or who do not conform to the Protocol's inclusion and exclusion criteria or for whom serious deviations from the Protocol are made. The budget contained in Schedule A is inclusive of all applicable taxes. Should any tax laws require withholding, the party legally responsible shall be liable for withholdings. Medpace, as Sponsor's payment agent, shall make payment to Payee under this Agreement from funds provided by Sponsor. Notwithstanding the foregoing, Medpace may issue a written amendment, signed only by Medpace, for the purpose of increasing the Study costs as described in the Schedule A.

7 TERM AND TERMINATION

7.1 This Agreement shall commence as of the Effective Date and, unless terminated earlier as provided for in this section, shall continue until the completion of the Study.

7.2 Institution and Principal Investigator may terminate this Agreement if Medpace materially breaches this Agreement and Medpace fails to cure the breach within thirty (30) days after receipt of written notice from a Party specifying in detail the nature of the breach. Medpace may terminate this Agreement at any time upon giving thirty (30) days' advance written notice to Institution and Principal Investigator. The Parties agree that in the event of a breach of this Agreement, the non-breaching Party shall be entitled to seek its expenses and attorney fees.

7.3 Medpace shall be obligated to pay Payee solely for those items set forth in the Schedule A that have been incurred prior to the date of notice of termination. Institution shall promptly refund

to Medpace or shall cause Payee to promptly refund all unearned advance payments made by Medpace under the Schedule A.

7.4 Upon completion or termination of this Agreement, in no event shall Medpace be obligated to pay any invoices submitted after the time period for submitting final invoices set forth in Schedule A has expired.

7.5 Upon completion or termination of this Agreement, Institution and Principal Investigator shall, upon Medpace's request, return or destroy all documents, information, and/or supplies, including, but not limited to, Study drug(s) and related devices, equipment, and any biological samples or other materials provided by Medpace or Sponsor for the conduct of the Study, to Sponsor or Medpace within thirty (30) days. If Medpace requests that such documents, information or supplies be destroyed, Institution or Principal Investigator, as applicable, agrees to destroy same and provide Medpace with written certification of such destruction. The Principal Investigator, Confidential Information, Recordkeeping, Access to Records, Costs and Payment Schedule, Term and Termination, Intellectual Property, Publications and Publicity, Indemnification and Insurance, Anti-Bribery/Anti-Corruption and Miscellaneous sections shall survive the termination or expiration of this Agreement.

8 INTELLECTUAL PROPERTY

8.1 It is agreed that none of Sponsor, Medpace, Principal Investigator, or Institution transfers to any other by operation of this Agreement any patent right, copyright, trademark right, or other proprietary right of Sponsor, Medpace, Principal Investigator, or Institution, except as expressly set forth herein.

8.1.1 "Invention" means any discovery, invention, technology, result, data, material, improvement, or idea, whether or not patentable, resulting from or reduced to practice as a result of conducting the Study, or made using the Study Drug or Confidential Information.

8.2 Institution and Principal Investigator will notify Sponsor, promptly and in writing, of any Invention made by Institution, Principal Investigator, and Study Personnel.

8.3 Sponsor shall own all right, title, and interest in and to any Invention and shall have the sole and exclusive right to obtain, at its option, patent protection in the United States and other countries on any such Invention. If Sponsor requests, Principal Investigator and Institution will execute and will cause Study Personnel to execute any application, assignment, or instrument or to testify as Sponsor deems necessary for Sponsor to obtain patents or otherwise to protect Sponsor's interest in an Invention. Sponsor will reasonably compensate Institution or its designated Payee for the time devoted to such activities and will reimburse Institution, Principal Investigator or their designated Payee for reasonable and necessary expenses incurred.

9 PUBLICATIONS AND PUBLICITY

9.1 It is understood that the Study is part of a multicenter trial, and Institution and Principal Investigator may publish the results of their part of the Study in collaboration with the other investigators, but in complete compliance with this section and with the Confidential Information section. After the multicenter publication or twenty-four (24) months after

completion of the Study, whichever occurs first, Institution and/or Principal Investigator may publish the results of their data from the Study. Institution and Principal Investigator shall provide Sponsor and Medpace with an advance copy of any proposed publication or oral presentation at least sixty (60) days prior to the planned date of submission or presentation and Sponsor shall have sixty (60) days to review the proposed publication for the purposes described below. Sponsor and Medpace may request in writing, and Institution and Principal Investigator shall agree to, (a) the deletion of any Confidential Information, (b) any reasonable changes requested by Sponsor or Medpace, or (c) a delay of such proposed submission for an additional period, not to exceed ninety (90) days, in order to protect the potential patentability of any technology described therein. Sponsor, at its election, shall be entitled to receive in any such publication an acknowledgement of its sponsorship of the Study.

9.2 None of the Parties shall use another Party's name or Sponsor's name, or issue any public statement about this Agreement, or publish any information about the Study, without the prior written permission of the Party to be named except as required by law. Such prior permission shall not be unreasonably withheld. The Parties agree that in order for Institution and Principal Investigator to satisfy their reporting obligations, they may identify Medpace or Sponsor and the amount of funding received from Medpace for the Study, but will not include in such report any information which identifies the name of the Study Drug or the therapeutic areas of the Study.

9.3 Notwithstanding the foregoing, nothing contained in this Agreement shall prevent the Study from being registered with www.clinicaltrials.gov, or any equivalent registry, including all information required by the Uniform Requirements for Manuscripts Submitted to Biomedical Journals of the International Committee of Medical Journal Editors in effect as of the date of initiation of the Study (see www.icmje.org).

10 NOTICES

Any notice required or permitted under this Agreement shall be in writing and shall be deemed made and given three (3) days after sending, if mailed by registered or certified mail, postage prepaid, return receipt requested, or one (1) day after sending, if sent by express courier service or facsimile/electronic transmission. In addition, the Institution and Principal Investigator will communicate to Medpace in writing (email is considered a writing for the purposes of this section), any changes to the Payee name, Payee address, tax identification number, corporate address, or corporate name. Any such notification shall originate from an Institution official having the same or greater authority as the Institution official who signs this Agreement on behalf of the Institution or in the case of changes to Principal Investigator Payee information, the notification shall originate from Principal Investigator. All notices must be addressed to the contact set forth below:

IF TO MEDPACE:

Medpace Clinical Research, LLC
Attention General Counsel
5375 Medpace Way
Cincinnati, OH 45227

IF TO INSTITUTION:

Sanjay Gandhi Postgraduate Institute of Medical Sciences
Department of Medical Genetics, Main Hospital, Raebareli Road, Uttar Pradesh, Lucknow, 226014
India.

IF TO SPONSOR:

Catalyst Biosciences, Inc.,
611 Gateway Blvd., Suite 710,
South San Francisco, CA 94080

WITH A COPY TO

Medpace Clinical Research India Pvt. Ltd.
Office No. 817, 8th Floor
Rupa Solitaire
Building No. A-1, Sector-1
Millenium Business Park
, Mahape
Navi Mumbai 400710, India

IF TO PRINCIPAL INVESTIGATOR:

Dr. Shubha Phadke
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Department of Medical Genetics,
Main Hospital, Raebareli Road, Uttar
Pradesh, Lucknow, 226014
India.

11 ELECTRONIC SIGNATURES

Institution and Principal Investigator consent to electronic communication and electronic signatures being equal to signatures inked on paper. Institution and Principal Investigator acknowledge and agree that electronic communication is an acceptable method of communicating information from Medpace to Institution and Principal Investigator without having to communicate the same subject matter on paper. Therefore, any communication and subsequent electronic signature that has been sent or signed in the past, present, or future between the Parties will hold the same force and effect as a document signed and inked on paper. Electronic signature includes without limitation a scanned copy of a signature, a typed signature, or the click of a mouse on an "I agree" icon or button. All communications that Medpace provides to Institution and Principal Investigator in electronic form will be provided either: (1) via e-mail by requesting Institution or Principal Investigator download a PDF or DOC file containing the communication; or (2) in the case of the License Agreement, will be provided immediately prior to the log-in screen for ClinTrak. Institution and Principal Investigator can obtain a paper copy of an electronic communication by printing it or by requesting that Medpace mail a paper copy, provided that such request is made within a reasonable time after Medpace first provided the electronic communication.

12 INDEMNIFICATION AND INSURANCE

12.1 Sponsor shall indemnify Institution and Principal Investigator pursuant to the terms and conditions of a separate letter of indemnification between Sponsor, Institution and Principal Investigator, as requested. Medpace shall not have any obligation to indemnify Principal Investigator(s), Institution and/or their agents, employees and representatives.

12.2 Medpace and Sponsor shall not be liable for incidental, special, indirect or consequential damages to persons or property including but not limited to the right to be paid for loss of time, loss of services, loss of production, lost profits, lost business, lost savings or other economic or business loss or claims of any kind whatsoever, arising out of or as a consequence of the services performed or otherwise under this Agreement, even if advised of the possibility of such damages.

12.3 Institution and Principal Investigator shall maintain insurance as required by applicable law, with limits consistent with statutory minimum amounts. Institution and Principal Investigator shall maintain such coverage for the duration of this Agreement and for two years thereafter. Proof of said insurance shall be supplied to Medpace upon request.

13 DEBARMENT

Each of Institution and Principal Investigator represents that neither of them, nor any of their management or any other employees or independent contractors or agents who will have any involvement in the Study, have been debarred by any regulatory authority. Institution and/or

Principal Investigator shall immediately notify Medpace in writing upon becoming aware of any such debarment, threat of debarment, or conviction or other matter that could result in any such debarment. Medpace may, upon its receipt of such notice or otherwise becoming aware of any debarment, threat of debarment or other matter that could result in any such debarment, terminate this Agreement in accordance with the Term and Termination Section.

14 ANTI-BRIBERY/ANTI-CORRUPTION

In carrying out its responsibilities under this Agreement, neither Party nor it nor any of its respective representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof corruptly for the purpose of improperly (i) influencing any act or decision of that person in his official capacity, including a decision to fail to perform his functions with such governmental agency or instrumentality or such public international organization or such political party, (ii) inducing such person to use his influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof or (iii) securing any improper advantage; provided however, the foregoing representation shall not apply to any facilitating or expediting payment to a foreign official, political party, or party official, the purpose of which is to expedite or to secure the performance of a routine governmental action by a foreign official, political party, or party official.

15 ASSIGNMENT AND DELEGATION

This Agreement shall be binding upon and for the benefit of the Parties hereto, and their successors and permitted assigns. This Agreement, and all rights, duties and obligations hereunder, may not be assigned or delegated by Institution or Principal Investigator without the prior express written consent of Medpace. Any attempt made by Institution or Principal Investigator to assign or delegate this Agreement in violation of this section shall be of no force or effect. Institution and Principal Investigator acknowledge that Medpace shall have the right to assign or delegate this Agreement or any portion thereof without the consent of Institution or Principal Investigator.

In the event where Institution and/or Principal Investigator are responsible for use of a subcontractor or affiliate for performing study obligations under this Agreement. Institution and Principal Investigator shall remain responsible for the proper performance of such services, in accordance with this Agreement. In case of change in subcontractors of Institution, Institution and/or Principal Investigator will inform Sponsor and Medpace in writing.

16 INDEPENDENT CONTRACTOR

The relationship of the Parties is that of independent contractors, and no employment or agency relationship shall be construed to exist between the Parties. Neither Medpace nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding or employment-related taxes relating to Institution, Principal Investigator or Study Personnel.

17 CHANGES TO THE PROTOCOL

The Protocol may be amended only at the direction of Sponsor, subject to subsequent approval of the Ethics Committee. No financial adjustments shall be made because of such modifications unless the Parties hereto amend this Agreement accordingly.

18 MISCELLANEOUS

18.1 This Agreement represents the entire understanding of the Parties and supersedes all prior negotiations, understandings or agreements (oral or written) between the Parties concerning the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. If a provision of this Agreement is or becomes (i) illegal under any applicable law or regulation, (ii) invalid or (iii) otherwise unenforceable, such illegality, invalidity or unenforceability shall not affect the validity or enforceability of any other term or provision of this Agreement. All waivers of the terms of this Agreement shall be in writing. Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, but the same shall remain at all times in full force and effect.

18.2 This Agreement shall be governed by and construed in accordance with the laws of India. For any legal action arising from or related to this Agreement, the Parties hereby consent and submit solely to the jurisdiction and venue of the courts located at Lucknow and agree that such courts shall be the sole courts utilized and hereby waive any jurisdictional or venue objections to such court.18.3 This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement and shall become binding when any one or more counterparts hereof, individually or taken together, bears the signature of each of the Parties hereto. A facsimile or PDF electronic submission of this Agreement or any subsequent amendment(s) signed by a Party's duly authorized representative shall be legal and binding on all Parties.

19 SPONSOR AS THIRD-PARTY BENEFICIARY

The Parties to this Agreement recognize and agree that Sponsor takes the benefit of this Agreement as a third-party beneficiary and agree that Sponsor may enforce such rights either directly itself or indirectly through Medpace.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement by proper persons thereunto duly authorized and that this Agreement shall be effective as of the Effective Date.

For Medpace, on its own behalf and as payment agent of Sponsor

Meghana Subramanian

By (signature)

Meghana Subramanian

Name (print or type)

Sr. CRA Manager

Title

Institution

By (signature)

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

Name (print or type)

Title

o/c UCCal

Principal Investigator

By (signature)

Dr Shubha Phadke

Name (print or type)

Professor,

Title

Department of Medical Genetics, SGPGIMS.

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

CATALYST BIOSCIENCES, INC.

PROTOCOL ID: MAA-304

// DR. SHUBHA PHADKE//

SITE: // 35601//

SCHEDULE A VERSION: 1.0

COUNTRY: INDIA

PROTOCOL VERSION: AMENDMENT 1 02JUN2020

SCHEDULE A

A1 STUDY BUDGET

Medpace, as Sponsor's payment agent, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. All fees listed include overhead. 18% GST is applicable on all the invoices generated. Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject

1.1.1	*Non-pediatric*	*INR 153,626.00*
1.1.2	*Pediatric*	*INR 175,501.00*

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit Month 1 (MarzAA Month 1 or SOC Month 1, based on Sequence A or Sequence B Patient Assignment).

A2 SETUP FEES & VISIT PAYMENTS

☒ Please check box if Payee must submit an invoice to Medpace prior to receiving payment. Payment will be made within forty-five (45) days of receipt of invoice.

A2.1 Setup Fees

2.1.1	*Non-refundable Administrative Set-up Fee*	*INR 35,000.00*

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation;
- IRB/EC approval; and
- Medpace's receipt of the fully executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. It is expected that all visits are completed per protocol requirements and will be paid based on EDC entry of visit. With prior notice to Payee and in exceptional circumstances, visit fees may require an adjustment if routine review of data identifies a significant concern with incomplete procedures or visits. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

Table 1 - Fees for Completed Clinical Visits for Randomized Subjects (Sequence A or Sequence B)

VISIT	Non-Pediatric Fee (including 25% overhead)	Pediatric Fee (Including 25% overhead)
Screening (-30 to -1 Day)	INR 17,913.00	INR 22,288.00
MarzAA Treatment Period Month 1	INR 10,538.00	INR 11,788.00
MarzAA Treatment Period Month 2	INR 9,475.00	INR 10,725.00
MarzAA Treatment Period Month 3	INR 9,475.00	INR 10,725.00
MarzAA Treatment Period Month 4	INR 9,475.00	INR 10,725.00
MarzAA Treatment Period Month 5	INR 9,475.00	INR 10,725.00
MarzAA Treatment Period Month 6	INR 9,475.00	INR 10,725.00
IAP	INR 10,475.00	INR 11,725.00
SOC Treatment Period Month 1	INR 9,475.00	INR 10,725.00
SOC Treatment Period Month 2	INR 9,475.00	INR 10,725.00
SOC Treatment Period Month 3	INR 9,475.00	INR 10,725.00
SOC Treatment Period Month 4	INR 9,475.00	INR 10,725.00
SOC Treatment Period Month 5	INR 9,475.00	INR 10,725.00
SOC Treatment Period Month 6	INR 9,475.00	INR 10,725.00
EOS	INR 10,475.00	INR 11,725.00
TOTAL PER PATIENT	**INR 153,626.00**	**INR 175,501.00**
MarzAA Treatment Period Month >6	INR 9,475.00	INR 10,725.00
SOC Treatment Period Month >6	INR 9,475.00	INR 10,725.00

Sequence A: MarzAA Treatment Period monthly visits will occur prior to SOC Treatment Period monthly visits.
Sequence B: SOC Treatment Period monthly visits will occur prior to MarzAA Treatment Period monthly visits.

A2.3 Screen Failures

Table 2 - Screen Failures

VISIT OF FAILURE	FEE (NON-PEDIATRIC)	FEE (PEDIATRIC)
Screening (-30 to -1 Day)	INR 11,643.45	INR 14,487.20

Payment for up to three (3) screen failures will be made and thereafter, once the required number of subject(s) have been randomized per ratio (1 failures:3 randomized) for screen failures for whom Medpace has received all appropriate documentation of procedures/visits completed with the next scheduled payment owed to the Payee. Eligible screen failure payment will be based on the order (by date) of when the subject is consented.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Medpace after:

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor;
- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Ancillary Supplies Reimbursement Advanced Payment — INR 10,000.00

Payee will receive a one-time advanced payment for purchase of ancillary supplies required Study conduct, specifically [10ml sWFI, 3ml syringe, 18 gauge- 1' needle, 30 gauge- ½ " needle], paid with start-up payment. Payee is responsible for maintaining records of funds utilized for ancillary supplies purchases (vendor invoice, receipts, etc), as well as subject dispensing records of ancillary supplies purchased for Study. Records will be accessible during monitoring visits for CRA's review. Subsequent advanced payments may be available upon pre-approval by Sponsor based on enrollment needs and after CRA verification of sufficient records of funds utilized. Subsequent advanced payments will be paid within forty-five (45) days of Medpace's receipt of invoice, Sponsor approval, and CRA's verification of first advance depletion. At Study closure, if excessive funds remain and will not be utilized for Study purposes, Payee may be required to return remaining funds or amount may be deducted from Institution's final payment, at discretion of Sponsor. Medpace will notify Payee in writing of the amount of any refund due and Payee shall return within thirty (30) days after receipt of Medpace's notification.

A3.2 Additional Procedures

Payment will be made for procedures listed below if required by the protocol and not considered as standard of care.

Table 3 – Unitized Procedures (Including 25% overhead)

FEES	COST
Pregnancy Test - Serum	INR 687.50
Pregnancy Test – Urine	INR 62.50
Accountability Applicable during MarzAA Treatment Month 1 to Month6, EOS and Unscheduled visit.	INR 531.25 per occurrence
Central Laboratory Specimen Draw and Processing (Immunogenicity Assays, Coagulation Assays, Thrombogenicity Markers, and MarzAA PK sampling nonbleeding/bleeding state) Applicable for scheduled protocol and unscheduled visits	INR 1,000 / per time point
Overnight Bed Fee charges	INR 1,375/ day

A3.3 Unscheduled Visit

3.3.1 *Non-pediatric* — *UP TO INR 9,475.00*

3.3.2 *Pediatric* — *UP TO INR 10,725.00*

Unscheduled Visit must be entered into EDC and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit. Itemized invoice included subject ID, unscheduled visit date, and list of completed procedures required.

A3.4 Subject travel fee — up to INR 1,000/ visit

A subject travel fee shall be reimbursed on actuals.

Additional funds may be available for travel costs exceeding INR 1,000/ per visit with prior written approval from the Sponsor.

A3.5 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Medpace/Sponsor.

A3.6 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Medpace/Sponsor.

A4 MEDPACE RIGHTS

Medpace reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Medpace within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.

A5 MEDPACE INVOICING

All payment inquiries and invoices submitted shall include the Protocol number and Principal Investigator name and be sent to the following:

Email: siteinvoices@medpace.com
Phone: 513-579-9911

Medpace Clinical Research, LLC
Attn: Clinical Operations Site Payments
5375 Medpace Way
Cincinnati, Ohio 45227

All invoices must be submitted to Medpace within ninety (90) days of occurrence or up to thirty (30) days after receipt of the final payment.

A6 PAYEE INFORMATION

All payments made by Medpace as set forth herein shall be payable solely to Payee at the address set forth below. Any such payments which are due to any other party performing services in connection with the Study shall be a matter solely between Payee and such party.

Table 4 - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name*	Director S.G.P.G.I.M.S Research Account
Payee Mailing Address	Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli road, Lucknow-226014, Uttar Pradesh, India.
Contact Name	Dr. Shubha Phadke
Email Address	//director@sgpgi.ac.in//
Bank	State Bank of India
Account №	10095237491
IBAN №	NA
BIC Code/Swift Code	SBININBB500
IFSC Code (India)	SBIN0007789
Tax ID#**	AAAJS3913N
GST ID#:	09AAAJS3913N2ZN

**Requested for Medpace Accounting tracking purposes only

MEDPACE
THE ADVANTAGE OF FOCUS

CLINICAL STUDY AGREEMENT

PROTOCOL: MAA-304

SITE: //35601//

//DR. SHUBHA PHADKE//

CATALYST BIOSCIENCES, INC.

//DD-MON-YYYY//

VERSION: //VERSION #1//

COUNTRY: INDIA

सत्यमेव जयते

INDIA NON JUDICIAL

105

Government of National Capital Territory of Delhi

e-Stamp

Certificate No.	:	**IN-DL57763653645520T**
Certificate Issued Date	:	01-Dec-2021 01:24 PM
Account Reference	:	IMPACC (IV)/ dl777003/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL77700308009774628554T
Purchased by	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Second Party	:	Not Applicable
Stamp Duty Paid By	:	GEORGE INSTITUTE FOR GLOBAL HEALTH
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter the "**Agreement**") is executed at New Delhi on _____, (hereinafter referred to as the "**Effective Date**") between;

GIGH Representative Initials | Institution Representative Initials | PI Initials

Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014

PACE in COPD_CTA,V 1.0, 30-Oct-2020
Dr.Alok Nath,SGPGI, Lucknow _CTA,V 1.0, 06-Jul-2021

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

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences , with PAN AAAJS3913N, having its registered office at New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh- 226014, (hereinafter referred to as the "**Institution**," which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the Second Part;

AND

Dr. Alok Nath, the principal investigator at the Institution, with office at Department of Pulmonary Medicine , Department of Pulmonary Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014 , (hereinafter referred to as the "**Investigator**," which expression shall, unless repugnant to the meaning or context thereof, be deemed to mean and include his/her heirs, representatives and assigns) of the Third Part;

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

WHEREAS GIGH, as a sponsor is conducting a study, known as the "Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD): PACE in COPD (hereinafter referred to as the "**Study**")";

AND WHEREAS GIGH wishes the Study to be conducted in terms of the protocol, which includes the objectives, design, methodology, statistical considerations and organization of the Study attached hereto as Exhibit A including amendments made thereto from time to time (hereinafter referred to as the "**Protocol**");

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

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all references in this Agreement to 'Protocol' shall include the protocol related to such Sub-Study;

AND WHEREAS the continuance in force of this Agreement shall be related to the continuance of the provision of research funding and other support to GIGH;

AND WHEREAS in order to generally meet with international regulatory and other standards as also requirements as to the design and conduct of a clinical trial, and to better ensure the robustness and broader applicability of the results of the Study, it is necessary for GIGH to carry out the Study in collaboration with centers that are located in numerous cities across India;

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

AND WHEREAS the Parties wish to enter into this Agreement to record their understanding in this regard and other related understandings between the Parties.

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

1. PERFORMANCE OF THE STUDY

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

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

(ii) generally accepted standards of good clinical practice, including the *Guidance for Good Clinical Practice of the International Conference on Harmonisation* (hereinafter referred to as the "**ICH-GCP**");

(iii) revised Schedule Y of the *Indian Drugs and Cosmetic Rules 1945* (as amended from time to time (hereinafter referred to as "**New Drugs and Clinical Trials Rules, 2019**");

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

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(v) all Applicable Laws, applicable procedures, rules, regulations and guidelines established by law, or otherwise applicable within the Institution, governing the performance of clinical research involving human participants in the jurisdiction of the Study; and

(vi) all applicable rules, orders, regulations and guidelines Health Ministry Screening Committee (hereinafter referred to as the "**Regulatory Authority**", and all references to regulatory authority within this Agreement shall include Regulatory Authority).

Applicable Laws shall mean and include all statutes, enactments, acts of legislature or parliament, laws, ordinances, rules, bye-laws, regulations, notifications, guidelines, policies, directions, determinations, directives, writs, decrees, injunctions, judgments, awards or orders of any government authority, statutory authority, tribunal, board, court, and if applicable, international treaties and regulations, as amended from time to time and including but not limited to:

(i) Applicable provisions of the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945 (including Schedule Y);

(ii) International Conference on Harmonization - Good Clinical Practice (ICH-GCP) Guidelines;

(iii) WHO Guidelines for Good Clinical Practice (GCP);

(iv) Indian Council of Medical Research (ICMR) Guidelines;

(v) Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002;

(vi) Indian Good Clinical Practice of the Central Drugs Standard Control Organization;

(vii) WMA Declaration of Helsinki;

1.2. Institution and Investigator represent and agree that:

(i) they have, and at all times during the course of the Study shall have, personnel with appropriate training, information, licenses, approvals, and certifications as are necessary to safely, adequately and lawfully perform, conduct and coordinate the Study in accordance with generally accepted standards of good clinical practice, including ICH-GCP and Applicable Laws;

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

(iii) Investigator has received, read and understood the Protocol, and confirms and acknowledges that he/she shall strictly adhere to all conditions set out therein and a written confirmation of which is attached hereto as Exhibit B.

1.3. Investigator shall obtain written approval from the IRB/IEC for the Protocol and for the patient information sheet and informed consent form, to be used (hereinafter referred to as the "**Consent Form**") and patient material (if any) prior to initiation of the Study and

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during the conduct of the Study, if required, and shall immediately provide copies of all such documentation to GIGH. GIGH shall provide Investigator with a sample Consent Form along with the protocol and other study documents for IEC review and approval. Investigator may add additional information to the sample Consent Form, if required by the IRB/IEC and Institution; however, such changes should not be material and should not change GIGH's intent concerning the minimum level of information provided to each human subject (hereinafter referred to as the "**Participant**") in order to obtain Participant's consent, and must not modify the compensation provision without GIGH's consent.

1.4. The Investigator shall obtain a written consent from each Participant or from their legally acceptable representative participating in the Study as specified in the Protocol and as required by the Applicable Laws prior to enrolling a Participant into the Study and shall further ensure that all Participants or their legally acceptable representative understand the latest information sheet and consent form approved by the IRB. The Institution /Investigator shall maintain each Participant's Consent Form in the Participant's permanent record. The Investigator will be responsible to obtain an audio-visual informed consent process for all vulnerable participants in addition to the written consent. Such audio-visual recording and related documentation must be preserved adhering to the principles of confidentiality by the Investigator.

1.5. It is anticipated that 300 to 500 Participants will be recruited from approximately 06 centres in India. The Investigator shall start recruiting Participants only after he/she has received written authorisation from GIGH to start recruitment, such authorization to be provided after receipt of all relevant documentation at GIGH. GIGH reserves the right to limit the recruitment of further Participants or cease the recruitment at the Study Site, notably if the overall recruitment target for the Study has been reached. Upon receipt of written notice from GIGH to cease recruitment, the Investigator shall immediately cease further recruitment of Participants.

1.6. Institution and Investigator undertake, represent and agree that they are not, and shall not at any time during the performance of the Study be, under any obligation to a third party, or subject to any other legal impediments, which would create conflict with their duties set out herein, or that might otherwise impair the acceptance by a regulatory authority of the data collected by the Study Site.

1.7. Institution and Investigator agree to provide to GIGH, any documentation required by regulatory authorities and/or under Applicable Laws, including but not limited to Investigator's curriculum vitae, each signed by Investigator, or any other documentation or information that relates to disclosure of Institution and Investigator's

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interests, including any financial interests of Institution and/or Investigator, in the Study.

1.8. Institution and Investigator warrant and represents that: (i) Investigator has not been debarred pursuant to any Applicable Laws or by any regulatory authority; and (ii) neither the Institution nor the Investigator have been disqualified from participating in a clinical study by any regulatory authority. Additionally, Institution and Investigator agree not to use any person for the services provided hereunder who has been: (i) debarred, disqualified or is under investigation by the FDA/MHRA/DCGI for debarment action or disqualification; or (ii) found by any regulatory authority to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations (all of the foregoing in items (i) and (ii) hereinafter referred to as "**Disqualified**"). Furthermore, Institution agrees that they shall promptly notify GIGH in the event of such debarment, conviction, threat, disqualification or indictment of Investigator or any person who has provided services under this Agreement, during the term of this Agreement or three (3) years following its expiration or earlier termination.

1.9. Investigator may appoint other individuals as may be deemed appropriate and approved by the Institution (hereinafter referred to as the "**Study Team**") to assist in the conduct of the Study in accordance with the Protocol, provided that Investigator shall be required to act in accordance with proper professional judgment in making all such appointments. Investigator shall be solely responsible for the Study and for leading the Study Team, who in all respects shall be bound by the same obligations as Investigator under this Agreement, and Investigator shall inform and keep informed in detail the Study Team about all such obligations as they may exist from time to time. Further, Investigator shall be responsible for ensuring that all members of the Study Team are appropriately qualified to conduct the Study and have read and understood the Protocol.

1.10. During the course of the Study, should the Institution and/or Investigator receive any correspondence from a regulatory authority or the IRB/IEC in relation to the Study, such receiving Party shall immediately provide to GIGH a copy of any such correspondence and take appropriate action in this regard as may be appropriate including actions in accordance with the lawful instructions and advice of GIGH.

1.11. Institution and Investigator shall prepare and maintain complete and up to date accurate medical records, accounts, medical notes, reports, and data including all supportive documentation for each Participant (hereinafter referred to as the "**Source Documents**") in accordance with the operating procedures required by GIGH and the Applicable Laws. The Institution and/or the Investigator shall ensure that information collected for the Study is recorded into the database via the corresponding electronic Case Report Forms (eCRFs) found in the web-based management system for each Participant, if and as required by the Protocol. Investigator shall ensure that any data

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or supportive documentation provided to GIGH does not include any information that would personally identify a Participant.

1.12. The Investigator shall immediately inform GIGH of any Serious Adverse Events (hereinafter referred to as "**SAE**"), as defined in the Protocol provided by GIGH. The Institution and the Investigator shall comply with and shall ensure compliance with all the requirements of New Drugs and Clinical Trials Rules, 2019 in terms of safety reporting including notifying GIGH in writing of any SAE as defined in the Protocol and Site Manual of Procedures. During the period of the Study, Investigator and/or the Institution shall submit periodic reports to GIGH regarding progress of the Study, in form and manner as may be acceptable to GIGH or as recommended by GIGH, to enable GIGH to assess the progress of the Study being carried out at the Study Site.

1.13. Institution and/or Investigator shall maintain a copy of all documents, including the Source Documents, relating to this Study for longer of: (i) fifteen (15) years after the Study is completed or discontinued by GIGH; or (ii) a period as may be required by the applicable laws. GIGH will be consulted before the destruction of the documents. Further details are in clause 3.2 (xvii).

1.14. Institution and Investigator shall cooperate and permit, upon the request of GIGH or an official of any regulatory authority, such party to examine and inspect Institution's facilities and equipment required for performance of the Study and inspect and copy all data, reports, work products and results relating to the Study. GIGH's access to records for monitoring or audit does not entitle them to copy any Participant's personal identifiable information. If the Institution or the Investigator is notified of an inspection by a regulatory authority, the Party so notified shall immediately inform GIGH about the pending inspection and shall ensure and authorize GIGH, or any person designated by them, to participate in such inspection, to the extent permitted under Applicable Laws. The Institution or the Investigator shall immediately communicate to GIGH the information that arises from such inspections by a regulatory authority, to the extent permitted under Applicable Laws. It is expressly agreed that GIGH shall not compensate the Institution and/or the Investigator for the cost and/or expense incurred by the Institution and/or the Investigator in relation with any audits and/or inspections and that the assistance and availability of the Institution and/or the Investigator for the audits and inspections is included as part of their obligations to be performed in consideration of payment of the amount mentioned in clause 6 of this Agreement.

1.15. GIGH's monitor shall ensure to send monitoring follow up report promptly.

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

1.17. GIGH to notify, up to two years post study closure, relevant safety findings from the study data.

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

1.19. Notwithstanding the foregoing, GIGH, in its sole and absolute discretion, may elect not to approve a person proposed as a replacement investigator, in which event GIGH shall have the right to terminate the Agreement in accordance with clause 10.1 of this Agreement.

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

1.21. During the term of this Agreement, neither Institution nor Investigator shall conduct any other study, investigation or trial on the Participants recruited for the Study which might in any way hinder the results of the Study.

1.22. GIGH represents and warrants that:

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

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

iii. It is not subject to/party to, any covenants, agreements or restrictions including without limitation any covenants, agreement or restrictions arising out of its prior engagements or independent contractor relationships, which would be breached or violated by it because of execution of this Agreement or by performance of its duties hereunder.

2. PERFORMANCE PERIOD

2.1 This Agreement commences from the date specified on the first page of this Agreement, or if such date is not included on the date this Agreement is last signed by either Party. Unless terminated early, in the ordinary course of events this Agreement terminates on Study Completion.

2.2 Investigator and Institution understand and acknowledge that Participant enrolment will commence only after all approvals (IEC/IRB etc.) have been obtained.

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3. DUTIES AND RESPONSIBILITIES OF THE PARTIES

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

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

(ii) making timely payments to the Institution (in accordance with clause 6 of this Agreement), subject always to approvals mentioned in clause 3.1(i) above;

(iii) supplying Institution and Investigator with appropriate Study documents necessary to conduct the Study;

(iv) providing all necessary information as per Protocol, and related Study material, and study drug, to assist the Institution and Investigator to comply with its obligations under this Agreement;

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

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

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

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

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

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

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

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

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

(iii) understanding and strictly adhering to all requirements of the Protocol and this Agreement;

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

(v) appointing and monitoring of research staff and other appropriately trained and qualified personnel with clinical knowledge necessary to conduct the Study at the Study Site;

(vi) evaluating and keeping GIGH informed of any outcomes, and adverse events identified during the conduct of the Study;

(vii) maintaining updated and accurate records pertaining to the Study;

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

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

(x) complying with all Applicable Laws, rules and regulations governing the Study and any conditions imposed by relevant regulatory authorities from time to time;

(xi) permitting the representatives of GIGH access to the Study Site as and when required; during normal duty hours;

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

(xiii) ensure that the equipment used by the Institution and/or the Investigator for conduct of the Study are properly maintained;

(xiv) having and continuing to have all licences, authorisations, consents, approval and permits required by all Applicable Laws and regulations in order to perform their obligations under this Agreement;

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

(xvi) ensure that any agreement concluded, or arrangement reached by them with any and all agents or personnel or members of the Study Team appointed by them, if any, in connection with the Study shall be subject to and not inconsistent with the provisions of this Agreement.

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

4. OWNERSHIP OF DATA, RESULTS, INTELLECTUAL PROPERTY

4.1 The Parties acknowledge and agree that GIGH shall have all right, title and interest in and to all data and results of the Study, including without limitation all inventions, patents, tests, applications, creations, research data and Confidential Information that may be developed, produced, created, furnished or disclosed by any Party made during the conduct of the Study, or arising from the performance of the Study, including:

(i) any discovery, concept, or idea, whether or not patentable, including but not limited to processes, methods, software, tangible research products, formulas and techniques, improvements thereto, and know-how related thereto;

(ii) any patents and designs; and

(iii) any other material in which any intellectual property rights subsist or may subsist (hereinafter referred to as **"Intellectual Property"**).

4.2 The ownership of any or all intellectual properties owned by the Institution before the execution date of this Agreement and used under this Agreement by the Institution

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(**"Background IP"**) for the purpose of the Study shall remain with the Institution. GIGH agrees not to claim the ownership of the Background IP, in any whatsoever manner, either directly or indirectly.

4.3 Institution and Investigator hereby specifically disclaim any right, title or interest of any kind whatsoever to the Intellectual Property or to any information received by Institution or Investigator as a result of or in the course of performing the Study, including ownership rights thereof, except to the extent that such rights are specifically granted hereunder for the purposes of the Study.

4.4 In the event of any discovery or invention made by Institution, Investigator, Study Team or any agents or employees of Institution or Investigator in the course of or in connection with the performance of the Study, such discovery or invention shall be communicated immediately to GIGH. All right, title and interest in and to any such discovery and invention shall belong to GIGH and/or its assignee (in its sole and absolute discretion). Institution and Investigator shall have no right, title or interest in or to such discovery or invention, and consequently shall refrain from, and shall cause Study Team and other employees or agents to refrain from filing any application on their discovery or invention with any patent or other relevant authority.

4.5 If GIGH and/or its assignee desires to file patent applications on such discovery or invention, whether in its name or in the name of any assignee, it will do so at its own expense, and those persons participating in the discovery or invention hereby assign all right, title and interests to such discovery or invention to GIGH (or to such third party as GIGH may instruct/ identify) without any additional compensation, and, if requested by GIGH to do so, assist in the preparation of such patent applications. It is expressly agreed by the Investigator that GIGH be under no obligation to patent, develop, market or otherwise utilise the results of the work done by Investigator, Study Team or other agents or employees of Institution or Investigator in connection with this Agreement.

4.6 Investigator and Institution shall ensure that all employees, Study Team or other agents hired to perform services hereunder shall agree to fulfill the obligations herein, especially in relation to the assignment of rights in discoveries and inventions to GIGH as applicable.

4.7 This Agreement does not grant either party any license grant or assignment, whether expressed or implied, with regard to such Intellectual Property that belongs to the other party. This Agreement also does not grant, transfer or assign to the party/ies any legal right or beneficial ownership in any Intellectual Property Rights of the other party/ies.

4.8 Each party will not use the other party's/ies' Intellectual Property in any publicity, advertising or news release without the prior written consent of the other party/ies. For the avoidance of doubt, this restriction does not apply to the inclusion in documents of

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or use of Intellectual Property for the proper performance of the services under this Agreement.

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

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

4.11 Nothing in this Section shall restrict the Institution from using the Intellectual Property and Know How generated from the Study for their normal hospital activities.

5. PUBLICATION

5.1 The Parties acknowledge that the Study is a multi-centre study that is overseen and supervised by a committee known as the 'Steering Committee' to be appointed GIGH (hereinafter referred to as "Steering Committee").

5.2 Institution and Investigator each acknowledge and agree that:

(i) there shall be no publication, report, release, disclosure or likewise of any preliminary or final Study findings or results prior to release of the multi-centre publication approved by the Steering Committee (hereinafter referred to as "**Multi-Centre Publication**"); and

(ii) the first publication of Study findings or results shall be made as part of the Multi-Center Publication, which will involve all participating investigators and institutions, including Institution and Investigator. Attribution and authorship shall be given in accordance with academic standards.

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

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

5.5 All publications must comply with the Protocol and Consolidated Standards of Reporting Trials (CONSORT) statement. Authorship of publications will be granted according to the guidelines from the International Committee for Medical Journal Editors (ICMJE).

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

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

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

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

6. PAYMENTS

6.1 As consideration for performance of the Study under the terms of this Agreement, upon receipt of necessary regulatory approval , GIGH shall pay to Institution the amounts as set forth in the Payment Schedule and Payment Rule Form that is attached hereto as Exhibit C (hereinafter referred to as the "**PRF**"). Payments shall be made in the manner and on the terms set forth in the PRF. All fees set out in the PRF shall be full and final and shall remain unchanged for the duration of the Study, unless otherwise agreed in writing by all Parties. All fees set out in the PRF shall be deemed to be inclusive of all applicable taxes. Institution and Investigator each agree and undertake not to seek any payment from any third party or Participant for any services provided to a Participant in connection with such Participant's participation in the Study or the costs incurred in connection therewith.

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

6.3 Institution and Investigator shall review the payment details generated by GIGH that shall accompany each payment and shall inform GIGH in writing in accordance with the instructions provided in the payment details of any discrepancies that may exist in the payment(s) received and the payment(s) expected. After each payment, Institution and Investigator shall ensure that any such discrepancies that may exist, if any, are brought to the attention of GIGH no later than one (1) month after the payment is received. The Parties shall work diligently and in good faith to resolve any such discrepancies. In the event GIGH does not receive written notice of any final discrepancies within such one (1) month period, then all payments required to be made hereunder shall be deemed to have been made in full, and Institution and Investigator shall be deemed to have, and each hereby waives, all rights to receive further compensation in connection with the Study.

6.4 The Parties agree that, other than as described herein, GIGH will not be liable to contribute and/or make any other payment to Institution or Investigator for undertaking the Study.

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

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7. CONFIDENTIALITY & PRIVACY

7.1 The Institution and the Investigator acknowledge and agree that they shall not disclose or publish Confidential Information to any third party, other than in accordance with this clause 7. For the purpose of this Agreement, "**Confidential Information**" shall mean any confidential or proprietary information, including without limitation, any derivatives thereof, which is confidential and proprietary in nature, including, but not limited to, past, present and future disclosing Party: business and financial records; business and marketing plans; contracts; sales; reports; billings; insurance filings; employees; customers; vendors; proof of concepts; products and/or services, in preliminary and final production form; pricing; intellectual property; source codes; object codes; technical knowledge; trade secrets; internal practices and procedures; feedback relating to any results of the Participant, Participant or Confidential Information; deliverables information; other information relating to disclosing Party's business, including, without limitation, the terms and conditions of this Agreement; and any third-party confidential information which disclosing party may be authorized, from time to time, to review, have access to and/or use and are provided by disclosing Party to any receiving Party (in any form) in connection with this Agreement which by its nature the other Party knows, or reasonably ought to know, is confidential, and in the case of GIGH (and/or its affiliates), Confidential Information shall include (but shall not be limited to): (i) all information collected in the course of, resulting from, or arising directly out of the conduct of the Study, whether at the Study Site or elsewhere; (ii) the Protocol, and information related to the Protocol and Study materials; (iii) know-how, trade secrets, ideas, concepts, technical and operational information, scientific or technical processes or techniques owned by GIGH (and/or its affiliates); (iv) know-how, methodology, trade secrets, processes, sequences, structure and organisation of the Study; and (v) information concerning the business affairs of GIGH (and/or its affiliates); and in the case of Institution, Confidential Information shall include (but shall not be limited to) information relating to the Institution's business, operations or strategies, intellectual or other property or actual or prospective suppliers or competitors.

The preceding obligations shall not apply to Confidential Information, Data or information that falls under Confidentiality:

a) which the Disclosing Party agrees in writing, may be used or disclosed,

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

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

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

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

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

7.2 A Party must not, and must ensure that its employees, agents and other authorised representatives do not use or disclose any Confidential Information of another Party, other than where and only to the extent that such use or disclosure is absolutely necessary for the performance of the Study, or the exercise of the first mentioned Party's rights or the performance of the first mentioned Party's obligations under this Agreement, or as otherwise permitted by clause 7.3.

7.3 A Party may disclose Confidential Information of another Party:

(i) as directed by the written consent of the Party whose Confidential Information is to be disclosed, provided that the recipient is subject to similar confidentiality obligations as set out in this Agreement; and

(ii) when required to do so by law, by court order or by order of a regulatory authority having jurisdiction to so direct, provided that prior to such disclosure the Party whose Confidential Information is to be disclosed is promptly advised and given reasonable opportunity to protect its Confidential Information, and then provided only to the extent that such Confidential Information is required to be disclosed to satisfy the particular law or order.

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

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

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

8. RELATIONSHIP OF PARTIES

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

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Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
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8.2 No employee, agent or authorised representative of the Institution and/or Investigator or any other person undertaking or performing work for the Study at the Study Site (hereinafter referred to as "**Study Site Personnel**") shall be considered or deemed to be, at any time during the term of this Agreement, an employee of GIGH. Study Site Personnel shall, at all times, be under the direct supervision and responsibility of Institution and/or Investigator. Institution shall be solely responsible for the disbursement of all wages/salaries to Study Site Personnel, and shall comply with all applicable labour laws and legislation. Institution shall indemnify and hold harmless GIGH (and its affiliates) against all claims and demands that may be made by any Study Site Personnel against GIGH for non-compliance by Institution and/or Investigator with this clause 8.2.

9. NOTICES

9.1 Any notice, consent, approval or other communication (each a "**notice**") under this Agreement shall be in writing and shall be delivered to the recipient Party by hand or by sending to the address or email specified below (or as subsequently varied by notice):

(i) If to GIGH:
Amit Khanna
George Institute for Global Health
308, Elegance Tower
Plot No. 8, Jasola District Centre
New Delhi 110025 , India
Email- akhanna@georgeinstitute.org.in

(ii) If to Institute:
Director SGPGI
Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
Email- director@sgpgi.ac.in

(iii) If to Investigator:
Name: Dr.Alok Nath
Department of Pulmonary Medicine, Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014
Email: draloknath@gmail.com

9.2 A notice given in accordance with clause 9.1 is taken to be received: (i) if hand delivered to a Party's address, on the day of delivery; (ii) if sent by courier to a Party's address, upon the day of the courier's delivery (as verified by the courier's records); (iii) if sent

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

10. TERMINATION

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

(i) any regulatory authority requires the Study to be discontinued or materially altered;

(ii) Investigator or Institution is Disqualified (as defined by clause 1.8 of this Agreement);

(iii) Institution proposes a replacement investigator and GIGH does not approve of the proposed replacement;

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

(v) Institution and Investigator do not randomize at least four (4) Participant within one (1) months of receiving an authorisation letter from GIGH to commence recruitment (as provided by clause 1.5 of this Agreement);

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

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

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

10.3 Institution and Investigator may terminate this Agreement by written notice to GIGH, which notice and termination shall, subject to the ongoing obligations of each of the Parties pursuant to paragraph 10.4 below, be effective immediately upon receipt of written notice by GIGH if:

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

(ii) GIGH fails to perform, or performs improperly, any of its material obligations under this Agreement (hereinafter referred to as "**GIGH Default**"), provided that

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the Institution and/or Investigator shall first have: (i) notified GIGH of such GIGH Default; and (ii) permitted GIGH a period of thirty (30) days to cure the GIGH Default, which Cure Period shall be stated in the notice from the Institution and/or Investigator.

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

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

10.6 Clauses 1 (Performance of the Study), 4 (Ownership of Data, Results, Intellectual Property), 5 (Publication), 7 (Confidentiality & Privacy), 10.4 (Termination), 11 (Indemnities, Limitation of Liability & Insurance) and 14.4 (Arbitration) of this Agreement, and any other clauses or provisions giving operational effect thereto, and any other clause or provision that should by its nature, shall survive expiry or termination of this Agreement.

11. INDEMNITIES, LIMITATION OF LIABILITY & INSURANCE

11.1 GIGH shall hold harmless the Institution and the Investigator and their respective officers, directors and employees (hereinafter individually referred to as an "**Indemnified Party**" and collectively referred to as the "**Indemnified Parties**"), as applicable, from and all claims made by third parties and against any and all liabilities, losses, damages and expenses (hereinafter collectively referred to as "**Losses**") that one or more of the Indemnified Parties may sustain or incur in connection with any injury, (including death), suffered by any Participant participating in the Study resulting only from the administration of the Study drug described in the Protocol, when used in the Study in accordance with the approved labelling, the Protocol and any written instructions of GIGH provided that the Indemnified Party has (i) used reasonable medical judgment in the conduct of the Study, (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice and (iii) duly complied with all Applicable Laws and regulations and all ethical and professional standards relating to the protection of human Participants, including with respect to ensuring appropriate IRB approval and oversight, obtaining effective informed consent and maintaining patient privacy in accordance with the Protocol and the instructions/guidance/advice issued by GIGH, from time to time.

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

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

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

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

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

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

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

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11.6 Institution and Investigator may secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:
(i) medical professional and/or medical malpractice liability; and
(ii) general liability; and
(iii) employee's compensation,
each such insurance coverage in amounts appropriate to the conduct of Institution's business activities and the services contemplated by the Study and in compliance with minimum amounts of insurance required by Applicable Laws or regulations.

12. ENTIRE AGREEMENT, AMENDMENT

12.1 All exhibits, schedules attached hereto, including the Protocol referenced herein, shall be incorporated by reference and will form part of this Agreement. This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter herein and, other than expressly provided herein, no part of this Agreement may be modified except where agreed to in writing by the Parties. All previous negotiations, understandings, representations, warranties, memoranda or commitments concerning the subject matter of this Agreement are merged in and superseded by this Agreement and are of no effect. No oral explanation or information provided by any Party to any other Party affects the meaning or interpretation of this Agreement, or constitutes any collateral agreement, warranty or understanding between the Parties.

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

13. ASSIGNMENT& SUBCONTRACTING

13.1 The parties shall not assign or transfer any of its rights or obligations under this Agreement or any part thereof without the prior written consent of the other party. Further, the parties shall not sub-contract the performance of all or any of its obligations under this Agreement without the prior written consent of the other party, such consent not to be unreasonably withheld or delayed.

14. CONCLUDING PROVISIONS

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

14.2 The obligations of a Party under this Agreement are suspended during the period and to the extent that such Party is prevented or hindered from complying by causes or circumstances: (i) beyond its reasonable control not due to its own fault or negligence;

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(ii) which are not reasonably forseeable; and (iii) which the Party is by exercise of reasonable diligence, unable to prevent, including (a) act of God; (b) industrial dispute of any kind; (c) act of public enemy, war (whether declared or undeclared), blockade, revolution, riot, insurrection, malicious damage, civil commotion; (d) natural disaster/ pandemic/epidemic, medical emergency; (e) order of any court or authority, restraint, restriction, requirements, prevention, frustration or hindrance by or of any person, government or competent authority; and (f) embargo, unavailability or shortage of essential equipment, chemicals or other materials, goods, labour or services, lack of transportation or communication, breakage of facilities or machinery (each hereinafter a "**Force Majeure Event**"). A Party relying on this clause 14.2 must promptly provide notice to the other Parties of the occurrence or cessation of any Force Majeure Event. Where such Majeure Event continues for more than three (3) calendar months, the other Parties have the right to promptly terminate the Agreement by written notice to the affected Party, and clauses 10.4 and 10.6 of this Agreement will apply.

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

14.4 The Parties agree to first attempt to negotiate in good faith to resolve any dispute or difference arising out of or in connection with this Agreement or in respect of any defined legal relationship associated therewith or derived therefrom (hereinafter referred to as the "**Dispute**"). However, if the Parties are unable to resolve the Dispute within fourteen (14) days after first commencing good faith negotiations, the Parties agree to submit such Dispute for arbitration before a sole arbitrator to be appointed by mutual agreement of the Parties under the Arbitration and Conciliation Act, 1996 having jurisdiction in Luckow, India. Each Party to the Dispute will be responsible for its own costs and expenses, and arbitration fees will be shared equally between the Parties to the Dispute. The decision of the arbiter shall be final and binding between the Parties subject to legal remedies under the Arbitration and Conciliation Act, 1996.. The Parties agree to continue to perform this Agreement despite the existence of a Dispute or any proceedings under this clause 14.4. Nothing in this clause prevents a Party from obtaining urgent injunctive relief from any court, including with respect to the protection of its confidential or proprietary information.

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

14.6 This Agreement may be executed in any number of counterparts, and all counterparts together shall be taken to constitute one instrument.

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Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences

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

On Behalf of GIGH:

Signature

Date: 01st December, 2021

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

Signature

Date: 01st December, 2021

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

INSTITUTION:

23/12/21

Signature

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

Date: _____

Name: Prof. RK Dhiman
Designation: Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow. 226014

INVESTIGATOR:

Signature

Date: 9/12/21

Name: Dr.Alok Nath
Designation: Additional Professor & Head, Department of Pulmonary Medicine

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Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014

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EXHIBIT A

Enclosed: Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD) study protocol
STUDY PROTOCOL- PACE in COPD, V6.0, 24 February 2021

Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
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EXHIBIT B
INVESTIGATOR CONFIRMATION

Study Name: Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD)

Investigator: Dr.Alok Nath

I, the Investigator, confirm that I have received the PACE in COPD trial Protocol. I represent that I have read and fully understand the Protocol and other study related obligations. I will provide copies of the Protocol, and all information furnished by GIGH, to the Study Team and to discuss this material with them and ensure they are fully informed and understand the Protocol.

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

Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014

Signature

8/12/21

Date

Name: Dr.Alok Nath

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Institution Representative Initials

PI Initials

Dr. Alok Nath
Professor & Head
Deptt. of Pulmonary Medicine
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014

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EXHIBIT C

PAYMENT SCHEDULE, AND PAYMENT RULE FORM

STUDY: Preventing Adverse Cardiac Events (PACE) in Chronic Obstructive Pulmonary Disease (COPD)

COUNTRY: INDIA

Target Recruitment at the site (randomized patients): 50 - 100

Payment distribution will be as shown below. Payments will be made as per the below schedule if all study visit data has been entered and queries resolved. Payments will be processed on a quarterly basis with the payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued and sent out within 25 days from the processing/run date (i.e. Payment for run date Mar 31st will be mailed on or prior to April 25th.)

All payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws and GIGH will deduct the tax at the time of making payments unless a valid certificate for Tax Exemption is made available from the tax authority in a timely manner.

Payments will be made as per the below schedule if all study visit data has been entered and queries resolved adequately.

ITEM	Per Month/Visit (INR)	No. of months/ visits
Study Coordinator/Nurse	30,000	36
Site Investigator	13,000	36
Participant travel	700	8
Overheads @ 25%		

Institutional Ethics Committee Fees: Institutional Ethics Committee (IEC) fees shall be reimbursed for initial review, annual reviews, ICF reviews and amendments only if applicable as per the IEC SOP. Processing of payment will begin upon receipt of original invoice/disbursement request.

Fee for Study Coordinator and Site Investigator + 25% overheads shall be paid quarterly in advance, except for the last quarter of third year which will be retained until all data has been entered and all outstanding data queries have been responded to.

Fee to cover participant travel + 25% overheads will be paid quarterly in arrears for all visits attended within the previous quarter.

Fee for Study Coordinator and Site Investigator is based on the assumption that a minimum of 50 participants will be randomised within the first year of recruitment. Institution will be paid

as per the above schedule so long as the Study Site randomises a minimum of 50 participants within the first year of recruitment. If the site fails to recruit 50 participants, fee for Study Coordinator and Site Investigator (plus overheads) shall stand reduced proportionate to the number of participants randomised in the first year, and will be adjusted from payments in subsequent quarters .

All payments will be based on completion of visits and collection of all required data for each visit completed and includes ALL costs (including but not limited to investigator & study team salary, patient recruitment and follow-up, events reporting, overheads, laboratory costs, monitoring visits, patient travel expenses, any applicable taxes, etc.)

Disbursement of travel cost for participants (as per table above) will be at the discretion of the Investigator.

Payments will be made to the following party:

(ALL INFORMATION BELOW MUST BE PRINTED)

Payable to:Director, SGPGIMS, Research a/c

PAN No. of Institution: AAAJS3913N

Account Number: 10095237491

Bank Name & Address: State bank of India, SGPGI Branch, Lucknow, U.P

IFSC Code: SBIN0007789

Mailing Address: Sanjay Gandhi Postgraduate Institute of Medical Sciences PMSSY Block, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh-226014

Signature of the authorized signatory of the Institution: _____ 27/12/21.

Prof. R. K. DHIMAN
Director
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW (U.P.) INDIA

Name of authorized signatory:. Prof. RK Dhiman

Phone: 05222492668112

Email address: director@sgpgi.ac.in

Date:_____

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Bond

Indian-Non Judicial Stamp
Haryana Government

Date :20/10/2020

Certificate No. G0T2020J2691

GRN No. 68423865

Stamp Duty Paid : ₹ 101
(Rs. Only)

Penalty :₹ 0
(Rs. Zero Only)

Deponent

Name: Eli Lilly and company India Pvt ltd

H.No/Floor : 92 Sector/Ward : 32 Landmark : Na

City/Village : Gurugram District : Gurugram State : Haryana

Phone : 98******18

Purpose : AGREEMENT to be submitted at Others

OUS Templates
OUS LOA
Revised: 01 2018

Date:06-Aug-2019

Dr. Amita Agarwal
Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI),
RaeBareli Road,
Lucknow – 226014, UP,
India

Dear Dr. Agarwal,

This agreement ("Agreement") is by and between Eli Lilly and Company (India) Pvt. Ltd ("Lilly") **Dr. Amita Agarwal** as the principal investigator ("Investigator"), and **Sanjay Gandhi Post Graduate Institute of Medical Sciences, RaeBareli Road, Lucknow – 226014, UP, India.** ("Institution") for the performance of the study ("Study) entitled **"A Randomized, Double-Blind, Placebo-Controlled, Withdrawal, Safety and Efficacy Study of Oral Baricitinib in Patients from 1 Year to Less Than 18 Years Old with Systemic Juvenile Idiopathic Arthritis "** protocol **I4V-MC-JAHU** ("Protocol"), which Protocol is incorporated herein by

reference. Investigator is an employee of Institution. This agreement ("Agreement") sets forth the obligations of Lilly, the Investigator and Institution.

I. INVESTIGATOR AND INSTITUTION OBLIGATIONS

Investigator and Institution agree to assume the following obligations in executing this Agreement:

A. Conduct of the Study

Investigator and Institution agree that Investigator will personally conduct or supervise the Study at Institution and any Lilly-approved sub-sites or satellite sites (collectively "Study Sites"), if applicable. Investigator and Institution agree that Investigator and Institution will not use sub-sites or satellite sites in the conduct of the Study unless Lilly has given written approval for use of the sub-sites and satellite sites. If any portion of the Study is performed by Investigator or a sub-investigator at a facility or hospital other than Institution, Investigator and/or Institution shall be responsible for ensuring that any such Study Site is aware that it is involved in the Study and consents to such participation. Investigator and Institution (and colleagues, including sub investigators) agree to comply with the following: all conditions specified in the Protocol and Protocol amendments and/or addenda; Good Clinical Practice Guidelines; the approval of Ethical Review Board ("ERB"); data privacy laws and all other applicable national, state and local laws regulations and standards. Investigator and Institution shall ensure that all of sub investigators , associates, colleagues and employees involved in the conduct of the Study at Study Sites also understand and agree to comply with these obligations and the provisions of this Agreement.

In carrying out Investigator and Institution's responsibilities under this Agreement, Investigator and Institution agree to comply with all applicable anti-bribery laws in the countries where Investigator and Institution have Institution's principal place of business and where Investigator and Institution conduct activities under this Agreement. Additionally, Investigator and Institution understand and agree to comply with the U.S. Foreign Corrupt Practices Act, as revised, which generally prohibits the offer, promise, payment or giving of anything of value either directly or indirectly to any government official for the purpose of obtaining or retaining business or any improper advantage. For purposes of this section, "government official" means any official, officer, representative, or employee of, including any doctor employed by, any non-U.S. government department, agency or instrumentality (including any government-owned or controlled commercial enterprise), or any official of a public international organization or political party or candidate for political office. Additionally, if Investigator and Institution or any of Institution's owners, directors, employees, agents, and consultants are government officials, Investigator and Institution agree that Lilly's payment of Investigator and Institution in connection with this Agreement is not intended to influence any decision that any individual may make in their capacity as a government official. Investigator and Institution further represent that neither Investigator and Institution nor any of Institution's owners, directors, employees, agents, or consultants will directly or indirectly offer to pay, promise to pay or give anything of value to any government official for purposes of (i) influencing any act or decision of such government official in his official capacity; (ii) inducing such government official to do or omit to do any act in violation of the lawful duty of such official; (iii) securing any improper advantage; or (iv) inducing such government official to use his influence with the government or instrumentality thereof to affect or influence any act or decision of the government or such instrumentality with respect to any activities undertaken relating to this Agreement. Additionally, Investigator and Institution will make reasonable efforts to comply with requests for information, including answering questionnaires and narrowly tailored audit inquiries, to enable Lilly to ensure compliance with applicable anti-bribery laws. Investigator and Institution agree that Lilly's payment to Investigator and Institution in connection with the services to be provided under this Agreement is not

intended to influence any decision Investigator and Institution may make regarding the prescription of Lilly medicines or to otherwise influence any pending or future Lilly business.

Investigator and Institution shall also ensure that each investigator and sub-investigator at Institution's Study Site (s) provides Lilly with the appropriate financial information for compliance with all applicable laws and regulations and Lilly policy, and Investigator and Institution understand and shall ensure that each investigator and sub-investigator understands that laws, regulations and Lilly policy may require certain financial information to be submitted to regulatory authorities.

If Investigator is not a licensed physician, Investigator and/or Institution shall ensure that a licensed physician is an investigator or sub-investigator at Study Site (s) and will be responsible for patient care and other appropriate aspects of this Study.

Investigator acknowledges that Investigator has read and understands all information in the investigator's brochure provided to Investigator by Lilly, including the potential risks and side effects of the Study drug.

Investigator and Institution agree not to pay fees to another physician for the referral of patients.

Investigator and Institution agree that if Investigator and/or Institution collect any biological samples for independent research from Study subjects, such samples will only be collected prior to the administration of the Study drug(s) or device(s). Additionally,. Investigator and Institution agree to obtain separate informed consent documents, as well as distinct ERB approval for such research, and to comply with all applicable privacy laws related to such samples.
Investigator and Institution agree to only use an informed consent document which has been reviewed and approved by Lilly.

Investigator and Institution agree that Lilly, Lilly-designated representatives and domestic or foreign regulatory agencies may inspect procedures, facilities and Study records (including portions of other pertinent records for all patients in the Study) and those procedures, facilities or Study records of any contractor, agent Study Site (s) used in conducting the Study. Investigator and Institution shall provide Lilly with immediate notice of any governmental or regulatory review, audit or inspection of of the facility or processes related to the Study Lilly shall be given the opportunity to provide assistance to Investigator and Institution in responding to any such review, audit or inspection. Investigator and Institution shall provide Lilly with the results of any such review, audit or inspection. When data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Information obtained from such inspections may be shared with Lilly and Lilly-designated representatives. In the event that there is a lack of compliance with this Agreement, Lilly is entitled to secure compliance or discontinue shipments of Study drug and end Investigator and/or Institution's participation in the Study.

B. Clinical Trial Materials and Record Retention

Drugs furnished for the Study will be used solely under the Protocol and may not be used for any other purposes. Investigator and Institution shall follow Lilly's instructions related to disposition of clinical trial materials. Investigator and Institution shall be responsible for compliance with all laws and regulations applicable to any destruction or disposition of clinical trial materials at Study Site(s). All Study records must be retained for fifteen (15) years after completion or termination of the Study, provided, however, that in the unlikely event that ICH or FDA record retention requirements, (i.e., two

(2) years after the date of marketing application approval by FDA for the Study drug(s) indication investigated, or if an application is not approved, two (2) years after the FDA is notified by Lilly of discontinuation of the IND) are longer than fifteen (15) years, Lilly will notify Investigator and Institution regarding any additional length of time that records must be retained to meet such requirements. The Investigator and/or Institution shall use their best efforts to prevent premature destruction of Study records.

If there is a change of responsibility/ownership of Study records (ex. Investigator retires or hospital closes), Investigator and Institution must notify Lilly.

C. Confidentiality and Non-Use

All information provided to Investigator and/or Institution by Lilly or Lilly-designated representatives, or generated by Investigator and/or Institution in connection with the Study, will be kept in confidence and not used for any purpose not expressly provided for in this Agreement for at least five (5) years after the termination or conclusion of the Study, except to the extent that Lilly gives Investigator and/or Institution written permission or particular information is required by laws or regulations to be disclosed to the ERB, the patient or local regulatory agencies. To the extent disclosure is requested by any other person or entity, Investigator and/or Institution shall promptly notify Lilly and shall not disclose any information without Lilly's prior written consent. If such disclosure is sought by a third party under a claim of legal right, Investigator and/or Institution will reasonably cooperate with Lilly in the event Lilly wishes to take legal action to challenge such claim or the disclosure; provided, however, in no event shall Investigator and/or Institution be obligated to defy any law, regulation or judicial or governmental order. Investigator and Institution shall be responsible for ensuring that their employees, sub investigators, contractors and agents are obligated to these same terms of confidentiality and non-use. The terms of confidentiality and non-use set forth herein shall supersede any prior terms of confidentiality and non-use agreed to by the parties in connection with this Study. The terms of this Agreement shall also be considered confidential information and may be disclosed only to the extent required by law or necessary for approval of this Study.

Additionally, in the event Investigator is invited to be an author of a Lilly publication or presentation during the course of or after the conclusion of the Study covered by this Agreement, Investigator and Institution agree that they will hold all new information (including data from other investigator sites for multi-site studies) provided to Investigator or Institution by Lilly or Lilly-designated representatives, or generated by Investigator or Institution in connection with such authorship, in confidence for five (5) years from the date of such disclosure or the generation of information, as applicable. This obligation survives the expiration, cancellation or termination of this Agreement.

The foregoing obligations of confidentiality and non-use will not apply to information that:

(1) is or later becomes part of the public domain other than through Investigator or Institution's act or omission;

(2) was known by Investigator and/or Institution prior to disclosure by Lilly or becomes known from an independent source or third party under no obligation to Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or

(3) is independently developed, as shown by written documentation, by Investigator or Institution or their personnel who have not had access to confidential information provided by Lilly.

D. Data

Data generated in connection with the Study, excluding patient medical records not recorded as case report forms, , raw source data, original medical records, "Source Documents" and "Source Data" as defined in ICH guidelines, other personal record and the Investigators personal notes shall be the sole property of Lilly and shall be subject to the obligations of Confidentiality and Non-Use set forth above. Institution and/or Investigator shall have the right to use the data for their own internal non-commercial educational, research, quality assurance, and/or patient care purposes.

E. Information Security

Institution and Investigator represent and certify that they have documented information security policies, standards and/or procedures in place to protect the confidentiality and integrity of confidential information, as well as certain protected health information as that term is defined under local privacy laws. Institution and Investigator further represent and certify that they have procedures and/or processes for identifying threats and vulnerabilities to their information system(s), and will train their personnel accordingly. The Institution agrees that all personal data transferred to or stored on any mobile device, including but not limited to smart phones, laptop computers, compact discs, PDAs, thumb drives, backup tapes, and/or zip drives, shall utilize encryption.

F. Publications

Notwithstanding the obligations of Confidentiality and Non-Use set forth above, Investigator and Institution will be free to publish and present the results of the Study subject to the following conditions: Lilly will be furnished with a copy of any proposed publication or presentation for review and comment thirty (30) days prior to such presentation or submission for publication. Such thirty (30) day period does not begin until receipt of the proposed publication or presentation at Lilly in Indianapolis, Indiana. At the expiration of such thirty (30) day period, Investigator and/or Institution may proceed with the presentation or submission for publication; provided, however, that in the event Lilly has notified Investigator or Institution in writing that Lilly reasonably believes that prior to such publication or presentation it must take action to protect its intellectual property interests, such as the filing of a patent application claiming an invention or a trademark registration application, Investigator and/or Institution shall either (1) delay such publication or presentation for an additional sixty (60) days or until the foregoing action(s) have been taken, whichever shall first occur; or (2) if Investigator and/or Institution are unwilling to delay the publication or presentation, Investigator and/or Institution will remove from the publication or presentation the information which Lilly has specified it reasonably believes would jeopardize its intellectual property interests. Under certain circumstances, a shorter review period may be granted in writing by Lilly. Investigator and/or Institution will assist Lilly in obtaining reprints of Investigator or Institution's publication(s) resulting from the Study.

Notwithstanding the foregoing, scientific conclusions and professional judgments regarding the results of a Study in any publication submitted by Investigator shall be determined solely by Investigator and will adhere to the policies and principles of the International Committee of Medical Journal Editors and other major medical journals and will not be subject to censor or unreasonable control or delay by Lilly.

G. Inventions

If during the course of the Study or within one (1) year after termination of this Agreement, Investigator and/or Institution conceive or actually reduce to practice what Investigator and/or Institution believe to be a new invention (including, without limitation, new uses, processes, formulations, therapeutic combinations or methods) occurring as a result of the performance of the Study covered by this Agreement or involving the Study drug(s), device(s), or simple derivatives of the Study drug(s) (e.g. but not limited to, antibody fragments, analogs, salts, solvates, conformers, stereoisomers, racemic mixtures, amorphous forms, crystal forms, crystal habits, metabolites, prodrugs, free acids, chelates, complexes, synthetic intermediates, isotopic or radiolabeled equivalents or mixtures thereof), Investigator and/or Institution shall promptly notify Lilly. The new invention or use shall be the sole property of Lilly. As such, Institution and Investigator hereby assign the exclusive ownership of any such Invention to Lilly.

H. Publicity

Consistent with the obligations of Confidentiality and Non-Use set forth above Investigator and/or Institution agree to the following:

(1) Solicitation of patients. Lilly and the ERB must approve, in writing, the text of any communication soliciting patients for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, internet advertisements or communications and newsletters. Such communications must comply with applicable laws and guidelines.

(2) Press releases. Lilly must approve, in writing, press statements by Investigator and/or Institution regarding the Study or the Study drug(s) before the statements are released.

(3) Inquiries from media and financial analysts. During and after the Study Investigator and Institution may receive inquiries from reporters or financial analysts. Investigator and Institution agree to confer with Lilly's Research Physician or Medical Director at +91-124-4753000 or Lilly's Corporate Communications Department in the United States at (001-317-276-3402) to discuss such inquiries before responding to them.

(4) Use of name. Neither Lilly nor Investigator and Institution will use the name or names of the other party or their employees in any advertising or sales promotional material or in any publication without prior written permission; provided, however, Investigator and Institution agree to the use of their names in Study publications and communications, including clinical trial web sites and Study newsletters and Lilly may disclose Investigator and Institution's name, business contact information and the names of any sub-investigators, the type of services performed by Investigator and Institution and and/or any sub-investigator for Lilly under this Agreement, the existence and terms of this Agreement, and the amount of compensation Lilly paid in exchange for Investigator and Institution's services or the services of any sub-investigator, in order to comply with applicable laws and regulations. Investigator and Institution shall be responsible for ensuring that all sub-investigators have consented to these same terms of disclosure.

I. Debarment Certification (Generic Drug Enforcement Act of 1992)

Investigator and Institution agree that they are not and have not been debarred or disqualified from participating in clinical research by any United States regulatory authority or by any other regulatory authority, and that they will not use or involve any person or organization in connection with this Study that is or has been debarred or disqualified by any regulatory authority from participating in clinical research. In the event that Investigator and/or Institution or any person or organization they use or involve

in connection with the Study should become debarred or disqualified during the course of the Study, Investigator and/or Institution agree to promptly notify Lilly in writing.

J. Contract Research Organization Involvement
Lilly shall be entitled to authorize a contract research organization to perform certain sponsor obligations for this Study. Investigator and Institution agree to cooperate with any Lilly-authorized contract research organization in performing this Study.

K. Equipment
Lilly is providing Investigator and/or Institution with equipment ("Equipment") for use in the Study. Investigator and Institution agree to comply with all manuals and instructions from Lilly regarding the use and care of the Equipment. Investigator and Institution agree that the Equipment shall remain in the same condition, ordinary wear and tear excepted, and that Investigator and Institution shall be responsible for the Equipment including the maintenance (and recalibration) or any risk of loss in connection with the Equipment during the term of the Study. Investigator and Institution will follow Lilly's instructions for disposition of the Equipment at the completion or termination of the Study.

II. LILLY SUPPORT

Lilly will provide Investigator and/or Institution with Study drug(s) and/or device(s) as applicable to the Study. In addition, Lilly will provide financial support for the Study as follows:

A. Payee
Payment in connection with the Study will be made to the name and address listed below:

Payee name: SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES
Address: Raebareli Road, Lucknow, Uttar Pradesh - 226014
PAN Number: AAAJS3913N
GST Number: 09AAAJS3913N2ZN
(Identification Number for Tax Purposes)

B. Payment Schedule
In connection with the Study, Institution will be paid in accordance with the terms set forth in the budget ("Budget"), attached hereto as Exhibit A. For those amounts designated for patient services, Institution will receive payment only for data received based on the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the Budget. Such compensation is limited to payment for the number of patients designated in the Budget who are enrolled in the Study by Close-Out4, unless Lilly gives Investigator or Institution written approval to enroll additional patients or extend the enrollment period. In the event that such approval is granted, Institution will be paid in accordance with the fees set forth in the Budget for the additional patients. Other than the final payment, Lilly shall not issue any payment for a total amount less than INR 1,000 (Rupees One Thousand Only). In the event the amount due in any given period is less than INR 1,000 (Rupees One Thousand Only), such amount shall carry over without payment to the next payment period. In addition to the payments set forth above, Lilly will also reimburse Payee for reimbursable expenses as set forth in the Budget.

To be eligible for payment, all procedures must be performed in full compliance with the Protocol and this Agreement, and the data submitted must be complete and correct. For data to be complete and correct, each patient must have signed an ERB-approved consent document, and all procedures designated in the

Protocol must be carried out on a "best efforts" basis; omissions must be satisfactorily explained. Final payment will be made by Lilly to the Payee when all patients at the Site have completed the Study and upon final acceptance by Lilly of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Lilly, the return of all unused supplies to Lilly, and upon satisfaction of all other applicable conditions set forth in this Agreement. It is expected that for all items required under the Protocol for which Lilly has agreed to provide compensation, Lilly will be the sole source of compensation. Institution will not seek payment from any third party payor, whether public or private, for any costs covered by payments made by Lilly under this Agreement. Matters in dispute shall be payable upon mutual resolution of such dispute.

When Investigator and/or Institution data are reviewed by an on-site scheduled visit of a Lilly-designated representative, Investigator and/or Institution will have all reasonably available data obtained through the preceding day complete and ready for evaluation. Lilly reserves the right to refuse payment for data not received by Lilly within ten (10) days after the representative's review.

In addition, if Lilly requests Investigator and/ or Institution attendance at a Study startup meeting or other meeting necessary to provide Investigator and/or Institution information regarding the Study or Study drug, Lilly shall reimburse Institution for reasonable and necessary travel and lodging expenses (including meals) that are incurred to attend such meeting(s) that have been specifically approved in advance by Lilly. Lilly shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses, provided that Lilly receives such documentation within sixty (60) days of the date that the expenses were incurred.

C. Subject Injury Reimbursement

Lilly agrees to reimburse Institution for the following additional costs:

(1) All reasonable and customary costs incurred and associated with the diagnosis of an adverse event involving the Study drug or a Protocol procedure; and

(2) All reasonable and customary costs incurred for treatment of physical injury to the subject if Lilly determines after consulting with Investigator that the adverse event was reasonably related to administration of the Study drug or Protocol; provided, however, that:

(a) such costs are not covered by the subject's medical or hospital insurance or other governmental program providing such coverage;

(b) the adverse event is not attributable to Investigator and/or Institution or any of their agents' or employees' negligence or misconduct;

(c) the adverse event is not attributable to any underlying illness, whether previously diagnosed or not; and

(d) Investigator and Institution have adhered to and complied with the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device used in the Study provided that deviations from the Protocol and recommendations resulting from

an imminent threat to the health or safety of a Subject that do not cause the injury to the Subject will not disqualify Institution and/or Investigator from reimbursement under this provision .

Lilly shall have the option of paying the additional costs directly to the provider of the service or to Institution .

D. Limit of Patient Entry or Enrollment and Study Termination

Lilly reserves the right to limit entry or enrollment of additional patients at any time. This may occur in a competitive-enrollment Study because sufficient patients have been entered by other investigators to complete the needs of the Study. Lilly also reserves the right to terminate Investigator, Institution or any patient's participation in the Study or the Study itself at any time for any reason. Investigator and/or Institution may terminate the Study upon thirty (30) days written notice in the event (1) there is a breach of a material provision of this Agreement by Lilly, which breach is not cured by Lilly within ninety (90) days following receipt from Investigator and/or Institution of written notice thereof; (2) if the Investigator becomes unavailable due to death or disability and Institution and Lilly are unable to agree upon an acceptable replacement; or (3) if the authorization and approval to perform the Study is withdrawn by any local regulatory authority, any United States regulatory authority or by the ERB. In the event Investigator and/or Institution's participation in the Study or the Study itself is terminated, Investigator and/or Institution agree to return, retain or dispose of all Study drug(s) in accordance with instructions to be provided by Lilly and regulatory requirements.

In the event of termination, payments will be made for all work that has been performed up to the date of termination and shall be limited to reasonable non-cancelable costs which were incurred by Investigator and/or Institution in connection with the Study as required under the Protocol and contemplated in the Budget. If any payments exceed the amount owed for work performed under the Protocol, Investigator and/or Institution agree to return the excess balance to Lilly.

III. Data Privacy and Security

(1) Site Personnel Data

Lilly may collect personal information from Investigator and Institution personnel including but not limited to names, titles and business contact information ("Site Personnel Data") and may provide that information to Lilly's business partners and vendors working with Lilly on matters related to the Study to fulfill Lilly's business purposes, including:

(1) Compliance with laws and regulations regarding possible financial conflicts of interest;
(2) Assessment of personnel qualifications to conduct the Study;
(3) Quality control and Study management; and
(4) Disclosures to ERBs, Ethics Committees or national or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Study.

Site Personnel Data may also be aggregated with data from other Lilly sources and evaluated for business decisions including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists.

Investigator and Institution personnel may have access to Site Personnel Data about themselves that Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate.

Investigator and Institution agree to obtain the permission of their personnel for the transfer and use of Site Personnel Data for the purposes described in this section

Investigator and Institution may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data. Lilly agrees to comply with all applicable laws and regulations regarding Lilly's use of Site Personnel Data.

IV. INDEMNIFICATION and INSURANCE

In consideration of the performance by Investigator, Institution and their staff, officers, agents and employees ("Indemnitees") of the Study, Lilly agrees to indemnify, defend and hold harmless the Indemnitees from and against loss, damage, cost and expense of claims and suits (including reasonable legal fees) resulting from an injury to a patient seeking damages alleged to have been directly caused or contributed to by any substance or procedure administered in accordance with the Protocol, including the cost and expense of handling such claims and defending such suits; provided, however, (1) that Indemnitees have adhered to and complied with all applicable federal, state and local regulations (including, without limitation, obtaining informed consents and IRB approvals), the specifications of the Protocol and all recommendations furnished by Lilly for the use and administration of any drug or device described in the Protocol; (2) that Lilly is promptly notified of any such claim or suit; (3) that the Indemnitees cooperate fully in the investigation and defense of any such claim or suit; (4) that Lilly retains the right to defend the lawsuit in any manner it deems appropriate, including the right to retain counsel of its choice; and (5) that Lilly shall have the sole right to settle the claim or suit; provided, however, that Lilly shall not admit fault on Indemnitees' behalf without Indemnitees' advance written permission. In addition, Lilly's obligation of indemnification shall not extend to any loss, damage or expense arising from the negligence, willful malfeasance or unlawful act or malpractice by the Indemnitees, it being understood that the administration of any substance in accordance with the Protocol shall not constitute negligence, willful malfeasance or unlawful act or malpractice for purposes of this Agreement. Lilly hereby agrees that any deviations from or failures to adhere to the terms of the Protocol that are mutually agreed upon in writing by all parties to the Study (including the ERB) or any deviations from the Protocol that are necessary to eliminate an immediate safety hazard to the Study participants are not considered violations of the Protocol or failures to adhere to the terms of the Protocol pursuant to this provision.

Lilly warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the obligations of indemnification provided above. Upon written request, Lilly will provide evidence of its insurance, or if self-insured, its most recent audited financial statement to Institution.

V. SURVIVORSHIP CLAUSE

The obligations under the sections INVESTIGATOR AND INSTITUTION OBLIGATIONS, PRIVACY DATA AND SECURITY, SUBJECT INJURY REIMBURSEMENT and INDEMNIFICATION shall survive the expiration, termination or cancellation of this Agreement. Investigator and/or Institution shall promptly notify Lilly in the event Investigator and/or Institution breach any of the terms and/or obligations contained in this Agreement or become aware of such breach.

VI. ASSIGNMENT

Institution shall not assign, transfer or otherwise delegate any of its obligations under this Agreement without Lilly's prior written consent in each instance. Institution and Investigator acknowledge that Lilly will have the right to assign this Agreement to any of its affiliates, to a contract research organization in connection

with the transfer of sponsor obligations, or in connection with a merger or other corporate reorganization, or otherwise in connection with the transfer of all or substantially all of Lilly's assets that bear on the Study drug(s) or device(s)

VII. AMENDMENTS

This Agreement may be amended by an instrument in writing signed by the parties to this Agreement, pursuant to the terms of Payment Schedule or as otherwise agreed by the parties. Amendments may be required or requested in order to document changes or modifications to the Protocol, the Study Budget and/or Institution or Investigator information. Institution and Investigator shall use their best efforts to review any amendments to this Agreement in good faith and in a timely manner and, if applicable, to facilitate the timely execution of said amendments.

VIII. INDEPENDENT CONTRACTOR

Investigator, Institution and Lilly will be acting as independent contractors and not as agents, partners or employees of any other party. No party has the authority to make agreements with third parties that are binding on any other party.

By signing this Agreement, Investigator and Institution represent and warrant that they have the authority and ability to or will otherwise contractually bind any individual or entity who performs services for Investigator and Institution in connection with the Study hereunder to the terms and conditions of this Agreement. This Agreement is legally binding when, but not until, each party has received from the other a counterpart of the Agreement signed by the authorized representative. The parties' representatives may sign separate, identical counterparts of this document; taken together, they constitute one agreement. A signed counterpart may be delivered by any reasonable means, including facsimile or other electronic transmission. Additionally, the parties agree that facsimile or email copies of this Agreement are considered to be a legal original and signatures thereon shall be legal and binding agreement.
This Agreement represents the entire understanding between the parties and supersedes all other agreements, express or implied, between the parties concerning the subject matter hereof. This Agreement has been thoughtfully considered by the parties and, consequently, shall not be strictly construed against either party. This Agreement shall be interpreted in accordance with the laws of India (Lucknow Jurisdiction).

If the foregoing is acceptable, please sign the enclosed Agreement and return it to Lilly by: (1) forwarding the scanned or electronically signed document to **sharma_roopesh@lilly.com**; (2) by facsimile transmission to **91-124-4753036**; or (3) by mail/courier service to **Roopesh Sharma, Eli Lilly and Company, Plot No. 92, Sector**

– 32, Gurugram, Haryana - 122001. If You have any questions, please call **Roopesh Sharma** at **91-8826462220.**

Sincerely,

ELI LILLY AND COMPANY (INDIA) PVT. LTD.

(Signature of Authorized Official)

Dr. Rajeev Sharan Shrivastava
Associate Director – Regulatory Affairs and Pharmacovigilance
(Typed or Printed Name and Title)

15-Dec-2020.
(Date)

AGREED AND ACCEPTED:
Investigator

Dr. Amita Agarwal

21-Dec-2020
(Date)

AGREED AND ACCEPTED:
Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI)

(Signature of Authorized Official)

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

(Typed or Printed Name and Title)

(Date) 05/01/21

Initials: Eli Lilly and Company

Initials: Principal Investigator

Initials: Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI)

Exhibit-A

The following table outlines cost and frequency of grant heads that will be paid for in the trial I4V-MC-JAHU:

S. No.	Investigations	Visit Frequency (X)	Cost/frequency INR (Y)	Total Amount (X*Y*Z)
1.	**Principal Investigator Fee:** @Rs. 5500/- per patient **clinic** visit x 22 visits for 05 enrolled patients **(Z)**	V1 – V21 & V801/ET	5500	6,05,000
2.	**Co-Investigator Fee:** @ Rs. 3300/- patient **clinic** visit x 22 visits for 05 enrolled patients	V1 – V21 & V801/ET	3300	3,63,000
3.	**Phlebotomist Fees** @ Rs. 1000/- per patient **clinic** visit x 22 visits for 05 enrolled patients	V1 – V21 & V801/ET	1000	1,10,000
4.	**Patient & Parents Reimbursement** including TDS @ Rs. 2222/- per patient x 22 visits x 05 enrolled patients	V1 – V21 & V801/ET	2222	2,44,420
5.	**Archival Fees (payable after site close-out)**	One time	50,000	50,000
6.	**Start-up Fee** Includes communication expenses for telephone & fax, Courier, stationary, storage, high speed internet etc.	Initial Start-Up Fee after SIV	60000	60,000
7.	**Study Close-Out Fee** payable at the time of study close-out	NA	30000	30,000
8.	**Study Cordinator Fee** @ INR 18000 per month effective after SIV for 36 months or until LPV whichever comes earlier	NA	18000	6,48,000
9.	**Institutional Grant**	25% of total grant of Sr. No. 1, 2, 3		2,69,500
	TOTAL			**23,79,920**

Initials: Eli Lilly and Company

Initials: Principal Investigator

Initials: Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI)

Exhibit B Payment Schedule

The payments will be made per patient visit entered into the data management system (based on the investigation schedule and cost outlined in the table number 1, unless indicated otherwise, as per the following table:

S. No.	Particulars	Cost INR
	Total Payment for each visit inclusive of 25% institutional Grant on PI, Co-I, & Phlebotomist per visit	
1.	Visit 1	14472
2.	Visit 2	14472
3.	Visit 3	14472
4.	Visit 4	14472
5.	Visit 5	14472
6.	Visit 6	14472
7.	Visit 7	14472
8.	Visit 8	14472
9.	Visit 9	14472
10.	Visit 10	14472
11.	Visit 11	14472
12.	Visit 12	14472
13.	Visit 13	14472
14.	Visit 14	14472
15.	Visit 15	14472
16.	Visit 16	14472
17.	Visit 17	14472
18.	Visit 18	14472
19.	Visit 19	14472
20.	Visit 20	14472
21.	Visit 21	14472
22.	Visit 801	14472
23.	Early termination visit (If applicable)	14472

Exhibit C: Procedural Payment

S. No.	Investigations/Frequecy	Name of Test/Procedure	Cost in INR/Procedure	Estimated No. of Procedures/Patients	Estimated Total Cost
1.	As Applicable	Urine Pregnancy Test (Assuming 5 patients)	500	20/Patient	50,000
2.	As Applicable	TB test (Assuming 5 patients)	1000	1/Patient	5,000
3.	As Applicable	ECG (Assuming 5 patients)	500	1/Patient	2,500
4.	As Applicable	X-ray (Assuming 5 patients)	700	1/Patient	3,500
5.	As Applicable	Uveitis evaluation (Assuming 5 patients)	1500	1/Patient	7,500

Exhibit D: COVID-19 Related Expenses

Sr. No.	Particulars	Amount (INR)
1.	**Ancillary Supplies (PPE) and Study Site Cleaning** - Costs that are a study-specific expense incurred as part of continued protocol compliance. *(e.g., gloves, masks, PPE Kit etc.)* ***Notes: These expenses can be reimbursed by invoice that indicates the dates of completed clinic visits for each patient during the period of heightened coronavirus protections/restrictions. If the site completes multiple clinic visits for the patient on different dates of service, each visit's costs could be included on the invoice.***	INR 1000 per visit
2.	**Patient Travel Reimbursement (Local Transportation by Taxi/Cab etc..) for Clinical Trial Site Visit** - This local transportation reimbursement is NOT applicable for any travel by flight/Air fare - Reimbursement to be based on actual expenses supported by third-party receipts - Investigator site will need to provide Tax Invoice after deducting the Patient Inconvenience/Patient Travel cost as mentioned in Exhibit A. which will be paid along with standard patient visit payment.	Maximum of INR 20000 per visit

Additional details for the COVID-19 related expense reimbursement

- The investigator site will be responsible to provide valid invoices with requested detail as mentioned in the Table above for reimbursement.
- Institutional overhead will NOT be applicable for the COVID-19 expenses.

Descriptions:

- Total budget for one patient: **Rs. 4,79,684**
- The site enrollment target (Z): 05 patients
- Total Budget for site for 05 patients including screen failure cost, Procedural cost & admin grant: **Rs. 25,93,140**

Payment Cycle and Procedure:

- Payments will be made on a monthly basis, based on invoices received **on or before 5th working day of every month**
- All the visits and procedures included in the invoice must be entered into eCRF (Case Report Form) for the payment to be processed

Goods & Services Tax:

- The above mentioned calculation of visit payment does not include goods & services tax. Goods & Services Tax will be paid as applicable based on the invoices received.

Screen Failure & Early Discontinuation Patients:

- The Payment of screen failure patients would be paid on the basis of patients who have signed the ICF and the eCRF data entry for the same has been completed in Electronic Data Management System (INFORM) and as per amount specified for screen failure in Exhibit A (Visit 1).
- Early discontinuation visit will be paid at Rs. 14472, as applicable.

Patient Reimbursement:

- Patient reimbursement amount is inclusive of the TDS amount.
- This LOA is valid for a maximum of 10 Screen-failure & 05 Randomized patients.
- Screen failure visit cost i.e. Rs. 14472 will be paid as applicable.

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INDIA NON JUDICIAL

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA89629265139670T
Certificate Issued Date	:	30-Aug-2021 03:20 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ PADMANABHANAGAR3/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08390604997279 78T
Purchased by	:	SHIRE HUMAN GENETIC THERAPIES INC
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	SHIRE HUMAN GENETIC THERAPIES INC
Second Party	:	SGPGIMS
Stamp Duty Paid By	:	SHIRE HUMAN GENETIC THERAPIES INC
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

AMARAJYOTI CO-OPERATIVE SOCIETY LTD. DRB-3/REG/02/ 42156/2017-18 BANGALORE

Please write or type below this line

Statutory Alert:

1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

(139)

Sponsored Observational Study Agreement
(Non-Interventional)

[A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India]

Clinical Protocol No. SHP669-406

THIS SPONSORED OBSERVATIONAL STUDY AGREEMENT (the "**Agreement**") is made as of 01 Sept 2021 (the "**Effective Date**"), by and among [**Shire Human Genetic Therapies, Inc**], a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, having a place of business at 300 Shire Way, Lexington, MA 02421, United States ("**Sponsor**"), **IQVIA RDS (India) Private Limited** (formerly Quintiles Research (India) Private Limited) , a corporation organized under the laws of India having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road, Bangalore – 560103, Karnataka, India ("**CRO**"), Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPIMS) organized under the laws of India with its principal place of business at Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow- 226014, Uttar Pradesh, India ("**Institution**") and Dr. Shubha R Phadke, (the "**Investigator**" and together with the Institution, the "**Site**"). . For purposes of this Agreement, each of Sponsor, CRO, and Institution may be referred to as a "**Party**" and together as the "**Parties**."

RECITALS

WHEREAS, Sponsor is interested in collecting safety and/or efficacy data on a product and during routine application and desires to obtain the services of Institution and the Investigator to conduct a non-interventional clinical study;

WHEREAS, the Investigator is an employee of Institution, experienced in the conduct of clinical research studies in humans, who shall serve as the principal investigator for the Study (defined below);

WHEREAS, the Investigator and Institution have reviewed sufficient information regarding the Protocol (defined below) to evaluate his/her/its interest in participating in the Study, and the Investigator and Institution both are equipped to undertake the Study and desire to perform the Study on the terms and conditions set forth herein;

WHEREAS, Sponsor has entered into a separate agreement with CRO to provide support services to facilitate Sponsor's oversight, monitoring, and administration of the Study in

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accordance with 21 CFR Part 312.52 and with this Agreement; Sponsor has authorized CRO to handle Sponsor communications with Institution and Investigator with respect to the Study and this Agreement; and, upon written notice to Institution and Investigator, Sponsor may designate other such organizations to replace or work with CRO in the performance of such services for Sponsor, and Institution and Investigator shall permit such other organizations to perform any or all of Sponsor's obligations under this Agreement;

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

1. Study Protocol.

The Site will conduct the study entitled "[A Post Marketing Surveillance (PMS) Study for VPRIV® (velaglucerase alfa) in India]" (the "**Study**") at Institution in accordance with the Protocol, incorporated herein by reference, as may be further amended pursuant to the terms of this Agreement (the "**Protocol**"). The Protocol sets forth the Study activities and responsibilities to be undertaken by the Parties. The Protocol shall be considered final after it is signed by Sponsor and the Investigator and approved by the relevant institutional review board ("**IRB**") or Ethics Committee ("**EC**"). Thereafter, the Protocol may be amended only by prior written consent of Sponsor and subsequent approval by the IRB/EC. The Parties agree that in the event of a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement shall govern, except in the case of matters relating directly to clinical procedures or patient safety, with respect to which the terms of the Protocol shall prevail.

2. Conduct of Study.

A. The Site shall, and shall ensure that its employees and agents shall, conduct the Study in strict compliance with any and all applicable federal, national, state, local or other jurisdictional laws, rules, regulations, policies, guidelines, guidances, governmental requirements, as may be applicable to the Parties, Study Personnel, and/or the Study, DCGI New Drugs and Clinical Trials Rules, 2019, NMC Regulations [National Medical Commission], 2019 as may be amended from time to time or any replacement regulations], and state and local tax and finance regulations ("**Applicable Law**"), including without limitation:

i. the U.S. Code of Federal Regulations, 21 C.F.R. Parts 50, 54, 56 and 312; the requirements of the Federal Food, Drug and Cosmetic Act ("**FDCA**") and any similar or successor legislation; any policies or guidance issued by the FDA;

ii. all applicable rules, policies, or guidance issued by the European Medicines Agency ("**EMA**"); all applicable requirements of the U.S. Federal Controlled Substances Act, as enforced by the U.S. Drug Enforcement Administration ("**DEA**");

iii. the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**") Guidelines for Good Clinical Practices as adopted or issued by any governmental or other regulatory authority, including FDA and EMA (collectively, "**GCP**" or "**GCP Guidelines**"),

iv. all applicable local, state, federal, and national laws and regulations regarding the protection of privacy, personal data, and medical data, including the Health Insurance Portability and Accountability Act of 1996 and any regulations and official

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guidance promulgated thereunder ("**HIPAA**"), and the General Data Protection Regulation ("**GDPR**") (collectively, the "**Privacy Regulations**");

v. all applicable state HIV testing laws;

vi. all applicable local, state, federal, and national laws and regulations regarding the reporting of any fees and other expenditures paid to healthcare professionals, including without limitation, the Physician Payment Sunshine Provision set forth in Section 1128G(e)(6) of the Social Security Act, added in by Section 6002 of the Affordable Care Act (the "**US Federal Sunshine Act**");

vii. all applicable anti-bribery legislation, including without limitation, the Foreign Corrupt Practices Act of 1977, as amended, 15 U.S.C. §§ 78dd-1, et seq., and the UK Bribery Act, and the rules and regulations promulgated thereto; all applicable requirements of the U.S. Federal Anti-Kickback law; and

viii. all generally accepted professional standards.

B. The Site further agrees to conduct the Study in accordance with all conditions imposed by the FDA and the IRB/EC, and all requirements of the Institution.

C. For the avoidance of doubt, Sponsor also shall be subject to Applicable Law.

D. Upon the prior written consent of Sponsor, Institution and/or Investigator may use sub-investigators, other employees of Institution, and contractors to perform Study-related services under this Agreement (together with Investigator, "**Study Personnel**"). Institution shall ensure that:

i. Adequate numbers of qualified Study Personnel are assigned to the Study to meet its obligations under this Agreement;

ii. All Study Personnel perform their Study responsibilities and fulfill their obligations under this Agreement, including strict adherence to the Protocol and the Investigator's instructions;

iii. All Study Personnel have the necessary licenses and certifications as may be required to perform their Study responsibilities, and shall, upon request of Sponsor, provide such documented evidence of any such licenses and certifications;

iv. All Study Personnel receive the necessary information, education, and training in any applicable regulatory requirements, proper performance of the Protocol, GCP Guidelines, and any other applicable guidelines relevant to the Study and performance of the Protocol, and shall, upon request of Sponsor, provide such documented evidence of any such education and training; and

v. Any Study Personnel not employed by Institution shall comply with the same terms that bind Investigator hereunder.

E. Without limitation of the foregoing, the Site further agrees that, in the performance of the Study, the Site and the Site's employees and agents shall:

i. provide to each potential subject verbal and written information about the risks, benefits, and requirements associated with Study participation and obtain in advance

from each Study subject a signed and dated written consent form that has received prior approval from the IRB/EC and Sponsor and that is consistent with the Protocol, this Agreement, and complies with 21 C.F.R. Parts 50 and 56, HIPAA or other Privacy Regulations, the GCP Guidelines, and other Applicable Law;

ii. require that no subject in the Study may participate concurrently in any other clinical study in which a study drug is given. Should Site become aware of any such concurrent study participation, it shall notify Sponsor promptly;

iii. maintain and prepare records relating to the Study and subjects participating in the Study as specified in the Protocol and consistent with the requirements of 21 C.F.R. Part 312, GCP Guidelines, and other Applicable Law;

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

v. submit all data and all requested information to Sponsor or its designee, and undertake all activities hereunder in a timely, efficient, and competent manner so that the time schedules set forth in the Protocol and this Agreement are strictly met;

vi. ensure that all clinical data are accurate, complete, and legible, and that such data are promptly and fully disclosed to and produced for the inspection and use of Sponsor or its designee at any time upon reasonable request during normal business hours;

vii. cooperate with Sponsor and its designee in all of their efforts to support and monitor the Study, including without limitation, allowing Sponsor and/or its designee on-site access to the facilities where the Study is being conducted and any and all records and other documents associated with the conduct of the Study as reasonably requested by Sponsor or its designee, providing all requested documentation in a timely and organized manner, and keeping Sponsor fully apprised of the progress of the Study;

viii. record all adverse events on the Adverse Events page(s) of the CRFs and report all adverse events and serious adverse events in accordance with 21 C.F.R. Part 312, GCP Guidelines, and the Protocol and cooperate with Sponsor in identifying and resolving unexpected occurrences involving the Protocol;

ix. retain all records relating to the Study, including without limitation, all records that the FDA requires to be maintained under 21 C.F.R. Part 312, for the period required by Applicable Law, and prior to the Site's disposition of any Study records, the Site shall provide prior written notice to Sponsor, and upon Sponsor's request and at Sponsor's reasonable expense, the Site shall either retain such Study records for the period specified by Sponsor or send such records to Sponsor, as designated by Sponsor;

x. cooperate with and support the Sponsor with regard to the relevant applications or communications with the relevant IRB/EC; and

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xi. conduct the Study solely at the Site's facilities; the location for the conduct of the Study may not be changed without Sponsor's prior written consent.

F. Institution further represents and warrants to Sponsor that:

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

ii. Institution shall properly supervise all persons performing the Study under its direction and shall ensure that such persons comply with the terms of this Agreement;

iii. Institution has the capability in-house to perform the Study and will not engage any external sub-investigators or third parties to participate in the conduct of the Study without obtaining Sponsor's prior written consent to do so subject to the terms of this Agreement; and

iv. The Institution has obtained and will maintain all licenses, authorizations, and permits required by law for the Institution to conduct the Study under this Agreement and in compliance with the Protocol.

3. Investigator; Replacement.

A. In the event that the Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Institution shall promptly notify Sponsor of such event, and shall cooperate, in good faith and expeditiously, to find a replacement investigator acceptable to Sponsor (a "**Replacement Investigator**"); provided, however, that the Site and/or Investigator shall continue to be bound by all obligations and conditions stipulated in this Agreement until a Replacement Investigator acceptable to the Sponsor is found. In the event an acceptable Replacement Investigator is not found within thirty (30) days of Sponsor's receipt of such notice (or such longer period as mutually agreed upon by the Parties), Sponsor may terminate this Agreement in accordance with the terms of this Agreement. The Site's cooperation in finding a Replacement Investigator does not negate its obligation to perform its obligations under this Agreement up to Completion (defined below) or the effective date of any termination of this Agreement. The Parties hereto agree, in the event that a Replacement Investigator is designated pursuant to this article, that such Replacement Investigator shall be bound by all terms of this Agreement that are applicable to the Investigator, and the Parties shall amend this Agreement accordingly.

B. Investigator shall provide Sponsor with a copy of the Investigator's current curriculum vitae, which shall include a description of the Investigator's relevant experience.

C. Investigator shall provide CRO and Sponsor with sufficient accurate financial disclosure information to permit Sponsor to submit a complete and accurate certification or disclosure statement as required by 21 C.F.R. Part 54, and will promptly update the information if any relevant changes occur during the course of the Study and for one (1) year following completion or termination of the Study.

4. Term; Study Initiation.

A. This Agreement shall commence as of the Effective Date and shall continue until completion of all obligations herein, including without limitation receipt by Sponsor or its designee of all Study data and resolution of all corresponding queries in a form acceptable to Sponsor ("**Completion**"), unless otherwise terminated in accordance with this Agreement.

B. The Study shall be initiated on the date that Sponsor or its designee notifies the Investigator to begin enrollment, which notification will occur only after: (i) the Investigator obtains IRB/EC approval to conduct the Study; and (ii) the Site has received sufficient materials from Sponsor to initiate the Study. The Investigator shall deliver a copy of the IRB/EC approval letter to Sponsor or its designee, and Sponsor shall not deliver Study materials to the Site until it has received a copy of such approval letter. If IRB/EC approval is not obtained, this Agreement shall be null and void. No subject may be enrolled and no Study procedures may be performed unless the subject has given all necessary permissions to participate in the Study consistent with the Protocol and the terms of this Agreement. The Site shall not request informed consent from any subject or allow any subject to participate in the Study prior to the initiation of the Study in accordance with the Protocol and the terms of this Agreement. The Site shall immediately notify Sponsor by telephone promptly followed by written notification if IRB or EC approval for the Study is lapsed, suspended, or withdrawn in whole or in part.

5. Payment Terms and Budget.

A. In consideration for performance of the Study, Sponsor or its designee will compensate Institution in accordance with the payment terms and budget set forth in Schedule A attached hereto and made a part hereof (the "**Budget**"). No other benefits or compensation, beyond those expressly included in the Budget, or as otherwise approved by Sponsor in advance in writing, will be provided by Sponsor to Institution. Absent a good faith dispute, payments shall be made by Sponsor within thirty (30) days of receipt of a detailed invoice from Institution, which invoice shall be consistent with the provisions set forth in the Budget. All invoices will be itemized as set forth in the Budget. Any expenses, including travel expenses, for which reimbursement is sought, shall be paid only if (i) the request for reimbursement for such expenses is accompanied by original receipts and (ii) Sponsor has expressly agreed to reimburse such expenses in the Budget, or as otherwise approved in advance by Sponsor in writing. Such expenses may include, if identified in the Budget or as otherwise approved in advance by Sponsor in writing, Investigator's reasonable travel-related expenses and registration fees incurred in presenting Study Results (defined in Article 9 - Ownership of Data; Publication, below) at medical conferences, in accordance with and subject to the terms of Article 9. The last payment due pursuant to the Study will be made by Sponsor after the Site completes all of its obligations hereunder, and Sponsor has received all completed CRFs, all deliverables defined in the Protocol, and all other data and rights to which Sponsor is entitled under this Agreement. Reports comparing actual costs incurred by Institution to costs paid by Sponsor will be provided by Institution to Sponsor within thirty (30) business days of any written request. The terms of the Budget may be modified only upon the prior written consent of the Parties.

B. Non-emergency additional tests or services (i.e., those tests or services not required by the Protocol or performed in excess of Protocol requirements) shall not be compensable hereunder without the prior written consent of the Sponsor.

C. The Parties to this Agreement specifically intend to comply with all applicable laws, rules, and regulations, including (i) the federal anti-kickback statute (42 U.S.C. 1320a-7(b)) and the related safe harbor regulations; and (ii) the Limitation on Certain Physician Referrals, also referred to as the "Stark Law" (42 U.S.C. 1395 (n)). Accordingly, the Parties acknowledge and agree that the amounts payable by Sponsor under this Agreement represent the fair market value of the covered costs associated with the Study and no part of any consideration paid hereunder is a prohibited payment for the recommending or arranging for the referral of business or the ordering of items or services; nor are the payments intended to induce illegal referrals of business.

D. If applicable, any equipment supplied by Sponsor or its designee for use in the Study will be used solely in connection with the Study and will be returned to Sponsor or its designee promptly upon completion or termination of the Study, unless otherwise agreed in writing by Sponsor.

E. Pursuant to Applicable Law, the Site understands and acknowledges that Sponsor may be required to disclose to relevant governmental authorities the payments made by or on behalf of Sponsor to the Site under this Agreement, as well as the purpose and nature of such payments.

6. Confidentiality.

A. All information (including, but not limited to, verbal, written, and electronically stored or transmitted information), materials, and documents provided to the Site by or on behalf of Sponsor in connection with the Study, including but not limited to preclinical data and case report forms, and all information, data, reports and knowledge developed by Site as a result of work in connection with the Study shall be considered "**Confidential Information.**" Confidential Information includes, without limitation, the Protocol, the Investigators' Drug Brochure, Study correspondence, and Study Results; provided, however, that Institution and Investigator may use and/or publish Study Results in accordance with the terms of this Agreement. During and after the term of this Agreement, the Site hereby agrees that it: (i) shall maintain in strict confidence all of the Confidential Information, (ii) shall not disclose or disseminate Confidential Information to any third party, (iii) shall not use the Confidential Information for any purpose other than the performance of the Study, and (iv) shall safeguard the Confidential Information using the same degree of care, but no less than a reasonable degree of care, as the Site uses to protect its own confidential information. Such Confidential Information shall remain the exclusive confidential and proprietary property of Sponsor, and shall be disclosed only on a need-to-know basis and only to the Site and the Site's employees and agents. The Site agrees to ensure that each of the Site's employees and agents rendering services hereunder are obligated to treat, and do treat, the Confidential Information as confidential consistent with the terms hereof.

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

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

ii. is lawfully disclosed to the Site by a third party entitled to disclose such information not subject to any obligation of confidence;

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

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

C. In the event that Confidential Information is required to be disclosed by law or regulation, (i) Site shall immediately notify Sponsor and provide Sponsor an opportunity to object to such disclosure, prior to making any such disclosure, and (ii) in no event shall Site disclose more than the minimum amount of Confidential Information required to be disclosed to comply with such law or regulation. Site shall reasonably cooperate, at Sponsor's expense, with Sponsor to enable Sponsor to challenge or limit such disclosure.

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

E. Institution and Investigator acknowledge and agree that any violation of the terms of this Agreement relating to the disclosure or use of Confidential Information may result in irreparable injury and damage to Sponsor not adequately compensable in monetary damages, and for which Sponsor may have no adequate remedy at law. Institution and Investigator acknowledge and agree, therefore, that if the disclosure and non-use terms herein are violated, Sponsor may need to seek injunctions, orders, or decrees in order to protect the Confidential Information and will be entitled to do so without having to post a bond.

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

8. Use of Study Results.

The Site shall maintain the security of Study subject data and shall obtain all authorizations or other necessary documentation from Study subjects to allow disclosures of Study subjects' data to Sponsor and its agents and contractors, and, if this is a multi-site Study, with researchers at other Study sites, to the extent necessary for them to comply with this Agreement, the Privacy Regulations, and other Applicable Law, and for purposes related to the Study (including, without limitation, Study monitoring, analysis of Study data, and preparing applications and other reports to be submitted to regulatory authorities). The Institution and the Investigator agree to transfer to Sponsor only those data, including but not limited to clinical data regarding patients, which are made anonymous. This means that the data could be transferred by the Sponsor to any country in the world for processing including countries which do not have data protection laws as strict as those in force in the European Union (including, without limitation, the United States of America).

9. Ownership of Data; Publication.

A. All data, information, and results generated during the course of conducting the Study, including, without limitation, the completed CRFs and any reports prepared by the Site (collectively the "**Study Results**") shall be provided promptly to Sponsor or its designee and shall be the sole property of Sponsor. The Site shall have the right to publish or otherwise publicly disclose the Study Results for its own internal, bona-fide, academic, non-commercial purposes, in accordance with the terms of this article. The medical records or other Source Documents, as defined by current ICH Guidelines, that support the Study Results shall remain the property of Institution.

B. For purposes of this Agreement, "Publication" shall mean any paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video,

instructional material, presentation (in the form of a written summary), or other public disclosure of the Study Results, in printed, electronic, oral, or other form. The Parties understand and agree that participation in the Study may involve a commitment to publish the data from all sites participating in the Study in a cooperative publication with other investigators prior to publication or oral presentations of the Study Results on an individual basis. The Site agrees not to publish or present the Site's Study Results until such time as either the aggregate multi-site Study results are published in a cooperative Publication or for a period of one (1) year after termination or Completion of the Study at all participating sites, whichever shall first occur. After that time, the Site may publish the Site's Study Results in scientific journals or present the Study Results at symposia or other professional meetings in accordance with the following provisions:

At least ninety (90) days prior to submitting an abstract, manuscript, or other document for publication, a copy of the proposed Publication will be provided to Sponsor by the Site for review. Upon Sponsor's request, the Site agrees to remove any and all Confidential Information (expressly excluding Study Results) identified in the Publication and to delay such submission or presentation for an additional ninety (90) day period in order to allow Sponsor time to file any patent application(s). All Publications of the Study Results shall appropriately reference the multi-site study Publication, if any, or the fact that the Study Results are a subset of data resulting from a larger multi-site study.

D. The Parties agree that all related research Publication, as defined below, will be submitted to journals that offer public availability via Open Access (including publisher platforms/repositories and self-archiving). Open Access refers to the free at point of entry, online availability of published research output with, where available, rights of re-use according to an End User License. Unless otherwise required by the journal in which the publication appears, or the forum in which it is made, authorship will comply with the International Committee of Medical Journal Editors (**ICMJE**) Recommendation for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical journals. Participation as an investigator, in and of itself, does not confer any rights to authorship of publications.

E. Site warrants the compliance of all Study Personnel with the provisions of this article.

10. Release of Information; Use of Name. Sponsor may use, refer to, and disseminate reprints of scientific, medical, and other published articles relating to the Study that disclose the name of the Investigator and/or Institution, consistent with U.S. copyright laws. Sponsor also may disclose the name of Investigator and Institution and shall provide a description of this Study on public websites (e.g., www.clinicaltrials.gov) consistent with and as required by Applicable Law. No Party shall use the name of any other Party or such other Party's affiliate's name(s) in connection with any advertising or promotion of any product or service without the prior written permission of such other Party or such other Party's affiliate, as applicable; provided, however, that the limitations contained in this article shall not apply to any documents that may be necessary or appropriate for Sponsor or the Site to provide to a federal, state, or local governmental agency or in scientific publications and grant applications. The Site and its employees, agents, and representatives shall not communicate with or provide any information to any media representative (including, but not limited to, traditional and alternative press outlets such as newspapers, magazines, television, radio and Internet) regarding Sponsor, Sponsor's products or the Study without the prior express written approval of Sponsor.

11. **Independent Contractors**. The Site shall act as an independent contractor and shall not be construed for any purpose as the partner, agent, employee, servant, or representative of the Sponsor or CRO. Accordingly, the employee(s) and agent(s) of the Site shall not be considered to be employee(s) and agent(s) of the Sponsor or CRO, and the Site shall not enter into any contract or agreement with a third party that purports to obligate or bind the Sponsor or CRO. Site personnel performing the Study hereunder shall at all times be under the exclusive direction and control and shall be employees or agents of the Site and shall not be employees, agents, or representatives of the Sponsor or CRO.

12. **[RESERVED]**

13. **[RESERVED]**

14. **Inspections, Audits, and Study Monitoring.**

A. **Regulatory Inspection**. The Site shall notify Sponsor and its designee immediately by telephone promptly followed by written notification of any inquiries, correspondence, or communications with or from the FDA or any other governmental or regulatory authority relating to the Study. If a regulatory authority, including without limitation the FDA, requests permission to or does inspect the Site's facilities or research records relating to the Study, the Site will cooperate with the regulatory authority's representative(s) and permit such inspection, and will make all reasonable efforts to permit Sponsor to review the records before the inspection and be present and available during such inspections. The Institution shall provide sufficient and appropriate space as deemed needed by the Investigator and/or Sponsor for such inspections without delay at no additional cost to Sponsor. Investigator and appropriate Study personnel will be available during such inspection to comply with the legitimate requirements of the inspection and to explain and discuss records and documentation related to the Study. The Site shall provide to Sponsor or its designees, in writing and in an organized manner, copies of all materials, correspondence, statements, forms, and records that the Site receives, obtains, or generates in connection with any such inspection or in connection with any inquiries, communications, or correspondence from the FDA or any other governmental or regulatory authorities. The Site will make reasonable efforts to segregate, and not disclose, all documents and materials that are not required to be disclosed during such an inspection, including financial data and pricing information.

B. **Sponsor Inspection/Audit.**

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

ii The Site agrees to take reasonable actions requested by Sponsor to cure deficiencies noted during an audit or inspection. The Site will have five (5) days to cure a breach of the requirements of Schedule B. If the breach is not cured within five (5) days or is incapable of cure, Sponsor has the

right to immediately terminate the Agreement, including any applicable Statements of Work hereunder, without penalty.

C. Each Party shall bear their own expenses in relation to audits conducted pursuant to this article.

15. Termination.

A. This Agreement may be terminated in whole or in part prior to Completion upon written notice as follows:

i. by any Party, effective immediately upon written notice, if (1) the authorization and approval to conduct the Study in the United States is permanently and irrevocably withdrawn by the FDA; or (2) the emergence of any adverse reaction or side effect related to the Study is of such magnitude or occurs with such frequency that either the Investigator, in his or her reasonable medical judgment, or Sponsor, determines that subject safety requires such termination;

ii. by Sponsor, effective immediately upon written notice, if (1) the Investigator is unwilling or unable to serve as the principal investigator and the Parties are not able to agree on a substitute pursuant to the terms of this Agreement; (2) the Site fails to perform the Study in accordance with the terms of the Protocol (excluding permitted deviations pursuant to the Study Protocol and under the terms of this Agreement), this Agreement, or Applicable Law; or (3) Sponsor deems enrollment to be insufficient to reasonably complete the Study in the time frame necessary to meet Sponsor requirements;

iii. by Sponsor or CRO, upon thirty (30) days written notice; or

iv. by the Site, upon forty-five (45) days written notice, in the event of a material breach of this Agreement by Sponsor and Sponsor's failure to remedy such breach within such forty-five (45) day period.

B. In the event of termination of this Agreement prior to Completion, the Site shall, upon receipt or delivery of notice of termination, make all reasonable efforts to minimize incurring further costs. In the event of such early termination, Sponsor shall make a final payment to the Site for outstanding amounts due for services performed in accordance herewith and for reasonable, actual, direct costs incurred as set forth in the Budget through the date of notice of termination. Sponsor also shall reimburse Institution for any reasonable, non-cancelable commitments properly incurred (i) prior to the date of notice of termination and (ii) after the date of notice of termination but reasonably necessary to ensure the safety of enrolled subjects. Upon reasonable request by Sponsor, Institution shall provide Sponsor with documentation of any such committed and non-cancellable costs.

C. Immediately upon receipt or delivery of notice of termination, the Site shall (i) comply with post-termination procedures included in the Protocol, if any, and (ii) unless otherwise directed by Sponsor, cease enrolling subjects into the Study and cease the Study-related treatment of subjects already enrolled in the Study, except if the safety of such enrolled subjects could be compromised. Notwithstanding the foregoing, the Site shall continue to provide follow-up care to subjects as long as necessary to ensure the safety of such enrolled subjects.

D. **[RESERVED]**

E. Promptly upon Completion or termination of this Agreement for any reason, the Site will furnish to Sponsor or its designee all CRFs, whether complete or incomplete, up to the effective date of termination, as well as all devices, equipment, and Sponsor materials that were furnished to the Site in connection with the performance of the Study, whether the same are in the Site's actual possession or under its control. Confidential Information and materials will be returned, at Sponsor's instruction, to Sponsor, except for record copies or samples which the Site is required by law to retain. Within thirty (30) days of termination of this Agreement or completion of the Study (whichever comes first), Investigator will submit a final written report of the Study to Sponsor.

16. Patent Rights and Inventions.

A. It is recognized and understood that certain existing intellectual property, inventions, and technologies of Sponsor and the Institution are the separate property of each Party and are not affected by this Agreement, and neither shall have any claims to or rights in such separate existing intellectual property, inventions, and technologies of the other Party.

B. Any new invention, development, improvement, or discovery made or conceived by the Site, whether or not patentable, resulting from the Study or Confidential Information ("**Invention**") shall be promptly disclosed by the Site, in writing, to Sponsor. Except as otherwise expressly stated herein, and except as prohibited by federal or state law, any and all Inventions are the sole and exclusive property of Sponsor regardless of the inventor or discoverer. The Site shall, at Sponsor's expense, execute any and all applications, assignments, or other instruments and give testimony which Sponsor shall deem necessary to apply for and obtain letters of patent of the United States or of any foreign country or otherwise to protect Sponsor's interest therein. The Site shall not take any action that is inconsistent with Sponsor's ownership of such Inventions.

C. Title to any Inventions arising from the Site's proper conduct of the Study and conceived and reduced to practice solely by the Site and not arising from any Confidential Information shall be owned solely and exclusively by the Site. The Institution will offer Sponsor a first right of refusal to enter into an exclusive license for the Institution's rights in any such Invention. Such license shall be perpetual, exclusive, and worldwide to the maximum extent permitted by law, shall be on commercially reasonable terms, and shall provide Sponsor with an exclusive right to make, have made, use, sell, have sold, and offer to sell such Invention. If Sponsor declines to enter into such a license, and Institution then offers such license to a third party on terms more favorable than those offered to Sponsor, Sponsor shall have the right to enter into negotiations for said license on terms at least as favorable as those offered to such third party.

D. The Site represents that it has no present obligations to assign or exclusively license to any person or entity other than Institution or Sponsor any Inventions or other intellectual property covered by this article. The Site represents and warrants that all Study Personnel, consultants, or other parties engaged by the Site to conduct work under this Agreement shall be, prior to undertaking such work and for the entire duration of such work, contractually obligated to assign their rights in any Inventions to the Institution.

E. The obligations set forth in this article shall continue beyond Completion or any termination of this Agreement and shall be binding upon the Site and the Site's employees and agents.

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17. Indemnification; Insurance.

A. Sponsor Indemnification. Sponsor agrees to indemnify, defend and hold harmless Institution, its trustees, officers, employees, staff, subcontractors, and agents ("**Institution Indemnitees**") against any independent third party claim (each, a "**Claim**") arising out of (i) any side-effect or adverse reaction, illness, or injury directly resulting from procedures performed pursuant to the Protocol. The foregoing indemnity will not apply to the extent a Claim arises out of (1) the negligence, omission, or willful misconduct of any Institution Indemnitee or (2) the failure of any Institution Indemnitee to adhere to the terms of this Agreement, the Protocol, or any written instructions from Sponsor or its designee, or to comply with any Applicable Law or governmental requirements.

B. Institution Indemnification. Institution agrees to indemnify, defend, and hold harmless the Sponsor, its directors, officers, employees, staff, and agents (the "**Sponsor Indemnitees**") against any Claim arising out of (i) the negligence, omission, or willful misconduct of any Institution Indemnitee or (ii) the failure of any Institution Indemnitee to adhere to the terms of this Agreement, the Protocol, or any written instructions from the Sponsor or its designee, or to comply with any Applicable Law or governmental requirements.

C. Indemnification Procedure. The Party or Parties seeking indemnification under this article shall (i) give written notice to the indemnifying Party within five (5) business days after (1) receiving any Claim or (2) learning of any potential Claim; (ii) permit the indemnifying Party to assume the defense and/or disposition of any such Claim or related litigation, provided that counsel selected by such indemnifying Party is reasonably acceptable to the Party or Parties seeking indemnification; and (iii) cooperate with the indemnifying Party in all reasonable respects with regard to the defense of such Claim, with reasonable out-of-pocket costs of the Party or Parties seeking indemnification to be reimbursed by the indemnifying Party. The indemnifying Party under this article shall not enter into any settlement agreement with a claimant without the prior written permission of the Party or Parties seeking indemnification, which permission shall not be unreasonably withheld.

D. Sponsor Insurance. Sponsor agrees to maintain a policy or program of insurance or self-insurance at levels sufficient to support its obligations assumed herein. Sponsor shall provide a certificate of insurance evidencing such coverage upon written request by the Institution.

E. Institution Insurance. The Site represents and warrants that it has and will maintain appropriate insurance, including malpractice insurance, in amounts sufficient to pay all claims arising from its activities or obligations under this Agreement. Sponsor represents that it has and will maintain appropriate insurance and/or self-insurance in amounts sufficient to respond to events that may occur in the conduct of the Study.

18. [RESERVED]

19. Consequential Damages. Neither CRO nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to CRO or Sponsor for any lost profits, lost opportunities, or other consequential damages.

20. Anti-kickback and Anti-Fraud. Institution and Investigator agree that their judgment with respect to the advice and care of each Study subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or CRO provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation pursuant to this Agreement, or which are not part of the ordinary care they would normally provide for the Study subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

21. Anti-bribery. Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or items of value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a government official or otherwise, in order to assist Sponsor to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any items of value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, CRO or Sponsor may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if CRO or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

22. <u>CRO DISCLAIMER</u>

CRO expressly disclaims any liability in connection with the Study, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by CRO.

This Section 22 "CRO Disclaimer" shall survive termination or expiration of this Agreement.

23. Complete Agreement; Amendment; Notice. This Agreement together with all attachments hereto constitutes the entire agreement among the Parties with respect to the subject matter hereof and all prior negotiations, representations, agreements, and understandings with respect to the subject matter hereof are superseded hereby. No agreements amending, altering, or supplementing the terms hereof may be made except by means of a written document signed by the duly authorized representatives of each of the Parties. Any notice to be given hereunder shall be given by personal delivery, by recognized express courier, or by registered or certified mail, return receipt requested. Such notice shall be addressed to a Party at the address set forth below, except as set forth in Schedule A. Any Party may change its address for notice by giving written notice of such change to the other Parties.

To Sponsor:	**Shire Human Genetic Therapies, Inc** **[300 Shire Way, Lexington, MA 02421, United States]** **Attn: Project Manager – Protocol # [*SHP669-406*]**
With a copy to:	Attn: Legal Department (same Sponsor address)
To Institution:	Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow-226014, Uttar Pradesh, India Attn: Dr.R K Dhiman (Director)
To Investigator:	Dept. of Medical Genetics, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow-226014, Uttar Pradesh, India

24. Binding Effect; Survival of Terms. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. The rights and obligations of the Parties which by intent or meaning have validity beyond termination of this Agreement (including, but not limited to, rights with respect to ownership, patents, confidentiality, and indemnification) shall survive Completion or any termination of this Agreement.

25. Governing Law. This Agreement and all matters arising out of or relating to this Agreement shall be governed by, and construed and enforced in accordance with, the laws of the country in which Institution is located without regard to the conflicts of law provisions thereof. Any dispute arising hereunder shall be tried exclusively by the courts where Institution is located i.e. Lucknow, India and each Party hereby consents to the jurisdiction of such courts and waives any objections thereto.

26. Waiver. Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect. All waivers must be set forth in writing and executed by duly authorized representatives of the Parties.

27. Severability. If a judicial determination is made that any of the provisions contained in this Agreement constitute an unreasonable restriction against any Party or are otherwise unenforceable, such provision or provisions shall be rendered void or invalid only to the extent that such judicial determination finds such provision or provisions to be unreasonable or otherwise unenforceable, and the remainder of this Agreement shall remain operative and in full force and effect.

B. Data Protection Schedule

[*Remainder of page intentionally left blank*]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as the Effective Date defined above.

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS)

By: _____ 22/X/21
(Signature)
Name: Dr. R K Dhiman
Title: Director

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

Dr. Shubha R Phadke (Principal Investigator)

_____
(Signature)
Name: Dr Shubha P Phadke

Shire Human Genetic Therapies, Inc

By: _____
(Signature)
Name:
Title:

IQVIA RDS (India) Private Limited

By: _____ 3 Sep 2021
(Signature)
Name: Shweta Pradhan
Title: Director and Head Site Management

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as the Effective Date defined above.

Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS)

By: _____
(Signature)
Name: Dr. R K Dhiman
Title: Director

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

Dr. Shubha R Phadke (Principal Investigator)

_____
(Signature)
Name: Dr Shubha Phadke

Shire Human Genetic Therapies, Inc

By: _____
(Signature)
Name:
Title:

IQVIA RDS (India) Private Limited

By: Pradhan
(Signature) 3/Sep/2021
Name: Shweta Pradhan
Title: Director and Head Site Management

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Schedule A

BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAIL

Site agrees that the payee designated below is the proper payee for this Agreement, and that payment under this Agreement to the payee designated below will not violate any rules or policies of the Site, will not violate applicable national, state, or local laws or regulations, and that payment under this Agreement will be made only to the following payee (the "**Payee**"):

PAYEE NAME:	Director SGPGIMS Research Account
PAYEE ADDRESS:	Director, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, lucknow-226014, Uttar Pradesh, India
PAYEE EMAIL ADDRESS	director@sgpgi.ac.in
BANK NAME	State bank of India
BANK ADDRESS	SGPGIMS, Raebareli Road, Lucknow
BANK ACCOUNT NUMBER	10095237491
IFSC	SBIN0007789
IBAN NUMBER	NA
SWIFT CODE / BRANCH CODE	SWIFT CODE: SBININBB500
VAT/GST/TAX ID NUMBER	GST Number: 09AAAJS3913N2ZN

In case of changes in the Payee's bank details above, Payee is obliged to inform Company in writing. The parties agree that in case of any such changes, a formal amendment to this Agreement shall not be required, and that Payee shall inform Company of the change in bank details by written notice provided to the Company.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, shall be determined by a separate agreement between the Investigator and the Payee, which may involve different payment amounts and different payment intervals than the payments made by Company to the Payee. The Investigator acknowledges that if the Investigator is not the Payee, Company will not pay Investigator even if the Payee fails to reimburse the Investigator.

B. PAYMENT TERMS

Company, or a Company affiliate on behalf of Company, will reimburse the Payee Quarterly, in accordance with this Agreement and attached budget. Compensation will be based upon completed Case Report Forms ("**CRFs**").

Services performed that result in disqualified data due to major, disqualifying Protocol violations are not payable under this Agreement.

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by Company or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility.

Company will pay the Payee *quarterly*, based on a completed months per subject basis in accordance with this Compensation Schedule. Payment will be made upon verification of actual subject visits, and will be paid by Company to the Payee. The compensation will be made based upon prior month enrollment data confirmed by subject CRFs received from the Site supporting subject visitation.

Site shall be responsible to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to the Investigator, the Site and its employees and/or collaborators.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Goods and Services Tax ("**GST**") in India, and that it is required to charge GST for the services rendered to Company at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide Company with an invoice, to be sent to Company at the address mentioned in Section E of this Exhibit B, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

C. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

D. DISCONTINUED OR EARLY TERMINATION PAYMENTS

Reimbursement for discontinued or early termination of Subjects will be prorated based on the number of completed CRFs/Month for those Subjects in accordance with the Protocol.

E. INVOICE

Original invoices pertaining to this Study of the following items must be issued for reimbursement to:

IQVIA RDS (India) Private Limited
(formerly **Quintiles Research (India) Private Limited**)
Attn: Accounts Payable
Address: III Floor, Etamin Block, Prestige Technology Park, Sarjapur- Marathahalli Outer Ring Road, Bangalore– 560103, Karnataka, India

Invoices will not be processed unless they reference the Sponsor name, Study name, Protocol number, Investigator name, Site name and Payee GST registration number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for Study activity.

F. Institutional Review Boards ("IRB")/Ethics Committee ("EC") Payments

IRB/EC costs will be reimbursed on a pass-through basis and are not included in the budget above. Any subsequent re-submissions or renewals, upon approval by Company and Sponsor, will be reimbursed upon receipt of appropriate documentation.

H. BUDGET

The Budget is as follows:

Payment Milestone Table(s):

MILESTONES	Investigator Grant Per Subject		Institutional Over heads 25% (IOH)	Investigator Grant Per Subject (Inclusive of Institutional Over Heads 25%)
	Consumables & Contingency	Manpower for source and Data entry		
Month 1: Screening & Enrollment	28000	5000	11000	44000
Month 2	6550	5000	3850	15400
Month 3	6550	5000	3850	15400
Month 4	6550	5000	3850	15400
Month 5	6550	5000	3850	15400
Month 6	6550	5000	3850	15400
Month 7	6550	5000	3850	15400
Month 8	6550	5000	3850	15400
Month 9	6550	5000	3850	15400
Month 10	6550	5000	3850	15400
Month 11	6550	5000	3850	15400
Month 12/End of Study / Early Withdrawal	11500	5000	5500	22000
Total (INR)	105000	60000	55000	220000

*All amounts are inclusive of any overhead.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED.

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Schedule B

DATA PROTECTION SCHEDULE

Where Institution jointly Controls the Processing of Personal Data (defined below) created, collected, or received pursuant to the Services under the Agreement, the Parties agree that the terms of this Schedule B shall apply to the Agreement. In the event of a conflict between this Schedule B and the Agreement with respect to the Processing of Personal Data, the terms and definitions of this Schedule B shall control and govern.

A. Definitions. Capitalized terms used herein shall have the meanings set forth in this Section A or in the Agreement.

1. **"Affiliate"** means an entity related to Institution or Sponsor, respectively, through common ownership or control.

2. **"Data Controller"** shall mean the entity which alone or jointly with others determines the purposes and means of the Processing of Personal Data.

3. **"Data Processor"** shall mean an entity which Processes Personal Data on behalf of the Data Controller.

4. **"Data Security Breach"** means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, Personal Data transmitted, stored, or otherwise processed.

5. **"Encryption"** or **"Encrypted"** means the transformation of data through the use of an algorithmic process, or an alternative method at least as secure, into a form in which meaning cannot be assigned without the use of a confidential process or key. For the purposes of this agreement, any encryption mechanism used must accord with industry best practices for data encryption. "Unencrypted" means data that is not encrypted or is encrypted using an encryption method of insufficient strength.

6. **"Government Authority"** means a legislative, executive, administrative, or regulatory entity, judicial body, or other public agency or authority of any country, state, territory, or political subdivision of a country, state, or territory, or a person or entity acting under a grant of authority from or under contract with such public agency or authority, that is authorized by law to enforce individual rights with respect to Personal Data, or to oversee or monitor compliance with privacy, data protection, or data security laws, rules regulations, or other Applicable Law.

7. **"Joint Controllers"** shall mean two or more entities, each a Data Controller, which jointly determine the purposes and means of the Processing of Personal Data.

8. **"Personal Data"** shall mean all individually identifiable information created, collected or received pursuant to the Agreement. Personal Data includes, without limitation, individually identifiable information created, collected or received concerning research subjects, patients, consumers, caregivers, and health care professionals.

9. **"Process"** or **"Processing"** shall mean any operation or set of operations which is performed upon Personal Data, whether or not by automatic means, such as collection, recording,

organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

10. **"Security Incident"**shall mean:
    a. any of the following:
        i. a Data Security Breach;
        ii. a security vulnerability that carries a material risk of compromising the confidentiality, integrity, or security of Personal Data; or
        iii. a violation of Applicable Law relating to the Processing of Personal Data under this Agreement;
    b. but shall exclude:
        i. any unintentional acquisition, access, or use of Personal Data by an employee or agent of Institution if such acquisition, access, or use was made in good faith and does not result in further unauthorized or inappropriate Processing of Personal Data;
        ii. any inadvertent disclosure by a person who is authorized to access Personal Data on behalf of Institution to another person authorized to access Personal Data on behalf of Institution, provided the information received as a result of such disclosure is not further used or disclosed in an unauthorized or inappropriate manner; or
        iii. any loss or unauthorized acquisition of or access to Encrypted Personal Data, provided the confidential process or key that is capable of compromising the security, confidentiality, or integrity of the Encrypted Personal Data is not also subject to loss or unauthorized acquisition or access.
    c. Notwithstanding paragraph (b), a "Security Incident" shall include any loss or unauthorized acquisition, access, or use of Personal Data that triggers a breach notification requirement under Applicable Law.

11. **"Technical, and Organizational Security Measures"** means those administrative, technical, and physical safeguards designed to protect the confidentiality, security, integrity and confidentiality of Personal Data, including measures aimed at protecting Personal Data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, in particular where the Processing involves the transmission of data over a network, and against all other unlawful forms of Processing.

B. <u>Identification of Parties</u>. The Parties agree that:

1. Institution and Sponsor both may Process Personal Data for their own, independent purposes. When Processing Personal Data for their own, independent purposes, each Party acts as a separate Data Controller.

2. When Processing Personal Data for purposes of fulfilling an obligation under the Agreement, Institution and Sponsor are jointly determining the purposes and means for the Processing of Personal Data and the Parties are acting as Joint Controllers.

3. Nothing in this Section B shall be interpreted to alter Institution's obligation to conduct the Study pursuant to the terms of the Agreement.

C. <u>Joint Controllers</u>. The Parties agree that with respect to Processing of Personal Data for purposes of fulfilling an obligation under the Agreement:

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1. *Use and Disclosure of Personal Data.*
   a. The Parties' Processing of Personal Data shall be governed by the Agreement, which sets out the subject matter, duration, nature, and purpose of the Processing, type of Personal Data and categories of data subjects, and obligations and rights of the Parties.
   b. Institution shall Process Personal Data in accordance with the Study Protocol. Institution agrees to obtain from each data subject, prior to that individual's participation in the Study, a signed informed consent approved in writing by Sponsor and any applicable ethics committee. Such consent shall authorize Sponsor and its representatives to Process Personal Data for the following purposes:
      i. conduct the research and to confirm research results;
      ii. report the research results to Government Authorities;
      iii. evaluate and improve the treatment, diagnostic, or preventative therapy being investigated;
      iv. assure the safety, effectiveness and quality of the research and the treatment, diagnostic, or preventative therapy being investigated;
      v. comply with Applicable Law;
      vi. conduct new research related to the disease or condition being investigated, or related to the treatment, diagnostic, or preventative therapy being investigated;
      vii. develop proposals for new research protocols; and
      viii. improve the design and efficiency of future research studies.
   c. Sponsor shall not attempt to re-identify data subjects except as necessary:
      i. To comply with Applicable Law.
      ii. For purposes of monitoring the conduct of the Study.
      iii. For purposes of monitoring, investigating, and responding to adverse events.
      iv. In order to respond to a claim or proceeding brought by a data subject in connection with the Study.

2. *Compliance with Applicable Law.*
   Both Parties agree to comply with all Applicable Law throughout the term of the Agreement.
   a. Both Parties understand that they have a duty to stay informed of possible changes to such laws throughout the course of this Agreement.
   b. Both Parties mutually covenant not to place the other in violation of Applicable Law.

3. *Registration of Data Processing.*
   It is the responsibility of each Party to effect and maintain all registrations for the Processing of Personal Data as required under Applicable Law.

4. *Data Protection Assistance.*
   a. *Data Protection Impact Assessment.* The Parties shall cooperate and assist each other with respect to any data protection impact assessments and/or prior consultations with Government Authorities that may be required in respect of Processing carried out under the Agreement.

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b. The Parties shall promptly make available to each other all information necessary to demonstrate compliance with this Schedule B and Applicable Law, and shall cooperate with relevant Government Authorities.

5. *Privacy and Security Programs.*
During the term of this Agreement, the Parties will each maintain a comprehensive privacy and security program designed to ensure that Personal Data will only be Processed in accordance with this Schedule B (a "Privacy Program"), including the appointment of a data protection officer as required by Applicable Law.
   a. *Security Measures*. The Parties will implement appropriate Technical and Organizational Measures to protect Personal Data and ensure a level of security appropriate to the risk as required by Applicable Law. The Parties agree to regularly test, assess and evaluate the effectiveness of the measures for ensuring the security of Processing.
   b. *Encryption.* The Parties agree that all Personal Data transferred to or stored on any mobile device, including but not limited to smart phones, laptop computers, compact discs, PDAs, thumb drives, backup tapes, and/or zip drives, shall utilize Encryption.

6. *Oversight of Personnel.*
   a. *Confidentiality*. The Parties shall ensure that their personnel engaged in the Processing of Personal Data are informed of the confidential nature of the Personal Data, have received appropriate training on their responsibilities, and have executed written confidentiality agreements. Institution shall ensure that such confidentiality obligations survive the termination of the personnel engagement.
   b. *Limitation of Access.* The Parties shall ensure that access to Personal Data is limited to those personnel performing services in accordance with the Agreement.

7. *Security Incidents.*
   a. *Notification of Security Incidents.* The Parties agree to notify each other within thirty-six (36) hours of discovery of a Security Incident.
   b. In the course of notification to each other, the Parties will provide, as feasible, sufficient information for the Parties to jointly assess the Security Incident and make any required notification to any Government Authority within the timeline required by Applicable Law. Such information may include, but is not necessarily limited to:
      i. The nature of the Security Incident, the categories and approximate number of data subjects and Personal Data records;
      ii. The likely consequences of the Security Incident, in so far as consequences are able to be determined; and
      iii. Any measures taken to address or mitigate the incident.
   c. The Parties will jointly decide on the basis of all available information and Applicable Law if the Security Incident will be considered a Data Security Breach and arrange for notification to data subjects and/or Government Authorities if required by law. Where the Parties decide that notification is required by law, Institution shall be responsible for providing such notification.
   d. *Assistance in Event of Security Incident.* In the event of a Security Incident relating to the Personal Data collected or received by Institution under this Agreement, Institution agrees to assist and fully cooperate as instructed by Sponsor with any internal investigation or external investigation by third parties, such as law enforcement, through the provision of information, employees, interviews,

materials, databases, or any and all other items required to fully investigate and resolve any such incidents and provide information necessary to provide required notifications. Institution agrees to take such remedial actions as the Parties mutually agree is warranted, such agreement not to be unreasonably withheld by Institution.

e. Institution shall not disclose, without Sponsor 's prior written approval, any information related to the suspected Security Incident to any third party other than a vendor hired to investigate/mitigate such Security Incident and bound by confidentiality obligations, except as required by Applicable Law.

f. Institution agrees to indemnify Sponsor for all losses resulting from any Security Incident due to negligence or willful misconduct by Institution, its agents, its affiliates, or any Processor retained by Institution, including but not limited to legal damages, government penalties, and/or mitigation expenses.

8. *Rights of Data Subjects.*

a. The Parties agree that, as between them, Institution is best able to manage requests from data subjects for access, amendment, transfer, blocking, or deletion of Personal Data. In the event Sponsor receives a request from a data subject for such access, amendment, transfer, blocking, or deletion, Sponsor shall forward the request to Institution.

b. Institution shall respond to data subjects' requests for access, amendment, transfer, blocking, or deletion of Personal Data in accordance with Applicable Law and the Agreement. Institution acknowledges that in order to maintain the integrity of Study results, the ability to amend, block, or delete Personal Data may be limited, in accordance with Applicable Law.

c. Sponsor acknowledges that data subjects may withdraw their informed consent to Study participation and consent to Processing of Personal Data at any time. Institution shall promptly notify Sponsor of any such withdrawal that may affect the use of the Personal Data under the Agreement.

9. *Notification of Inspection.*

Institution agrees to promptly notify Sponsor of any inspection or audit by a Government Authority concerning compliance with Applicable Law to the extent related to the services provided under the Agreement.

10. *Cross-Border Data Transfers.*

a. The Parties agree to only transfer Personal Data outside of the European Economic Area or Switzerland as allowed pursuant to Applicable Law.

11. *Records.*

Each Party shall maintain a written record of all Processing activities carried out under the Agreement. Such record shall contain, at a minimum:

a. The name and contact details of any Processors;

b. The name and contact details of the Processors' data protection officers;

c. The categories of Processing carried out;

d. Transfers to third countries or international organizations and documentation of the suitable safeguards employed;

e. A general description of the Technical and Organizational Measures taken to safeguard the Personal Data.

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Institution shall provide such written record to Sponsor promptly upon request and agrees that such written record may be submitted by Sponsor to any third- party data controller (where applicable) and to relevant Government Authorities.

12. *Processors.*
    a. The Parties agree that all Processing agreements shall be in writing and that Processors shall be required to comply with the terms of this Schedule B.
    b. Each Party shall be responsible for any noncompliance with the terms of this Schedule B by a Processor it has engaged, which noncompliance will constitute a breach as if committed directly by that Party.

13. *Delegation.*
    Sponsor may delegate its rights and obligations under this Schedule B to an Affiliate of Sponsor.

14. *Effect of Violation.*
    Failure to comply with any provision of this Schedule B shall constitute a material breach of the Agreement.

15. *Survival.*
    The obligations of confidentiality and data privacy under this Schedule B will survive the termination and/or expiration of this Agreement.

D. <u>Personal Data of Study Staff</u>. Institution shall be responsible for obtaining any necessary consents from Principal Investigator and all other Study Staff to the Processing of their Personal Data, as required under applicable laws Such consent shall inform Principal Investigator and Study Staff of, and obtain their agreement to, the following:

1. That their Personal Data, including name, contact details, government identification number, and financial information relating to, among other matters, compensation and reimbursement payments for Study conduct, will be Processed by Sponsor and Sponsor's Affiliates and agents in order to:
    a. Comply with Sponsor's and its Affiliate's obligations under Applicable Law,
    b. Assess the suitability of the Investigator and Study Staff for the Study,
    c. Prepare and submit regulatory filings, correspondence, and communications to Government Authorities concerning the Study,
    d. Conduct safety reporting and pharmacovigilance relating to the Study,
    e. Disclose payments and other transfers of value to Institution and Investigator in order to comply with transparency reporting laws, including but not limited to the US Physician Payments Sunshine Act and implementing regulations, as well as industry codes of practice or standards to which Sponsor and/or Sponsor's Affiliates are subject, and
    f. Consider from time to time potential sites and investigators for future studies.

2. That their Personal Data may be made available to Government Authorities and ethics committees in jurisdictions around the world.

3. That their Personal Data may be transmitted to countries around the world, including to countries whose data protection laws do not provide the same level of protection as that where they are located.

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4. That they may request access, amendment, blocking, or deletion of their Personal Data by Sponsor and Sponsor's Affiliates under Applicable Law.

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA53015018441773R
Certificate Issued Date	:	04-Dec-2019 01:19 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ K R PURAM/ KA-BN
Unique Doc. Reference	:	SUBIN-KAKACRSFL0822883039667938R
Purchased by	:	NOVO NORDISK INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	NOVO NORDISK INDIA PVT LTD
Second Party	:	Dr NARAYAN PRASAD SANJAY GANDHI P G I OF M SCIENCE
Stamp Duty Paid By	:	NOVO NORDISK INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	200 (Two Hundred only)

Karnataka SDDM-Co Society Ltd # 30010, K.R. Puram, Bangalore 36
Sign.........

Please write or type below this line

This non-judicial stamp of INR 200 forms an integral part of the **INVESTIGATOR AGREEMENT** (Novo Nordisk Sponsored Clinical Trial) executed between the following three parties, for the trial ID: NN9535-4321.

05 FEB 2020

1) Novo Nordisk India Private Limited ____________________

2) Dr. Narayan Prasad ____________________

10.02.20

3) Sanjay Gandhi Post Graduate Institute of Medical Sciences ____________________

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

INVESTIGATOR AGREEMENT
NOVO NORDISK SPONSORED CLINICAL TRIAL
Trial ID: NN9535-4321

This Investigator Agreement (hereinafter referred to as the "**Agreement**"), is entered into and executed at Bangalore, India and shall become effective as of on the last date of execution by the Parties to this Agreement (the "**Effective Date**")

By and between

NOVO NORDISK INDIA PRIVATE LIMITED

a Company registered under the Companies Act, 1956, having its registered office at Plot No. 32, 47-50, EPIP Area, Whitefield,
Bangalore - 560 066
CIN: U24111KA1994PTC015194

(hereinafter referred to as "**Sponsor**")

And

Dr. Narayan Prasad

a healthcare professional, having address at Department of Nephrology, C block Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebarli Road Lucknow

PAN: AAAJS3913N
(hereinafter referred to as the "**Principal Investigator**")

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences

a healthcare organization, located at Department of Nephrology, C block Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebarli Road Lucknow

PAN: AAAJS3913N
(hereinafter referred to as "**Institution**")

In the following, Sponsor, Principal Investigator and Institution are also referred to individually as "Party" and collectively as "Parties".

PREAMBLE

WHEREAS Sponsor wishes to conduct the following clinical trial in India: FLOW - Effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease; **Protocol ID:** NN9535-4321 (hereinafter referred to as the '**Trial**'). The nature of the Trial is further elaborated upon in this Agreement;

WHEREAS Sponsor wishes to conduct the Trial in cooperation with Investigator at the Institution;

WHEREAS The Investigator has the expertise and the Institution has the necessary resources relating to clinical trial design, conduct, evaluation and analysis. The Institution has agreed to assist Sponsor in the conduct of the Trial at the Institution under the supervision of its employee the Principal Investigator, under the terms and conditions of this Agreement.

1. DEFINITIONS

1.1 "Adverse Event" shall be defined as in APPENDIX 1.

1.2 "Confidential Information" shall mean all information, whether written, oral, or in any other form, pertaining to either Party's business, whether developed or acquired hereunder and whether kept in its original form.

1.3 "CRF" shall mean Case Report Form.

1.4 "FPFV" shall mean First Patient First Visit.

1.5 "Healthcare Organisation (HCO)" shall mean any legal person (i) that is a healthcare, medical or scientific association or organisation (*irrespective of the legal or organisational form, whether it is a Company, Sole Proprietorship, Partnership, Trust or otherwise*) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations within the scope of the EFPIA Patient Organisation Code) or (ii) through which one or more HCPs provide services.

1.6 "Healthcare Professional (HCP)" shall mean any natural person that is a member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of their professional activities, may prescribe, purchase, supply, recommend or administer a medicinal product. For the avoidance of doubt, the definition of HCP includes: (i) any official or employee of a government agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply or administer medicinal products and, (ii) any person whose primary occupation is that of a practising HCP irrespectively of any other employment

1.7 "Intellectual Property" shall mean any and all know-how, inventions, improvements and discoveries, whether patentable or not, arising from or related to the clinical trial covered by this Investigator Agreement.

1.8 "LPFV" shall mean Last Patient First Visit.

1.9 "LPLV" shall mean Last Patient Last Visit.

1.10 "Personal Data" shall mean the personal data as stipulated in APPENDIX 3.

1.11 "Protocol" shall mean protocol number [NN9535-4321]: [FLOW - Effect of semaglutide versus placebo on the progression of renal impairment in subjects with type 2 diabetes and chronic kidney disease], attached herein as APPENDIX 1.

1.12 "Serious Adverse Event" shall be defined as in the Protocol.

1.13 "SPC" shall mean Summary of Product Characteristics.

1.14 "SUSARs" shall mean Suspected Unexpected Serious Adverse Reactions.

1.15 "Termination Date" shall mean [24] weeks after LPLV unless this Agreement is terminated pursuant to Clause 12.4.

1.16 "Trial Materials" shall mean the materials used to conduct the Trial, including but not limited to CRF and auxiliary supplies.

1.17 "Trial Product" shall be defined as in the Protocol.

1.18 "Trial Subject" shall mean any subject participating in the Trial.

2. INTRODUCTION

2.1 The Parties hereby agree that the Principal Investigator shall carry out the Trial in accordance with the Protocol, as amended over time, and this Agreement. All appendices and amendments to the Protocol and the Agreement shall be deemed to be an integral part of this Agreement and may be updated from time to time by mutual agreement.

3. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

3.1 Prior to the Trial the Principal Investigator must:

a) assist the Sponsor to obtain all necessary approvals from the Institutional Ethics Committee (IEC) and relevant regulatory bodies, from the relevant departmental head of the Institution and from any other authority that is responsible for the administration of the Institution;

b) be fully informed of the Trial Protocol and the Trial Product and attend, or ensure a delegate attends, all Investigator's meetings for the Trial from time to time as required by Sponsor;

c) ensure all the Institution's employees and collaborators who are involved in the Trial fully understand and adhere to the Trial Protocol and the obligations of both the Institution and the Principal Investigator;

d) obtain prior written approval from Sponsor and the Institutional Ethics Committee (IEC) for any proposed recruitment material to be used for the purpose of Subject recruitment in the Trial;

e) resolve any revenue issues in respect of the Trial with the Institution and keep Sponsor informed of such issues and the progress of resolution of such issues;

3.2 During the Trial each of the Institution and Principal Investigator must:

a) conduct the Trial in accordance with the terms of this Agreement and:

i. all applicable laws and regulations in India including any guidelines governing the conduct of clinical studies, including but not limited to the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines

ii. the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP),

iii. the Declaration of Helsinki as referenced in the Protocol,

iv. the Protocol, any amendments, separate manuals and specific procedures provided by Sponsor applicable for conducting the Trial, depending on which of the stated options ensures the greatest protection for the patient;

b) ensure that all Trial Materials are handled correctly and stored securely for the duration of the Trial and any period thereafter as required by law or this Agreement, whichever is later, in accordance with Article 7 Treatment of the Protocol;

c) ensure that Trial Product is used only for the conduct of the Trial in accordance with Article 7 Treatment of the Protocol;

d) do all possible efforts to ensure that the target number of 15 eligible subjects are recruited for the Trial and that data from all eligible subjects are available on or before the Termination Date. Any over-recruitment of Subjects not authorised by Sponsor will not be financially compensated;

e) have all available data entered in the CRF [5] days after each visit. Principal Investigator shall ensure that the patient record is updated with final information and signed as applicable as soon as possible after each visit;

f) maintain accurate data collection and up-to-date records of all Trial Materials and Trial related correspondences by the Principal Investigator, the Institution's employees, Sponsor and any other person involved in the Trial, during the Trial;

g) submit written reports, in accordance with all laws, regulations and guidelines including the Ethics Committee standards, to Sponsor and the Ethics Committee regarding the Trial being conducted at the Institution on request.

h) record and evaluate all Adverse Events experienced by the Trial Subjects in accordance with Article 9.3 Adverse events of the Protocol;

i) retain Trial Records in accordance with the Protocol, Article Appendix 3, point 11, and under storage conditions conducive to their stability and protection. The Principal Investigator and the Institution further agree to permit Sponsor to ensure that the records are retained for a longer period if necessary, at Sponsor's expense, under an arrangement that protects the confidentiality of the records (e.g. secure off-site storage);

j) provide to Sponsor timely updates of their contact data; and

3.3 Principal Investigator shall comply with the requirements of Appendix 3: Data Protection.

3.4 In the cooperation with Sponsor the following shall apply:

a) The Institution and Principal Investigator must allow any person nominated by the Sponsor during regular business hours and with one Business Day notice in advance access to the following:

i. subject records relating to the Trial;

ii. the Institution and facilities where the Trial is being conducted; and

iii. any Trial Materials.

Regulatory or other authorities shall be allowed direct and immediate access to the same information.

b) Subject to Clause 8 of this Agreement the Institution and the Principal Investigator must not, without the prior written approval of Sponsor, disclose any Confidential Information to any third person other than for the proper conduct of the Trial and in accordance with this Agreement provided that such recipients are bound by obligations of confidentiality and non-use to Sponsor which are equal to the terms of this Agreement. Principal Investigator shall ensure that said recipients be fully aware of the obligations of confidentiality of this Agreement and shall be responsible for any breach of these provisions by such recipient.

c) Institution and Principal Investigator acknowledge and agree that in accordance with Protocol, Article 5, Trial Design,

i. the Trial is being conducted as part of a multi-centre clinical trial,

ii. that the number of clinical trial sites will be decided solely by Sponsor,

iii. that these sites may enroll Trial Subjects in mutual competition, and

iv. that Sponsor reserves the right to end Trial Subject enrolment under this Agreement when the desired number of Trial Subjects for all clinical trial sites has been reached. Institution and Principal Investigator agree that further screening or randomisation of subjects must not take place after Trial Subject enrolment has been sended by Sponsor.

d) If electronic systems are used in the Trial, it may be required to file these site specific data at the Trial site. If the Sponsor provided media is found not readable during the retention period, a new copy can be provided by Sponsor.

4. OBLIGATIONS OF SPONSOR

4.1 Sponsor shall obtain all necessary approvals from the Institutional Ethics Committee (IEC) and relevant regulatory bodies, from the relevant departmental head of the Institution and from any other authority that is responsible for the administration of the Institution;

4.2 Sponsor must:

a) conduct the Trial in accordance with the terms of this Agreement and:

i. all applicable laws and regulations in India including any guidelines governing the conduct of clinical studies,

ii. the International Conference on Harmonization Guideline for Good Clinical Practice (ICH-GCP),

iii. the Declaration of Helsinki as referenced in the Protocol.

iv. the Protocol, any amendments, separate manuals and specific procedures provided by Sponsor applicable for conducting the Trial, depending on which of the stated options ensures the greatest protection for the patient.

4.3 Sponsor agrees to provide:

a) all Trial Materials necessary for the conduct of the Trial;

b) all relevant clinical pharmacology and toxicology information and advice to the Principal Investigator and the Institution which are required for the proper planning and conduct of the Trial throughout the Trial period. Such information will include the Investigator's Brochure and information on SUSARs for unlicensed products or the SPC for licensed products; and

c) reasonable supervision, training and monitoring during the conduct of the Trial.

4.4 The Parties agree to adhere to all applicable laws and regulations pertaining to medical confidentiality of the subjects. The Principal Investigator shall not disclose to Sponsor the identity of the subjects or information from which the identity of the subject can be deduced without prior written consent of the subject.

4.5 Any amendment to the Protocol must be agreed upon by both the Principal Investigator and Sponsor and be documented in writing. Implementation of amendments cannot take place until approval by health authorities, as applicable, and IEC/IRB's has been obtained unless required for the safety of the Trial Subjects or for administrative reasons in accordance with ICH/GCP.

5. DISCLOSURE REQUIREMENTS

5.1 The Principal Investigator shall ensure that he/she provide the appropriate financial disclosures required for compliance with DCGI, and under any other applicable law, rules or codes.

5.2 The Principal Investigator and the Institution represent and warrants that neither he/she nor the Institution involved in conducting the Trial nor any member of the staff of the Institution, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct. The Investigator shall immediately notify the Sponsor should he/she be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Agreement.

6. PAYMENT

6.1 Each payment under this Agreement shall be made on the basis of an invoice stating all relevant details regarding number of Trial Subjects and number of

visits. Furthermore, each invoice shall include full details regarding the bank account to which the payment shall take place. Any payment payable by sponsor is due forty-five (45) days after receipt of a correct and proper invoice prepared in accordance with the sponsor invoicing instructions set out in Appendix 2. The parties acknowledge that this payment deadline has been actively negotiated and agreed between the parties as fair and reasonable. For the avoidance of doubt, all bank fees related to receipt of interbank transfers must be borne by the recipient.

7. TRIAL TIME SCHEDULE

7.1 For the whole project the following dates are in force:

FPFV: 23 Sep 2019
LPFV: 01 Feb 2021

LPLV: 19 Aug 2024

The date of the FPFV can be delayed locally; however, in such case date of LPFV shall still be valid.

7.2 If the Principal Investigator has not screened 03 Trial Subjects after 12 weeks from FPFV, it may be decided by Sponsor to re-allocate Trial Subjects to other sites and the site may be closed.

8. CONFIDENTIAL INFORMATION

8.1 The information obtained during the conduct of this trial is considered Confidential Information and will be used by Sponsor for registration purposes and for the general development of the drug.

8.2 All information supplied by Sponsor in connection with this Trial shall at all times during the term of this Agreement and thereafter remain the sole property of Sponsor and is to be considered Confidential Information. The Parties shall take all reasonable steps to ensure that any Confidential Information shall not be disclosed, whether directly or indirectly, to third (3rd) parties without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except:

a) for the purpose contemplated, pursuant to and in accordance with the terms of this Agreement;

b) with the consent of the other Party and then only to the extent specified in such consent; and

c) to the extent as may be required by law or in accordance with the order of a court of competent jurisdiction, regulation, effective government policy or by any regulatory authority arising out of this Agreement or relating to or in connection with the other Party, provided that the Party so required must give the other Party prompt written notice and make a reasonable effort to obtain a protective order.

8.3 The restrictions on disclosure of Confidential Information described above shall not extend to information which:

a) is, at the time of the disclosure hereunder in the public domain, or subsequently enters the public domain through no breach of this Agreement,

b) can be shown by the receiving Party to have been in its possession at the time of disclosure hereunder,

c) is lawfully acquired by the receiving Party from a third party under no obligation of confidentiality to the disclosing Party,

d) is independently developed by an employee of the receiving Party or its Subsidiaries without reference to or reliance upon Confidential Information disclosed by the other Party, or

e) is required to be disclosed by law, or by order of a court of competent jurisdiction; provided, however, that the receiving Party shall provide the disclosing Party with notice as soon as possible enabling the disclosing Party to contest such potential use or disclosure.

9. INTELLECTUAL PROPERTY

9.1 All Intellectual Property provided by Sponsor shall remain the sole property of the Sponsor.

9.2 The Principal Investigator shall promptly disclose and assign to Sponsor all inventions and discoveries made by the Principal Investigator related to the Trial.

9.3 The Principal Investigator/ Institute shall have a royalty-free right to use the results for non-commercial research and teaching purposes.

10. REPORTS AND PUBLICATIONS

10.1 Preparation and publication of information obtained during the conduct of the Trial shall be carried out in accordance with Article 12 Appendices – Appendix 3 Trial governance considerations of the Protocol.

11. INSURANCE & INDEMNIFICATION

11.1 Principal Investigator and Institution hereby confirm that they have adequate insurance coverage for employers' liability and professional liability for all its activities under this Agreement. Principal Investigator and Institution shall provide Sponsor with proof of the existence of such insurances. Such proof, to be received by Sponsor before the proposed starting date, shall include the duration and cover of the insured and the insured amounts.

11.2 Sponsor will indemnify and defend the Principal Investigator and personnel working under his/her direct supervision against any claim or suit brought against any of them by or on behalf of Trial Subjects taking part in the Trial and based on a bodily injury directly resulting from the use of any product submitted by Sponsor for clinical investigation or any procedure provided for or required by the Protocol to which the Trial Subjects would not have been exposed but for the participation in the Trial.

11.3 For this indemnification under Clause 11.2 to apply, use of the product and the conduct of the investigation must be in accordance with the relevant laws and regulations and the approved Protocol for clinical investigation and any other

information, instructions, or warning furnished by Sponsor. Also, Institutional Review Board or other Ethics Committee approval must be obtained and the Subject Informed Consent Form must comply with all relevant regulations and a copy must be received by Sponsor at commencement of the investigation.

11.4 In addition, for this indemnification under Clause 11.2 to apply, Principal Investigator must immediately notify Sponsor, upon receipt of notice of any claim or lawsuit and must permit Sponsor authorised attorneys and personnel (at Sponsor's discretion and cost) to handle and control the defence to such claims or suits. Principal Investigator cannot settle any such claims or suits without the prior written consent of Sponsor. By signing this Agreement, Principal Investigator agrees to fully cooperate and aid in such defence. Principal Investigator understands that the sole liability of Sponsor to the Principal Investigator and those employees engaged in conducting the approved clinical investigation at the request of Sponsor will be the indemnification described above.

11.5 Sponsor does not agree to indemnify, defend or hold harmless any person or Institution against any claim or suit in which it is determined that the individual or Institution was negligent, committed malpractice or breached a representation or warranty given by any of them; such a person or Institution will repay to Sponsor any defence costs incurred by the Sponsor on its behalf.

11.6 The Principal Investigator and Institution will indemnify, defend and hold harmless Sponsor and any Sponsor Affiliate, staff and subcontractors against any claim or suit brought against any of them by or on behalf of Trial Subjects taking part in the Trial and based on an injury caused by the Institution's or Principal's Investigators or staff working under their supervision negligence, wilful misconduct, mal practice, breach of Protocol, Sponsor's instructions, applicable laws and regulations or otherwise breach of this Agreement.

12. TERM AND TERMINATION

12.1 This Agreement shall commence on the date set forth at the beginning of the Agreement and shall terminate without further notice upon completion of the Trial in accordance with the Protocol. Clauses 3.2b), c), h), i), j), 8 and 12 shall survive the termination of this Agreement.

12.2 The anticipated FPFV date for the Trial is 23 Sep 2019, provided applicable approvals have been obtained, and provided that all Trial Materials except Trial Products have been received from Sponsor 5 (five) working days before the FPFV date.

12.3 Sponsor shall be entitled to have FPFV date delayed by up to 3 (three) weeks for ethical reasons. However, in case Sponsor notifies Investigator of the delay later than 1 (one) week before the FPFV date Sponsor may upon negotiation between the Parties compensate Investigator for his/her direct and fully documented costs caused by such delay.

12.4 Sponsor may terminate this Agreement as follows:

a) if Principal Investigator negligently fails to perform or performs negligently any material work in accordance with this Agreement and such failure continues for thirty (30) days after receipt of written notice of Sponsor;

b) if Investigator for administrative or other reasons becomes unable to recruit Trial Subjects for the Trial;

c) with immediate effect, if Sponsor and/or regulatory authority recognise that any safety concerns necessitate discontinuation of the Trial;

d) if continuation of the Trial becomes unfeasible for Sponsor for efficacy reasons, by giving Principal Investigator one (1) month's prior written notice;

e) if Sponsor licenses the Trial product to a third party who wishes to conduct the remaining part of the Trial themselves, by giving Investigator one (1) month's prior written notice.

f) forthwith upon written notice in the event of either Principal Investigator's or Institution's voluntary or compulsory liquidation, dissolution, insolvency, suspension of its payments, bankruptcy or any statutory or private composition or agreement with its creditors in order to escape a bankruptcy, or if either of the Principal Investigator or the Institution discontinues substantial parts of its established business or its business is placed in the hands of a receiver, assignee or trustee in bankruptcy, whether voluntarily or otherwise.

In the event of termination of this Investigator Agreement by Sponsor pursuant to Clause 12.4b), c), d), e) or f) above, Sponsor shall pay Principal Investigator for all services properly performed in accordance with this Investigator Agreement until the point in time of the expiry of the notice of termination, if relevant. Upon receipt of a termination notice Investigator shall cease any work not deemed necessary by Sponsor for the orderly close out of Trial or for the fulfilment of regulatory requirements.

12.5 The Principal Investigator may terminate this Agreement as follows:

a) if Sponsor negligently fails to perform or performs negligently any material work in accordance with this Agreement and such failure continues for thirty (30) days after receipt of written notice of the Principal Investigator;

b) if the Principal Investigator becomes incapacitated or terminates his/her relationship with the Institution and a replacement suitable and agreeable to Sponsor cannot, after reasonable efforts by the Institution, be found.

13. GOVERNING LAW AND DISPUTE RESOLUTION

13.1 Both Parties will use commercially reasonable efforts to settle all matters in dispute amicably. All disputes arising out of or in connection with this Agreement must be settled under Rules under the Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Rules. The arbitration shall take place in Lucknow, India and shall be conducted in the English language. The award of the Arbitrator shall be final and binding on both Parties. The Parties bind themselves to carry out the awards of the Arbitrator.

13.2 This contract shall be construed and interpreted pursuant to the Laws of India and shall be subject to the exclusive jurisdiction of the Courts at Lucknow.

14. GENERAL

14.1 Any notice, report, request, approval, consent, invoice, payment or other communication required or permitted to be given under this Agreement shall be in writing and shall for all purposes be deemed to be fully given and received if

delivered in person or sent by registered mail, or by facsimile transmission (with an appropriate transmission receipt) to the respective Parties at the following addresses:

If to the Sponsor:

Novo Nordisk India Private Limited
Plot No. 32, 47-50
EPIP Area, Whitefield
Bangalore – 560 066

Att: Director - CMRQ

If to the Principal Investigator: Dr. Narayan Prasad
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow- 226014

If to the Institution:

Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow- 226014
Att:

15. ASSIGNMENT

15.1 This Agreement shall not be assigned by either Party, in whole or in part, without the prior written consent of the Parties hereto.

15.2 Sponsor shall have the right at any time to assign or transfer any or all of its rights and obligations under this Agreement to any of its Affiliates. For the purpose of this Agreement "Affiliate" means any corporation, company, partnership, joint venture or other entity which controls, is Controlled by, or is under common Control with a person or entity. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of the party in question. For the avoidance of doubt, none of Novo Holdings A/S, Novozymes A/S, NNIT A/S, NNE Pharmaplan A/S nor any entity, which Controls, is Controlled by, or is under common Control with such entities, other than entities within the Novo Nordisk group of companies, will be deemed to be an "Affiliate" of Novo Nordisk. This shall bind the Parties, their successors and permitted assigns.

16. INDEPENDENT CONTRACTOR

16.1 In the performance of the Trial hereunder:

a) Principal Investigator shall be deemed to be and shall be an independent contractor and, as such, Principal Investigator shall not be entitled to any benefits applicable to employees of Sponsor.

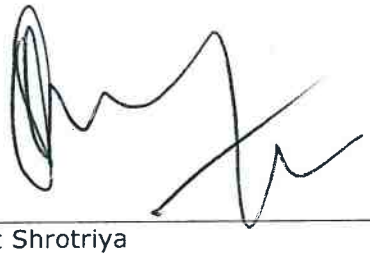
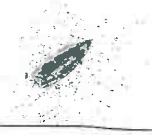
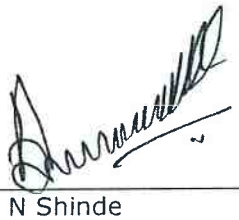
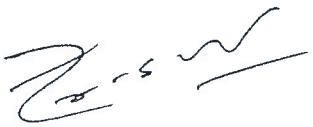
b) Principal Investigator and Institution on one side, and Sponsor on the other side acknowledge that the relationship between them is that of independent contractors, and not that of employer and employee, or principal and agent, or partners in a joint venture, nor any similar relationship whatsoever. Neither Party shall exercise control over the business of the other Party, nor is neither Party granted any right or authority to assume or to create any obligation or responsibility, express

or implied, on behalf of, or in the name of the other Party, or in any other way to act on behalf of, or to bind, the other Party.

16.2 IN WITNESS HEREOF, the Parties have executed and delivered this Agreement,

(SIGNATURE PAGE FOLLOWS)

Signed and Delivered by the within named **Novo Nordisk India Private Limited**	Signed and Delivered by the within named **Institution**
	DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
Name: Vikrant Shrotriya Title: Managing Director Date: 05 FEB 2020	Name: Title: Director Date:
	Signed and Delivered by the within named **Principal Investigator**
Name: Dr. Anil N Shinde Title: Director - Clinical, Medical, Regulatory Affairs & Quality (CMRQ) Date: 05 FEB 2020	Name: Dr. Narayan Prasad Title: Principal Investigator Date: 10.02.20

Signed and Delivered by the within named **Novo Nordisk India Private Limited**	Signed and Delivered by the within named **Institution**
	
Name: Vikrant Shrotriya Title: Managing Director Date: 05 FEB 2020	Name: Title: Director Date:
	Signed and Delivered by the within named **Principal Investigator** 
Name: Dr. Anil N Shinde Title: Director - Clinical, Medical, Regulatory Affairs & Quality (CMRQ) Date: 05 FEB 2020	Name: Dr. Narayan Prasad Title: Principal Investigator Date: 10.02.20

APPENDIX 1: (THE PROTOCOL)

Attached herewith is a link to the soft copy/electronic copy of the Protocol. The Sponsor, through its Authorized Signatory, and the Principal Investigator have already agreed upon in writing to conduct the trial as outlined in the Protocol. The Parties hereby agree that for the sake of convenience, the hard copies of the Protocol are not annexed to this Agreement. The updated, as amended from time to time, electronic copy of the Protocol shall be made available at all times to the Institution and the Principal Investigator by the Sponsor, upon request, or as a standard procedure, whichever applies. The Protocol shall at all times be considered to be an integral part of this Agreement and reference to this Agreement includes reference thereto to the Protocol.

Link -

4321-protocol-versi
on-2.pdf

APPENDIX 2: PAYMENT

a) Following the screening phase, payment shall only cover eligible Trial Subjects. Payment for screening and randomization and for each fully performed visit per Trial Subject shall be as follows:

	Amount in INR (Rs.)
Visit 1	17740
Visit 2	17690
Visit 3	4100
Visit 4	4100
Visit 5	14600
Visit 6	13600
Visit 7	15500
Visit 8	14600
Visit 9	4100
Visit 10	17100
Visit 11	4100
Visit 12	14600
Visit 13	4100
Visit 14	17100
Visit 15	4100
Visit 16	14600
Visit 17	4100
Visit 18	17100
Visit 19	4100
Visit 20	14600
Visit 21	4100
Visit 22	17100
Visit 23	4100
Visit 24	14600
Visit 25	4100
Visit 26	17100
Visit 27 (V-EOT)	16250
Visit 28 (V-FU)	15350
Total Cost per Trial Subject: (The payment will be made on pro-rata basis depending upon the Subjects recruitment. The Institution is allowed to recruit additional Subjects for this Trial based on the confirmation from the Sponsor. The Invoice shall be raised on pro-rata basis and accordingly payment will be made)	314330

The travel allowance for the Subjects is included in the above cost up to INR 600.

In addition, a start-up fee of INR 50000 shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission and approval activities. The

payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

b) If Trial Subjects drop-out of the Trial, payment will be calculated on the basis of the visits performed.

c) Full fee will only be paid for patients fulfilling all inclusion and exclusion requirements as defined in the Protocol (eligible Trial Subjects). Patients that do not fulfil all inclusion and exclusion requirements will only be reimbursed the screening and randomization fee set above.

d) Patients that do not fulfil all inclusion and exclusion requirements must be withdrawn from the study, unless exception to allow the specific patient continuing in the study is granted by Sponsor and the Ethics Committee/Institutional Review Board according to local regulations;

e) Payment will be made every 06 months. Payment for the last 06 month visits for all subjects will be paid as soon as all queries have been solved and data are clean.

f) The Institution will be paid 25 % overhead to cover administrative costs which is included in the per patient cost mentioned in Appendix-2.

g) All payments shall be made by Sponsor to the Institution in the following bank account:

Bank details of Institution:

Recipient:	Sanjay Gandhi Post Graduate Institute of Medical Sciences
Bank name:	State Bank of India
Bank address:	SANJAY GANDHI PGIMS, LUCKNOW, RAEBARELI ROAD, LUCKNOW- 226014
IFSC Code:	SBIN0007789
Account Holder:	Director SGPGIMS Research A/C
Account Number:	10095237491
Transfer Purpose:	Conduct of Clinical Trial

h) All invoices shall be sent to Sponsor as follows:

Novo Nordisk India Private Limited
Plot No. 32, 47 - 50,
EPIP Area, Whitefield,
Bengaluru - 560 066

APPENDIX 3: DATA PROTECTION APPENDIX

1. **Scope**. This Data Protection Appendix sets out the requirements and obligations applicable to the Supplier and/or its sub-processors processing of Personal Data on behalf of Novo Nordisk.

2. **Parties**. For the purpose of this Data Protection Appendix:

    a. "Novo Nordisk" means Novo Nordisk India Private Limited and any Novo Nordisk subsidiary or other group company that in accordance with the Data Protection Requirements is data controller in respect of the Personal Data;

    b. "Supplier" means [Dr. Narayan Prasad, Department of Nephrology, C Block, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014] who will act as a data processor in respect of Personal Data processed under the Agreement.

3. **Precedence**. This Appendix shall govern the processing of Personal Data by the Supplier, notwithstanding any other obligations made by the Parties under the Agreement or otherwise agreed by the Parties.

4. **Terms used in this Appendix**. Capitalised terms used in this Data Protection Appendix, unless defined in this Appendix or in the Agreement, will have the meaning given in the Data Protection Requirements, which include any requirements under the EU Directive 95/46/EC and the General Data Protection Regulation (EU) 2016/679 as well as any applicable laws implementing or amending the same.

5. **Purpose of processing Personal Data**. The Supplier will, during the term of the Agreement, be processing Personal Data on behalf of Novo Nordisk for the purpose of performing its obligations under the Agreement.

6. **Type of Personal Data**. The Supplier will be processing the following types of Personal Data under the Agreement:

    a. ***Categories of (non-sensitive) Personal Data***:

        i. Contact information, including name, address, phone number, email etc.;
        ii. Job related information, including title, position, work tasks, department, performance; and

    b. ***Special (sensitive) categories of Personal Data***:

        i. Genetic data, biometric data for the purpose uniquely identifying a natural person;
        ii. Clinical data originating from clinical trials, studies and other research work;
        iii. Other data concerning health; and
        iv. Data concerning a natural person's sex life or sexual orientation.

7. **Categories of data subjects**. The Personal Data regards the following categories of data subjects: employees, customers, healthcare professionals, patients, trial subjects etc.

8. **Obligation to comply with Data Protection Requirements**. The Supplier represents and warrants that:

   a. It will comply with and ensure that all sub-processors will comply with all of applicable obligations under the Data Protection Requirements that arise in connection with the Agreement;

   b. It will perform its obligations under the Agreement and ensure that all sub-processors perform their obligations in such a manner that allows Novo Nordisk to comply with the Data Protection Requirements;

   c. Unless otherwise requested by Novo Nordisk, process Personal Data only to the extent necessary for the performance of the Agreement; and

   d. Subject to any other notification requirements set out in this Data Protection Appendix, notify Novo Nordisk of any unauthorised or unlawful processing or any accidental loss, destruction, damage, alteration or disclosure of the Personal Data as soon as it becomes aware and keep Novo Nordisk informed of any related developments.

9. **Reliance on Supplier's skills**. Novo Nordisk is relying upon the Supplier's skill and knowledge to assess what is "appropriate" to protect Personal Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure.

10. **Requirements to Supplier personnel**. The Supplier will ensure that all its employees and sub-processor personnel perform their duties strictly in compliance with the confidentially obligations imposed under the Agreement by treating such Personal Data as confidential information and are informed of the security procedures applicable to the processing of or access to the Personal.

11. **Compliance with the processing instruction**. The Supplier will and will procure that it's sub-processors Process the Personal Data only to the extent strictly required in order for the Supplier to perform its obligations in accordance with the Agreement or as instructed by Novo Nordisk, from time to time.

12. **Access to information and assistance**. Upon request by Novo Nordisk and without undue delay, the Supplier will and will cause its sub-processor to:

   a. Make available to Novo Nordisk and/or any Data Protection Authority having jurisdiction over Novo Nordisk, documentation and any and all other information that is reasonably necessary for Novo Nordisk to comply with its obligations under the Data Protection Requirements

   b. Provide Novo Nordisk with full cooperation and assistance in relation to any complaint or request from Data Subjects or a Data Protection Authority;

   c. Permit Novo Nordisk, or any third party appointed by Novo Nordisk (subject to reasonable and appropriate confidentiality undertakings), to inspect and audit the Supplier's data processing activities (and/or those of its group entities, agents, subsidiaries and sub-contractors)

   d. Comply with all reasonable requests or directions by Novo Nordisk to enable Novo Nordisk to verify and/or procure that the Supplier and/or sub-processors are in full compliance with their obligations under the

Agreement, including by providing an account of the technical and organisational security measures implemented by the Supplier or its sub-processor to comply with applicable security controls; and

e. Provide Novo Nordisk with detailed information on the current location of any Personal Data being Processed or stored by the Supplier and/or any of its sub-processors.

13. Use of sub-processors.

a. The Supplier will be entitled to assign processing of Personal Data under the Agreement to a designated sub-processor subject to the following requirements:

   i. Novo Nordisk pre-approves the sub-processor in writing; or

   ii. The Supplier gives Novo Nordisk at least six (6) months written notice before engaging the sub-processor and Novo Nordisk has the right to object to the engagement such that (i) Supplier refrains from engaging the sub-processor; (ii) Supplier amends the sub-processor engagement so that it becomes acceptable to Novo Nordisk; or (iii) Supplier allows Novo Nordisk to terminate the Agreement without incurring any liability to pay compensation or termination fees.

b. The Supplier's agreement with sub-processor(s) must be in accordance with the Data Protection Requirements and may not contain terms that are less restrictive than those agreed between Novo Nordisk and the Supplier.

c. The Supplier must ensure that its sub-processors do not engage any further sub-processors without prior written approval by Novo Nordisk.

d. Supplier will remain responsible for all acts and omissions of its sub-processors and the acts and omissions of those employed or engaged by the sub-processors as if they were its own.

14. Technical and organisational security measures. The Supplier will implement and maintain throughout the term of the Agreement and will procure that its sub-processors implement and maintain throughout the term, appropriate technical and organisational security measures to protect the Personal Data against unauthorised or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure. These measures will be appropriate to prevent the harm which might result from any unauthorised or unlawful processing, accidental loss, destruction or damage to the Personal Data and having regard to the nature of the Personal Data which is to be protected.

15. Notification of a Personal Data breach. Supplier will, in writing, notify Novo Nordisk of a Personal Data breach (including any security breach affecting Personal Data or any breach as defined under applicable law) immediately after becoming aware of such breach. Such notice must be provided in accordance with the provisions of the Agreement.

16. Documentation of Personal Data breaches. The Supplier will, upon request, submit to Novo Nordisk documentation on any breaches of Personal Data. The documentation should include information sufficient to enable a Data Protection Authority to verify compliance with the Data Protection Requirements.

17. **Other notifications**. The Supplier will:

    a. Notify Novo Nordisk in writing immediately if it receives (i) a request from a data subject to have access to that person's Personal Data; or (ii) a complaint or request relating to Novo Nordisk's obligations under the Data Protection Requirements; and

    b. Notify Novo Nordisk immediately in writing if it receives a request from any Data Protection Authority or other governmental body requiring the Supplier or any of its sub-processors to grant the Data Protection Authority or other governmental body access to inspect or provide information regarding the Supplier's and/or the sub-processor's processing of Personal Data covered by the Agreement.

18. **Liability**. The Supplier shall hold Novo Nordisk, fully and effectively indemnified against any and all claims, expenses, losses and damages or liabilities suffered due to the Supplier or sub-processors not fulfilling the data protection obligations under this Schedule.

19. **Transfer of Personal Data**. The Supplier will process or permit processing of Personal Data outside the European Economic Area (EEA), Switzerland, or any country determined officially by the relevant Data Protection Authority to have adequate data protection measures in place, only pursuant to a signed agreement between on the Supplier and Novo Nordisk using the European Commission's Standard Contract Clauses.

    a. With respect to any sub-processors, the Supplier will either (i) enter into the above mentioned agreement on behalf of the sub-processors or (ii) cause the sub-processors to enter into the agreement with Novo Nordisk.

    b. The Supplier will provide Novo Nordisk with a copy of all such signed agreements in advance of permitting the transfer or processing.

APPENDIX 4: NOTICE OF PERSONAL DATA PROCESSING

NOTICE OF PERSONAL DATA PROCESSING

Novo Nordisk India Private Limited is required by law to protect your Personal Data. This Notice explains how we process (e.g. collect, use, store, and share) your Personal Data. We will process any Personal Data about you in accordance with this Notice and with applicable law.

1. WHO ARE WE?

The company responsible for processing your Personal Data is:

Novo Nordisk India Private Limited
CIN: U24111KA1994PTCO15194
Plot No.32, 47-50,
EPIP Area, Whitefield,
Bangalore - 560 066

Toll-free number: 18001039527
Switchboard: +91 80 4030 3200
Fax No.: +91 80 4112 3518
prindia@novonordisk.com

You can always contact Novo Nordisk India Private Limited or the Novo Nordisk Data Privacy Officer at privacy@novonordisk.com with questions or concerns about how we process your Personal Data.

2. HOW DO WE COLLECT PERSONAL DATA ABOUT YOU?

We get your Personal Data from the following sources:

- From you directly
- From publicly available publications, websites, or social media
- From a previous employer
- From other Novo Nordisk entities
- From vendors or consultants

3. WHY DO WE PROCESS YOUR PERSONAL DATA?

We process Personal Data about you for the following purposes:

- To analyse data for compliance
- To meet transparency obligations
- To investigate compliance/fraud
- To coordinate a conference or event
- To reimburse you
- To conduct interviews as part of a research project
- To respond to your questions or request for information

You are not required to provide us with your Personal Data. If you do not want Novo Nordisk to use your Personal Data, we will not be able to enforce this Agreement.

4. WHAT PERSONAL DATA DO WE PROCESS ABOUT YOU?

For the purposes described above in Section 2, we may process the following types of Personal Data:

- Contact information (name, address, telephone number, email address)

- Financial information (bank account number, amounts paid to you for services rendered)
- Emergency contact (e.g., name and telephone of family members)
- Data concerning health;
- Data on trade union membership;
- Genetic data, biometric data for the purpose uniquely identifying a natural person;
- Data concerning sex life or sexual orientation.
- Data relating to criminal convictions and offences

5. WHY ARE WE ALLOWED BY LAW TO PROCESS YOUR PERSONAL DATA?

Our processing of your Personal Data requires a legal basis. By law, we are allowed to process your Personal Data described above in Section 1 based on the following legal bases:

- You gave consent for us to process your Personal Data;
- The processing is necessary to fulfil a contract with you;
- The processing is necessary for our compliance with a legal obligation;
- The processing is necessary to protect your vital interests or the interests of another person;
- The processing is necessary for our legitimate interests.

6. HOW DO WE SHARE YOUR PERSONAL DATA?

We may share your Personal Data with:

- Suppliers or vendors that assist our company (e.g., consultants, IT service providers, financial institutions, law firms)
- Other Novo Nordisk entities (e.g., Novo Nordisk affiliates in other countries)
- Public authorities

7. WHEN DO WE TRANSFER YOUR PERSONAL DATA OUTSIDE INDIA?

For the purposes described above in Section 2, we transfer your Personal Data to countries outside India. We therefore use the following safeguards, as required by law, to protect your Personal Data in case of such transfers:

- The transfer is to a Novo Nordisk entity covered by Novo Nordisk's Binding Corporate Rules, available at https://www.novonordisk.com/about-novo-nordisk/corporate-governance/personal-data-protection.html.

8. HOW LONG WILL WE KEEP YOUR PERSONAL DATA?

We will keep your Personal Data for the following period of time:

- For as long as needed to provide you with the services requested by you
- For as long as required by applicable law.

9. WHAT ARE YOUR RIGHTS?

In general, you have the following rights:

- You can get an overview of what Personal Data we have about you
- You can get a copy of your Personal Data in a structured, commonly used and machine-readable format

- You can get an update or correction to your Personal Data
- You can have your Personal Data deleted or destroyed
- You can have us stop or limit processing of your Personal Data
- If you have given consent for us to process your Personal Data (see Section 5), you can withdraw your consent at any time. Your withdrawal will not affect the lawfulness of the processing carried out before you withdrew your consent
- You can submit a complaint about how we process your Personal Data to a Data Protection Authority.

Under applicable law, there may be limits on these rights depending on the specific circumstances of the processing activity. Contact us as described in Section 1 with questions or requests relating to these rights.

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CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("Agreement") is made as of _____ (the "Effective Date") by and among

Medclin Research Pvt. Ltd. Having its registered office at Acropolis, unit 10/5 , 10th floor 1858/1, Rajdanga Main Road, Kol-107("CRO")

And

Sanjay Gandhi Postgraduate Institute of Medical Science, New PMSSY Rd, Raibareli Rd, Lucknow, Uttar Pradesh, 226014.

Prof. Uday C Ghoshal, Department of Gastroenterology to be the signatory for this agreement and he will perform this research work.

WHEREAS,

Sponsor (Zydus Healthcare Limited, CTS No. 460/6, I. B. Patel Road, Village Pahadi, Goregaon (East), Mumbai 400063, Maharashtra) based on the representation and warranties given by the CRO, desires to engage CRO on non-exclusive basis to initiate study of "Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess effectiveness and safety of Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12® in the treatment of Non-Constipated Irritable Bowel Syndrome in adults aged 18 years to 65 years" (hereinafter referred to as the "Study")

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a. The CRO has approached the Institution and Principal Investigators to perform the study in accordance with the corresponding Protocol, and all applicable rules and regulations. The Institution and PI agree to conduct the study in accordance with the same.

b. The Institution is equipped to undertake the Study and the Institution, CRO and Principal Investigator have agreed to perform the Study according to the terms and conditions hereinafter set forth.

1. REPRESENTATIONS AND WARRANTEES:

a. Each party represents and warrants to and covenants with the other that:

i. It has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this agreement; wherever applicable,

ii. It has the corporate power and authority to enter into and perform its obligations under this Agreement, whenever applicable,

iii. This Agreement has been duly authorized, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

iv. Neither the execution and delivery of this Agreement by either party, nor the performance by such party of its obligations here under nor compliance by such party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any indenture, mortgage, lease, agreement, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such party;

b. CRO represents and warrants that

It has the facilities, professional, technical and clerical staff, experience, and expertise sufficient in quality and quantity to perform the Services and the Clinical Study pursuant to the Protocol within the time frame set forth herein and all appropriate permits and authorizations necessary to provide and perform, to the highest of professional standards, the services for the conduct of the clinical study in accordance with this agreement, the Protocol, ICH - GCP and all applicable standard operating procedures and has capability to perform or arrange for the performance of all services required by Sponsor.

c. Institution represent that

i. It is entitled to procure the services of Principal investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.

ii. The Institution shall notify Medclin if the Principal Investigator ceases to be employed by or associated with the Institution and shall use its best endeavors to find a replacement acceptable to both The Sponsor and CRO. In order to ensure high

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standard of clinical trials, if no mutually acceptable replacement can be found, The CRO may terminate this agreement pursuant to clause 22(d).

d. Principal Investigator represents :

i. A competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub investigators and research staff and the Institution.

ii. Free participation in Clinical Studies and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.

iii. Non-involvement in any regulatory or misconduct litigation or investigation by the Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Evaluation Agency (EMEA), The Drug Controller general of India (DCGI) or other regulatory authorities. No data produced in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

iv. That facilities appropriate to the Clinical Trial are available at the Trial Site and that there is support of medical and other staff of sufficient number and experience to perform the Clinical Trial efficiently and in accordance with the provisions of this Agreement.

2. OBLIGATIONS/RESPONSIBILITIES:

a. Principal Investigator:

i. Will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub investigators or research staff. The duties and responsibilities delegated will be only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.

ii. Will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is accountable for the compliance of Investigators to the terms of this Agreement.

iii. Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from Sponsor and CRO.

iv. Will comply with the policies and procedures of the organization / institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify CRO promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

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v. Shall be responsible for obtaining and maintaining all approvals from the relevant local research ethics committee/other Authorities for the conduct of the Clinical Trial keeping The CRO fully apprised of the progress of ethics committee submissions. The written evidence of review shall be provided prior to initiation. All other communications, upon request be made available to Medclin. The Principal investigator shall not consent to any change in the Protocol requested by the relevant ethics committee without the proper written consent of The Sponsor and CRO, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study. Investigator will notify The CRO and the responsible Institutional Review Board as soon as possible. Any emergency change to the Protocol must be followed by a written Amendment.

vi. Agrees to use best efforts to provide Sponsor's with the data called for in the Protocol, including copies of each research subject's signed informed consent form, a signed authorization as required under any applicable India regulations/policies and properly completed case report forms, in a timely manner. The PI and Institution will provide for (i) access to the research subject's medical records by Sponsor/CRO and other appropriate regulatory agencies and (ii) the facilities where the Study is being conducted (iii) Raw data (iv) the use of Study data by Sponsor/CRO for any purpose that it deems appropriate provided that the research subject's personal identifying information has been removed. In the event of a conflict between terms of the Protocol and this Agreement, the terms of this Agreement shall govern (v) any other relevant information necessary for Sponsor, other regulatory authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. The Principal Investigator shall notify Sponsor immediately if another regulatory authority schedules or, without scheduling, begins such an inspection.

vii. Agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

viii. Shall promptly report to CRO any significant developments that may occur during the Study, including but not limited to adverse clinical events as described in the Protocol.

ix. Agrees to maintain records and data related to the Study in compliance with all applicable regulations, and in any event, for the period as per Indian GCP after the completion/termination of the study.

x. In the event that during the term of this Agreement, either the Institution or Principal Investigator becomes debarred or receives notice of an action or threat of an action with respect to its debarment, the Institution or Principal Investigator, as the case may be, shall notify Sponsor immediately.

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b. Institution:

i. The Institution shall ensure that all employees and agents of Institution who are assigned to perform services under the Agreement are made aware of the obligations contained in the Agreement and the Protocol and are bound by such obligations.

ii. The Institution and Principal Investigator shall all the time comply with all types of License, permission or certificates as required under laws, rules and regulations.

iii. The Institution shall bear all costs related to the performance of the Study except as expressly set forth in section 23.1 and attached budget.

iv. Institution shall apply its best efforts to retain the services of the Principal Investigator.

v. In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform The CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, who shall have a similar background and also knowledge of the Clinical Trial.

vi. Any successor to the Principal Investigator must be approved, in writing, by The Sponsor and CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this agreement and to sign each such document as evidence of such agreement (although failure to sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

vii. The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India, and agrees to immediately inform The Sponsor/CRO if such cases arise.

viii. The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with the Protocol and all other terms of this Agreement; Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs; Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP; All applicable laws and regulations.

c. Sponsor /CRO:

i. Medclin agrees to provide to the PI all information concerning the Study Material that is necessary for safe and proper handling and storage of the Study Material and for performance of the Study which is in accordance to the Protocol.

ii. Medclin shall be held responsible and therefore train all personnel involved in the clinical trial at site to ensure compliance to GCP and Protocol.

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iii. The CRO in collaboration with the Sponsor may make any changes, amendments, addendum or supplements to the Protocol from time to time, as it may think fit and shall inform PI by giving a written notice to abide by the same.

iv. The CRO in consultation with the Sponsor may designate a different investigator or other supporting personnel.

v. May visit Site with a prior written notice at reasonable times and with reasonable frequency during normal business hours to obtain information regarding the progress of Study.

3. PAYMENT:

i. Institution / Investigator fees for the services shall be made in the amounts and upon the terms specified in the Study Budget attached to and made a part of this agreement.

ii. Institution / Investigator shall not revise its prices for any reason unless mutually agreed in writing by all parties during the term of this Agreement. In any case, Institution / Investigator shall endure that the overall budget shall not exceed the total study budget as specified which shall form the part of this Agreement unless agreed by Sponsor / CRO.

iii. Institution / Investigator will not charge any amount to Sponsor / CRO for their services which were not provided to the Sponsor / CRO or agreed upon by and between the parties.

iv. Any income tax, withholding tax or similar taxes deductible from the payment will be deducted by CRO.

4. NO ADDITIONAL RESEARCH: No Additional Research. The Institution & PI Investigator ensures that no additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol.

5. SUBJECT ENROLMENT: Investigator has agreed to enroll in Study approximately 52 subjects within approximately three to four months. The same can be extended with an intimation from the CRO. If Investigator fails to enroll subjects at a rate adequate to meet the enrolment requirement, Sponsor/CRO shall be free to terminate the Study early (see Section 22(d) Termination).

6. ETHICS COMMITTEE ("EC"): Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct

7. STUDY DISAPPROVAL: Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with

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all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct.

8. DATA PROTECTION: The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. The Sponsor / CRO will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any other requirements. Such data may be disclosed or transferred to other members of sponsor team, to representatives and contractors working on behalf of The Sponsor. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause (13).

9. INFORMED CONSENT AND AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION: Investigator will obtain written informed consent from each study subject and will maintain a signed original of that consent in the subject's record. Investigator will allow Sponsor/ CRO to inspect signed informed consent forms or photocopies there during monitoring visits or audits (see Monitoring and Audits, Section 15).

10. CONFIDENTIAL INFORMATION: During the course of the Study, Investigator may receive or generate information that is confidential to The Sponsor. Any information marked by The Sponsor as confidential and provided to the investigator before the execution of this agreement will also be treated as confidential information

11. OBLIGATIONS OF CONFIDENTIALITY: Unless The Sponsor provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

a. Required disclosure of Confidential Information to the EC or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 17, Publications, of this Agreement.

11.1 Disclosure Required by Law: If disclosure of Confidential Information to any party other than the EC is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator :

a) Notifies the sponsor in writing in 15 working days advance of the disclosure so as to allow The Sponsor to take legal action to protect its Confidential Information,

b) Discloses only that Confidential Information required to comply with the legal requirement, and

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c) Continues to maintain the confidentiality of this Confidential Information with respect to all other parties.

11.2 Individually Identifiable Health Information: If, in connection with this Study or performance of this Agreement, the Sponsor comes into contact with individually identifiable health information relating to subjects, the Sponsor agrees to maintain the confidentiality of such information and not to use it for any purpose.

11.3 Survival of Obligations: These obligations of confidentiality survive termination of this Agreement and continue for a period as required after completion of the studies.

11.4 Return of Confidential Information: If requested by The Sponsor in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

12. Study Product and Document:

a) All the trial product and document necessary to conduct this study, as described in the Protocol, shall be supplied free of charge to the PI/Institution. In certain circumstances the Sponsor/CRO may request the PI/Institution to purchase the control product and/or concomitant product. In such cases, the PI/Institute will be reimbursed on actuals.

b) All trial product/ documents and all other material being provided shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to this agreement. It is understood that the trial product is provided by the Sponsor for the sole purpose of conducting the clinical trial.

c) The sponsor makes no warranties, express or implied, concerning the trial product or its merchantability or fitness for a particular use or purpose, other than for its use in this clinical study.

d) Upon delivery, the PI and Institution shall be responsible for the Dispensing, administration, storage and handling of the trial product.

e) All used and unused products provided by the Sponsor shall be returned to the Sponsor/CRO or destroyed by the site as instructed by the Sponsor/CRO. The site shall conform with all laws and regulations pertaining to the destruction and provide the Sponsor and CRO with a destruction certificate of the same.

13. STUDY DATA AND STUDY RECORDS:

13.1 Study Data: During the course of the Study, Investigator will collect and submit certain data to The Sponsor/CRO, as specified in the Protocol. This may include case report forms or their equivalent, or other types of medical reports, subject diary, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data within the time periods.

a) **Ownership of Study Data**. Subject to Investigator's right to publish the results of the Study (see Section 17, Publications), The Sponsor is the exclusive owner of all Study Data.

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b) **Non-exclusive License**. The Sponsor grants Investigator no right to use study data for any purpose including research and/or education purpose.

13.2 Data Management and statistical Analysis: The CRO shall carry out the data management and statistical analysis. The CRO may consult and / or provide The Principal Investigator for interpretation during report writing.

13.3 Study Records: Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a) **Retention.** Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period as per Indian GCP after the completion/termination of the study unless the Sponsor authorizes, in writing, earlier destruction. Investigator agrees to notify The Sponsor and CRO before destroying any Study Records after the required retention period. Investigator further agrees to permit The Sponsor to ensure that the records are retained for a longer period if necessary, at the Sponsor expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

14. MONITORING AND AUDITS:

14.1 Monitoring and Audits: The Sponsor / CRO shall be entitled at its absolute discretion (and in such form as the Sponsor / CRO sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit The Sponsor's / CRO's representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by Sponsor / CRO will relieve the Investigator of any of its obligations hereunder.

a) **Cooperation.** Investigator will cooperate with the Sponsor / CRO in the conduct of audits and will ensure that Study Records are maintained in a way that facilitates such activities.

b) **Resolution of Discrepancies**. Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

c) **Data Clarification Form**: The CRO may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which the PI or his/her nominee shall clarify within a specified time.

d) **Study Conduct Evaluations**. The Sponsor / CRO may document and evaluate the performance of Investigator in the conduct of the Study. The Sponsor / CRO or its representative will use these evaluations solely for internal purposes

15. INVENTIONS:

15.1 Notification. If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform the Sponsor and CRO.

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15.2 Assignment. Investigator will assign all interest in any such Invention to the Sponsor, or its representative free of any obligation or consideration beyond that provided for in this Agreement.

15.3 Assistance. Investigator will provide reasonable assistance to the Sponsor or its representative in filing and prosecuting any patent applications relating to Invention, at the Sponsor's expense.

16. PUBLICATIONS: The findings of this study may be published in a scientific journal or presented at a scientific meeting with prior permission from Sponsor and CRO. The Sponsor reserves the right to review all manuscripts prior to submission for publication or any paper before it is presented. In accordance with standard editorial and ethical practice, the Sponsor will generally support publication of multicentric trials only in their entirety and not as individual center data. Authorship will be determined by mutual agreement between The Sponsor in conjunction with the CRO and the Principal investigator(s).

17. DEBARMENT AND EXCLUSION: Investigators certify that s/he is not debarred and that s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and after its termination, Investigator will notify the Sponsor/CRO promptly if either of these certifications needs to be amended in light of new information.

18. USE OF NAME: Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, the Sponsor reserves the right to identify The PI and Investigator in association with a listing of the Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

18.1 Assignment and Delegation: The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from the CRO, any attempt to assign, delegate, or subcontract is invalid. The Sponsor / CRO will authorize delegation or subcontracting any duties.

18.2 Affiliates: As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with The Sponsor / CRO.

18.3 Successors and Assigns: This Agreement will bind and inure to the benefit of the successors and permitted assigns of each party.

19. CONFLICT WITH ATTACHMENTS: If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

20. Liability and Indemnification:
The PI/CRO shall indemnify, defend and hold harmless the indemnity, from and against any demands, claims, actions, which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from participation in this Clinical Trial.

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a) Sponsor shall maintain with the CRO, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this section and shall also provide the clinical trial liability coverage.

b) CRO shall maintain the aforementioned insurance during and after the subsistence of the Clinical Trial. The CRO shall provide the Institution with written evidence of such insurance upon the written request of the Indemnity. This obligation to maintain insurance shall survive the termination of this Agreement.

c) In the event a claim is made or an action is brought against the Sponsor and/or Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the CRO's representative and shall assist the CRO's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses.

d) Violation of the Protocol, scientific misconduct or negligence by CRO or the Institution/Principal Investigator, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the Principal Investigator, then the Institution/Principal Investigator will be liable to reimburse to the Sponsor the expenses on such medical management and financial compensation that The Sponsor has paid;

e) The Sponsor's representative shall indemnify, defend and hold harmless the indemnity, from and against any demands, claims, actions, which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from participation in this Clinical Trial. Notwithstanding anything contained herein, the liability of The Sponsor will be limited to The Sponsorship amount paid to CRO.

f) In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its additional personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to The Sponsor's / CRO's representative and shall assist The Sponsor's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses.

g) Notwithstanding the foregoing, The Sponsor's representative shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless The Sponsor, officers, directors, agents and employees for loss or damage resulting from:

I. Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

II. Failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

III. Any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

21. TERM: The term of this Agreement shall commence on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol unless sooner terminated as provided herein.
Termination Conditions. This Agreement terminates upon the earlier of any of, the following events:

a) **Disapproval by EC**. If, through no fault of Investigator, the Study is never initiated because of EC disapproval, this Agreement will terminate immediately.

b) **Study Completion**. For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by The Sponsor / CRO of all Protocol-required data; and receipt of all payments due to either party.

c) **Termination upon Notice**: CRO reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

d) **Immediate Termination by The CRO**: The CRO further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the CRO's opinion pose risks to the health or all being of Study subjects

e) **Termination upon Notice by Investigator**: The Principal Investigator may terminate the study, if The Sponsor / CRO does not comply with the agreement related to finance and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to The Sponsor / CRO fifteen days prior to termination and The Sponsor / CRO shall have fifteen days to cure its default.

f) **Immediate Termination by Investigator**. Investigator reserves the right to terminate the Study immediately upon notification to The Sponsor / CRO if requested to do so by the responsible EC or if such termination is required to protect the health of Study subjects.

g) **Payment upon Termination**. If the Study is terminated early in accordance with Section 22 Termination Conditions, above, The Sponsor / CRO will provide a termination payment equal to the amount owed for work already performed, in accordance with Exhibit A, less' payments already made. If the Study was never initiated because of disapproval by the EC (see Section 22b, Disapproval by EC , above), The Sponsor / CRO will reimburse Investigator for EC fees and for any other expenses that were prospectively approved, in writing, by The Sponsor or its representative.

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h) **Return of Materials**. Unless The Sponsor / CRO instructs otherwise in writing, Investigator will promptly return all materials supplied by The Sponsor / CRO for Study conduct, unused Case Report Forms, other study related material and any The Sponsor / CRO - supplied Equipment.

i) **Survival of Obligations**. Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification, and Debarment and Exclusion survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

22. FORCE MAJEURE: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance cause a delay or failure in performance ('a Delay') and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator / Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to Sponsor / CRO. Sponsor / CRO shall have the right to terminate an agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

23. NOTICE: Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to CRO:

Dr Monjori Mitra (Research Director, Medclin Research Pvt. Ltd); Phone: 9831075734

If to Institution:

Prof. R. K. Dhiman, The Director of SGPGIMS, Lucknow
Phone: 05222494001/2/3
OR

If to Principal Investigator:

Dr.Uday Chand Ghoshal
Phone: 9628842456

24. ENTIRE AGREEMENT: This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.
To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial will be retained for a period as per required Regulations after the completion/termination of the study whichever is later. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform The Sponsor, the Parties shall discuss in good faith in order to find an alternative solution

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for the proper archiving of these elements in. Subjects' files should be retained as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of The Sponsor

25. GOVERNING LAW: This agreement shall be interpreted and enforced under the laws of India and courts of India shall have exclusive jurisdiction to resolve any dispute under this Agreement. Any dispute or difference which may at any time arise between the parties hereto as to the construction, meaning or effect hereof or as to any clause, matter or thing herein contained or as to the rights or liabilities of the parties hereunder then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within 90 days, then such a question or dispute shall be referred to the arbitration of a sole arbitrator to be mutually appointed by both the parties, under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996 and the rules thereunder, as amended from time to time. The venue of such Arbitration shall be in Lucknow and the arbitration proceedings shall be conducted in English. The decision of such arbitrator shall be final, binding and conclusive on the Parties. The parties hereto agree that the Courts in Lucknow, India alone shall have exclusive jurisdiction in respect of any matters pertaining to, arising out of or in connection with Agreement.

Prof. Uday C Ghoshal will do this research work and He will be the signatory in this document in addition to authority of SGPGIMS.
Executed by the parties
PI, CONTRACT RESEARCH ORGANIZATION and INSTITUTION

CRO: Medclin Research Pvt. Ltd., Kolkata	**The Principal Investigator**	**The Institution**
Signature: Monjori Mitra	Signature: U C Ghoshal	Signature:
Name: Dr.Monjori Mitra	Name: Prof. Uday C Ghoshal	Name: Prof. R. K. Dhiman
Designation: Research Director	Designation: Principal Investigator	Designation: Director of SGPGI, Lucknow
Date: 07/OCT/2020	Date: 12/10/2020	Date: 16/10/2020
Stamp: MEDCLIN RESEARCH PVT. LTD.	Stamp:	Stamp: Director S.G.P.G.I.M.S., Lko.

EXHIBIT A

Budget		
Study Name	Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess efficacy and safety of Providac (Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12®) in the treatment of Irritable Bowel Syndrome in adults aged 18 years to 65 years.	
CRO Name :	Medclin Research Pvt Ltd, Kolkata	
Cost Head	**Details**	
Research Grant Including Manpower And Travel Allowances	**52 Subjects**	**338000**
Institutional overhead charges	25%	65000
Gut Microbiota	Analysis	500000
EC Fees	On actuals	25000
Total Study Fees		928000

a) The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess effectiveness and safety of Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12® in the treatment of Non-Constipated Irritable Bowel Syndrome in adults aged 18 years to 65 years.

b) The investigator agrees to the protocol of this trial and will perform the study in accordance with ICMR Good Clinical Practice, and applicable laws, rules and regulations.

EXHIBIT B

SL. No	Milestone	Amount
1	Study Start up(At the time of SIV)	240000
2	30 subject Enrolled	98000
3	last subject Last Visit(Institutional Overhead)	65000

For Gut Microbiota			
SL. No	**Milestone**	**Percentage**	**Amount**
1	Before Analysis	60%	300000
2	Completion of Analysis	40%	200000

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ BB 805237

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००० १९
15 DEC 2020
सक्षम अधिकारी

Novartis Healthcare Private Limited, (FIRST PART);

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, (SECOND PART);

AND

Dr. Jayantee Kalita (THIRD PART);

(84)

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of [18th DECEMBER 20]20 ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

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

AND

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

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: AMG334 (hereafter the "Trial Drug") in accordance with a protocol entitled "***A 12-week phase 3, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of once monthly subcutaneous erenumab 70 mg in adult chronic migraine patients, CAMG334A2304***" and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by

Novartis. all, as amended from time to

time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments, unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Trial is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 5.3 (d) provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon signature by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

4.2 The following provisions shall survive the termination or expiry of this Agreement: Section 11 (Intellectual Property), Section 13 (Publication), Section 14 (Confidentiality) and Section 15 (Data Privacy), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not shall make payments for new Trial Subjects.

During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drug in sufficient quantity to conduct the Trial. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

(c) not permit Trial Drug to be used for any purpose other than the conduct of the Trial in compliance with the Protocol;

(d) shall not make the Trial Drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(e) keep full and accurate records of who dispenses the Trial Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor entrusted with the oversight of the Trial ("Novartis Monitor") at any scheduled monitoring visit;

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

(g) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Trial Drugs to Novartis.

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the qualification of each prospective Trial Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Trial Subject's suitability for participation in the Trial, and abide by Novartis's decision as to whether or not to enrol that Trial Subject;

(c) ensure that, before their participation in the Trial, the Trial Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Trial that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Trial; and
(ii) the collection, processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF") in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Trial Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with; and

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (1 Subjects per month) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

Novartis will review the Trial Subjects recruitment on an on-going basis to ensure that the enrolment continues at an acceptable rate. Novartis is empowered to discontinue the Trial at Institution medical facilities in case of no or poor enrolment.

In a multicentre trial, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrolment of Trial Subjects prior to enrolment of the targeted number of Trial Subjects. Institution and Principal Investigator undertake to cease such enrolment upon request of Novartis and further undertake not to seek any compensation thereof.

5.5 Recordkeeping

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(a) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Trial Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial; and obtain Novartis approval prior to disposing of any Records that would not be owned by the patient under Applicable Laws. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

(f) Make available all Records to Novartis, its nominee or Health Authorities promptly upon request for monitoring and/or auditing purposes;

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Trial; and

(b) Make the hospital notes and Case Report Forms for each Trial Subject available for source data verification or auditing purposes by representatives of Novartis and the officers of any competent regulatory authority.

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

The Institution and the Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given whether or not notification was initially given by telephone. This Section shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis.

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Trial Subject or which could result in a re-assessment of the risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per current ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the Protocol) in accordance with the trial Protocol, applicable trial procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

These reporting obligations shall survive expiration or earlier termination of the Agreement.

During the Trial Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Trial and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Trial procedures.

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annexure 1) and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto (but in any case within ten (10) days after the Indemnitee shall have received notice thereof);

(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

The PI of Institution warrants that it has appropriate and adequate professional indemnity insurance cover claims or damages for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred

in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

6 & 7 floor, Inspire

BKC, G Block, BKC

Main Road,

Bandra Kurla Complex ,

Bandra (East), Mumbai –

400051

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

9. EQUIPMENT

9.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution, the Investigator and/or the designated Trial Staff: The Equipment shall only be used for the conduct of the Trial in accordance with the Protocol, Novartis instructions and until the Trial is completed or discontinued.

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall

remain in the same condition during the Trial, with the exception of ordinary depreciation.

9.3 During the term of the Trial, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

9.4 Following completion of the Trial or upon discontinuation of the Trial for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

10. TERMINATION

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution accordingly. Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations (as set out in Annex 3), or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis

all documents, Trial results and material used, generated or referred to in the course of the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution and/or Principal Investigator by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Trial or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion to any of its Affiliate or such third parties with no further payment or other obligation to the Institution and/or Principal Investigator. The Institution and/or Principal Investigator shall have no rights whatsoever therein

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1 shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those, which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

13. PUBLICATION

13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement,

and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary or confidential information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.2 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement.

13.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Trial are made available to Novartis, whichever is later.

13.4 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis.

13.5 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.6 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.7 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.8 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

14. CONFIDENTIALITY

14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Trial (collectively "**Information**") shall be treated as confidential. The Institution agrees not to disclose to any third parties or to use any Information for any purpose other than the performance of the Trial. The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

14.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said Information, its collection or creation did not occur during or in connection with the Trial;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning any Trial Subjects) shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for obtaining appropriate consent to the extent it is required by the Applicable Laws.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual competent authorities or Applicable Laws, for example to report serious adverse events and comply with drug safety laws and regulations.

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15.5 Retention of data. Personal data will be kept only for the period necessary to fulfil the purposes of the collection unless a longer retention period is required or permitted by Applicable Laws.

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution of its obligations hereunder.

Whenever a subcontractor is appointed and approved by Novartis, the Principal Investigator shall be responsible for the oversight of the subcontractor's personnel as part of the Trial Staff.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the Parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT OF INSTITUTION/PRINCIPAL INVESTIGATOR OR OTHER RESTRICTIONS FROM THE COMPETENT AUTHORITIES

(a) **Debarment.** The Institution and the Principal Investigator certify that they are not debarred or more generally under a prohibition under the relevant Applicable Laws to perform their activities. They certify that they will not use in any capacity the services of any person debarred (or otherwise under a prohibition to perform their activity) with respect to services to be performed under this Agreement. During the term of this Agreement and for three (3) years after its termination, the Institution and the Principal Investigator will notify Novartis promptly if this certification needs to be amended in light of new information. Principal Investigator also certifies that he/she does not have a revoked or suspended medical license or applicable certification.

(b) **Investigations, Inquiries, Warnings or Enforcement Actions Related to Conduct of Clinical Research**. The Institution and the Principal Investigator certify that they are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Competent Authority Action**") related to its conduct of clinical research that has not been disclosed to Novartis. The Institution and the Principal Investigator will notify Novartis promptly if it receives notice of or becomes the subject of any Competent Authority Action regarding its compliance with ethical, scientific, or regulatory standards for the conduct of clinical research, if the Competent Authority Action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

23. CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

23.1 The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

23.2 As the case may be, the Institution and the Principal Investigator shall ensure that the Principal Investigator and all Sub-Investigators involved in the Trial provide Novartis or its designee with the appropriate financial disclosures required by the U.S. Food and Drug Administration under 21 CFR Part 54, on such forms as Novartis or its designee may supply or approve. During the term of this Agreement and one (1) year following its expiration or earlier termination, the Institution and the Principal Investigator agree to assist the Sponsor or its designee in obtaining updated forms.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Trial; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services. In addition, disclosures of transfers of value in accordance with national pharmaceutical industry association codes to which Novartis is a party shall also apply.

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy. This term is mandatory for clinical studies that have sites in China as they have to be registered in the "Drug Clinical Trial Registry", and this registration includes investigator's personal data. Please inform clinicaltrial.cn@novartis.com if this term could not be included due to Local Regulations on Data Privacy so that individual consent request could be administered.

The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws or pharmaceutical industry codes applicable to Novartis. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Trial Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Trial Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. AUDITS AND INSPECTIONS

(a) Audit by Novartis and Records. The Institution shall grant access to its premises periodically as frequently as required for the proper performance and oversight of the Trial site in order to proceed with any and all monitoring activities required for the Trial. In addition, the Institution shall permit Novartis and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the Institution and the Principal Investigator in the course of conducting the Trial and to inspect the facilities at which the Trial is conducted to verify compliance with this Agreement, the Protocol, Applicable Laws and the accuracy of information provided in connection with the Trial. The Institution shall ensure that the Principal Investigator and other relevant staff is available for Novartis and its agents during an audit in order to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Novartis or its agents, the Institution and the Principal Investigator shall immediately correct any errors or omissions in such records and reports.

(b) Cooperation during Audit by Novartis. The Institution shall cooperate, and shall cause the Principal Investigator and the staff to cooperate, with Novartis and its contractors and agents in the event of any internal audits, upon reasonable notice and during normal business hours. The Institution shall furthermore make available to Novartis and its contractors and agents (for examination and duplication) all documentation, data and information relating to the Trial. Trial Subject medical records will be made available where appropriate for the purpose of source document verification procedures as part of the audit. The Institution also shall make the Principal Investigator and staff available to Novartis and its contractors and agents to explain and discuss such documentation, data and information. For the avoidance of doubt audits shall be supported at no cost by the Principal Investigator and investigational staff.

(c) Inspection by Competent Authority. The Institution and the Principal Investigator acknowledge that the Trial is subject to inspections by regulatory agencies worldwide, and that such inspections may also occur after completion of the Trial. In the event the Institution or the Principal Investigator receives notice that the Institution shall be the subject of an investigation or audit by any competent authority or Ethics Committee, as applicable, in relation to the Trial, it shall notify Novartis immediately within twenty four (24) hours the latest and shall obtain approval for Novartis or its agents to be present at the inspection or otherwise keep Novartis timely and constantly informed of the progress. In the event the Institution or the Principal Investigator does not receive prior notice of said inspection, it shall notify Novartis as soon as practicable after receiving knowledge of said inspection. Institution shall provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response. The Institution will promptly forward to Novartis copies of any inspection findings that the Institution receives from a competent authority or Ethics Committee, as applicable, in relation to the Trial. The Institution will provide Novartis with an opportunity to prospectively review any Institution responses to competent authority inspections in regard to the Trial.

(d) The Institution, the Principal Investigator and the staff shall cooperate with the relevant competent authorities or Ethics Committee, as applicable and comply with the legitimate requirements of an inspection. This also includes the making available (for examination and duplication) of documentation, data and information relating to the Trial. Subject medical records shall be made available where required for source document verification procedures as part of the inspection. The Institution also shall make the Principal Investigator and other staff available to the relevant competent authority to explain and discuss such documentation, data and information.

26. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The Parties hereby submit to the exclusive jurisdiction of Lucknow, India, without restricting any right of appeal.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in relation with trial procedures.

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IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: SAUMYA MATHEW

Title: COUNTRY TRIAL OPERATIONS LEAD

Date: 18·DEC·2020

Sanjay Gandhi Post Graduate Institute of Medical Sciences

By: _____ Name: Prof. R. K. DHIMAN

Prof. R K Dhiman

Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Title: Director

Date: 07.01.2021

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Jayantee Kalita

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

Title: Professor, Department of Neurology

Date: 01/Jan/2021

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Annex1: Payment (and Equipment)

Schedule STUDY NUMBER: CAMG334A2304

STUDY NAME: A 12-Week Phase 3, Randomized, Double-Blind, Placebo-Controlled Study To Evaluate The Efficacy And Safety Of Once Monthly Subcutaneous Erenumab 70 Mg In Adult Chronic Migraine Patients

Investigator's Name: Dr. Jayantee Kalita

Institute Name: Sanjay Gandhi Post Graduate Institute of Medical

Sciences Payee Name: Director, SGPGIMS Research Scheme

Account

Pan Card Number:

AAAJS3913N GSTIN:

09AAAJS3913N2ZN

Committed Number of Study Subjects: 20

List of Equipments provided to Institution / Principal Investigator:

- Thermohygrometer- To be retrieved post DBL
- ECG Machine – To be retrieved post DBL
- Log Pads – To be retrieved post DBL

1. Payment shall be made directly by Novartis
2. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be any and all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial;
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved;
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will not receive remuneration in the amount of a screening visit cost.
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.

- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting receipts.

- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.
- Add provision of equipment terms E.g. leasing, Novartis own equipment lent or other ad hoc solution
- CRC salary of INR 35,000/- per month will be paid by sponsor from SIV till Close out visit.

The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Study Budget:

CAMG334A2304_ Master Budget Sheet			Treatment							Post study treatment	
Visit	Screening	Baseline	Day-1	Wk-4	Wk-8	EOT	WK-4 FU	WK-8 FU	WK-12 FU	FUP	
Week		0	6	12	18	24	30	36	42	96	
Protocol Procedures	4000	4000	4000	4000	4000	4000	4000	4000	4000	4000	
Investigator Fees	3000	3000	3000	3000	3000	3000	3000	3000	3000	3000	
Coordinator Fees	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	
Subject travel Expense	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	
Institutional Overhead @ 25% (Variable)	2500	2500	2500	2500	2500	2500	2500	2500	2500	2500	
TOTAL (INR)	12500	12500	12500	12500	12500	12500	12500	12500	12500	12500	125000

(61)

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.

You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

(6)

☑ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..

☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.

☑ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.

☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date: 01/Jan/2021

Name: Dr.

Jayantee Kalita

Principal

Investigator

ANNEX 3

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.

(1)

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INDIA NON JUDICIAL

Government of Uttar Pradesh

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Unique Doc. Reference	:	SUBIN-UPUP14251904532891363038 24T
Purchased by	:	LUCKNOW SMART CITY
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	
First Party	:	LUCKNOW SMART CITY
Second Party	:	SGPGI
Stamp Duty Paid By	:	LUCKNOW SMART CITY
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

Memorandum of Understanding

"Health Kiosk ATM"

Smart & Specialist Tele-Health

This Memorandum of Understanding, (hereinafter referred to as MOU) between School of Telemedicine & Biomedical Informatics (STBMI), Sanjay Gandhi Postgraduate Institute of

1.1.1 To act as Smart & Specialist Tele-Health Hub (*Health Kiosk ATM*) for digital health access to smart citizen residing in the Lucknow city

1.1.2 To facilitate Basic Tele-Health services from the Doctors appointed under the *Health Kiosk ATM* of LSCL

1.1.3 To facilitate the Specialist Tele-Health services from SGPGI existing resources

1.1.4 To act as domain expert for the Smart City project in the field of digital health technology intervention across platform

1.1.4.1 SGPGI will provide the qualifications and the details of the manpower to be deployed for the operations of the smart health kiosk.

1.1.4.2 SGPGI will provide the details and specifications of medical equipment that may be required to be provided at Kiosk.

1.1.5 To assist the Lucknow Smart City Ltd for rolling out the project execution, monitoring and supervision for effective delivery of the outcome digital health project

1.1.5.1 SGPGI shall be responsible for Overseeing, monitoring, attendance and performance management of manpower deployed at to operate and maintain the smart health Kiosk.

1.1.5.2 SGPGI shall be responsible for vetting the quality of the consumables, coordinating with the consumables suppliers for stocking and smooth operations of the kiosks, to place orders and rationalize the usage of the consumables as per medical requirements at the kiosks.

1.1.6 To monitor, manage and evaluate the project on regular basis. Preparation of report on weekly/ monthly/annual basis and submit to the competent authority as per requirement

1.1.7 To evaluative the performance of each node in terms of quantitative & qualitative and made recommendation for any modification / update into the system as per the approval of LSCL

1.1.8 A develop a tripartite agreement between SGPGI, LSCL and identified agency for operation & maintenance of system

1.1.8.1 SGPGI will propose and put in place protocols for emergencies and will coordinate with UP112 for their services wherever required.

1.1.9 Orientation training/ re-training of the personnel to be deployed at each node for operating the platform.

1.1.10 Any other responsibilities agreed on mutual agreement basis time to time

1.1.11 Project Manager Key Responsibilities - SGPGI will appoint a Project Manager at the Hub Level to liaison and coordinate with LSCL and supervise the project entirely in terms of management of the proposed hub and spokes. The Project Manager needs to coordinate and periodically conduct meetings with LSCL in order to update them about the Operational status, issues and challenges.

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महाप्रबंधक (परियोजना)
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3. **Payment provisions**

3.1 LSCL, shall provide funds in a manner it is already submitted by the STBMI, SGPGI, Lucknow for the identified activities within the scope of this MOU.

3.2 The proposal shall be examined and funds released on yearly advance basis based on the discretion of the LSCL.

4. **Modification**

The Memorandum of Understanding may be amended by mutual consent through an exchange of correspondences between the two Partners.

5. **Conflict of Interest**

SGPGI, Lucknow will not engage in consulting activities that conflict with the interest of the LSCL under this MoU and will provide professional, objective and impartial advice

6. **Professional Liability**

SGPGI, Lucknow will carry out the activities specified in this MoU with due diligence and in accordance with prevailing standards of the profession and highest standards of ethics shall be solely liable for any and all claims, losses, liabilities, and/or damages arising out of, or in connection with, the activities undertaken in relation, or pursuant to this MoU.

7. **Applicable Law and Settlement of Disputes**

In the event of any dispute relating to the interpretation or performance of this MoU arising between the Parties, both Parties will first do their utmost to settle their dispute amicably.

8. **Seal of the Parties**

In witness thereof the Parties hereto have signed this Agreement on the day, month and year mentioned hereinbefore of their free will and accord.

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महाप्रबंधक (परियोजना)

Minutes of 7th meeting of Executive Working Committee for Mobile Tele-oncology project held on 22.01.2022

The seventh meeting of Executive Working Committee for the Mobile Tele-oncology project was held under the Chairmanship of Prof. Aneesh Srivastava, Dean, SGPGI on 22nd January 2022 at 12.00 PM in the e-tumor board room of School of Telemedicine & Biomedical Informatics, SGPGIMS, Lucknow to review the progress of Mobile Tele-oncology project.

Following members were present in the meeting;

1. Prof. S.K. Mishra, Advisor, SGPGI Telemedicine Program (over V.C.)
2. Mr. T.K. Dixit, Advisor, Dr. K.L. Garg Memorial Trust
3. Dr. Sushma Agarwal, Dept. of Radiotherapy, SGPGI
4. Dr. Zafar Niyaz, Dept. of Radio- diagnosis, SGPGI
5. Prof. P.K. Pradhan, Member-Secretary & Nodal Officer, TM

Mr. Piyush Gupta, Cancer Aid Society could not attend the meeting due to the pre-occupied schedule.

Chairman welcome all the members and Member-Secretary apprised the members about the activities under taken during the FY 2019-20.

At the outset, Prof. P.K. Pradhan & Prof. S.K. Mishra, gave a detailed background of the project and progress made till date. During the Covid-19 pandemic, the activity of the project was hampered. The detailed accounts report for the last year' was presented by the Nodal Officer. The committee members were satisfied with the details of the accounts presented by the Nodal officer.

The following new agenda were deliberated in detail and recommendation was made for onward action;

1. **Renaming the project name from outreach Mobile Tele-oncology care to Primary care:** Member Secretary apprised the committee members that the oncology care using the mobile unit could not be carried out in all dimensions as envisaged due to local logistics issue at the community and people did not coming forward for the cancer screening. Most of the patient comes for general health screening followed by consultation and ultimately free medicine for immediate health care, which is a primary care in nature. Therefore, the suggestion to change the project name proposed. The chairman suggested to modify the name as "Mobile Tele-oncology and Primary Care" in place of **Primary Care**. All the members agreed upon the suggestion.
2. **Renewal of Memorandum of Understanding (MOU)** A MOU was signed on 14th Sept. 2011for execution of the project. Further, it was amended as per the recommendation of the third executive working committee with due approval of competent authority. As per the clause no. (11) of original MOU "*The duration of the period for three years initially and will be extendable as per the outcome of the Mobile Telemedicine Unit* ". Committee felt that outcome of the project is satisfactory and community are getting benefitted through this project, the project period is to be extended for three more years' **w.e.f. 14th Sept. 2020 to 13th Sept. 2023** on the same terms & conditions as had been extended in first & second renewal (i.e. from 14th Sept. 2014 to 13th Sept. 2017 & 14th Sept. 2017 to 13th Sept. 2020). Shri Dikshit, advisor of the funding agency agreed upon the recommendation of the committee.

5/2/22

(Dr. PK Pradhan)

3. **Account Management due to superannuation of Prof. S.K. Mishra**

Member Secretary apprised the members that the account, which is being operated by Prof. S.K. Mishra, will be handed over to the Prof. P.K. Pradhan, Nodal Officer, Telemedicine due to his superannuation. All the members were agreed and same procedure of budget utilization will be followed as laid down in the agreement.

4. **Revision of honorarium and salary of manpower laid down within allocated budget**

Member Secretary apprised the members that the honorarium & salary amount approved in the FY 2014-15 needs to be upgraded keeping escalation rate at the current scenario. Shri T.K. Dikshit, Advisor, Trust agreed upon the suggestion made by the committee with note that allocated annual budget should not be exceeded. As approved, the revised/upgraded as per followings;
Honorarium for personnel: Medical Doctor (MBBS/ BDS/ BHMS/BUMS)@Rs 2,500/- per camp, Paramedical Staff (Nurse/x-ray tech.) @ 1000/- per camp, Technical Staff@ 1000/- per camp. The stipend of Accounts handling personnel be increased from 3,000 to Rs. 5,000 . Manpower engaged in the project should be given annual increment @7% from FY20-21 & 2021-22 respectively.

5. **Table Agenda incorporating Prof. S.K. Mishra, outgoing Project In-charge as Advisor to this project from the funding agency side:** Mr. T.K. Dixit appreciated the contribution of Prof. S.K. Mishra from starting till execution of the project for the last several years. He suggested that Prof S.K. Mishra to be included in the Executive Working Committee as an Advisor from the side of funding agency. The committee had given the concurrence for the same.

Meeting ended with thanks to the chair.

(Prof. S.K. Mishra)
Member

(Dr. Sushma Agarwal)
Member 5/2/22

(Dr. Zafar Niyaz)
Member

(Mr. T.K. Dixit)
Member

(Prof. P.K. Pradhan)
Member-Secretary

(Prof. Aneesh Srivastava)
Chairman

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BP 633418

SUPPLEMENTARY MEMORANDUM OF UNDERSTANDING

THIS SUPPLEMENTARY MEMORANDUM OF UNDERSTANDING, supplement to the original Memorandum of Understanding dated 14/09/2011, executed on dated 19/03/14 among the parties as under

(1) **Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS)**, Raibareli Road, Lucknow, (hereinafter referred to as "Institute") of the one part,

(2) **Cancer Aid Society**, a society registered under society Registration Act, 1860 and having office at 2A, 1st Floor Regency Avadh, Complex, Chowk, Lucknow (hereinafter referred to as "Society") of the second part

And

(3) **Dr. K. L. Garg Memorial Charitable Trust**, a Trust under Indian Trust Act, 1882 and having office at second floor, Eldeco Corporate Chamber-1, Vibhuti Khand, Gomati Nagar, Lucknow (hereinafter referred to as "Trust") of the Third Part for implementing the Mobile Telemedicine Project programme under the title of "Martyr Dr. Garg – SGPGIMS – Mobile Tele- Oncology Programme".

This Supplementary M.O.U. is required to be formed because of the decision taken in the Third Review meeting of Executive Committee held under the Chairmanship of Prof. R.N. Misra, Dean SGPGI on 18th January 2014 at 12.30P.M. at the Board Room Of School Of Telemedicine & Biomedical Informatics, SGPGIMS, Lucknow.

Following members were present in the meeting;

1. Prof. P.K. Pradhan, Member
2. Mr. T.K. Dixit, Advisor, Dr. K.L. Garg Memorial Trust
3. Prof. S.K. Mishra, Member - Secretary

Meeting held and several decisions were taken for better implementation of the programme. There was a discussion on one subject - UTILIZATION OF THE BUDGET.

Second Party

Sanjay Kumar

As per the M.O.U. dated 14.09.2011 point no. 7 the Trust was to provide annual grant of Rs.12,00,000/- (Rs.Twelve Lacs) per annum and the heads were also mentioned for the allocation of the Budget. Chairman informed the committee that the fixation of the budget under the different heads is causing problem to meet out the expenditure other than broad heads mentioned in the M.O.U.

Chairman felt that this project is non research project so the funding agency can directly operate this account as per their organizational rules and regulations. Members present at the meeting agreed with the view of the Chairman, for the solution, Committee decided that clause no.7 of the M.O.U. be replaced with the clause as under –

"TRUST MANAGES THE BUDGET DIRECTLY WITH SAME RECURRING GRANT AMOUNT i.e. (Rs.12.00 Lacs). P.I. WILL FOLLOW THE ADMINISTRATIVE NORMS OF THE TRUST IN MANAGING THE GRANT".

Besides the above, other terms and conditions of the MOU dated 14.09.2011 remain unchanged.

In witness whereof, the parties, named above, have signed this MOU on the day, month and year first above written.

1. For and on behalf of Institute

(Prof.S.K. Mishra)
Nodal Officer, Telemedicine, SGPGIMS

(Prof. R. K. Sharma)
Director, SGPGIMS,

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

2. For and on behalf of Society

(Mr. Piyush Gupta)
Principal Executive Officer
Cancer Aid Society, Lucknow.

3. For and on behalf of Trust

(Mr. S. K. Garg)
Chairman,
Dr. K. L. Garg Memorial Charitable Trust

Witness: 1. (G.K. Dikshit)
B-703, Mahanagar
Lucknow

Third ~~First~~ Party

2. Neha Tripathi
2A, Ist Floor
Regency Avadh Complex
Chowk, Lucknow

Second Party

3. (Prof. P.K. Pradhan
Dept. of Nuclear medicine
SGPGIMS
Lucknow - 226014)

Third Party

Drafted by:

Typed by:

MEMORANDUM OF UNDERSTANDING

BETWEEN

SOFTWARE TECHNOLOGY PARKS OF INDIA, GOVT. OF INDIA

AND

DEPARTMENT OF IT AND ELECTRONICS, GOVT OF UP

AND

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES
LUCKNOW, UTTAR PRADESH

FOR SETTING UP

CENTER OF EXCELLENCE

IN

MEDICAL ELECTRONICS & HEALTH INFORMATICS

AT

SGPGI, LUCKNOW, UTTAR PRADESH

ARTICLE I

(Background & Objectives)

1.1 *Background.* The idea of setting up a Centre of Excellence is to boost start-ups in the field of medical equipment and devices/electronics & health informatics etc., and, to contribute to "Make-in-India" & "Digital India" programs of Govt. of India by reducing Health Care Equipment imports and recognize value of Health Care Equipment & Technology indigenously.

Software Technology Parks of India (STPI), under the Ministry of Electronics & Information Technology, Government of India is working with distinct focus of promoting IT/ITES/ESDM Industries and boosting the export of Software and IT services from the country.

Since inception, STPI being a pioneer in promoting the IT/ITES industries specially the Start ups, MSMEs & SMEs which has become a catalyst for their sustainable growth. STPI is working in the forefront for bringing entrepreneurial revolution, start-up and innovation and becomes a key driver for several of the flagship programs of Government of India. STPI is working closely with State Governments, Industry and Academia for promotion of innovation led entrepreneurship with a focus to propel the growth in IPR generation and product development as well as boosting IT exports and employment generation across the countryMeanwhile, MSME department, Government of Uttar Pradesh started the Startup India, Startup UP India Initiative to further promote entrepreneurship activities in the State.

In order to promote startup activities and research work in medical equipment/electronics & health informatics etc. and other related emerging areas in health care, it is planned to establish CoE at SGPGI, Lucknow.

c) Help in branding & marketing the facility.

d) Extending STPI's promotional events/programmes to these start-ups for market access and visibility of their products/solutions.

e) Hiring the Head of CoE and staff.

f) Outreach, Branding, Publicity of CoE.

g) Provide 10 Mbps Internet bandwidth on promotional rates.

Responsibilities of SGPGI:

a) Provide Built Up space of 15000 to 20000 sq.ft.

b) Invite key experts from the industry to conduct hands on training workshops in the CoE and lectures by experts for start-ups on regular basis.

c) Supporting the start-ups to build PoC, Products & Solutions.

d) Guide start-ups on the relevant medical electronics and health informatics related issues including relevant data sharing.

e) Support and assistance for clinical trial (process) for start-ups

f) Share common facilities including auditorium/meeting room for conducting technology sessions as and when required.

g) Formulation of problem statement

Responsibilities of IT and Electronics Department of GoUP (UPLC)

Department of Information Technology and Electronics, Govt. of Uttar Pradesh will provide grant-in-aid of Rs. 10 Crores for setting up of Centre of Excellence for medical electronics and health informatics as Capex and Opex.

2.4 *Tasks for Participants*. Each Participant will maintain regular and reasonable contact with the other Participant and engage in discussions regarding various aspects of collaboration and the research and entrepreneurial activities listed herein. Each Participant shall nominate a senior official serve on the Advisory Committee of the CoE. Further, each Participant will nominate a member of its senior staff to be responsible for overseeing matters pertaining to this MoU.

2.5 Mentorship Assistance: As per state IT and start up policy Mentorship Assistance of INR 2 Lakhs per mentor associated with Incubator/Accelerator. The honorarium amount shall be linked with startups being guided by each Mentor in the Incubator/Accelerator. This assistance shall be given for covering expenses incurred on coaching, guiding, travelling, lodging etc. Further, Coaches would also be appointed. These coaches would be the mentor, who passes deeper knowledge about the local ecosystem of the state.

2.6 *Funding:*

a) The Total capital and operational expenditure for 5 years of the COE will be about INR 22 crores. IT and Electronics department of GoUP will provide a grant in aid of INR 10 crores, MeitY- Govt of India will provide contribution amounting to INR 6 Crores and AMTZ(Andhra Pradesh Meditech Zone) will provide seed funding of INR 6.25 Crores.

b) The SGPGI shall provide a space (built-up of about 18000 sqft well-furnished will all services including AC, fire safety, electrical water with DG backup etc. costing amount 10 crores approximately.

The amounts received from all the sponsors would be deposited in the bank account. The executive officer of STPI, with assistance from PRSG (Project Review Steering Group)/GC(Governing Council) of the CoE and the corresponding Project Monitoring

giving new research and application ideas from time to time. The Project Review Steering Group (PRSG)/GC will also set guidelines for facilitating incubation by startup and extending the facilities to students, professionals and startups. The Project Review Steering Group (PRSG)/GC will meet as and when it is needed at a frequency not less than once in a year.

Project Monitoring Group

Project Monitoring Group (PMG) consisting of the following members:

1. Jurisdictional Director of STPI, Chief Mentor/ eminent industry expert as Chairperson and Member as approved/nominated by DG STPI
2. Representative(s) of Industry, Industry Association, Academia, Investment/ Funding Agencies, other stakeholder(s) viz. SGPGI, UPLC etc.
3. Representative(s) from STPINEXT
4. Head of CoE

ARTICLE IV

(Duration, Termination and Amendment)

3.1 *Duration*. This MoU shall remain in force for Five (5) years from the date of the last signature. All the Participants may mutually agree to review/extend the MoU after the period of validity.

3.2 *Extension and Renewal*. The Participants may extend or renew this MoU by agreement, confirmed in a written amendment signed by each Participant's authorized signatory.

3.3 *Amendment*. No amendment of the terms of this MoU will be effective unless made in writing and signed by each Participant's authorized signatory.

agreement, return to the disclosing Participant any and all documents provided by the disclosing Participant setting out as Confidential Information.

4.3 *Potential for Intellectual Property Development*. It is understood that activities contemplated under this MoU are expected to be cooperative in nature and that Participating Researchers may collaborate in such research activities.

4.3.1 "Intellectual Property" or "IP" means all patentable discoveries, innovations, inventions, improvements, devices, equipment, and designs, conceived and reduced to practice under the term of and in performance of this agreement.

4.3.2 Participants hereby agree that ownership & management of intellectual property rights generated from the CoE will be with the Start-ups.

4.3.3 In general, all copyrights, patents, trademarks, trade secrets, and any other intellectual property rights ("IPR") disclosed in connection with this MoU shall jointly remain the property of the Participant introducing and/or disclosing the same to the other Participant(s) for the purposes of this MoU. It may be however, be deliberated and decided on case to case basis.

4.4 Notices. The Participants must give all notices under this MoU in writing. All communications must be sent to the addresses set forth below or to such other address designated by the Participants by written notice. Notices are effective upon receipt.

4.5 Disputes: In case of any disputes arising between the participants or otherwise, efforts shall be made to settle /resolve them through mutual discussion amicably. However if any matter still remains unresolved ,it will be referred to chairman and co-chair PRSG/GC who would resolve the matter after due discussion with all concerned and his decision with all concerned regard shall be final and binding on all concerned.

4.6 Exit Clause: Each party will have option to exit from the MoU, by serving a notice of Six months to the other parties to the MoU, with or without assigning any reason thereof.

4.7 *Indemnification*: All Participants agree to defend, indemnify and hold other Participants, its officers, employees and agents harmless from and against any and all liability, loss/ expense, attorneys' fees, or claims for injury or damages arising out of the activities under this MoU, but only in proportion to and to the extent such liability, loss, expense, attorneys' fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of the Participant.