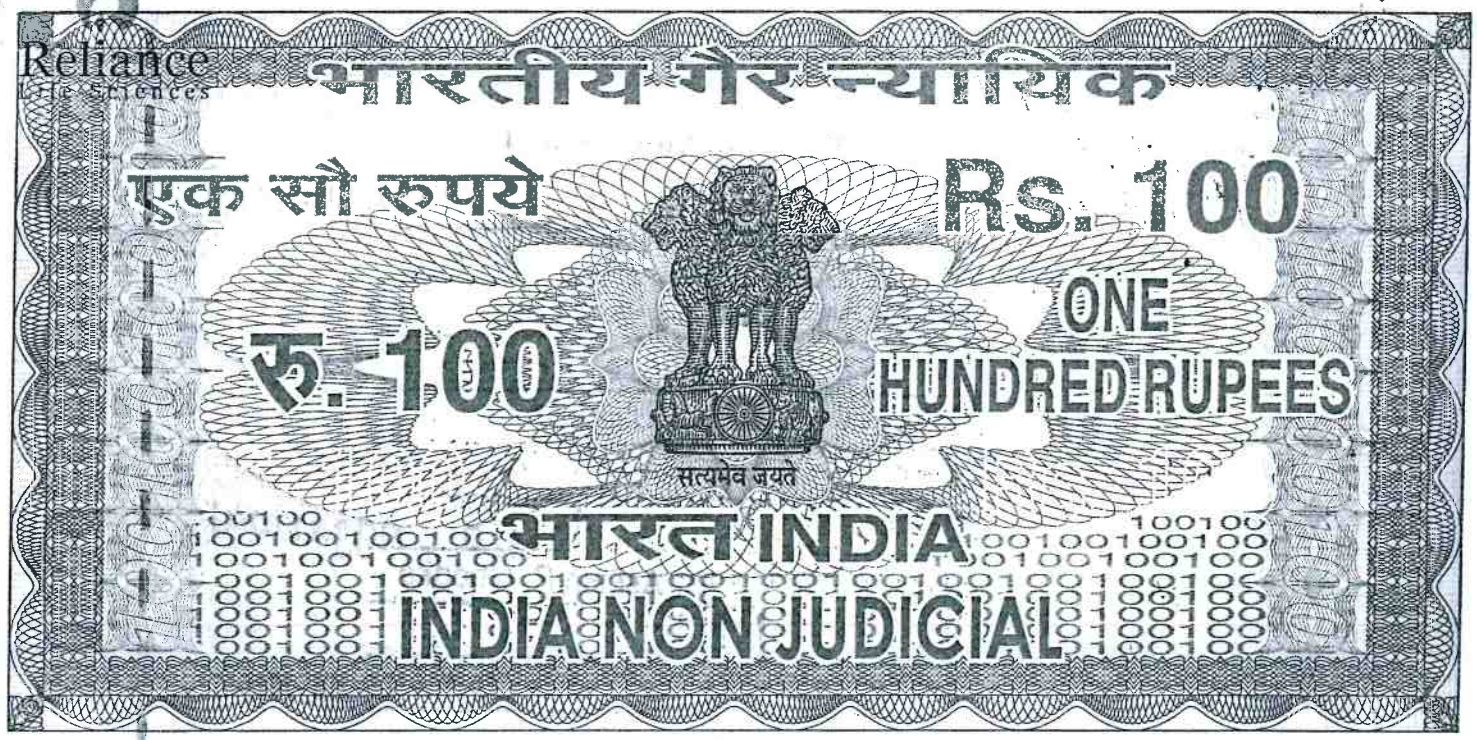

महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ VA 097916

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11 JUL 2019

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is entered into, on the _____**day of**_____**2019** between **1) Dr. Amita Aggarwal, Professor, Department of Clinical Immunology at** Sanjay Gandhi Post Graduate Institute of Medical Sciences, having an address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India ("Investigator") and **2)** Sanjay Gandhi Post Graduate Institute of Medical Sciences **("Institution")** having its address at Raebareli Road, Lucknow-226014, Uttar Pradesh, India and **3) Reliance Life Sciences Pvt. Ltd.**, ("**Reliance**"), with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701.

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"Investigator", "Institution", and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	**RLS/IMM/2014/01**
PROTOCOL TITLE:	**Prospective, multi-centric, single-arm, clinical study to evaluate the efficacy, safety, and pharmacokinetic properties of ImmunoRel® in patients with Primary Immunodeficiency Disease**
STUDY PRODUCT:	**ImmunoRel®**
	Reliance Life Sciences Pvt. Ltd.
INVESTIGATOR:	**Dr. Amita Aggarwal**
INSTITUTION/SITE:	**Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, at Raebareli Road, Lucknow-226014, Uttar Pradesh, India**

WHEREAS, Reliance Life Sciences is involved in clinical trials management and related clinical development activities;

WHEREAS, Reliance wishes to engage the Investigator to carry out Reliance's designated clinical study set out and described in protocol RLS/IMM/2014/01 and the Investigator is able and willing to conduct a clinical study (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator for conducting the Study at the Institution.

WHEREAS, the Investigator is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Study that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement. The Investigator and Institution agree to ensure that all associates, employees and contractors, assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein, (d) the International Council on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Indian GCP Guidelines, Declaration of Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), New Drugs and Clinical Trials Rules, 2019 and all applicable laws and regulations and amendment to these

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that arise from time to time (hereinafter "Applicable Laws and Requirements", and the approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget attached as Appendix A to this Agreement, with the last payment being made after the Investigator and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed Case Report Forms (CRFs) have been completed and data queries have been resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Package Insert/ Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

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TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and applicable laws, regulations, guidelines, and other requirements, hereinafter referred to as "Applicable Laws and Requirements", including:

a. Written approval or favourable opinion from all relevant ethics committees or institutional review boards (the "Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Table 4, covered under Third Schedule of GSR 227(E)of the New Drugs and Clinical Trials Rules, 2019, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution and Investigator shall cause any co-investigators or sub-investigators to submit such documentation to Reliance in a timely manner.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by the Ethics Committee, and (iii) any other documentation filed with and/or received from Ethics Committee or any Regulatory Authority related to the Study.

d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Package Insert/ Investigator's Brochure, and shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study subject are met. Investigator will complete a Case Report Form (CRF) for each Study subject in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRFs to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Ethics Committee and provide a summary of the Study report.

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1.2 Site Visits. The Institution and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study files and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product. (a) Upon the receipt by Reliance of the written approval of the Institution's Ethics Committee, Reliance shall provide the Investigator, at no charge, with such quantities of the Study Product as may be required for the Study. The Investigator and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Product. Upon completion or termination of the Study, Reliance may retrieve all unused Study Product and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator and Institution will keep full and accurate records of who dispenses the Study Product, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Product being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Product and Study materials provided by Reliance in a locked, secured area at all times.

(b) The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, identity of the person who dispenses the Study Product, the quantity dispensed, and the quantity returned to Reliance or disposed off.

(c) Institution and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from Reliance.

1.4 Adverse Events. The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Package Insert/ Investigator's Brochure on the Study Product is available for dissemination to the Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and Informed Consent Form template.

1.5 New findings. Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation, influence the conduct of the

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study, or alter the Ethics Committee's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. Recruitment. Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by Reliance from time to time. Investigator acknowledges that Reliance reserves the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Ethics Committee and Reliance to any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. Enrolment; Notices; Informed Consent; Authorization:

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects, including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution and/or Investigator and their study team, (b) persons monitoring the Study or conducting an independent evaluation of the Study, (c) the representatives of the Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Reliance related to the Study.

3.3 The status of enrolment of the trial subjects shall be submitted by the Investigator/ Institution on a quarterly or more frequent basis as per the duration of treatment in accordance with the approved clinical trial protocol; such reports will be processed in accordance with Protocol and Applicable Laws and Requirements.

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4. Confidential and Proprietary Information. All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator and Institution by Reliance or Reliance's agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Reliance. The Investigator and Institution will undertake to keep in strict confidence and not, at any time, to use other than in the Study, or to disclose or permit to be disclosed to any third party, the data and results of the Study and any information provided directly or indirectly by Reliance or Reliance's Representatives under this Agreement. The Investigator and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of fifteen (15) years after disclosure of said Confidential Information to Investigator and /or Institution under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator and Institution; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to Ethics Committees or applicable Regulatory Authorities; d) must be included in any Study subjects Informed Consent Form; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. Intellectual Property Rights -All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain, by virtue of this Agreement, any rights in or ownership of, copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator and Institution hereby agree that Reliance shall own all intellectual property rights arising out of the Study and related to the Study Product, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator and Institution will, at Reliance's expense, execute any documents and give any testimony necessary for Reliance to effect the transfer of the title of such property, obtain patents in any country or to otherwise protect Reliance's interests in such inventions. The Investigator and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator and Institution during the course of the Study that are wholly unrelated to the Study Product and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer Reliance the right of first refusal as to any sales or licenses of such inventions. The Investigator and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

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6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by randomization number and/or screening number/ code assigned to the subjects rather than by the subjects' name(s), personal identification information and / or addresses. The Investigator shall retain the Records of the Study, including the original of all volunteer consent forms, for upto fifteen years from the date of the end of the study

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Reliance. Upon expiration of the applicable retention period, Reliance shall, upon Institution or Investigator's request, direct that such Records be delivered to Reliance or Reliance's representative, be destroyed, or be retained by Institution/Investigator, and Institution/Investigator shall comply with Reliance's directions.

7. Publication. The results of the Study including all obtained data will be the property of Reliance. The Investigator and Institution should not publish or communicate the data in public without written authorisation by Reliance, unpublished data should not be disclosed to any third party by the Investigator and Institution without the written approval of Reliance. The Investigator and /or Institution may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Reliance shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Reliance desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Reliance requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a

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delay in publication to allow the filing of patent applications before publication or release, Investigator shall take the requested action.

8. Subject Injury Reimbursement

8.1 Subject to Investigator, Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Reliance agrees to reimburse Institution and/or Principal Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Study Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 42 of New Drugs and Clinical Trial Rules [GSR 227(E), 19 March 2019 in case of Subject's injury and/or death. Institution and Principal Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Subject as a result of the Subject's participation in the Study. Institution and Principal Investigator further agree to promptly notify Reliance of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Study Product or procedures prescribed in the Protocol, which are different from the medical management the Subject would have received if he/ she had not participated in the Study.

9. Inspection and Debarment.

9.1 Investigator and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator and Institution agree to communicate with Reliance in writing or contact Reliance by telephone or fax prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator and Institution agree, upon reasonable notice, to disclose, from time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator and Institution shall permit Reliance to attend any such inspections. The Investigator and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study Subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the Subject in the signed Informed Consent Form.

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9.2 The Investigator and / or Institution shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator and Institution shall permit Reliance to inspect and audit the Institution. The Investigator and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, Applicable Laws and Requirements, and Reliance requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator and Institution shall promptly notify the same to Reliance.

9.4 The Investigator and Institution represent and warrant that neither the Investigator nor the Institution or nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical studies or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to, any of the following occurrences:

i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or

ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

iii) If no subjects have been enrolled, or the Investigator recruits no subjects, or recruits such a low number (less than 04 in number) of subjects that it can be assumed that the agreed number of subjects will not be reached during the planned recruitment phase;

iv) Reliance terminates the Study, or the development of the Study Product or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A Regulatory Authority or other pertinent institution decides to terminate the Study in the Institution or as a whole;

vii) The Investigator/ Institution fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Applicable Laws and Requirements and the Study Protocol.

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b. Should the Investigator/Institution recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of Serious Adverse Events or (iii) perceived insufficient efficacy of the treatment with Study Product; then he/ she will promptly notify Reliance as well as the Ethics Committee in writing. Should Reliance, or the Ethics Committee agree that continuation is not justifiable, the Investigator/Institution may arrange termination of the Study in accordance with Applicable Laws and Requirements and the Study Protocol.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory Authorities as appropriate of early termination, except that the Investigator will notify the Ethics Committee.

10.2 Effect of Termination Upon receipt of notice of termination, the Investigator shall immediately cease any subject recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination, Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Reliance of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator or the Institution for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the Ethics Committee that approved the Study (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, and expenses to the extent that it relates to the death of a Subject caused by: a) the administration of Reliance Study Product (b) a properly-performed Protocol-required procedure, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or

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(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Reliance and/or generally accepted medical standards and the applicable SOPs; and/or

(iii) any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,

(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by Reliance for the use and administration of the Study Product and/or

(v) failure to have complied with all Applicable Laws and Requirements.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved, gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;

b. Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance is promptly notified in writing of any such claim or suit;.

c. Indemnified Parties reasonably cooperate with Reliance and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and

d. Indemnified Parties permit Reliance to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent Indemnified Parties and

e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of Reliance.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Product.

11.2 Investigator and Institution shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain a signed Informed Consent Form in

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compliance with the terms of this Agreement or otherwise fails to comply with Applicable Laws and Requirements provided:

a. Investigator and Institution are promptly notified in writing of any such claim or suit;
b. Reliance cooperates fully in the investigation and defense of any such claim or suit;
c. Investigator and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Reliance's behalf without Reliance's advance written permission.

11.3 The Investigator and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlement negotiations), and shall cooperate fully with Reliance in its handling of the claim.

11.4 Institution and Investigator acknowledge that the Study Product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages' (including without limitation to damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. Financial Disclosure. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Reliance and their agents and Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reported to Reliance.

13. Insurance: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. Shipping of Dangerous Goods and Infectious Materials. The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. Publicity.

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15.1 Solicitation of subject: Reliance and Ethics Committee shall approve in writing, any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 Press Releases: Reliance shall approve, in writing, any and all press statements by Investigator and Institution regarding the Study or the Study Product before such statement is released. It is the Investigator's obligation to take such prior approval from Reliance.

15.3 Enquiries from media and financial analysts: During and after the Study, the Investigator and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution must confer with Reliance and Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R-282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 Use of Name: Investigator and /or Institution or any of the Investigator, Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. Reliance shall not use the name of the Investigator or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator and Institution. It is agreed that all Study Reports, Study Proposals, and notifications to Regulatory Agencies by Reliance may contain the name of the Investigator and Institution.

16.0 Additional Contractual Provisions.

16.1 In conducting the Study, the Investigator and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance, and the Investigator and /or Institution has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names).

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16.3 Amendments: No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution shall directly or indirectly conduct any study as set out in the protocol no. RLS/IMM/2014/01 and any subsequent amendments thereto or participate in the study, which is same or similar to Reliance designated study mentioned in this Agreement, without prior written approval of Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with his/her entering into this Agreement. Investigator and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Data Privacy. The Parties shall comply with all the Data Privacy related requirements prescribed by Applicable Laws and Requirements, and implement administrative, physical and technical safeguards to protect personal/sensitive personal information that are no less rigorous than accepted industry practices.

16.8 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.9 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.10 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof, shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties.

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The place of Arbitration shall be at Lucknow and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

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A.2 Per Visit Payment schedule

Week	Screening within 21 days of W0	Week 0/ Day 1	4/3	8/6	12/9	16/12	20/15	24/18	28/21	32/24	36/27	40/30	44/33	48/36, 39,42, 45,48	52 or Early Withdrawal	
												40/30	44/33			
Visit	1	2	3	4	5	6	7	8	9	10	11	12	13	14-18		Total
Written Informed Consent	1000															1000
Inclusion/ Exclusion Criteria	1000															1000
Demographics	200															200
Body Weight & Height	100	100	100	100	100	100	100	100	100	100	100	100	100	500		1800
Medical History	100															100
Prior Medications	100															100
Physical Examination	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Concomitant Medication review	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Adverse Event Recording	200	200	200	200	200	200	200	200	200	200	200	200	200	1000	200	3800
Patient diary details	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Vital signs	100	100	100	100	100	100	100	100	100	100	100	100	100	500	100	1900
Study Coordinator	700	700	700	700	700	700	700	700	700	700	700	700	700	3500	700	13300
Study Medication Administration		1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	7500		25500
Hospitalization cost		1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	1500	7500		25500
12-Lead ECG	300	300	300			300	300		300		300	300		1500	300	4200
Chest X ray	500							500		500						1500
Patient travel reimbursement	500	500	500	500	500	500	500	500	500	500	500	500	500	2500	500	9500
Total (A)	5100	5200	5200	4900	4900	5200	5200	5400	5200	5400	5200	5200	4900	26000	2100	95100
25% Overhead (B)	1275	1300	1300	1225	1225	1300	1300	1350	1300	1350	1300	1300	1225	6500	525	23775
Per Visit Budget (A+B)	**6375**	**6500**	**6500**	**6125**	**6125**	**6500**	**6500**	**6750**	**6500**	**6750**	**6500**	**6500**	**6125**	**32500**	**2625**	**118875**
GST (18%)	1148	1170	1170	1103	1103	1170	1170	1215	1170	1215	1170	1170	1103	5850	473	21398
Per Visit Budget with 18% GST	**7523**	**7670**	**7670**	**7228**	**7228**	**7670**	**7670**	**7965**	**7670**	**7965**	**7670**	**7670**	**7228**	**38350**	**3098**	**140273**

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Note:

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

In addition to the above Reliance shall make the following payments:

- The screen failure cost will be reimbursed on actual in the ratio of 2:1, i.e. for every 2 patients enrolled into the study. The laboratory and Investigation cost incurred for every screen failure would be reimbursed to the site. Additionally, Investigator Charges for Screen failure will be paid 50 % of the total screening of Investigator charges. However, site need to send prescreen report to Reliance before performing actual screening
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, Reliance's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- The per visit activity cost will be paid on the completion of the corresponding activity and the completion of the corresponding CRF.
- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment will be made for those evaluable subjects enrolled in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Forms. The Payee agrees to refund any excess amount previously paid, and Reliance agrees to promptly pay any amount owing based to the receipt of acceptable CRFs at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from Reliance. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to reallocate subjects budget to other sites originally reserved for the site if site is having difficulty in enrolling and qualifying subjects.
- Site and Investigator are responsible to archive all study documents including source data as per regulatory requirements. The archival activity is to be undertaken at a third-party location; the archival facility should comply with global standards of safety, security, temperature and humidity controls, and controlled access. Reliance will pay the third-party directly for this archival. However, the investigator and site will have full control to the documents archived at all times.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted at applicable rate.

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महाराष्ट्र MAHARASHTRA

15 FEB 2014

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प्रधान मुद्रांक कार्यालय, मुंबई
ए मु वि क ६०००१०
13 FEB 2014
अधिकारी

कमांक 2325 दिनांक
M/s /Mrs / Amgen Technology Pvt. Ltd.
Dynasty Business Park
A Wing
Andheri - Kurla Road
Andheri (E)
Mumbai - 400059

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is made and entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India, and its parent or wholly owned subsidiaries of the parent ("**Company**") and Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Site**"). This Agreement shall be considered fully executed on the latest date that a party executes the same.

1. SCOPE OF SERVICES

1.1 Engagement. The execution of this Agreement alone, in the absence of any duly executed Order, as defined below, shall neither create any obligation of Site to perform hereunder nor create any obligation of Company to give Site any compensation. An "**Order**" is a document executed, at a minimum, by Company and Site, and issued pursuant to, and to be governed by, the terms of this Agreement. Unless otherwise specified, references to Agreement herein include all applicable Order(s).

1.2 Scope of Services. Company may engage Site through one or more Orders. An Order will be in a format similar to the document attached hereto and, among other things, shall set forth the particulars of the services to be performed ("**Study**"), including the clinical research and definition of the applicable Study drug ("**Study Drug**"). If engaged, Site agrees to and shall cause its employees, contractors, agents, representatives, including the principal investigator and sub-investigators (collectively, "**Site Representatives**") to perform the Study in accordance with this Agreement and Study protocol (as defined, including subsequent amendments) ("**Protocol**"). Site represents and warrants that it has the authority to require that Site Representatives comply with the applicable terms of this Agreement. Site shall notify Company of any material changes to Site Representatives, but in no event may Site change the principal investigator or any sub-investigator for a Study without Company's prior written consent. This Agreement,

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together with a duly executed Order, will be used by the parties for one Study only. Should the parties agree to use the Agreement for additional Study(ies), such agreement will be evidenced by an Order duly executed by all parties.

1.3 Biological Materials. All samples derived from Subjects enrolled in the Study, including blood, bone marrow, sera, platelets and other biological materials (the "**Biological Materials**") shall only be used in accordance with the Protocol and the EC approved informed consent.

1.4 Changes. In the event of a change to a Study that results in an increased cost, or if any increase in the compensation due for the conduct of a Study is necessary or appropriate, Company shall provide written notice in the form of a budget increase letter ("**Change**") to the Site to memorialize such increase in compensation. Unless the Site objects to such Change within ten (10) calendar days of the Change's date, said Change shall constitute an amendment to the applicable Order.

1.5 Protocol Deviations. If principles outlined in the ICH Harmonized Tripartite Guidelines for Good Clinical Practice ("**ICH GCP**") relating to the safety of Subjects (as defined herein) require a deviation from the Protocol, ICH GCP should be followed and the deviation shall immediately be reported to the other parties of this Agreement. Site shall also, within twenty-four (24) hours, notify Company of any Serious Breach of which Site becomes aware. For the purposes of this provision, a "**Serious Breach**" shall mean a breach of ICH GCP or Study Protocol, which is likely to affect (i) the safety of physical or mental integrity of the Subjects of any Study; or (ii) the scientific value of any Study. In addition, Site shall promptly inform the Institution Review Board or Independent Ethics Committee ("**IRB/IEC**") and any governmental authority as may be required by Applicable Law (as defined herein) of such deviation or breach.

2. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

2.1 Site shall use its best efforts to enroll evaluable subjects who meet all of the Protocol eligibility requirements ("**Subject(s)**").

3. COMPENSATION

3.1 Compensation. Compensation and payment terms for the applicable services shall be as set forth in the applicable Order. Site represents and warrants that the compensation provided under the terms of this Agreement as may be amended by subsequent Changes, represents fair market value and complies with Applicable Laws (as defined herein) and is consistent with fees charged for similar activities in Site's geographical area, has been negotiated at arms-length, and is unrelated to any procurement decision or promotion of Company's (or its affiliates') products, the volume or value of any referrals or other business otherwise generated between Company and Site.

3.2 Subject Withdrawal. Company shall have no obligation to compensate Site for a Subject who is determined to be ineligible for a Study, except for screen fails if provided for in the Schedule A, or for additional individuals who are enrolled in a Study without Company's prior written approval. In the event that a Subject (i) withdraws voluntarily; or (ii) is withdrawn from a Study for any reason other than the Subject failing to meet eligibility requirements, then Company shall compensate Site pursuant to the terms of the Schedule A for the procedures completed through the date of such withdrawal.

3.3 Payment Reconciliation. If, at the completion of a Study, Company has paid sums under the terms of this Agreement that exceed the total Study cost as provided in the Schedule A, Site shall, within 30 calendar days reimburse to Company any amount paid by Company that exceeds the adjusted Study cost. Site agrees to provide Company or its representative with all requests for payment under the terms set forth in the Schedule A within 30 calendar days after receipt of the adjusted Study/final payment. Where this is not possible, Site shall make all payment requests at the latest within 12 calendar months thereafter. Company shall not be obligated to make any payments after this period has expired.

3.4 Taxes, Customs, Fees, and Import/Export Duties. The pricing, fees, and compensation stated herein are inclusive of all applicable employment-related, consumer, use and other similar taxes (except Value Added Tax ("**VAT**")/sales tax), levies, duties, fees, and assessments which are legally enacted on or before the Effective Date (as defined herein), whether or not then in effect. VAT/sales tax, if applicable, will be paid by Company at the applicable rate and upon receipt of a valid VAT/sales tax invoice. Site, not Company, shall be responsible for any and all taxes on any and all income Site receives from Company under this Agreement.

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4. CONFIDENTIAL INFORMATION

4.1 Confidential Information. In view of Company's proprietary rights and interests, Site agrees to maintain as confidential all information received from or on behalf of Company or obtained as a result of the performance of this Agreement or developed under a Study ("**Confidential Information**"), and further agrees to limit access to any Confidential Information to only those persons who, under Site's direct control, will be engaged in employing such information for the purposes of fulfilling the obligations under this Agreement. At no time shall such information be employed for any purpose other than as described herein or disclosed to any third party without the prior written consent of Company.

4.2 Exclusions. The obligations set forth in this Article shall not apply to any portion of Confidential Information which (i) is or later becomes generally available to the public by use, publication or the like, through no act or omission of Site; (ii) Site possessed prior to the latest execution date of this Agreement without being subject to an obligation to keep such Confidential Information confidential; (iii) is lawfully obtained without restriction from a third party who had the legal right to disclose the same to Site; or (iv) is independently developed by the Site without the use or benefit of Confidential Information as evidenced by the Site's written records. In the event Site becomes legally compelled to disclose any Confidential Information, it shall immediately provide Company with notice thereof prior to any disclosure, shall use its best efforts to minimize the disclosure of any Confidential Information, and shall cooperate with Company should Company seek to obtain a protective order or other appropriate remedy.

4.3 Return of Company's Confidential Information. Site must return to Company all of Company's Confidential Information in tangible form, including without limitation all copies, translations, interpretations, derivative works and adaptations thereof, immediately upon request by Company. Notwithstanding the foregoing, if and to the extent required by Applicable Law (as defined herein), Site may retain 1 copy of applicable Confidential Information for record keeping purposes only.

5. PROPRIETARY RIGHTS

5.1 Ownership. Site agrees that all information, inventions, discoveries, know-how and improvements resulting from a Study conducted under this Agreement, including but not limited to material that may be subject to patent, trademark, or copyright protection ("**Intellectual Property**") shall promptly be made known to Company and shall be the sole property of Amgen Inc. Site represents and warrants that it has secured from principal investigator and Site Representatives any and all transferable rights to Intellectual Property. Site hereby transfers and assigns to Amgen Inc. Site's full right and title to all Intellectual Property and agrees to undertake such actions reasonably requested by Company to give effect to such ownership. Amgen Inc. and its subsidiaries or affiliates including the Company shall be free to use the Intellectual Property. For each Study, Site shall furnish to Company all Study data, results, case report forms and an acceptable investigator's report. Any copyright in any such data, results, case report forms and investigator's report shall be the sole property of Company. Neither Company nor Site transfers to the other by operation of this Agreement any patent right, copyright right, or other proprietary right of any party, except as described in this Agreement.

5.2 Use of Study Drug. Site agrees that use of a Study Drug provided under this Agreement for any purpose outside of a Study is prohibited. If Site uses a Study Drug provided under this Agreement for any purpose outside of a Study, all data, results, conclusions, observations, discoveries, inventions, ideas, know-how, procedures, advancements and the like, whether patentable or not, shall be treated in all respects as Intellectual Property in accordance with this Agreement and shall be the sole property of Company.

6. PUBLICATIONS

6.1 Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or

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oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

6.2 Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7. COMPANY-PROVIDED MATERIALS

7.1 Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

8. REQUIRED EQUIPMENT AND SYSTEMS

8.1 Required Equipment. The parties acknowledge that certain equipment may be needed to properly conduct a Study. If Company and Site agree that Site does not have sufficient access to some or all of that certain equipment, then such equipment shall be identified in the Agreement and referred to as "Required Equipment." Unless otherwise specified, Company or its representative shall lend to Site for the duration of the Study such Required Equipment. As applicable, Company or its representative shall arrange for the delivery of such Required Equipment. At the completion or earlier termination of the Study, Company or its representative may retrieve any or all of the Required Equipment, title to which remains with Company or its representative.

8.2 Site's obligations. While the Required Equipment is on Site's premises, Required Equipment shall remain Company's or its representative's property at all times and shall be identified as such and can only be used to perform Studies. The Site shall ensure that the Required Equipment is stored, maintained and used properly. At all times after its delivery to Site and except for normal wear and tear, Required Equipment shall be at the sole risk of the Site as regards damage, loss, or destruction. While in Site's possession or control, Site shall be liable for the repair or replacement of any such Required Equipment that is damaged, destroyed, or lost.

8.3 Customized Required Equipment. If Company or its representative provides Site with Required Equipment that is specifically customized for use in a particular Study, then Site shall ensure that this Required Equipment is not used in any manner or for any purpose other than as set forth in the applicable Protocol. Additionally, at or before the conclusion of a Study, Company or its representative will provide instructions to Site regarding the destruction of or, at Company's expense, return to Company of such

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customized Required Equipment. Site agrees to destroy or return such Required Equipment pursuant to Company's or its representative's direction.

8.4 Required Systems. Site agrees to use any electronic system that Company may specify for use in the reporting and monitoring of clinical data and Study findings.

9. COMPLIANCE WITH APPLICABLE LAWS AND ACCEPTED PRACTICE

9.1 Accepted Practice. Site shall perform and shall cause Site Representatives to perform a Study in a professional and competent manner, using the degree of skill, diligence, prudence and foresight which would reasonably and ordinarily be expected from skilled and experienced professionals engaged in the provision of, and activities comprising, a Study.

9.2 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement before the Subject is allowed to participate in the Study. Site shall ensure that such consent permits Company's use of Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

9.3 Compliance with Applicable Laws. Site agrees to ensure that the Study is conducted in compliance with generally accepted standards of Good Clinical Practice, all laws, regulations, and guidance applicable to its performance hereunder, including the ICH GCP, Company's Protocol, written instructions and policies provided or referenced by Company and, applicable export control and economic sanctions regulations which prohibit the shipment of certain products and technology to certain restricted countries, entities and individuals, as well as applicable anti-bribery laws pertaining to interactions with government agents, officials and representatives ("**Applicable Law(s)**").

9.4 Data Protection. Site shall comply with the data protection provisions set forth by Applicable Law.

9.5 Records. Site shall maintain all records required under Applicable Law and the Protocol for 10 years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records.

9.6 Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors.

9.7 Governmental Contact by Site. Site shall not initiate any communications involving or relating to any Study with any governmental or regulatory authority (such as the United States Food and Drug Administration or the Drug Controller General of India) unless required by Applicable Law or requested to do so by Company and, then, only upon prior consultation with Company. However, if any governmental or regulatory authority initiates communications with, or gives notice to Site of its desire to meet with Site, conduct an inspection, or take any regulatory action regarding any subject matter relating to a Study, Site will promptly:

(i) Notify Company thereof;

(ii) Notify Company of any warning, violation or deficiency, including without limitation those noted by any governmental authority, with respect to a Study including without limitation facilities, equipment, or personnel supporting a Study;

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(iii) Provide Company with a copy of any correspondence or inspection reports issued with respect to a Study;

(iv) Provide Company with copies of and opportunities to comment on drafts of documents Site is required to submit to governmental authorities pursuant to its obligations hereunder; and

(v) Take action to correct any such violations or deficiencies or heed any such warnings.

Company acknowledges that it may not direct the manner in which Site fulfills its obligations to permit inspection by governmental authorities. Company representatives shall have the right to be on site during any such inspection by a governmental or regulatory authority, unless prohibited by Applicable Law.

9.8 For the purposes of this Agreement, Site shall ensure that the principal investigator for a Study and other Site Representative with applicable experience and knowledge are present during any inspections.

9.9 Debarment. Site represents and warrants that neither Site nor Site Representatives have been the subject of a debarment, disqualification or exclusion under any rules, in any jurisdiction where they have practiced, in particular in Europe or in the United States (where the main applicable texts are: Generic Drug Enforcement Act of 1992, Title 21 Code of Federal Regulations ("**C.F.R.**") Section 312.70 and 42 C.F.R. Part 1001 et seq.). Site shall notify Company immediately upon any inquiry concerning debarment, disqualification, or exclusion of Site or Site Representatives, or the commencement of any proceeding concerning the same. Notice of or failure to provide any such notice under this Section shall constitute a breach hereunder for which Company may terminate this Agreement immediately for default notwithstanding any right of Site to cure.

10. ANTI-CORRUPTION REPRESENTATION AND WARRANTY

10.1 Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site.

11. INDEMNIFICATION

11.1 Company's Indemnity. Company shall defend, indemnify, and hold harmless Site and Site Representatives (collectively, "**Site Indemnitees**") from any and all third party liabilities, claims, damages, losses, actions and suits ("**Claims**") for Personal injury or death arising out of, or in connection with the applicable Study. This includes medical management and financial compensation as may be required by Applicable Law.

11.2 Notwithstanding its obligations to the Subjects as defined per Applicable Law, Company's indemnification obligations towards the Indemnitees are contingent upon the following conditions:

(i) Site conducted the Study in accordance with, and otherwise complied with, this Agreement and Applicable Laws and such Claims do not arise out of or in connection with any of Site Indemnitees' failure to comply with the same;

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(ii) Such Claims do not arise out of the negligence or willful misconduct of any of the Site Indemnitees, or any other person on the Site Indemnitees' property who is not a Company employee;

(iii) Site timely provides written notice to Company of Claims such that Company is in no way prejudiced;

(iv) Site Indemnitees fully cooperate with Company and its legal representatives in the investigation and defense of Claims; and

(v) Company has sole control over the defense and settlement of Claims and Site Indemnitees do not settle or compromise Claims without Company's prior written consent (which consent shall not be unreasonably withheld).

11.3 Company's Indemnification Obligations. If Company is obligated pursuant to the terms of this Agreement to provide indemnity, Company shall do so diligently. Company shall not admit fault on behalf of any one or more of the Site Indemnitees without the relevant Site Indemnitees' written permission, such permission shall not be unreasonably withheld, conditioned, or delayed. Without limiting the Company's right to have sole control over the defense and settlement of Claims, Site Indemnitees shall have the right to retain separate legal counsel and representation at Site Indemnitees' sole cost.

11.4 Site's Insurance. Site shall maintain a policy or program of insurance at levels sufficient to support its obligations assumed under this Agreement and as required by Applicable Law, evidence of which shall be provided to Company upon written request, and Site shall provide prompt notice to Company of any cancellation in its coverage.

12. WAIVER OF CONSEQUENTIAL DAMAGES

12.1 IN NO CIRCUMSTANCES SHALL ANY PARTY BE LIABLE TO ANY OTHER PARTY IN CONTRACT, TORT (INCLUDING NEGLIGENCE OR BREACH OF STATUTORY DUTY) OR OTHERWISE HOWSOEVER ARISING OR WHATEVER THE CAUSE THEREOF, FOR ANY LOSS OF PROFIT, BUSINESS, REPUTATION, CONTRACTS, REVENUES OR ANTICIPATED SAVINGS, OR FOR ANY OTHER SPECIAL, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGE OF ANY NATURE, WHICH ARISES DIRECTLY OR INDIRECTLY FROM ANY BREACH OF THIS AGREEMENT ON THE PART OF ANY OTHER PARTY. NOTHING IN THIS SECTION SHALL OPERATE SO AS TO RESTRICT OR EXCLUDE THE LIABILITY OF ANY PARTY IN RELATION TO DEATH OR PERSONAL INJURY CAUSED BY THE NEGLIGENCE OR INTENTIONAL MISCONDUCT OF SAID PARTY OR TO RESTRICT OR EXCLUDE ANY OTHER LIABILITY OF ANY PARTY THAT CANNOT BE SO RESTRICTED OR EXCLUDED BY APPLICABLE LAW.

13. SUBJECT INJURY

13.1 Subject Injury. In the event that a Subject suffers personal injury or death as a consequence of participation in the Study, Company shall bear such responsibilities as may apply to Company under Applicable Law. This does not prevent Company from filing an action against the Site or Site Representatives in case the adverse reactions described above are the result of the negligence or misconduct of the Investigator or any of the Site Representatives. Company does not authorize Site to offer compensation on behalf of Company, or to bind Company to any indemnity obligations in favor of any Subjects.

14. TERM AND TERMINATION

14.1 Effective Date. "**Effective Date**" shall be defined in each Order and such definition shall apply only to that Order.

14.2 Company's Right to Terminate. Company shall have the right, at any time, to suspend or terminate an Order, with or without cause and in whole or in part, by issuing a thirty (30) calendar day written notice to Site specifying the date and extent of termination. In the event of such termination, Site shall be entitled to compensation in accordance with the terms of the applicable Order up to the date of termination.

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Company shall also have the right to terminate immediately if it is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.3 Site's Right to Terminate. Site shall have the right to terminate any Order (i) if a principal investigator is identified in an Order and such principal investigator is unable to perform its obligations thereunder and a successor acceptable to Company is not available; (ii) if Company is in breach of any of its obligations hereunder and has failed to remedy such breach where it is capable of remedy within thirty (30) calendar days of a written notice from Site specifying the breach and requiring its remedy; or (iii) if Site is reasonably of the opinion that a Study should cease in the interests of the Subjects.

14.4 Obligations Upon Termination. Immediately upon receipt of notice of termination, Site shall stop enrolling Subjects into the relevant Study(ies) and shall cease conducting procedures on Subjects already enrolled in such Study(ies) as directed by Company, to the extent medically permissible and appropriate. Site shall return to Company within 30 calendar days of the effective date of termination any funds not expended or irrevocably obligated by Site prior to the effective date of the termination. Additionally, within 30 calendar days of the effective date of the termination, Site shall submit to Company a final invoice identifying any amounts Company may owe relative to the terminated Study(ies) and pursuant to the terms of this Agreement. Upon termination, Site shall, in accordance with Company's instructions, (i) preserve any data relating to the Study; (ii) turn over such data; and (iii) furnish Company an acceptable investigator's report for the Study.

15. MISCELLANEOUS

15.1 Amendments. Except as otherwise expressly provided herein, the terms of this Agreement may be amended only by the mutual written consent of the parties.

15.2 Use of Names. Company and Site shall not use each other's names (including the names of the other party's subsidiaries or parent, (if any)), symbols or marks, or any derivatives thereof in any form of publicity without the prior written consent of the owning party or parties, except that, without prior written consent of Site, Company may disclose on publicly-accessible clinical trial registries or through a Company-operated call center the general geographic location of Site (e.g., city, state, and/or country) and contact information of any party to this Agreement. In addition, and without prior written consent of Site, Company may identify the existence of this Agreement and/or, the name, and/or contact information of any party to this Agreement as required by applicable law. In addition, and without prior written consent of either party, Company and Site may disclose the other party's name in connection with publications hereunder.

15.3 Entire Agreement. This Agreement, any Order, and any amendments or Changes thereto, shall constitute the entire agreement between the parties hereto regarding the subject matter hereof and sets forth the entire terms and conditions under which this Agreement will be performed. There are no other agreements, oral or written, between the parties with respect to the subject matter of this Agreement, and all oral and written correspondence regarding the subject matter hereof is superseded by this Agreement. In the event of any inconsistency between this Agreement and any Order and the Protocol, if applicable, the terms of this Agreement shall govern, except as otherwise expressly agreed upon by the parties in a specific Order.

15.4 Counterparts. This Agreement and any Order, and any amendments or Changes may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, binding on all parties notwithstanding that each of the parties may have signed different counterparts. Facsimiles or scanned copies of signatures or electronic images of signatures shall be considered original signatures unless prohibited by Applicable Law.

15.5 Severability. In the event any provision of this Agreement conflicts with the law under which this Agreement is to be construed or if any such provision is held illegal, invalid, or unenforceable, in whole or in part, by a competent authority, such provision shall be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with Applicable Laws. The legality, validity, and enforceability of the remaining provisions shall not be affected thereby, and shall remain in full force and effect.

15.6 Assignment and Sub-contracting. Neither the rights nor the obligations of Site under this Agreement may be assigned, transferred or otherwise disposed of, in whole or in part without the prior

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written consent of Company. In the event Company consents in writing to Site's use of a subcontractor or affiliate in the performance of Site's obligations hereunder, Site shall remain responsible for the proper performance of such Study, in accordance with this Agreement.

15.7 Waiver. No action or inaction by either party shall be construed as a waiver of such party's rights under this Agreement or as provided by Applicable Law. Except as expressly provided for in the Change Section, no other term of this Agreement may be waived except by an express notice in writing signed by the waiving party. The failure or delay of a party in enforcing any of its rights under this Agreement shall not be deemed a continuing waiver of such right. The waiver of one breach hereunder shall not constitute the waiver of any other or subsequent breach.

15.8 Equitable Relief. Each party understands and agrees that money damages may not be a sufficient remedy for any breach of this Agreement and that the non-breaching party shall be entitled to seek specific performance, injunctive, and other equitable relief as a remedy for any such breach. Such remedy shall not be deemed to be the exclusive remedy for breach of this Agreement but shall be in addition to any and all other remedies available at law or in equity.

15.9 Contractual Relationship. Site is engaged in an independent activity and not as an agent, employee, partner, or joint employer of Company. If applicable, Site represents and warrants that it is an employer subject to, and shall comply with, all Applicable Laws. Site shall be responsible for Site Representatives' and subcontractors' acts, errors, omissions, and conduct. Site acknowledges and agrees that Company shall have no responsibility or liability for treating Site Representatives as employees of Company for any purpose. Neither Site nor any Site Representative shall be eligible for coverage or to receive any benefit under any Company provided workers' compensation, employee plans or programs or employee compensation, bonus, incentives, retirement or other arrangements.

15.10 Governing Law. This Agreement shall be governed by the laws of the country where the services are performed, excluding conflict of law rules.

15.11 Survival. The parties' rights and obligations under any provisions set forth in this Agreement related to ownership of Intellectual Property, confidentiality, publications, use of names, Applicable Laws, governing law, Materials, subject injury, privacy, indemnification, and insurance, or which contemplate performance or observance subsequent to termination or expiration of this Agreement issued hereunder shall survive such expiration or termination.

15.12 Cooperation with Company Representatives. Site has been advised that, under separate agreements, Company may retain others (including without limitation contract research organizations) to perform certain services in connection with a Study. Site shall cooperate with, and to the extent appropriate, coordinate its performance hereunder with the services of such others so as to ensure successful completion of the Study.

15.13 Language. The official language of this Agreement is the English language. Should a party translate this Agreement into another language and a conflict in interpretation occur between versions, the original official language version shall prevail.

15.14 Notice. Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is: (i) delivered by hand; (ii) received by registered or certified mail, postage prepaid, return receipt requested; (iii) confirmed as received if by facsimile; or (iv) received by nationally recognized, overnight courier, and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing:

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Executive Registrar
SGPGIMS,Lucknow

If to Company:

Amgen Technology Private Limited
Dynasty Business Park, 'A' Wing Level 4
Andheri-Kurla Road, Andheri (East)
Mumbai, India 400059

If to Site:

Sanjay Gandhi Post Graduate Institute
Rae Bareli Road
Lucknow, Uttar Pradesh-226014
India

With a Copy to:

International Legal Group
Amgen (Europe) GmbH
Dammstrasse 23
6301 Zug
Switzerland
Fax Number: +41 41 369 0411

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Agreement.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb '19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rakesh Kapoor
(print or type name)

Title: _____

Date: 14.02.2019

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

05/03/2019
Dr. Amit Gupta
Professor & Head
Department of Nephrology
S.G.P.G.I.M.S., Lucknow

Amgen Technology Pvt. Ltd. Mumbai

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Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Institution**"); and Dr. Amit Gupta, Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 285105) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Agreement shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20150238 entitled "A Multicenter, Multiple-dose, Active-controlled, Double-blind, Double-dummy Study to Compare the Therapeutic Efficacy and Safety of Oral Doses of Cinacalcet Hydrochloride With Intravenous Doses of Etelcalcetide (AMG 416) in Asian Hemodialysis Subjects With Secondary Hyperparathyroidism", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that Company and its authorized representatives may (i) record any Investigator Meetings through audio and visual recording technology (whether existing or future technology), which may include attendees' (including Site Representatives) names, words, images, and likeness ("**Recordings**"); and (ii) use, edit, and reproduce Recordings worldwide for education and training purposes related to Company's clinical trials. Company will comply with all privacy laws applicable to Company's use of such Recordings. Site and Principal Investigator may contact the Amgen Privacy Office at privacyoffice@amgen.com for further information about any rights to access and remedy information held by Company. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for

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participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Company utilizes Electronic Data Capture ("**EDC**") to collect from Site and deliver to Company Study data, specifically as the electronic case report form ("**eCRF**"). Site agrees that it will (i) enter such Study data into EDC within 5 business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within 5 business days of the query being issued. In the event of delay(s) by Site in complying with these timelines Company, at its option, may delay payment, lock of IVRS, suspend enrollment, conduct quality audit or pursue any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: AMG 416 ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will supply the Site with the Required Material(s). The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

3.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(i) Access. Company agrees to provide or, as appropriate, reimburse Site for materials that Company is required to provide per the Protocol including Study Drug, devices, reagents and supplements as further detailed in the applicable Order ("**Materials**"). Only those persons who are under the principal investigator's direct control and who will be using the Materials for the Study shall have access to the Materials. Upon termination or completion of the Study, Site shall destroy all unused Materials or, at Company's sole option, return to Company, in accordance with Company's instruction and Applicable Laws.

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4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop, AV Camera. Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: Sanjay Gandhi Post Graduate Institute, Rae Bareli Road, Lucknow, Uttar Pradesh-226014, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop, AV Camera.

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop, AV Camera.

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	Director, SGPGIMS Research Scheme Account Lucknow **"Payee"**
Tax ID	AAAJS3913N

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

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7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement, including, without limitation, Site's name, description of services, and amount of payment.

7.3 The parties agree that for this Order the section(s) in the Agreement restated below shall be amended and restated in its entirety as follows:

(ii) Publication Rights. Site shall have the right to publish or present the results of a Study, and shall exercise all reasonable efforts to do so in a timely manner provided such publication or presentation is consistent with the terms set forth in this Agreement and, unless otherwise agreed in writing, is consistent with Company's publication polices (see high level description at www.amgen.com/about/how-we-operate/policies-practices-and-disclosures/ethical-research/amgen-guidelines-for-publications/). In addition, prior to submission for publication of any manuscript, poster, presentation, abstract, or other written or oral material describing the results of a Study, Site shall provide Company 45 calendar days to review a manuscript and 15 calendar days to review any poster, presentation, abstract, or other written or oral material derived from a Study. In addition, if Company requests in writing, Site shall withhold any publication or presentation an additional 60 calendar days. Company reserves the right to remove, or require Site to remove, all Confidential Information from any publications or presentations; however, Company will not otherwise exercise editorial control over the proposed publication. Authorship will be based on scientific contribution. Notwithstanding the Confidential Information Section in this Agreement, Study data for purposes of publication and any resulting publications pursuant to this Section shall not be considered Confidential Information under this Agreement. Site hereby grants Company a non-exclusive, irrevocable, fully paid-up, royalty-free, worldwide license (i) to distribute copies of any publication regarding the Study within the Company and to its licensees, licensors, affiliates, and authorized representatives and (ii) to prepare derivative works of any such publication.

(iii) Multi-Center Study. Site agrees that if a Study is part of a multi-center study, any publication by Site of the results of a Study shall not be made before the first multi-center publication. For the purposes of this Article, "multi-center publication" means a publication of the manuscript in a peer-reviewed scientific journal that reports on the results of the primary outcome measure(s) of a multi-center Study. Authorship of any multi-center publication will be determined by Company based upon substantial contribution to the design, acquisition, analysis, interpretation of data, drafting, and/or critical revisions to any manuscript(s), derived from a Study. In the event that, as verified with Company, there is no multi-center publication within 18 months after a Study has been completed or terminated at all centers, data has been received and analyzed by Company, and all queries have been resolved, Site shall have the right to publish its results from a Study subject to the requirements described above. Subject to the requirements described above, Site may publish the results of a Study earlier to the extent reasonably necessary in the event of any perceived public health risk related to a Study Drug and provided that Site reasonably considers any Company comments regarding such publication.

7.4 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all

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SGPGIMS,Lucknow

cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.5 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site."

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb' 19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rakesh Kapoor
(print or type name)

Title:

Date: 14.02.2019

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences
LUCKNOW-226 014, INDIA

DR. AMIT GUPTA

(signature) 05/03/2019

By: AMIT GUPTA
(print or type name)

Title:

Date: 05/03/2019

Dr. Amit Gupta
Professor & Head
Department of Nephrology
S.G.P.G.I.M.S., Lucknow

Amgen Technology Pvt. Ltd. Mumbai

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Executive Registrar
SGPGIMS,Lucknow

Protocol Number	20150238
Site Number	30006
Investigator	Dr. Amit Gupta
Contract Number	
Maximum number of Subjects	10
Number of Sites	1
Currency	INR

CONTRACT SUMMARY	COST	UNIT(S)	TYPE	TOTAL
SUBJECT VISIT TABLE	INR 4,86,390	10	Subject(s)	INR 48,63,900
SCREEN FAILURES	INR 12,005	1	per Subject	INR 1,20,050
ADMINISTRATIVE FEES				INR 50,000
MAXIMUM CONTRACT TOTAL*				**INR 50,33,950**

**Maximum Contract Total is inclusive of Hospital overhead fees, pharmacy costs, laboratory costs. Amgen has provided thermohygrometer for temprature reading.*

SUBJECT FEES (Overheads 25%)

VISIT TABLE: STUDY	Schedule A
Screening	INR 12,005
Day 1	INR 20,690
Week 2	INR 17,160
Week 3	INR 16,700
Week 4	INR 17,620
Week 5	INR 17,300
Week 6	INR 17,160
Week 7	INR 16,700
Week 8	INR 17,160
Week 9	INR 17,300
Week 10	INR 17,160
Week 11	INR 16,700
Week 12	INR 17,550
Week 13	INR 17,300
Week 14	INR 17,160
Week 15	INR 16,700
Week 16	INR 17,160
Week 17	INR 17,300
Week 18	INR 17,160
Week 19	INR 16,700
Week 20	INR 17,160
Week 21	INR 17,300
Week 22	INR 17,160
Week 23	INR 16,700
Week 24	INR 17,160
Week 25	INR 17,300
Week 26	INR 17,160
Week 27	INR 12,915
Follow-Up	INR 12,850
Early Term	INR 13,855
SUBJECT VISIT TABLE SUBTOTAL(S)	Schedule A

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Executive Registrar
SGPGIMS,Lucknow

Completers, Screening to Week 27, Safety Follow-Up	INR 4,86,390
Early Termination	INR 13,855
MAXIMUM PER SUBJECT FEE	**INR 4,86,390**

Screening costs are inclusive of costs associated with potential re-screens.
The Maximum Per Subject Fee includes Subject travel reimbursement. Subject travel reimbursement is included at a rate of INR 900.00 per protocol required in-clinic visit

VISIT TABLE: SCREEN FAILURE	Schedule A
Screen Failure	INR 12,005
MAXIMUM SCREEN FAIL	**INR 12,005**

NON-SUBJECT FEES

ADMINISTRATIVE FEES (Schedule A)	UNIT COST	UNIT(S)	TYPE	TOTAL
[1] Document storage/Archiving total 1	INR 0	1	per Site	INR 0
[2] Infrastructure Cost	INR 50,000	1	Total	INR 50,000
SUBTOTAL, ADMINISTRATIVE FEES				**INR 50,000**

1 Site has confirmed that archival fee is not applicable
2 Infrastructure cost will be reimbursed as per actual and upon original invoice. Prior approval of purchase must be obtained by site from study team before placing order for the infrastructure.

PAYMENT TERMS

Initial Payment	**50,000.00** *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment. In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Schedule - A

The payment of the study will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

The EC for this study will be 'Bioethics Cee, IEC' and the payment of the EC fees will be made in the favor of 'Director, SGPGIMS Research Scheme Account Lucknow' (PAN: AAAJS3913N)

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."
2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL88499236024515
Certificate Issued Date	:	06-Oct-2020 10:44 AM
Account Reference	:	IMPACC (IV)/ dl720603/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL72060385189813196337S
Purchased by	:	CENTRE FOR CHRONIC OF DISEASE CONTROL
Description of Document	:	Article Others
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	CENTRE FOR CHRONIC OF DISEASE CONTROL
Second Party	:	Not Applicable
Stamp Duty Paid By	:	CENTRE FOR CHRONIC OF DISEASE CONTROL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

SERVICE AGREEMENT

THIS SERVICE AGREEMENT (hereinafter as "Agreement"), executed at New Delhi on **July, 2020**. (hereinafter "the Execution Date")

By and Between,

Centre for Chronic Disease Control (CCDC), a society registered under the Indian Societies Registration Act, 1860 and having its registered office at Flat No. 70 Pocket-1, Sector-2, Dwarka, New Delhi 110075, India (hereinafter referred to as "CCDC" which expression shall unless be repugnant to context or meaning thereof shall mean and include its successors and assigns) as **First Party**;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences having its registered office at **SGPGIMS, Lucknow,** Uttar Pradesh – 226014 (hereinafter referred to as **"SGPGIMS, Lucknow"** which expression, unless repugnant to the context or meaning thereof, shall include its affiliates, successors in interest and permitted assigns) as **Second Party**.

CCDC and SGPGIMS, Lucknow are hereinafter collectively referred to as "Parties" and individually as "Party".

WHEREAS:

1. **Centre for Chronic Disease Control (CCDC)** is a registered society and is primarily intended to address the growing challenge of chronic diseases through knowledge generation, to inform policies and empower programmes for the prevention and control of chronic diseases, knowledge translation intended to operationalize research results by bridging the critical gaps between relevant research and effective implementation, through analytic work, capacity building, advocacy and development of educational resources for enhancing the empowerment of people and professionals.

2. **Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow (India)** is a University established under State Act in 1983. The institute offers its own degrees, which are duly recognized by the Medical Council of India. The Institute is rated amongst the top medical institutions in the country, delivering state-of-art tertiary medical care, super-specialty teaching, training and research. Dedicated faculty members endeavor to provide quality education, patient care and research and strive to meet the challenges and needs of the society. The Institute offers DM, M.Ch, MD, PhD, Post-Doctoral Fellowships (PDF) and Post-Doctoral Certificate Courses (PDCC), and Senior Residency in various specialties. The peers in the field have recognized the courses offered by the Institute and the candidates obtaining degrees from SGPGIMS have been highly placed both within the country and abroad.

3. **Purpose of entering into this MoU: CCDC, New Delhi** and **SGPGIMS, Lucknow**, have agreed to execute the following MoU with reference to the participation of **Dr. Sudeep Kumar, Professor-Department of Cardiology, SGPGIMS- Lucknow** to serve as a Regional Faculty at Lucknow center in the **Fourth Cycle of Certificate Course in Management of Hypertension (CCMH)**.

NOW THEREFORE IT IS HEREBY AGREED BY AND AMONGST THE PARTIES AS UNDER:-

1. Background

CCDC has undertaken to offer Certificate Course in Management of Hypertension (CCMH) Cycle-IV, a joint certificate program designed, delivered and implemented by Public Health Foundation of India (PHFI), New Delhi and Centre for Chronic Disease Control (CCDC), New Delhi, in collaboration with our partners International Society of Hypertension (ISH) and British & Irish Hypertension Society (BIHS) as an eight modular course from January 2021 based upon the funding from International Society of Hypertension (ISH).

The key features of the course are highlighted below:

1. The purpose of this said course is to train primary care physicians in prevention, care and management of hypertension with ultimate objective to improve patient outcomes.

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SGPGIMS,Lucknow

2. The said course is designed to enhance skills and competencies of primary care physicians in prevention, care and management of hypertension. The course will run as an intensive one-day dialectic lectures with eminent Cardiologists/Medicine Specialist as Regional Faculty, once a month for eight months covering eight modules on different aspects of hypertension. The program includes case based learning and group discussions on current issues in hypertension diagnosis, care, screening, management and prevention will be the focus of this said course.

3. Upon completion of the day long workshops through the said course, the participants will maintain contact with the Regional Faculty, so that the learning and discussion continue, lessons learned can be shared and best practices can be emulated.

4. The Certificate Course in Management of hypertension was conceptualized & launched its first cycle on 24th July 2016 as a 10 modular course (July 2016-April 2017) at 25 regional centres' (covering 21 cities in 13 states and 01 Union Territory) across India. The course was endorsed by 11 National Experts, 25 Regional Faculty and 28 Observers and have witnessed an enrollment of 612 participants. The class ratio is 1:15 with 1 Regional Faculty (Cardiologist / Medicine Specialist) for 15 participants.

5. The second cycle of the course was launched on 22nd October 2017 all across India as 10 modular course (Oct 2017 – July 2018) at 40 regional centres (covering 36 cities, 17 states and 01 Union Territory) across India and have witnessed an enrollment of 658 participants.

6. Cycle III of program was launched in 10 regional training centres with 10 participating Faculty on 26th May 2019 as 8 modular course(May 2019 – Dec 2019) at 10 regional centre (covering 9 cities, 6 states and 1 UT) across India and had witnessed an enrollment of 1 5 participants.

7. CCMH cycle-IV will be launched in 10 regional training centres & 1 online centre (for all the participants who are from other cities) with 11 participating Faculty. Each center will enrol minimum 15 participants per centre. Thus, approximately 165 Primary Care Physicians are proposed to be trained in this fourth cycle starting January 2021 to August 2021.

2. Course – Objectives

Primary objective

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

Secondary objectives

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

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SGPGIMS,Lucknow

3. Terms of Reference

Dr. Sudeep Kumar (from SGPGIMS- Lucknow) deliverables during the MoU:

On behalf of **SGPGIMS, Lucknow, Dr. Sudeep Kumar** will be responsible for completing below mentioned responsibilities:

3.1 Signing of this Agreement and successfully conducting and completing the first four course modules by **30th April, 2021**.

3.2 Successfully conducting & completing last four modules and exit exam by **31st August, 2021.**

Dr. Sudeep Kumar is required to share interim milestones regarding these deliverables regularly with CCDC, as per the project plan.

4. Period of Service Agreement

The Agreement shall be effective for a period starting from **July 2020 to August 2021**. It may be further extended for such period and on such terms and conditions as may be mutually agreed upon between both the parties.

5. Terms of Payment

CCDC will pay **SGPGIMS, Lucknow** a total amount of **Rs.60,000/-** for the entire duration of the Agreement as per the schedule detailed below in this section.

- The GST will be inclusive in the amount mentioned above. In case GST tax is applicable to you, please provide CCDC with your GST registration certificate.
- The amount mentioned above is also subject to TDS deduction as per prevailing Indian Income Tax Act and rules.
- Schedule of payment of the consultancy will be as follows:

  1. **50%** of the amount i.e. **Rs. 30,000/-** shall be payable upon satisfactory completion of the deliverable as mentioned in Clause 3.1.

  2. Remaining **50%** of the amount i.e. **Rs. 30,000/-** shall be payable upon satisfactory completion of the deliverable as mentioned in Clause 3.2.

- For conducting all monthly technical sessions, a fixed amount will be provided by CCDC to the regional faculty for conducting the session in a center.
- For each center, the session conduction charges will be **Rs.705/-** per participant per session (depending upon the total number of the participants registered under the respective center). This amount will be applicable for deduction of 1% TDS as per prevailing Income Tax Rules and provisions. On this payment TDS will be applicable as per prevailing Income Tax rates in India, as the case may be.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

- Four months advance payments for conducting technical sessions will be transferred electronically by CCDC to the specified bank account of the Regional Faculty one week prior to the conduction of the first module. The subsequent instalment for the conduction of sessions for the next four months (and the remaining two months) will be released after receiving the internal assessment sheet of all previous modules.
- The deliverables will be approved for suitability by the Project Leader at CCDC, whose opinion shall be final and binding. The payments will be released within the shortest possible time after receiving relevant invoices and documents and the PI's approval.
- CCDC may reimburse up to ₹ **20,000/-** on progressive basis towards office and other expenses of the Regional Faculty, subject to receipt of separate invoice.

6. Termination

6.1 CCDC shall have the sole right to terminate this Agreement with **SGPGIMS, Lucknow/Dr. Sudeep Kumar** without assigning any reasons thereof.

6.2 At the receipt of notice of termination from CCDC, **SGPGIMS, Lucknow/Dr. Sudeep Kumar** shall be liable to stop all the work immediately and shall not raise any invoice for the termination notice period.

6.3 Termination shall become effective in Fifteen (15) working days after receipt of written notice from CCDC.

7. Representation and Warranties

7.1 SGPGIMS, Lucknow/Dr. Sudeep Kumar has full legal capacity to enter into this Agreement and that there are no existing facts and/ or circumstances and/or contractual obligations with third parties and/or legal proceedings which prohibit and/or impair its capacity to enter into this Agreement;

7.2 SGPGIMS, Lucknow/Dr. Sudeep Kumar has the requisite capacity to fulfill all its obligations and activities under this Agreement;

7.3 SGPGIMS, Lucknow/Dr. Sudeep Kumar of its representatives shall not directly or indirectly infringe the Intellectual Property Rights of CCDC or disclose any confidential information or do anything which shall have material adverse impact on the goodwill and repute of CCDC.

8. Indemnity

SGPGIMS, Lucknow/Dr. Sudeep Kumar agrees to indemnify, keep indemnified and hold harmless CCDC against all claims, demands, damages, losses, expenses, suits or proceedings made against, incurred or suffered in connection with the performance of the Agreement, resulting from or arising out of (whether or not involving a third party claim) of any of its representations and warranties, covenants, and undertaking under this Agreement.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

9. Partial Invalidity

If any provision of this Agreement is declared by any judicial or any competent authority to be void, voidable, illegal or otherwise unenforceable, the Parties shall replace that provision with a provision which is valid and enforceable and most nearly gives effect to the original intent of unenforceable provision and the remaining provision of this Agreement shall remain in full force and effect.

10. Notices

All notices and other communication under this Agreement shall be in writing and in English and either delivered by hand or send by registered mail or courier by email or by facsimile telex or fax in each case in the name of the representatives given below at Clause 16 and at the addresses set out at the beginning of this Agreement.

11. Assignment

SGPGIMS, Lucknow/Dr. Sudeep Kumar shall not assign and/ or transfer any of their rights or interest or benefits under this agreement without the prior written consent of CCD.

12. Jurisdiction

This Agreement shall be governed by, and constructed in accordance with the law of India. Further, the Parties agree that the competent courts at Delhi shall have jurisdiction on all matters relating to this Agreement including for grant of injunctive relief and enforcement of arbitral awards.

13. Resolution of Disputes

- In the event of any dispute relating to the interpretation or performance of this Agreement arising between the Parties, both Parties will first do their utmost to settle their dispute amicably.
- In the case of failure to resolve the dispute, all such disputes shall be referred to arbitration under the Arbitration and Conciliation ACT, 1996 (or an amendments thereof).
- The parties shall appoint its own arbitrators and the two arbitrators shall I turn appoint the third arbitrator, who shall preside over the arbitration. The place of such arbitration shall be New Delhi. The language of arbitration shall be English only.
- Awards relating to any dispute shall be final and binding on the Parties to such dispute as from the date they are made. The arbitrator shall give a reasoned decision or award. The Parties agree and undertake to carry out any decision or ward of the arbitrator relating to such dispute without delay. The Parties further agree that there will be no appeal to any court of law or other judicial authority.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

14. **Copyright and other Intellectual property rights.**

14.1 All documents received by Dr. Sudeep Kumar on behalf of SGPGIMS Lucknow under this MoU shall be CCDC's sole property and shall be treated as confidential and shall be delivered only to the CCDC authorized representatives on completion of work under this MoU. Dr. Kumar shall not communicate at any time to any other person, Government or authority external to CCDC any information known to him by reason of his association under this MoU, which has not been made public, except by authorization of CCDC; nor shall he use such information to his private advantage. These obligations do not lapse upon termination of its MoU with CCDC.

14.2 CCDC shall, solely and exclusively, own all rights in and to any work created by Dr. Sudeep Kumar on behalf of SGPGIMS, Lucknow within the scope of this MoU. Dr. Sudeep Kumar will require prior written approval from CCDC before reproducing, distributing or using this work. Dr. Sudeep Kumar shall not use any drafts, data, questionnaires, and extracts in any form after the completion of this project. For obtaining such permission a written request shall be placed to the First party and the same shall be approved or rejected within a due time period of 7 working days. The request should not be denied merely on frivolous grounds and the objective of such request should be given due importance.

As a Regional Faculty, Dr. Sudeep Kumar is responsible to keep CCDC well informed of any other separate activities, undertaken in any circumstances, existing right from time of signing of MoU or arising at any time during the term. In the event of a conflict of interest, you will inform CCDC and CCDC shall decide the future course regarding the execution of the activities agreed upon in this MoU, based on mutual consultation.

15. Other Terms & Conditions

15.1 This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof and may not be modified or amended except in a written agreement signed by both Parties.

15.2 Nothing contained in this Agreement shall constitute or be deemed to constitute a partnership between the Parties, and no Party shall hold himself out as an agent for the other Party or any of them, except with the express prior written consent of the other Parties. The rights, duties, obligations and liabilities of CCDC on one hand and of Dr. Sudeep Kumar on behalf of SGPGIMS, Lucknow on the other hand, under this Agreement shall be individual, not joint or collective, unless specifically provided for herein this Agreement.

15.3 Any amendment or change regarding this agreement shall be done in writing only if both the party mutually agrees for the same.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

16. Representatives for the Purposes of this Agreement

16.1 CCDC's representative for the purposes of this Agreement is:

Prof. D Prabhakaran – CCDC

16.2 SGPGIMS, Lucknow representative for the purpose of this Agreement is:

Dr. Sudeep Kumar-SGPGIMS, Lucknow

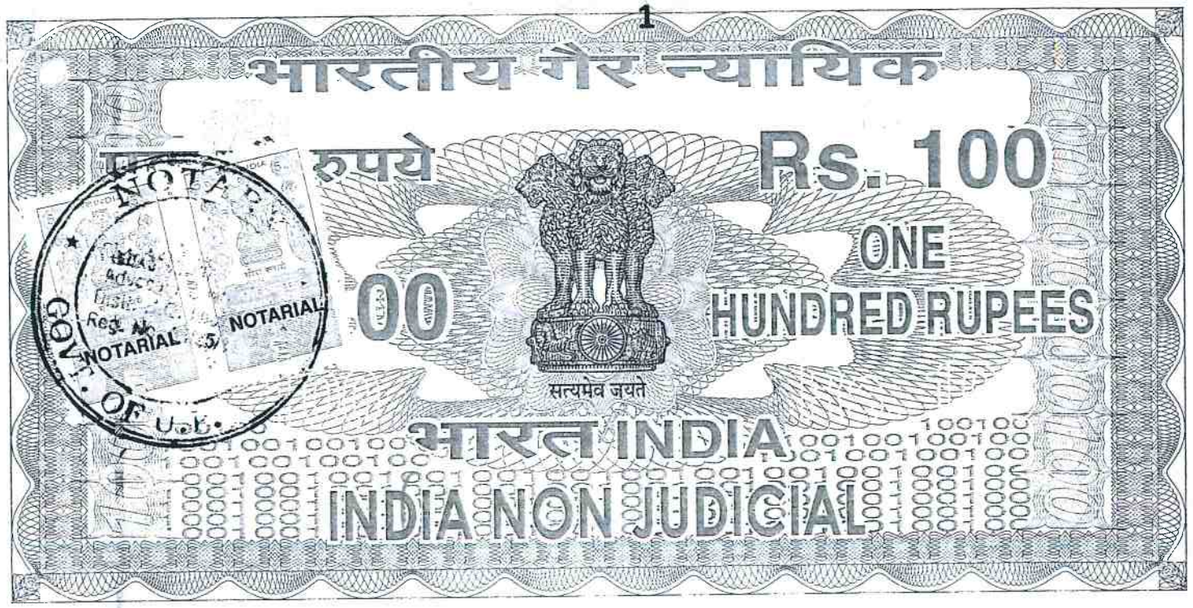
17. Miscellaneous

This MoU may be executed by the parties in two (2) separate counterparts each of which when so executed and delivered shall be original, but both of such counterparts shall together constitute one and the same instruments. All the Annexures, if any, in the MoU shall form a part of it.

The undersigned, being duly authorized thereto, have signed this MoU in two original copies in English at the place and on the date(s) indicated below:

For CCDC	**For SGPGIMS- Lucknow**
Name: Mr. Alex J **Designation:** Assistant Director, Finance **Authorized Signatory** **Date: 02-Sep-2020**	**Name:** Prof. R. K. DHIMAN **Designation:** Director **Authorized Signatory** **Date:** 05/01/2021
Name: Prof D. Prabhakaran **Designation:** Executive Director - CCDC **Date:14-Sep-20**	**Name:** Dr. Sudeep Kumar **Designation:** Professor, Department of Cardiology, SGPGIMS, Lucknow **Date:** 22/Dec/2020

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



उत्तर प्रदेश UTTAR PRADESH

FA 104737

MEMORANDUM OF UNDERSTANDING

BETWEEN

ARMED FORCES MEDICAL SERVICES
MINISTRY OF DEFENCE, CHURCH ROAD, NEW DELHI, 110001.

AND

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCESRAEBARELI ROAD, HABIT MAU MAWAIYA, LUCKNOW UTTAR PRADESH.226014.

REGARDING

COLLABORATIVE RESEARCH AND TRAINING

[04 OCTOBER-2019]

Chandrika Pd. Misra
Adv & Notary
HQ Collectorate
Lucknow U P INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This MoU is made and entered into on this [04th] day of [October] of [2019] between the Armed Forces Medical Services, a tri-service (Army, Navy and Air Force) defence organization, under Ministry of Defence, Government of India with its Headquarters at M Block, Church Road, New Delhi, 110001.

and

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Haibat Mau Mawaiya, Lucknow, Uttar Pradesh 226014, a University established under State Act in 1983. This MOU sets down the mutually agreed broad framework for joint research and academic activities in various fields of interest. It also incorporates the modalities for collaboration.

1. **Preamble.**

(a) Armed Forces Medical Services (AFMS) is a premier tri-service (Army, Navy and Air Force) organization having multiple hospitals with specialized medical/paramedical staff and facilities for patient care, training and research activities.

(b) Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Lucknow has the status of a State University. The institute offers its own degrees which are duly recognized by the Medical Council of India. The Institute is rated amongst the top medical institutions in the country, delivering state-of-art tertiary medical care, super-specialty teaching, training and research. Institute has the status of a State University and has the mandate to provide postgraduate teaching, training and to conduct research in the relevant disciplines of modern medicine and other allied sciences, including interdisciplinary fields of physical and biological sciences.

(c) The activities of AFMS and SGPGIMS, Lucknow are in several ways complementary. It is therefore felt that initiating collaborative research programs will be of considerable mutual benefit.

2. **Purpose**.

AFMS and SGPGIMS, Lucknow desire to implement, in the areas of mutual interest, cooperative and collaborative activities, which will address multidisciplinary scientific, technological and educational problems of relevance to the country.

Chandr.kn P.N. Misra
Adv & Notary
HQ Collectorate
Lucknow U.P. INDIA
Regd. No. 29/99

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

3. Scope of Cooperation.

The following areas of cooperation have been identified under this agreement.
(a) **Faculty Exchange Programme.** The two parties will explore opportunities for interaction among members of faculty between SGPGIMS, Lucknow and AFMS institutions as well as creating Visiting/Adjunct Faculty positions. Each such visit will require approval of the relevant authorities.

(b) **Joint Research Projects.** The two parties will explore opportunities of undertaking joint research projects under opportunities that may be funded by Department of Health Research, Ministry of Health & Family Welfare; Department of Biotechnology, Ministry of Science & Technology; and Indian Council of Medical Research and will work together for the purpose of identifying the needs of the country in terms of research and technology and collaborate in undertaking research in identified areas relevant to the country's needs. They may also carry out joint research in technology for distance and computer-based learning.

(c) **Joint Academic Activities and Events.** AFMS and SGPGIMS, Lucknow may formulate joint academic activities such as short courses, seminars, workshops or conferences based on mutual interests and available expertise in the institutions.

(d) Financing. AFMS and SGPGIMS, Lucknow will approach the government agencies for funding the various initiatives envisaged under this MoU. The two institutions may also consider providing initiation grant or other kind of support from their own resources. In case of faculty exchange programs salaries and travel will be the responsibility of the parent institute; whereas expenses on local hospitality will be borne by the host institute. There are no further financial obligations for the contract partners as a result of this contract.

4. Legal Status.

This document is a statement of intent to foster genuine and mutually beneficial cooperation and is not legally binding on the parties. Any disputes shall be resolved through mutual discussion.

5. Validity.

This MoU is valid for an initial period of five years and becomes effective from the date it is signed by the partners. The partnership period may be extended by mutual consent. In case one partner wishes to terminate in writing the MoU, intimation will have to be sent at least six months in advance. However, specific

Chandrika Pd. Mishra
Adv & Notary
HQ Colleges
Lucknow U.P. INDIA
Regd. No. 31 (725) 99

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Commitments made prior to such intimation shall be honored by both the partners.

In witness whereof undersigned, duly authorized thereto, have signed this MOU on this day 04 Oct-2019

Lt Gen Bipin Puri, PVSM, VSM, **PHS Director General** **Armed Forces Medical Services** **Date:** 05/K/19 **[OFFICIAL SEAL]**	**Professor Rakesh Kapoor** **Director** **Sanjay Gandhi Post Graduate Institute** **of Medical Sciences, Lucknow** **Date:** 5/10/19 **[OFFICIAL SEAL]**

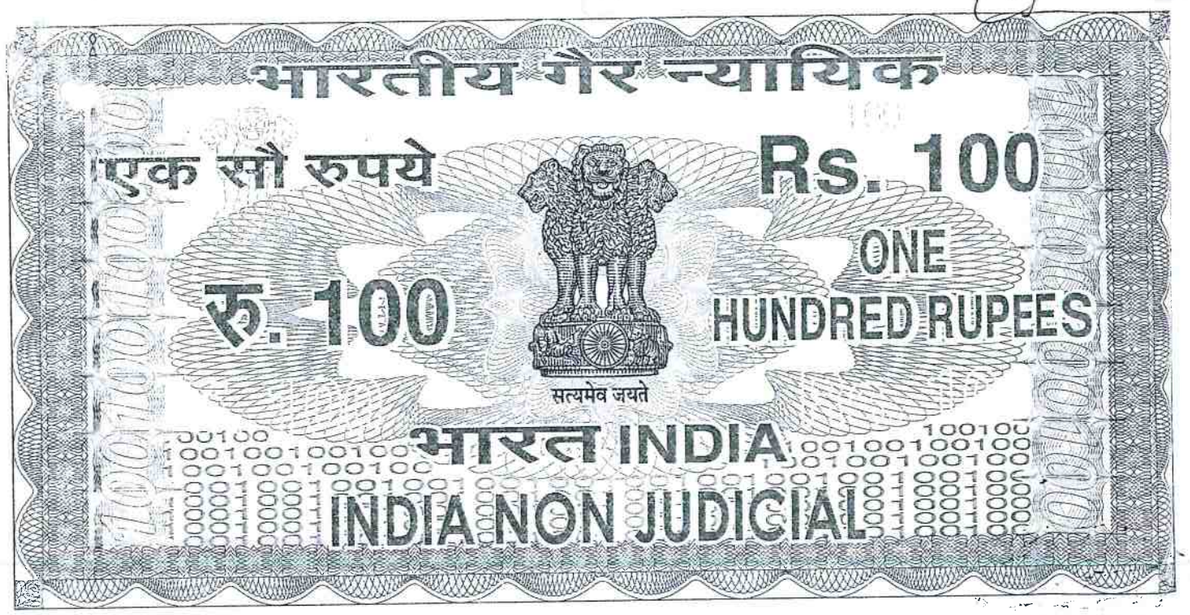
Witness
① (K A Khan) Lt Col
②

Witness
①
②

SIGNATURE & T.I. ATTESTED
Advocate & Notary
H.C. Collectorate
Lucknow U.P. INDIA
Reg. No. 3126/1999

Identify the deponent/Executant/Surety who has/have signed/Put T.I. before me.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



उत्तर प्रदेश UTTAR PRADESH

EN 099333

Agreement between SGPGI , Lucknow and NTPC NRHQ, Lucknow for implementing Telemedicine Network by SGPGI at two stations of NR-NTPC as a deposit work

This Agreement for deposit work (hereinafter referred to as Agreement) between Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh (hereinafter referred to as "SGPGI") and NTPC Limited, a company incorporated under companies Act, 1956, having its corporate office at Core 7, Institutional at Area, Lodhi Road. New Delhi-110001 hereinafter referred to as "NTPC".

1. Preamble :

1.1. Whereas SGPGI is a super- specialty hospital, established by the Govt. of Uttar Pradesh under State Act in 1983 as a center of excellence for providing tertiary care, education and research of high order and is chartered to function as university under the States of Uttaranchal, MP, Bihar, Orissa, West Bengal and Chhattisgarh. It is involved in development of telemedicine technology and gained necessary expertise to implement it instate health system. This technology will facilitate delivery of specialist health care, follow up and education at a distance with the help of modern information and Tele-communication technology.

1.2. Whereas NTPC a MAHARATNA, a Government of India Enterprise under its employee welfare Scheme, intends to use the potential of telemedicine technology to enable access to specialty health consultation for the employees of NTPC's projects located in Northern Region and Tele-CME for medical and paramedical professionals of the said hospitals of the projects

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(38)

by supporting setting up of a Telemedicine network between SGPGI and NTPC Northern Region projects.

1.3. Whereas NTPC hasunderstood the technology and accepted the project offered by SGPGI and intends to adopt the telemedicine technology to improve it's healthcare system in the Northern Region consisting of projects located at Rihand, Singrauli, Vindhyachal, Tanda, Unchahar, Auraiya and Meja.

1.4. Whereas, SGPGI Lucknow, and NTPC are willing to jointly participate in setting up the Telemedicine Network. It will start as a pilot project by setting up telemedicine at NTPC Hospital, at Rihand and Meja by connecting it with SGPGI through a Fiber backbone and network to be decided by SGPGI.

1.5. Whereas, the Chief Coordinator of the project will be Prof. S.K. Mishra, Professor & Head, Department of Endocrine Surgery and Nodal Officer, Telemedicine, SGPGI, Lucknow who will work under the supervision of the Director, SGPGI and GM(HR) NR, NTPC, will be the Coordinator of the project from NTPC side .

2. Scope of the Agreement:

This Agreement will cover the joint effort of SGPGI, and NTPC.

3. Responsibilities of SGPGI

3.1. **Pre-implementation Services:**

a) The scope of consulting service includes carrying out detailed study & evaluation of the proposed project site, as per requirement of the project and delivering plans, design documents and recommendations for setting up the proposed network including technical specification of the hardware, software, diagnostic equipment to be inter phased with Telemedicine system, tele-communication medium and its technical specifications in consultation with it's technical partners.

b) Site evaluation Teams from SGPGI and NTPC will visit the project sites to survey it and assess the site's preparedness, based on the following factors – Physical structure, civil, Engineering, Interiors Furniture & Fixtures, Accessibility, Local disease trends and Local medical expertise. The team will prepare a 'Site Evaluation Report' incorporating their observations.

c) Preparation of the Project Proposal and submission to appropriate authorities.

3.2. **Implementation of Methodology**

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Executive Registrar
SGPGIMS,Lucknow

a) The Telemedicine Centre will be opened in first phase at Rihandand MejaHospitalsof NTPC and then depending upon the usefulness of the facility the remaining five hospitals of NR may be connected on the same or improved pattern.

b) The school of Telemedicine & Premedical Informatics (STBMI) of SGPGI will establish and run the Telemedicine centre at NTPC Rihand and Meja.

c) Telecommunication equipment will be procured through GeM / Tendering process of SGPGI. Bandwidth will be hired from BSNL. The project will be extended on turnkey basis and all the money sanctioned for their project will be transferred to STBMI, SGPGI in advance after that SGPGI will initiate the process and will procure the listed equipment within three months. The telemedicine platform will be created in phase wise manner to cover all the NTPC hospitals situated in NR.

d) Rihandand MejaHospitals of NTPC will be connected with SGPGI in first phase through BSNL networkupto minimum one mpbsbandwidth. Remaining five hospitals of NTPC NRHQ will be connected on same pattern or improved technology in phase II.

e) BSNL line to be procured for the project will be in the scope of SGPGI. After completion of project it will be surrendered or if NTPC wish to continue, the same will be handed over to NTPC.

f) STBMI will implement the project on turnkey basis, which will include
   i. Procurement and installment of Health ATM and PC
   ii. Telemedicine videoconferencing software
   iii. High resolution display unit
   iv. Cost of bandwidth
   v. A3 Transparency Scanner
   vi. Electric fittings and fixtures etc. as required
   vii. Deployment of trained Human Resources (1-Project Manager at NRC – Lucknow, 1-Technician at SGPI, 1-Technician at Rihand, 1-Technician at Meja) for running the Centre.

g) The Telemedicine equipment (Health ATM will be procured by STBMI, SGPGI- Lucknow through GeM / tendering process of SGPGI.

h) The procurement of equipment is in the scope of SGPGI. All the assets acquired out of project by SGPGI under the agreement will belong to NTPC and will be handed over formally torespected hospitals of NTPC in proper running conditions after expiry of the agreement. The operation &

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Executive Registrar
SGPGIMS,Lucknow

maintenance of the equipment will be taken care by the SGPGI till the project / agreement period.

i) STBMI will also provide Tele-education, knowledge & skill development session and Web streaming / casting programme on different recent topic / disease trends held across the country.

j) This phase will be completed within three months of release of fund by NTPC and subject to the availability of communication link at the time of installation.

3.3. **Maintenance of hardware and software and diagnostic equipment:**

a) SGPGI in collaboration with it'stechnical partner will be responsible for providing maintenance support for telemedicine hardware, software and diagnostic equipment free of cost for one year (warranty period) and subsequently on establishment of AMC. The Service Level Agreement (SLA) to be entered into by SGPGI with its technical partner shall also be in principle vetted by NTPC.

3.4. **Providing consultation and educational services:**

a) SGPGI will provide tele-consultation and tele-follow up and tele-educational services free of cost for a period of three years after which fresh agreement has to be executed. Detailed modalities like scheduling of these services will be worked out on mutually agreed time sharing basis. SGPGI will try its best to render its services but will not be bound down with any Service Level Agreement since SGPGI is not following any revenue model for its services in this project.

b) Towards the cost of project related to manpower, travel and other incidental expenses in the budget head of "Implementation Expense" SGPGI will follow its own financial rules.

c) Preparation of Documents such as Project Evaluation Frame work, Mid-term review report and final project report.

d) SGPGI shall appoint manpower on contract basis as per established procedure for recruitments of project manpower. Therefore, no obligation lies on the NTPC during and after project agreement. Their training will also be in the scope of SGPGI.

3.5. **Services offered by STBMI, SGPGI using available infrastructure:**

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Executive Registrar
SGPGIMS,Lucknow

a) A telemedicine center will be established at NTPC run hospital at Rihandand Mejawithin three months. The date of installation will be counted from date of money received at STBM, SGPGI Lucknow.

b) STBMI will provide Tele-follow-up services at least 2-30 sessions in a month depending upto the services sought form the Rihandand Meja hospitals.

c) Tele-education, Knowledge & skill development session at least three in a week or depending upon the demand of doctors of the Rihand&Meja hospitals it will be facilitated more.

d) Tele-CMEs session at least 5-10 session in a month

e) Web streaming / casting programme on the different recent topic/disease trends held across the country

f) Knowledge support, sharing of knowledge material like research publications, articles, journals available at STBMI domain etc.

3.6. **Project Beneficiary :**

a) Tele-follow-up services to the patient who have taken treatment of SGPGI, Lucknow. Patient need not to come to SGPGI for follow up.

b) Second Opinion for making diagnosis: Patients who live in the campus of NTPC & surrounding hilly & rural area or far from hospital would be given a second opinion.

c) In addition, severely & complicated patients can be managed locally and access to medical specialist accessed by SGPGI doctors, hence the system may provide fast response to critical medical care in spite of geographic barriers.

d) Local hospitals usually do not have enough medical expert and nursing staff who are able to manage seriously ill patient. By using these technologies, this kind of problems may be alleviated.

e) Doctor & paramedical staff involved in the process will have the opportunity to learn and update the knowledge & skill in terms of getting expert opinion from the super specialist doctors from SGPGI and other premier tertiary level hospital.

4. Responsibility of NRHQ and Payment Terms

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.1. Total sum of Rs. 33,70,000/- (Rs. Thirty Three lacks seventy thousand only) details of which are annexed as annexure I to this Agreementwill be released to SGPGI within a period of 15days from the date of signing of thisAgreement.

4.2. For the second year annual running cost of Rs. 16,20,000 (Rs. sixteen lakhs twenty thousand only) shall be released to SGPGI within 15 days of start of second year ofAgreement and subject to submission of utilization certificate by SGPGI for utilization of Rs. 33,70,000/-

4.3. For the third year annual running cost of Rs. 17,51,800 (Rs. Seventeen lakhs fifty one thousand eight hundred only) shall be released to SGPGI within 15 days of start of third year of Agreement and subject to submission of utilization certificate by SGPGI for utilization of Rs. 16,20,000/-

4.4. NTPC shall be responsible for payment of Rs. 67,41,800/- (Rs 33,70,000/- + Rs.16,20,000/= + Rs.17,51,800/-) during the period of the Agreement.

4.5. In case any benefits occur to SGPGI on account of execution of agreement, the same will be passed to NTPC. Even if some budget is left in any sub head, the same will be intimated to NTPC as per the rule of SGPGI. In case of excess expenditure is to be made in any subhead, the approval of the funding agency i.e. NTPC will be sought thereafter the account section of the SGPGI can book the expenditure. Audited annual Utilization Certificate (UC) head wise will be furnished to NTPC.

4.6. As per the SGPGI procedure,the SGPGI cannot move any file for approval / procurement unless the amount, as per payment terms, is transferred into their account. Therefore, the fund towards fixed cost as well annual recurring cost will be transferred to SGPGI on annual basis in advance under this Agreement.

5. Monitoring of activities

5.1. There shall be a "standing monitoring committee" with representatives from SGPGI & NTPC to monitor on quarterly basis the implementation of the project. The venue and date of meeting will be decided on mutual consultation basis.

6. Validity of the Agreement

6.1. This Agreement will be in force for a period of three years from the date of its execution.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

8. Amendments to the Agreement

8.1. Amendment, if any, during the currency period of this Agreement, shall be made by the authorized representatives of both the parties on the basis of mutual understanding.

9. Resolution of Dispute

9.1. It is specifically agreed by and between the collaboration parties that all the differences or disputes arising out of the agreement or touching the subject matter of the agreement shall be resolved through mutual consultation. If the parties fail to resolve such a dispute or difference by mutual consultation, then the dispute maybe settled through Arbitration. The matter shall be referred to sole Arbitration appointed by NTPC. Arbitration will be conducted according to provisions of Arbitration & Conciliation Act, 1996 including any statutory modifications or re-enactment thereof and the rules made there under shall apply. The seat of arbitration shall be Lucknow or any other city whichever is most economical from point of view of travel and stay.

10. TERMINATION IN CASE OF DEFAULTS:

10.1. NTPC may without prejudice to any other remedy for breach of agreement,bywrittennoticeofdefaultsentto SGPGI,terminatethe agreement in wholeorinpart:.

a) If SGPGI fails to deliver any or all of the services within the time period(s) specified in the agreement or any extension thereof granted by NTPC in writing.

b) If SGPGI fails to perform any other obligation(s)under the agreement ;or

c) If SGPGI, in either of the above circumstances, does not cure its failure within a period of thirty (30) days after receipt of the default notice from NTPC.

10.2. In the event NTPC terminate the agreement in whole or in part, pursuant to Clause 10 (a,b,c), NTPC may get the services done, upon such terms and in such manner as it deems appropriate, similar to those not rendered, and SGPGI shall be liable to NTPC for any excess costs for such similar services. However, SGPGI shall continue performance of the agreement to the extent not terminated.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(31)

11. Seal of the Parties

11.1. In witness thereof the Parties hereto have signed this Agreement on the day, month and year mentioned hereinbefore of their free will and accord.

Parties :

Signed and delivered for and on behalf of SGPGI Lucknow

Signature 1/3/19 d/c 9

Name _____

Designation _____

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Seal _____

Signed and delivered for and on behalf of NTPC Limited

Signature _____

Name Pankaj Kumar,

Designation GM (HR), NTPC, NRHq, Lucknow.

पंकज कुमार
PANKAJ KUMAR
महाप्रबन्धक (मानव संसाधन)
General Manager (HR)
एन.टी.पी.सी. लि./ उ. क्षेत्र मुख्यालय, लखनऊ
N.T.P.C. LTD./N.R.H.Q., Lucknow

Seal _____

Witness (Name& Address)

1. Sangeeta Nodal officer Telemedicine, SGPG,

2. Basanta Kumar Pandhan Member, Telemedicine SGPGIMS.

Date:

Witness (Name & Address)

1. (ANIRUDH SINGH) DGMCHRI, NRHQ.

2. (Manik Jaisal) Dy Mgr (Law)

Date:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(30)

Annexure-I

Details of the projected cost for setting up Tele Medicine Centre at Rihand & Meja

A. Fixed Costs

Sl. No.	Item Description	Cost (In Rupees)	Qty	Total Cost	Remarks
1.	**Health Kiosk- Budgetary offer annexed in Annexure-I**	5,60,000 + GST	02	11,20,000	GST as pee actual
	Hardware / Software (including PC, Telemedicine, videoconferencing software etc.				
2.	High Resolution display Unit	75,000	02	1,50,000	
3.	A3 Transparency Scanner	2,50,000	02	5,00,000	
4.	Renovation, furniture electrical fittings, fixtures or any other non-electronic item	50,000	02	1,00,000	
	Total			**18,70,000**	

B. Annual recurring cost for 1st year

Sl. No.	Item Description		Yearly Cost (In Rupees)	Qty	Total Cost (In Rupees)	Remarks
1.	Bandwidth Cost (BSNL 01 Mbps Annual plan with static IP)		50,000	02	1,00,000	
2.	Human Resources					
	A.	Manager-Operation @ 40,000 per month at SGPGI, Lucknow	4,80,000	01	4,80,000	
	B.	Telemedicine Technician @ 20,000 per month (one at SGPGI, One at Rihand & one at Meja)	2,40,000	03	7,20,000	

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

3.	Maintenance of equipment	50,000	02	1,00,000	
4.	Contingency expenditure (Travel, stationary &misc expenditure)	50,000	02	1,00,000	
	Total			**15,00,000 (Rs Fifteen Lakh)**	

C. Details of the Human Resources to be deployed

Sl. No.	**Designation**	**No. of Post**	**Qualification**
1.	Project Manager at NRC, SGPGI, Lucknow	01	B.E. / B. Tech. in CS / IT / E & C, Master`s in IT / CS or MCA with More than five years experience in IT facility management
2.	Telemedicine Technician (one at SGPGI & One at Rihand & one at Meja)	03	Graduation & diploma in IT / CS or Diploma in Telemedicine & HIMS / Health IT
3.	TOTAL	04	

D. Annual Recurring Costs during 2nd Year

Sl. No.	**Item Description**		**Yearly Cost (In Rupees)**	**Qty**	**Total Cost (In Rupees)**	**Remarks**
1.	Bandwidth Cost (BSNL 01 Mbps Annual plan with static IP)		50,000	02	1,00,000	
2.	Human Resources					
	A.	Manager-Operation @ 44,000 per month at SGPGI, Lucknow	5,28,000	01	5,28,000	@10% increment
	B.	Telemedicine Technician @ 22,000 per month (one at SGPGI, one at Rihand & one at Meja)	2,64,000	03	7,92,000	@10% increment

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

3.	Maintenance of equipment	50,000	02	1,00,000	
4.	Contingency expenditure (Travel, stationary &misc expenditure)	50,000	02	1,00,000	
	Total			**16,20,000 (Rs Sixteen Lakh Twenty Thousand Only)**	

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(27)

E. Annual Recurring Costs during 3rd Year

Sl. No.	Item Description	Yearly Estimated Value (In Rupees)	Qty	Total Cost	Remarks
1.	Bandwidth Cost (BSNL 01 Mbps Annual plan with static IP)	50,000	02	1,00,000	
2.	Human Resources				
	A. Manager-Operation @ 48,400 per month at SGPGI, Lucknow	5,80,800	01	5,80,800	@10% increment
	B. Telemedicine Technician @ 24,200 per month (one at SGPGI, one at Rihand & one at Meja)	2,90,000	03	8,71,000	@10% increment
3.	Maintenance of equipment	50,000	02	1,00,000	
4.	Contingency expenditure (Travel, stationary &misc expenditure)	50,000	02	1,00,000	
	Total			**17,51,800 (Rs Seventeen Lakh Fifty One Thousand Only)**	

Summary of the Estimated Expenditure for Rihand&Meja

Sn	Expenditure Head	Amount (Rs.)
1	Fixed Estimated Expenditure in First Year	18,70,000
2	Recurring Estimated Expenditure in First Year	15,00,000
3	Recurring Estimated Expenditure in Second Year	16,20,000
4	Recurring Estimated Expenditure in Third Year	17,51,800
5	Total Estimated Expenditure in three years	**67,41,800**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

EX 984131

The National Institute of Health & Family Welfare

Munirka, New Delhi - 110067

Memorandum of Understanding (MOU) between The National Institute of Health & Family Welfare (NIHFW), Munirka, New Delhi-110067 and Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow regarding conducting training programs under "Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies " (A Project of NIHFW in collaboration with MOHFW, New Delhi)

THIS CONTRACT is entered on this day ..... 2019 by and between, **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** and **The National Institute of Health and Family Welfare** (in short NIHFW), having its principal place of office at Munirka, New Delhi, 110067 and Hereinafter, NIHFW will be called as Client and **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** as Institute.

WHEREAS, the Client wishes to have the Institute perform the services hereinafter referred to, and

WHEREAS, the Institute is willing to provide these services as under

Now, therefore, the Parties hereby agree as follows:

1. **Services**

i. The Institute shall conduct training of Senior Hospital Administrators **under "Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies"(One**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Week) belonging the States of Bihar and Jharkhand. Around 30 Senior Hospital Administrators, not below the rank of Deputy Medical Superintendents and Medical Superintendents shall be trained and at least one mentor from the NIHFW will be supervising the training program. A total of 3 training programs per annum will be conducted by the Institute from ……,2019 to ……..,2020.

The participants will be identified by name, designation, qualification, experience, area of expertise, by the state as agreed mutually by the Institute and client (through **Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies** at NIHFW in collaboration with MOHFW, New Delhi).

ii. The Institute shall conduct the training as per guidelines provided by Client.

iii. The Institute shall submit to the client the report related to the training program and expenditure of the training within a month of completion of the training program, providing details of the participants and internal/ external resource persons and over-all outcome of the training.

iv. The Institute shall ensure optimum quality in the delivery of training and shall provide evidence of acquisition of new knowledge and skills by participants.

v. The Institute shall hire/provide appropriate venue to organize training/workshop as may be suggested or directed and approved by the client.

2. **Term**

The Institute shall perform the services during the period commencing from ……..2019 after signing of this MOU and continue through the agreed period up to 31st March, 2020.The design and session plan of the training as per the standardized introductory document and resource material.

3. **Payment**

A. Ceiling

For services rendered as indicated at (I) of this contract, the client shall pay an amount of Rs. 13,06,000/- (Rupees Thirteen Lakh Six Thousand only) allocated for the activities of the 6 Days Training Course and an amount of Rs. 40,650/- (Rupees Fourty Thousand Six Hundred Fifty only) allocated for institutional overhead on Senior

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Hospital Administrators for one training course. The Total amount for one Training course is Rs. 13,46,650.00. Client will pay 90 % of the total amount of Rs. 13,46,650/- (Rupees Thirteen Lakh Fourty Six Thousand Six Hundred Fifty only)at same time and remaining balance (maximum 10%) is to be paid to the Institute after submission of details of actual expenditure incurred in the training by submitting Statement of expenditure and utilization certificate.

The project staff / NIHFW officials will deal in respect of client (NIHFW) regarding payments of their TA/DA etc. separately.

The norms for incurring expenditure are placed at annexure.

B. Schedule of Payment

The payment shall be made to the Institute by bank draft /RTGS in favors of the Institute Head or his / her authorized nominee

4. **Project Administration**

A. Coordinators:

The Client shall designate Dr. Manish Chaturvedi, Nodal Officer (**Capacity Building in Public Health Emergency and Hospital Preparedness for Health Emergencies**), Dr J. B. Babbar, Senior Consultant (Medical), Dr. Priyanka Singh, Junior Consultant (Medical) who will be responsible for coordination of activities under this contract including preparation, facilitation of the training and other required activities.

B. The Institute shall provide necessary support for coordination of activities under this training.

C. Reports.

The Institute shall submit the report to the client related to the training program, utilization certificate and a statement of expenditure duly signed by Accounts officer and Director, nominee by Director, within one month after

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

completion of the training course and not later than 31st March,2020 positively.

5. **Performance Standards** The Institute undertakes to perform the services with the highest standards of professional and ethical competence and integrity.

6. **Inspectors and Auditing** The Institute shall permit the client and/or persons or auditors, appointed by the client to inspect and/or audit its accounts and records and other documents relating to submission of the proposal to provide the services and performance of the contract. In case the Institute fails to comply with the obligations, the client shall be fully empowered to terminate the contract.

7. **Confidentiality** The Institute shall not, during the term of this contract and within two years after its expiration, disclose any proprietary or confidential information relating to the services without the prior written consent of the client.

8. **Ownership of Material** Any studies, reports or other material, graphics, software or other material prepared by the Institute for the client under the contract shall belong to and remain the property of the Client. The Institute may retain a copy of such documents and software.

9. **Assignment** The Institute shall not outsource this contract or sub-contract any portion of it without the Client's prior written consent.

10. **Law Governing Contract and Language** The Contract shall be governed by the Indian laws.

11. **Termination** The client may terminate this contract with prior written notice of at ***least ten (10) working days*** to the Institute after the occurrence of any of the events specified below:

(a) If the Institute does not remedy a failure in the performance of its obligations under the contract within ***seven (7) working days*** after being notified, or within any further period as the client may have subsequently approved in writing;

(b) If the Institute, in the judgment of the client, has committed any irregularity in performing the Contract.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(c) If the client, in its sole discretion and for any reason whatsoever, decides to terminate this Contract.

And, whereas in order to enable **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** and NIHFW, New Delhi to effectively discharge their respective responsibilities and obligations under the MOU, the Director, NIHFW and the Director, **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** do hereby commit to put in place effective systems to deliver on the measurable outcome set out in this MoU.

The Director, NIHFW, The Director, **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow** having accepted the respective responsibilities and obligations described in this memorandum and having agreed to the terms and conditions contained herein, do set their hand to this MOU on this day of the.....,2019.

( )
For the Client
Director
NIHFW, New Delhi

( )
For the Institute
Director
SGPGIMS, Lucknow

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

( )
For the Client
Head, Hospital Administration
SGPGIMS, Lucknow

( )
For the Institute
Faculty In-charge, Research Cell
SGPGIMS, Lucknow

Witness:
Name-
Signatures-

Witness:
Name-
Signatures-

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

54

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	**IN-DL59354563423124S**
Certificate Issued Date	:	20-Jul-2020 03:07 PM
Account Reference	:	IMPACC (IV)/ dl988103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL98810327332907933210S
Purchased by	:	JSS MEDICAL RESEARCH INDIA PVT LTD
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS MEDICAL RESEARCH INDIA PVT LTD
Second Party	:	SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
Stamp Duty Paid By	:	JSS MEDICAL RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT
DATED 21 Jul 2020

JSS Medical Research India Pvt Ltd, Vatika Mindscapes (Tower B), Plot 12/2, Sector 27D, Faridabad- 121003 (Haryana) India **(AS THE CRO)**
AND
Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014 **(AS THE SITE/INSTITUTION)**
AND
Dr. Vikas Agarwal, Professor, Clinical Immunology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014 **(AS THE PI)**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

63

TABLE OF CONTENTS

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This Clinical Trial Agreement (the "**Agreement**") is dated: 21 Jul 2020.

(52)

BETWEEN:

1. **JSS Medical Research India Private Limited.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through Dr. Renu Razdan, Vice President, India being authorized to sign this Agreement on behalf of Sponsor, Medanta Institute of Education and Research (hereinafter referred to as "**JSS India/ CRO**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

1. **Dr. Vikas Agarwal**, working as **Professor** at **Clinical Immunology & Rheumatology, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014** (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   OR

2. **Sanjay Gandhi Postgraduate Institute of Medical Sciences,**, a [*hospital*] registered under the provisions of [Indian Companies Act, 1956 OR any other relevant law], having its registered office at **Raebareli Road, Lucknow, Uttar Pradesh 226014** , Dr. R K Dhiman, Director of SGPGIMS being authorized to sign this Agreement (hereinafter referred to as the "**Site**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. JSS India is a CRO and is in the business of providing Clinical Trial Site Management Services, Clinical Trial Monitoring Services and Clinical Data Management Services and certain other services related to any clinical study including site and principal investigator identification, regulatory, pharmacy services, identification and management of other agencies related to a clinical study translation of documents.

B. Medanta Institute of Education and Research (hereinafter referred to as "**Sponsor**") has engaged JSS India as a CRO for conducting the Clinical Trial entitled "*A Multi-center, Randomized Controlled, Phase III Study to evaluate the Clinical Outcomes and Safety of Tocilizumab along with Standard of Care in Patients with Cytokine Release Syndrome associated with COVID-19 infection*".

C. The Site is engaged in [Clinical Trials] and the PI is a Professor at the Site. The PI is authorized to conduct the Clinical Trial at the Site.

D. JSS India, on behalf of the Sponsor, desires to conduct the Clinical Trial in respect of the Drug under the direction and supervision of the PI using the facilities of the Site and the PI and the Site have represented willingness to participate in the Clinical Trial.

E. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

51

1. **Definitions and Interpretations**

1.1 In this Agreement:

"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordnance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by JSS India.

"**Clinical Trial**" or "**Study**" shall mean a clinical trial entitled ***"A Multi-center, Randomized Controlled, Phase III Study to evaluate the Clinical Outcomes and Safety of Tocilizumab along with Standard of Care in Patients with Cytokine Release Syndrome associated with COVID-19 infection"*** conducted as per the approved Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from JSS India in respect of the Clinical Trial, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as JSS India may, from time to time, provide.

"**Confidential Information**" shall mean and include, but is not limited to: any and all information and documents disclosed by JSS India in relation to the Clinical Trial/ this Agreement or developed hereunder by the PI, the Site or its associated staff, whether such information is disclosed in writing, graphically, electronically or in other machine-readable format, by way of sample or specimen, or in any other format by JSS India/ Sponsor. Confidential information includes but is not limited to formulations, drug products, clinical studies, results of studies, study protocol, personal information relating to patients of a study, pricing, discounts, business proposals, specifications, operation methods, business plans, marketing information and customer information which JSS India/ Sponsor provides or discloses to the Site and PI or to any of the Site's directors, officers, employees, representatives, agents and advisors under this Agreement.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, pandemics, inclement weather or other reason or cause beyond that Party's reasonable control.

"Dispute Notice" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean '**Tocilizumab'** drug in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

50

"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and wellbeing of all such actual and potential research participants.

"Fee" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by JSS India, or if so authorized, by JSS India in respect of the Clinical Trial as provided in Schedule B; herein.

"ICH GCP Guidelines" shall mean the International Council for Harmonisation -Good Clinical Practice issued by Helsinki Declaration in June, 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"**Indian GCP**" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research.

"**Information Brochure**" shall mean the information brochure of Sponsor relating to the Clinical Trial.

"**Informed Consent Form**" or "**ICF**" shall mean a written consent form provided by JSS India which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.

"**Invoice**" shall mean an invoice raised by the PI and/ or the Site in respect of the Services performed by the PI and/or the Site, in accordance with this Agreement.

"**Subject**" shall mean the patient who is enrolled in the Clinical Trial by the PI as per the Ethics Committee approved Protocol and upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"**Payment Milestone**" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"Protocol" shall mean Protocol No. TCZ/COVID-19/01/2020 as provided by JSS India/ Sponsor and approved by the Ethics Committee.

"Price" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'C' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"**Screen Failure**" shall mean the screen failure as defined in the Protocol.

"**Serious Adverse Event**" or an "**SAE**" includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

"Services" shall mean the services to be provided by the PI and the Site as detailed in Schedule 'A'.

"Site Indemnitee" shall mean the Site and its employees and its associated staff.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

49

"Sponsor Property" shall mean all data and information generated or derived by the Site/ PI arising out of any Services performed by them and/ or resulting from the conduct of the Clinical Trial or this Agreement.

"**Standard Operating Procedures**" or "**SOP**" shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the Sponsor/ CRO.

1.2 In this Agreement:

1.2.1 words denoting the plural number include the singular and vice versa;

references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

references to this Agreement include the Recitals and the Schedules;

the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

references to any Party include its successors, transferees and permitted assignees.

2. **Scope of the Agreement**

The Site and the PI agrees to perform the Clinical Trial for and on behalf of the JSS India/ Sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by JSS India. The Site and the PI further agrees to adhere to ICH GCP, Indian GCP and all Applicable Laws and regulations for the conduct of the Clinical Trial.

3. **Term**

3.1 This Agreement shall commence on the Effective Date and shall continue for a period of 03 (three) years from the.Effective Date or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. **Clinical Trial**

4.1 Clinical Trial Initiation: JSS India shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the JSS India may terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

4.2 Duration: The estimated duration for a Clinical Trial is defined in the Protocol including follow-ups. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions from JSS India.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

4.4 Biological Materials: In the event the Protocol requires collection of bodily fluids from the Study Subjects ("Biological Materials") then the PI shall obtain prior informed consent of the Subjects in this regard.

5. Responsibilities and Obligations of the Parties

5.1 JSS India shall be responsible for the following:

i. Clinical Trial Documents: Providing all the Clinical Trial Documents in advance or on time to the PI and/or the Site on behalf of Sponsor.
ii. Other Duties: Site Monitoring, Medical Monitoring, Clinical Data Management, including electronic data capture Statistical Programming, Clinical Trial supplies, contract and vendor Management, Clinical Study Report preparation & IMP logistic management.

5.2 The PI and/or the Site shall be responsible for the following:

a. The PI shall be responsible that the Clinical Trial should be conducted as per the Protocol, GCP Guidelines and Investigator's undertaking. For the tasks performed, Standard Operating procedures are to be documented.

b. PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

c. Upon request by JSS India, the PI will provide JSS India all information needed by JSS India and/or Sponsor in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

d. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest. The PI will not postpone or cause delay in reporting any such information to JSS India and/or Sponsor irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

e. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

5.3 Regulatory Agency Audit: The PI and the Site will inform JSS India and Sponsor within twenty-four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India in any such investigation, and in the implementation of appropriate action plans for such observations.

6 Representations, Warranties and Covenants.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

47

6.1 JSS India represents, warrants and covenants as follows:

(a) Formation/ Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of the Clinical Trial.

(d) Freedom to Use: JSS India hereby represents and warrants that Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Site represents, warrants and covenants to JSS India and Sponsor as follows:

(a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Freedom to Use: The Site hereby represents and warrants that the JSS India/ Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The Site agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.3 The PI represents, warrants and covenants to JSS India as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with JSS India in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.
ii. Upon JSS India request from time to time, PI will certify in writing, the PI
iii. compliance with the foregoing provisions of this paragraph.

7 Use of Name

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

8 Ownership of Intellectual Property and Study Data

Sponsor shall have sole ownership and rights to the Study Data (defined below), Clinical Trial results including any deliverables, inventions or discoveries relating to the Drug/ Clinical Trial, whether patentable or not, made in the performance of this Agreement. The PI/ Site is obliged to report any inventions or discoveries promptly to JSS India.

9 Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least twenty five (25) years, following the latest of the following dates: **(a)** the date on

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

which a marketing application for the particular Clinical Trial Drug is approved by the appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (*any other applicable regulation*) **(b)** the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India / Sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India/Sponsor so elect, comprise: (a) inspection of the PI's and/ or the Site's facilities and records relating to the rendering of Services to or for a Clinical Trial; (b) review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

10 Publications

The Sponsor shall retain ownership of all original Case Report Forms, data, documents, analyses and reports that result from the Clinical Trial ("**Study Data**"). Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. Accordingly, the PI and the Site agree that they will not independently publish, publicly disclose, present or discuss any results of or information pertaining to the Clinical Trial until a multi-center manuscript is published provided however, that if a multi-center manuscript is not published within one year after completion of the Clinical Trial at all Clinical Trial sites, Site/ PI will have the right to publish the Clinical Trial results generated by the PI. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information to Sponsor and JSS India. The PI and the Site agrees to delete any information that may be confidential or proprietary.

11 Fees

11.1 Budget: The CRO/ Sponsor, PI and/or the Site shall provide an estimate of the budget to the other Parties on or before site selection. The Parties shall negotiate and agree on the Budget and the Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

11.1.1 The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the JSS India unless the PI and/or the Site have taken the prior written consent of JSS India before administration of such tests or services.

11.2 Payment of Fees and Expenses to the PI and/or the Site: The CRO- JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol, the consideration for their services will be prorated according to the actual number of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

11.2.1 Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will raise its Invoice for the Fees to the JSS India, on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(b) the JSS India, if so authorized, shall pay the invoiced amount within forty-five (45) business days of the date of receipt of the Invoice. The payment shall be made through crossed cheque/DD, as applicable:

PAYEE INFORMATION:

The total study budget will be paid to below payee details (after TDS deduction)

Payee details:

PAYEE NAME	Director SGPGIMS Research account
GST No.	09AAAJS39BN2ZN
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAAJS3913N
BANK NAME	SBI
BANK BRANCH & ADDRESS	SGPGI branch, Raebareli Road, Lucknow, 226014
ACCOUNT NO.	10095237491
IFSC Code	SBIN0007789

11.2.2 Taxes: Any goods and services tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the Services offered in this Agreement shall be to the PI's and/or Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

11.2.3 Final Payment: Upon completion or termination of the Study, the PI and/or the Site shall provide a written notice to JSS that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12 Insurance

a. Sponsor shall maintain appropriate and adequate insurance coverage, as per applicable regulatory guidelines, against any liability arising during the implementation of the Clinical Trial, including a clinical trial insurance during the Term of this Agreement.

b. The JSS shall deliver copies of the certificate evidencing the insurance coverage in accordance with this Clause 12 to the Site and the PI.

13 Indemnification

13.1 Indemnity: JSS India on behalf of Sponsor shall indemnify, defend and hold harmless the Site Indemnitees, against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("**Loss**") incurred by or imposed on the Site Indemnitees in connection with any claims, suits, actions, demands or judgments made or instituted against the Site Indemnitees to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

13.2 Exclusions from Indemnification: The JSS India obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 13 above, directly or due to a third-party claim shall give written notice to the JSS India, against whom such indemnification rights are claimed. Pursuant to Clause 13 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the JSS India/Sponsor shall not relieve the JSS India/Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the JSS India/Sponsor or its defenses. With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 13 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from Sponsor; provided, however, that: (i) the Indemnified Party shall obtain the prior written consent of the JSS India/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if (A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against Sponsor, (B) such settlement does not expressly unconditionally release the JSS India/Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or (C) involves criminal or quasi-criminal allegations against the JSS India/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim; (ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by Sponsor in connection with such claim or legal proceeding; (iii) the JSS India/Sponsor shall be entitled to participate in the defenses of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and (iv) if the Indemnified Party abandons or fails to reasonably assume the defenses of any such claim or legal proceeding, JSS India/Sponsor may assume control of the defenses of such claim or legal proceeding at its own expense; provided, however, that if the JSS India/Sponsor shall control the defenses of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Party, the JSS India/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if (A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party, (B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or (C) involves criminal or quasi-criminal allegations.

13.4 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site/ PI, and JSS India as contained in the Clinical Trial Agreement.

13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of JSS India/Sponsor in relation to the Study.

13.6 The CRO on behalf of Sponsor shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug in accordance with the Applicable Laws and/ or Ethics Committee's directives, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement. The CRO shall not be liable for payments for a Subjects' lost wages.

14 **Confidentiality**

a. Confidential Information disclosed by JSS India to the Site/ PI or developed hereunder by the PI, the Site or associated staff shall remain the confidential and proprietary property of the Sponsor, and shall only be disclosed to those who have a need to know the same and shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the said information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the said information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the Study, as provided in Clause 10 above. Notwithstanding the performance, or the discharge for whatever reason including breach of this Agreement, the provisions of this clause shall remain in force for a period of [05] years from the date of execution of this Agreement

b. Confidential Information shall not include any information which:

(i) is already in the public domain at the time of disclosure;
(ii) has been independently developed by the Institution or Investigator;
(iii) is required to be disclosed to a governmental authority pursuant to a valid court order.

c. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records including applicable privacy laws, regulations, and other standards regarding the protection of personal data.

15 **Termination**

15.1 JSS India may terminate the Agreement by written notice of at least one (1) month in advance.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

15.2 The CRO may terminate this Agreement for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or its representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India, to meet with JSS India or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI.

g. Determination by JSS India in writing that business or scientific considerations require termination.

h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India or its representatives for use in the Study, are not completed and forwarded to JSS India or its designated representative, within the timelines prescribed by JSS India.

15.3 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India. However, JSS India shall have the sole right to determine the acceptability of a new PI.

15.4 In the event that JSS India exercise its right to terminate the Study/ Agreement based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

15.5 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial, and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

16 Miscellaneous

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to JSS India JSS Medical Research India Private Limited
Vatika Mindscapes (Tower B), 6th Floor,

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SGPGIMS,Lucknow

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Plot 12/2, Sector 27D, Faridabad-121003, Haryana, India
Attention: Dr. Renu Razdan
Designation: Sr. Vice President, India
Telephone: +91 129 6613 500
E-mail: renu.razdan@jssresearch.com

If to the PI:

Dr. Vikas Agarwal
Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014
Designation: Professor at Clinical Immunology & Rheumatology
Telephone: +91- 9793245857
E-mail: vikasagr@yahoo.com

If to the Site:

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh 226014
Attention: Dr. R K Dhiman
Designation: Director
Telephone: 0522-2494001
E-mail: director@sgpgi.ac.in

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written amendment/ agreement signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by Sponsor, DCGI and Institutional Ethic Committee.

16.3 Independent Contractor Relationship: The Parties are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India.

16.4 Assignment: This Agreement may be assigned by JSS India to any of its affiliates or to any third party with the prior written confirmation of the Sponsor. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India.

16.5 Third Party Beneficiary: The Sponsor shall be considered a third-party beneficiary of this Agreement, entitled to all the rights and benefits hereunder as if it were a direct party to this Agreement.

16.6 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

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16.7 Survival: Sections 8, 9, 13, 14, 15, 16.2, 16.3 and 16.11 of the Agreement shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.8 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.9 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.10 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Delhi alone shall have exclusive jurisdiction in respect thereof.

16.11 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be Lucknow, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.12 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

JSS India		**The Principal Investigator**	
By:		By:	
Print Name:	Mr. Kishor Kumar	Print Name:	Dr. Vikas Agarwal
Title:	Chief Financial Officer JSS Medical Research India Private Limited	Title:	Professor at Clinical Immunology
Date:	21 JUL 2020	Date:	23 JULY 2020

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(38)

The Site

By:

Print Name: Dr. RK Dhiman,

Title: Director,
SGPGIMS, Lucknow

Date: 25.07.2020

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

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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;

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II. Failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

III. Any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

21. TERM: The term of this Agreement shall commence on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol unless sooner terminated as provided herein.
Termination Conditions. This Agreement terminates upon the earlier of any of, the following events:

a) **Disapproval by EC**. If, through no fault of Investigator, the Study is never initiated because of EC disapproval, this Agreement will terminate immediately.

b) **Study Completion**. For purposes of this Agreement, the Study is considered complete after conclusion of all Protocol-required activities for all enrolled subjects; receipt by The Sponsor / CRO of all Protocol-required data; and receipt of all payments due to either party.

c) **Termination upon Notice**: CRO reserves the right to terminate the Study for any reason upon 30 days written notice to Investigator.

d) **Immediate Termination by The CRO**: The CRO further reserves the right to terminate the Study immediately upon written notification to Investigator for causes that include, but are not limited to, failure to enroll subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in the CRO's opinion pose risks to the health or all being of Study subjects

e) **Termination upon Notice by Investigator**: The Principal Investigator may terminate the study, if The Sponsor / CRO does not comply with the agreement related to finance and supply of related material. Written notice of any such termination by principal investigator including the reasons therefore shall be provided by registered mail to The Sponsor / CRO fifteen days prior to termination and The Sponsor / CRO shall have fifteen days to cure its default.

f) **Immediate Termination by Investigator**. Investigator reserves the right to terminate the Study immediately upon notification to The Sponsor / CRO if requested to do so by the responsible EC or if such termination is required to protect the health of Study subjects.

g) **Payment upon Termination**. If the Study is terminated early in accordance with Section 22 Termination Conditions, above, The Sponsor / CRO will provide a termination payment equal to the amount owed for work already performed, in accordance with Exhibit A, less' payments already made. If the Study was never initiated because of disapproval by the EC (see Section 22b, Disapproval by EC , above), The Sponsor / CRO will reimburse Investigator for EC fees and for any other expenses that were prospectively approved, in writing, by The Sponsor or its representative.

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h) **Return of Materials**. Unless The Sponsor / CRO instructs otherwise in writing, Investigator will promptly return all materials supplied by The Sponsor / CRO for Study conduct, unused Case Report Forms, other study related material and any The Sponsor / CRO - supplied Equipment.

i) **Survival of Obligations**. Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification, and Debarment and Exclusion survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

22. FORCE MAJEURE: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance cause a delay or failure in performance ('a Delay') and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator / Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to Sponsor / CRO. Sponsor / CRO shall have the right to terminate an agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

23. NOTICE: Notices under this Agreement shall be duly given or forwarded by facsimile, by Certified Mail-Return Receipt Requested or by express courier service providing evidence of receipt to the parties at the addresses below or to such other addresses as the parties may from time to time indicate in writing.

If to CRO:
Dr Monjori Mitra (Research Director, 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:	Signature:	Signature:
Name: Dr.Monjori Mitra	Name: Prof. Uday C Ghoshal	Name: Prof. R. K. Dhiman
Designation: Research Director	Designation: Principal Investigator	Designation: Director of SGPGI, Lucknow
Date: 07/Oct/2020	Date: 12/10/2020	Date: 16/10/2020
Stamp: PVT. LTD. * MEDCLIN	Stamp:	Stamp: Director S.G.P.G.I.M.S., Lko.

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EXHIBIT A

Budget		
Study Name	Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess efficacy and safety of Providac (Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12®) in the treatment of Irritable Bowel Syndrome in adults aged 18 years to 65 years.	
CRO Name :	Medclin Research Pvt Ltd, Kolkata	
Cost Head	**Details**	
Research Grant Including Manpower And Travel Allowances	**52 Subjects**	**338000**
Institutional overhead charges	25%	65000
Gut Microbiota	Analysis	500000
EC Fees	On actuals	25000
Total Study Fees		928000

a) The Principal Investigator hereby confirms that he has read and understood the clinical trial protocol entitled Multicentric, Phase IV, randomized, double blind, placebo controlled trial to assess effectiveness and safety of Lactobacillus acidophilus LA-5® and Bifidobacterium BB-12® in the treatment of Non-Constipated Irritable Bowel Syndrome in adults aged 18 years to 65 years.

b) The investigator agrees to the protocol of this trial and will perform the study in accordance with ICMR Good Clinical Practice, and applicable laws, rules and regulations.

EXHIBIT B

SL. No	**Milestone**	**Amount**
1	Study Start up(At the time of SIV)	240000
2	30 subject Enrolled	98000
3	last subject Last Visit(Institutional Overhead)	65000

For Gut Microbiota

SL. No	**Milestone**	**Percentage**	**Amount**
1	Before Analysis	60%	300000
2	Completion of Analysis	40%	200000

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SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ BB 805237

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००९९
15 DEC 2020
सक्षम अधिकारी

Novartis Healthcare Private Limited, (FIRST PARTY);

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, (SECOND PART);

AND

Dr. Jayantee Kalita (THIRD PART);

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(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;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by

Novartis. all, as amended from time to

time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(65)

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

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

(67)

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INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA45269656888723S
Certificate Issued Date	:	14-Oct-2020 04:33 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ SHIVAJINAGAR1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL0885609692699820S
Purchased by	:	GEORGE CLINICAL INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	GEORGE CLINICAL INDIA PVT LTD
Second Party	:	SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL
Stamp Duty Paid By	:	GEORGE CLINICAL INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL STUDY AGREEMENT

BETWEEN

VISTERRA, INC (Sponsor)

Address: 275 2nd Ave, Waltham, MA 02451, USA

AND

Statutory Alert:

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

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SGPGIMS,Lucknow

GEORGE CLINICAL India Private Limited (GC India)

Address: Plot No. 5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road
Bangalore - 560 001, Karnataka, India
Business registration number: **U73100AP2012FTC083414**

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS)(**Clinical Site)**
Address: Department of Nephrology, SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, RAEBARLI ROAD, LUCKNOW-226014 (U.P.)
In the presence of: Dr. Narayan Prasad （**Principal Investigator)**

This agreement is effective from the last signature date (**Effective Date**).

BACKGROUND:

A. The **Sponsor** is performing a clinical study entitled "A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Multiple Dose Proof of Concept Study to Evaluate the Efficacy and Safety of Multiple Intravenous Doses of VIS649 in Patients with Immunoglobulin A (IgA) Nephropathy; VIS649-201"; VIS649 (Protocol Number 649-201) (the **Clinical Study**) involving the compound known as VIS649 (the **Trial Drug**).

B. GC India is responsible for the conduct of the Clinical Study in India as the local representative for the Sponsor.

C. The Clinical Site has the know-how, qualifications, facilities, personnel and equipment required to conduct a study under GCP and the Clinical Site wishes to participate in the Clinical Study in accordance with the terms and conditions of this Agreement.

D. The Clinical Study will be conducted on the terms and conditions below.

In this Agreement:

1. **Agreement** means this Agreement, including all the Schedules.

2. **Affiliate**: means a company which (directly or indirectly) controls, is controlled by or is under common control with the Sponsor or GC India.

3. **Background IP** of a party means information, techniques, know-how, software and materials existing prior to the start of the Agreement (regardless of the form or medium in which they are disclosed or stored) provided by or on behalf of that party to the other for use in the Clinical Study (whether before or after the date of this Agreement) or

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SGPGIMS,Lucknow

used by that other party in conducting the Clinical Study, and all Intellectual Property in them.

4. **GCP** means Good Clinical Practice.

5. **CRF** means a printed, optical or electronic document or database designed to record all the information required by the Protocol to be reported to GC India on each Eligible Subject.

6. **Eligible Subject** means a person recruited to participate in the Clinical Study.

7. **Ethics Committee** means an independent ethics committee established under the GCP to review the Clinical Study on behalf of the Clinical Site.

8. **GCP** includes the India GCP and the ICH-GCP.

9. **ICH-GCP** means Guideline for Good Clinical Practice of the International Conference on Harmonization.

10. **Intellectual Property** means all present and future industrial and intellectual property rights, including inventions, patents, copyright, trade business, company or domain names, rights in relation to circuit layouts, plant breeders rights, registered designs, registered and unregistered trademarks, know-how, trade secrets and the right to have confidential information kept confidential, and any and all other rights to intellectual property which exist anywhere in the world. It also includes an application or right to apply for any of those rights.

11. **Parties** means Sponsor, GC India and Clinical Site and **Party**, is a reference to either of them; a reference to a Party includes its Personnel.

12. **Personnel** means employees, agents and/or authorised representatives, and includes in the case of the Clinical Site, the Principal Investigator.

13. **Principal investigator** means the person responsible for conducting the Clinical Study at the Clinical Site.

14. **Protocol** means the document identified in **Exhibit A** which describes the objective(s), design, methodology, statistical considerations and organisation of the Clinical Study, and subject to **clause 2.2**, as amended from time to time, as agreed by the parties, and most recently approved by the Reviewing HREC

15. **Sponsor** means Visterra, Inc..

16. **Study Materials** means all the materials and information provided to Clinical Site or its Personnel by GC India or Sponsor, created for the Clinical Study or required to be submitted to GC India or Sponsor. It includes all reports, data, results, Case Report Forms (or their equivalent) in whatever form held, conclusions, discoveries, inventions, know-how, whether patentable or not, relating to the Clinical Study, which are discovered or developed as a result of the Clinical Study. It excludes the Clinical Site's ordinary patient records.

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NOW IT IS AGREED as follows:

RESPONSIBILITIES OF GC INDIA

1.1 Before execution of this Agreement, GC India and Sponsor must provide the Principal Investigator, and through the Principal Investigator the Clinical Site and the Ethics Committee, with all current and relevant information regarding the Study Drug as reasonably required to justify the nature, scope and duration of the Clinical Study.

1.2 In consideration of the Clinical Site performing the Clinical Study, GC India agrees to:

(1) pay the Clinical Site in accordance with this Agreement;

(2) provide the Clinical Site with all materials, access to its Personnel, facilities or information reasonably required to perform the Clinical Study satisfactorily;

(3) implement and maintain quality assurance and quality control systems with written standard operating procedures to ensure that the Clinical Study can be conducted, and data generated, documented, recorded and reported in compliance with all the documents referred to in **clause 2.1**;

(4) assist Sponsor and the Clinical Site to apply for approval of the Clinical Study according to relevant laws, and to obtain necessary regulatory approvals, notices or authorisations to perform the Clinical Study;

(5) provide relevant information to Sponsor who will be responsible for notifying and submitting the necessary documentation to the relevant regulatory authorities;

(6) appoint a project manager and other appropriately trained and qualified personnel, with the Clinical Study knowledge, necessary to monitor the Clinical Study and advise on Clinical Study related medical questions;

(7) Monitor the application of the Study Drug in other places and advise the Clinical Site, through the Principal Investigator if a relevant trial on the Study Drug ceases elsewhere or the Study Drug is withdrawn from a market for safety reasons; and

(8) Notify the Clinical Site of any adverse events (including serious adverse events) that occur during the course of the Study (either at the Study Site or other study sites, including overseas sites) which may require alteration of the conduct of the Study, or which may affect the rights, interests, safety or well-being of Study Participants.

RESPONSIBILITIES OF THE CLINICAL SITE

2.1 The Clinical Site agrees to conduct the Clinical Study and must ensure that Principal Investigator and Clinical Site's Personnel comply with and conduct the Clinical Study in accordance with:

(1) the **Protocol** (**Exhibit A**), any conditions of the Ethics Committee, and the **Budget** (**Exhibit B**) and do not amend or deviate from the Protocol or the Budget without GC India's prior written consent; and

(2) all applicable international, national and local laws and regulations, guidelines and directives, including but not limited to the ICH GCP, India GCP, applicable statutory provisions, this Agreement and GC India's and Sponsor's directions.

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Executive Registrar
SGPGIMS,Lucknow

2.2 The Clinical Site undertakes and agrees to:

(1) appoint Personnel who are properly registered with appropriate professional registration bodies, and who have not been disqualified from practice or disbarred or banned from conducting clinical trials by any applicable regulatory authority. If Clinical Site becomes aware of any disqualification of any Personnel it will notify GC India promptly;

(2) provide a list of all Personnel and copies of their curriculum vitae to GC India;

(3) ensure that all Personnel:

i. are made aware of the obligations in this Agreement and are bound by those obligations;

ii. attend all Clinical Study meetings and training sessions, as are reasonably required;

(4) ensure that if any Personnel becomes unavailable before completion of the Clinical Study or, if in GC India's reasonable opinion, is unsuitable for the tasks to be performed, to replace that person with another appropriately qualified, experienced and trained staff member within a reasonable time following their unavailability or written notice from GC India, so that the quality and schedule of Clinical Study is not affected. Clinical Site must promptly provide GC India with the curriculum vitae of that person;

(5) meet the deadlines of the Clinical Study in this Agreement and the Protocol;

(6) ensure that the Principal Investigator supervises the screening and recruitment of Eligible Subjects into the Clinical Study in accordance with the Protocol;

(7) Use best endeavours to recruit the target number of Eligible Subjects, within the recruitment period specified in [the Budget (exhibit B)] and that Eligible Subjects enrolment is completed on or before the inclusion period has ended (estimated date: **30 Jun 2021**]) The Clinical Study is conducted under competitive enrolment. If no Eligible Subjects are recruited by the Clinical Site within 60 days of initiation of the Clinical Study by the Clinical Site, GC India may terminate this Agreement immediately;

(8) Follow the adverse event and serious adverse event or other specified event reporting process set out in the Protocol (including reporting to relevant regulatory authorities, GC India, the Sponsor and the Ethics Committee); Clinical Site must make medical decisions relevant to the Clinical Study in a timely manner, and employ appropriate measures to ensure the safety of Eligible Subjects;

(9) Obtain any approvals required (such as Ethics Committee approval and Clinical Site's Board of Directors approval) to undertake the Clinical Study or to amend the Protocol. Neither the Clinical Site nor the Principal Investigator may consent to any change in the Protocol requested by a local Ethics Committee or competent authority without GC India's prior written consent;

(10) Ensure that all data collected for the Clinical Study is collected within the agreed time period, accurately and completely and respond promptly to all data queries; ensure that the required Clinical Study data and other Study Materials are sent to GC India promptly; and all End points (as defined in the Protocol) are followed-up until the end of the Clinical Study; and documentation for these submitted to GC India, regardless of whether the Eligible Subject has discontinued the Trial Drug before the end of the Clinical Study;

(11) Ensure that the records of Eligible Subjects remain complete and accurate in accordance with relevant regulations and this Agreement and ensure that all CRFs are complete and accurately reflect source documents;

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(12) Ensure that any clarifying or missing information is prepared and/or corrected following an Eligible Subject's visit, as provided in the Protocol, and is submitted to GC India within 2 working days after completion of Eligible Subject's visit and data; ensure that any request by or on behalf of GC India or its delegate for verification, clarification or correction of data are provided to GC India within 5 business days of receiving the request;

(13) Take all necessary steps to ensure the safety and integrity of Clinical Study data; and to ensure that the Clinical Site's Personnel, and any other third parties who has access to any confidential or personally identifiable information collected in the Clinical Study, receive appropriate privacy and security training, which is updated periodically as necessary;

(14) ensure that any personal information of Eligible Subjects obtained or held as a result of the conduct of the Clinical Study is collected, used, stored and disclosed by it in accordance with Applicable Privacy Laws; **Applicable Privacy Laws** means any legislation, code or guideline which applies in India and which relates to the protection of personal information;

(15) any Clinical Study equipment supplied by GC India or the Sponsor to Clinical Site is only used as specified in the Protocol; and

(16) retain and preserve a copy of all Study Materials, including copies of signed consent forms, completed CRFs, Protocol, information relating to the Trial Drug, correspondence and investigator files for at least 15 years from Clinical Study completion. Clinical Site must notify GC India before destroying any Study Materials and if reasonably required by GC India, must retain the Study Materials for a longer period at GC India's expense.

2.3 The Clinical Site must obtain informed consent to participate in the Clinical Study from each Eligible Subject before their enrolment in the Clinical Study. The consent forms must:

(1) be signed and dated before any study related procedures are performed in relation to the Eligible Subject;

(2) confirm the Eligible Subject's consent to participate in the Clinical Study as well as his/her understanding of the content of Clinical Study;

(3) permit the Eligible Subject's 'protected health information' to be obtained and used for the purpose of the Clinical Study; and

(4) permit disclosure of the protected health information by GC India, the Clinical Site and its Principal Investigator to the Sponsor and other professionals involved in the Clinical Study for purposes of the Clinical Study.

CLINICAL STUDY PAYMENTS

3.1 Budget

The **Budget** attached as Exhibit B describes all the activities Clinical Site and Principal Investigator must perform to complete the Clinical Study and the expenses that the Clinical Site may claim.

3.2 Payments

In consideration of the Clinical Site conducting the Clinical Study, GC India will pay the Clinical Site as nominated in the Budget in the manner and on the basis of the prices

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SGPGIMS,Lucknow

and at the times set out in the Budget. Follow-up for each Eligible Subject is considered complete when:

(1) CRFs have been completed to Eligible Subject death, Eligible Subject withdrawal or the end of the study follow-up period, whichever is first;

(2) Satisfactory information has been provided on potential study endpoints, serious adverse events and medical events of interest, as outlined in the Protocol; and

(3) GC India has confirmed that data collection and entry is complete and all data queries have been adequately resolved.

3.3 GC India may make prepayments which will be deducted from the further payments from GC India to Clinical Site.

3.4 Final payment will be made after Clinical Study completion but will be withheld until:

(1) all completed CRFs, are delivered to GC India and accepted by GC India as complete;

(2) all queries to the Principal Investigator have been resolved to GC India's reasonable satisfaction;

(3) Database lock has occurred;

(4) Return and receipt of all essential documents from the Principal Investigator;

(5) the Ethics Committee has been informed of study completion by the Principal Investigator; and

(6) Return of and receipt by GC India of any equipment provided to the Principal Investigator.

3.5 A change in scope that increases the cost of conducting the Clinical Study may be made only by a written agreement between Clinical Site and GC India. The amendment must be executed by authorised personnel, must include a statement of additional amounts to be paid in connection with the scope change and must be attached as an annex to this Agreement. E-mail or other electronic communication are not considered as written documentation for this purpose.

3.6 If there is a change in the scope of the Clinical Study that reduces the cost of conducting the Clinical Study compared to the Budget, the Budget will be amended accordingly, and the Parties agree to reconcile corresponding payment reductions in good faith.

3.7 GC India reserves the right to refuse to pay to Clinical Site payments specific to patients entered into the Clinical Study who do not meet the entry criteria specified in the Protocol. If an Eligible Subject discontinues their participation in the Clinical Study or the Clinical Study is terminated as a whole, only those costs incurred up to the date of discontinuation or termination, including costs of final visit and completion of all CRFs will be paid.

3.8 The payments in this clause constitute full payment for the Clinical Study and neither GC India nor the Sponsor has any other payment obligations.

3.9 If any tax is payable by Clinical Site on the income it receives for services supplied under this Agreement, the Clinical Site must pay that amount.

3.10 Neither this Agreement nor any consideration paid under it is contingent upon the Clinical Site's use or purchase of any of Sponsor's products

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TIMELINES

4.1 **Study Milestones**

Clinical Study Milestones	Estimated Dates
Protocol approved	30 Mar 2020
First Subject first visit	04 Aug 2020
Last Subject first visit	26 Nov 2021
Last - Subject last visit	31 Mar 2023
Final database lock	28 Apr 2023

4.2 Clinical Site must use all reasonable efforts to complete the Clinical Study according to the timelines above. Clinical Site must keep GC India continuously informed about the progress of the Clinical Study, and must immediately inform GC India in writing if Clinical Site reasonably anticipates 1 month or more delay in complying with those timelines. If those timelines are inconsistent with the timelines specified in the Protocol, the timelines in the Protocol prevail.

PRINICIPAL INVESTIGATOR

5.1 The Principal Investigator is responsible on a day to day basis for the conduct of the Clinical Study. The Principal Investigator does not have authority to amend this Agreement or the Protocol.

5.2 If the Principal Investigator leaves the Clinical Site or ceases to be available for any reason, the Clinical Site must immediately notify GC India, and GC India and the Clinical Site may negotiate to substitute the Principal Investigator. Clinical Site must use its best efforts to identify and obtain a substitute Principal Investigator acceptable to GC India and the Sponsor, and guarantee that the quality and agreed timelines of the Clinical Study will not be affected. If GC India and the Clinical Site cannot agree on a substitute Principal Investigator, or if GC India does not approve of the substitute Principal Investigator, GC India may immediately terminate this agreement in accordance with **clause 11**.

5.3 All medical and scientific communications to the Clinical Site, whether or not containing Confidential Information, must be addressed to the Principal Investigator. All information directed to GC India must be addressed to GC India's project manager.

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5.4 The Principal Investigator must disclose his or her economic interest and financial arrangements as specified by GC India and as required by applicable law.

INDEMNITY AND LIABILITY

6.1 Indemnity by the Sponsor

Sponsor indemnifies GC India under separate agreement between GC India and Sponsor. GC India indemnifies the Principal Investigator, Clinical Site and Ethics Committee (each an **Indemnified Party**) against any claim by or on behalf of an Eligible Subject for personal injury or death directly caused by the Study Drug or procedure required by the Protocol, provided the Principal Investigator and Clinical Site have complied with the Protocol, applicable laws and all reasonable instructions of GC India and Sponsor. GC India's liability to indemnify Indemnified Parties will be reduced proportionately to the extent that medical malpractice or the Indemnified Party's negligent or wrongful act or omission or material breach of this Agreement contributed to its loss.

6.2 **Liability**

6.2.1 The Clinical Site is liable for any loss, liability, cost and expense (**Loss**) arising from or in connection with the medical malpractice, negligence, wrongful act or omission, or wilful misconduct of Clinical Site and Clinical Site's Personnel or in relation to the non-payment, non-observance, or non-performance of any obligations under this Agreement.

6.2.2 The Clinical Site acknowledges and agrees that GC India and Sponsor make no representation or warranties in favour of the Clinical Site or its Personnel in respect of **clause 6.2.1**. The Clinical Site accordingly releases GC India and Sponsor from any compensation obligations in respect of **clause 6.2.1**.

6.2.3 If GC India and Sponsor incur any Loss which arises from the reasons in **clause 6.2.1**, Clinical Site will compensate GC India and Sponsor promptly on demand.

6.3 The Clinical Site agrees that:

(1) treatment of Eligible Subjects at the Clinical Site remains the responsibility of the Principal Investigator or other treating physician(s) at the Clinical Site, who can access all of the Eligible Subjects' clinical information, can make a complete assessment of the Eligible Subjects, and provide the most informed medical advice; and

(2) clinical judgement must prevail at all times before any treatment is administered to Eligible Subjects.

6.4 Clinical Site will be liable to GC India and Sponsor for any breach of this Agreement by the Clinical Site, the Principal Investigator or any other Personnel involved in the Clinical Study.

6.5 Despite any other clause in this Agreement but except for a breach of the confidentiality section, neither Party or Sponsor is liable to the other Party for any loss of profits, consequential, indirect or special damages, loss of business or goodwill.

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6.6 The Sponsor agrees to pay, and directs GC India to pay on Sponsor's behalf, compensation and medical management costs to Eligible Subjects suffering personal injury (including death) relating to his/her participation in the Clinical Trial to the extent required by and in accordance with applicable laws and rules in India. Sponsor shall reimburse GC India for such costs which have been approved by Sponsor, acting reasonably and without delay.

INSURANCE

7.1 The Sponsor has notified GC India that it maintains clinical trial insurance and comprehensive liability insurance as required by applicable law and will provide a certificate of insurance on request.

7.2 GC India maintains insurance with respect to its activities and indemnity obligations under this Agreement. GC India will provide a certificate of its insurance to Clinical Site and Principal Investigator on request.

7.3 Even though Sponsor maintains insurance, Clinical Site and Principal Investigator must also maintain their own liability insurance policies. Clinical Site and Principal Investigator must maintain such insurances as are reasonably available and necessary to provide indemnity in relation to any liability which they may incur in conducting the Clinical Study.

7.4 Clinical Site guarantees that, during the period of this Agreement, the Clinical Site, the Principal Investigator and Clinical Site's Personnel will not do anything knowingly to invalidate the Sponsor's or GC India's insurance policy.

CONFIDENTIALITY

8.1 All information disclosed by Sponsor or GC India to Clinical Site or its Personnel or produced during the Clinical Study, including the Protocol, investigator's brochure, CRFs, Clinical Study results and financial terms of this Agreement (**Confidential Information**) is confidential. Clinical Site and Principal Investigator each agree to keep the Confidential Information confidential and not use it, or disclose it to any third party without GC India's and Sponsor's prior written consent.

8.2 Information will not be subject to this **clause 8** if:

(1) the information was independently received from a third party who was free to disclose it;

(2) the information is in or has entered the public domain, other than as a result of breach of this Agreement by Clinical Site, Principal Investigator or other Personnel;

(3) the information was already known to Clinical Site and this can be established by prior written records; or

(4) the information was independently developed by or for Clinical Site, without use or reference to the Confidential Information.

8.3 Nothing in **clause 8** prevents the Clinical Site and the Principal Investigator from disclosing Confidential Information from GC India if required to be disclosed by law, regulatory authority or court order. If Confidential Information is disclosed under this **clause 8.3**, Clinical Site must provide GC India, Sponsor or their respective Affiliates

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with reasonable assistance and notice to resist disclosure or ensure confidential treatment for any required disclosure.

8.4 The Clinical Site may disclose Confidential Information to its Personnel who need to know the Confidential Information to undertake the Clinical Study. The Clinical Site must inform those Personnel of the obligations in this Agreement relating to Confidential Information and must ensure that they comply with those obligations.

8.5 The obligations of confidence under this **clause 8** apply during the term of this Agreement and survive for 10 years after termination of this Agreement.

INTELLECTUAL PROPERTY & PATENTS

9.1 Intellectual Property

9.1.1 Sponsor and GC India grants to Clinical Site and its Personnel the right to use their Background IP including the Study Materials as required to carry out the Clinical Study and perform this Agreement. Except for this right, neither the Clinical Site nor any of its Personnel acquires any right or interest in any Intellectual Property provided by or on behalf of the Sponsor or GC India.

9.1.2 To carry out the Clinical Study, Clinical Site may use its own Background IP. Clinical Site's Background IP remains its sole property. Clinical Site grants GC India and Sponsor a non-exclusive, perpetual, royalty-free licence to use (including the right to sub-licence) its Background IP for the purposes of commercialisation of the Study Materials and Trial Drug and for further research.

9.1.3 All Intellectual Property in the Study Materials and Trial Drug is owned by Sponsor, or will vest automatically upon its creation in Sponsor. Clinical Site presently assigns to Sponsor all Intellectual Property rights in the Study Materials and Trial Drug created in the course of conducting the Clinical Study. Clinical Site must execute or ensure that its Personnel execute any documents reasonably necessary to give effect to this assignment, at Sponsor's expense.

9.1.4 Clinical Site must promptly disclose in writing to GC India and Sponsor full particulars of any Intellectual Property that Clinical Site or Principal Investigator make, discover or conceive in the course of the Clinical Study that is related to the Study Materials.

9.2 Inventions

9.2.1 The Clinical Site and the Principal Investigator must promptly disclose to GC India and Sponsor, any discovery or invention made, developed, conceived, reduced to practice or resulting from performance of the Clinical Study or related to the Trial Drug, Study Materials, or Confidential Information (**Invention**).

9.2.2 All Intellectual Property in any Invention will be owned by Sponsor and Clinical Site hereby assign such Inventions and Intellectual Property in any Inventions to Sponsor.. Sponsor has the sole right to obtain patents on Inventions in any country in the world. The Clinical Site must assign and must ensure that its Personnel assign all Intellectual Property in any Invention to the Sponsor, or its nominated Affiliates. The Clinical Site must fully cooperate, and must ensure that its Personnel fully cooperate, with GC India and the Sponsor to give effect to this assignment. These obligations survive termination of this Agreement.

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9.2.3 No additional compensation is payable to the Principal Investigator or its Personnel for any Inventions assigned under **clause 9.2.2**.

9.2.4 If Sponsor files patent applications relating to an Invention, the Clinical Site must assist GC India and/or Sponsor to prepare those patent application(s) and must execute any documents requested by Sponsor to ensure title vests in Sponsor. Clinical Site's assistance is at Sponsor's expense.

PUBLICATION & PROMOTIONAL ACTIVITIES

10.1 Publication

10.1.1 The Principal Investigator and the Clinical Site each undertakes not to make any publication or release relating to the Clinical Study or its results without GC India's and Sponsor's prior written consent.

10.1.2 In multicentre studies, the Clinical Site and the Principal Investigator agree not to publish the results of the Clinical Study before the results of the multicentre study are published.

10.1.3 If no multicentre publication occurs within 18 months of Clinical Study completion at all global Clinical Study sites and Sponsor's receipt of all the data from all the global Clinical Study sites, the Principal Investigator or Clinical Site may publish or present the results from their own Clinical Site only subject to the procedures in this **clause 10** and in accordance with copyright law.

10.1.4 Clinical Site and the Principal Investigator must provide GC India and Sponsor with a copy of the proposed presentation or publication for review and comment at least 45 days before proposed presentation or submission for publication.

10.1.5 During the 45 day period, GC India and Sponsor may:

(1) comment on the proposed publication and Clinical Site and Principal Investigator must consider those comments;

(2) request delay of publication for no more than 120 days to allow Sponsor to file patent applications or take other measures to protect Intellectual Property; Clinical Site and Principal Investigator must comply with that request; or

(3) request that Clinical Site or Principal Investigator remove specified Confidential Information (other than results of the Clinical Study); Clinical Site must remove whatever Confidential Information is required to protect Confidential Information or Intellectual Property of GC India or Sponsor.

10.1.6 If Clinical Site receives no comments from GC India or Sponsor within 45 days of giving them a copy of the proposed publication, it may make the publication, subject to section 10.1.2 and 10.1.3.

10.1.7 Any person named as an author will be given a reasonable opportunity to review the publication. Any person acknowledged as an investigator of the Clinical Study in the publication will be given a reasonable opportunity to request removal of his or her name from the publication.

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55

10.2 Promotional activities

Clinical Site may not issue a press release that refers to the Protocol, Clinical Study or any other study conducted by Sponsor or GC India, or that uses Sponsor's or GC India's name or trademarks without their prior written permission. Clinical Site may identify GC India as a contract partner for the Clinical Study.

TERM AND TERMINATION

11.1 Term

This Agreement commences on the **Commencement Date** (the date it is last signed by all Parties). In the ordinary course of events, this Agreement terminates when GC India makes its final payment to Clinical Site.

11.2 Termination

11.2.1 GC India may terminate this Agreement by written notice to Clinical Site immediately:

(1) at any time, if a governmental or regulatory authority requests that the Clinical Study is terminated; or

(2) at any time 60 days after the Commencement Date, if Clinical Site has not enrolled any Eligible Subjects.

11.2.2 GC India may terminate this Agreement for any reason other than those mentioned in **clause 11.2.1** with 30 days' written notice. If GC India terminates early under this clause, GC India will pay Clinical Site's reasonable costs up until termination relating to the Clinical Study, incurred and calculated in accordance with the Budget.

11.2.3 Any Party may terminate this Agreement immediately by written notice to the other Party if it believes on reasonable grounds that:

(1) continuing the Clinical Study poses an unacceptable risk to the rights, interests, safety or well-being of Eligible Subjects; and

(2) terminating this Agreement is the most appropriate way to respond to that risk.

11.2.4 In addition, either Party may terminate this Agreement immediately by written notice if the other Party:

(1) breaches this Agreement or the Protocol and fails to rectify the breach to the other Party's satisfaction within 30 days of receiving a notice specifying the breach and requiring its remedy; or

(2) is declared insolvent or has an administrator or receiver appointed over any of its assets or ceases to carry on business.

11.2.5 GC India may terminate this Agreement immediately by written notice if the Clinical Site breaches either of **clauses 12.3 (Debarment)** or **12.4 (Anti bribery).** Clinical Site will not be entitled to further payment or compensation if the Agreement is terminated under this **clause 11.2.5**.

11.2.6 If this Agreement is terminated under **clauses 11.2.1, 11.2.3, or 11.2.4,** GC India must pay the Clinical Site for actual activities performed in accordance with this Agreement and the Protocol and reasonable non-cancellable expenses incurred before notice of

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termination. Any funds paid in advance will be prorated and any excess funds will be returned to GC India.

11.2.7 Termination of this Agreement by a Party does not affect the Parties' rights and obligations accrued before the effective date of the termination.

11.2.8 The following clauses survive termination of this Agreement: **clauses 2.2, 6, 7, 8, 9, 10, 11, 14, 15, 19, and 29**. Any other rights or obligations which by their nature should survive will remain in full force and effect following termination or expiry of this Agreement.

11.3 Obligations following termination

11.3.1 If this Agreement is terminated for any reason, clinical Site must promptly deliver to GC India all Clinical Study data, Study Materials and Confidential Information and all unused Trial Drugs or other related materials, subject to applicable retention requirements imposed by law.

11.3.2 On receipt of notice of termination for any reason whatsoever, the Clinical Site must:
(1) Take all appropriate action to close the Clinical Study promptly, in accordance with GC India's instructions and applicable law;
(2) Cooperate with GC India and Sponsor to ensure that Eligible Subjects who may be affected by termination receive adequate medical care;
(3) Use all reasonable efforts (i) to complete reports for all Eligible Subjects that have been entered into the Clinical Study before the termination date; and/or (ii) write a final report for that portion of the Clinical Study that has been completed before the termination date.
(4) If GC India requests, the Clinical Site must refer Eligible Subjects to other clinical sites designated by GC India for continued participation in the Clinical Study;
(5) Refrain from incurring additional costs or expenses to the extent reasonably possible and medically permissible; and
(6) Immediately cease enrolling patients in the Clinical Study and cease administering the Trial Drug and conducting medical procedures on Eligible Subjects to the extent medically permissible.

WARRANTY

12.1 The Clinical Site represents and warrants on behalf of the Clinical Site and the Principal Investigator to GC India and Sponsor that:

(1) its policies are not inconsistent with this Agreement, the Protocol or the GCP;

(2) its execution or performance of this Agreement does not and will not contravene its constitution or any applicable law or agreement binding on the Clinical Site.

(3) it will carry out its obligations under this Agreement with due care, skill and diligence and will employ techniques of a high quality and standard and best practices;

(4) it has full capacity to perform any activity contemplated by this Agreement; and

(5) it has procured any consent/permit and approval for the execution and performance of this Agreement.

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12.2 **Conflict of Interest**

The Clinical Site and the Principal Investigator confirm that there is no conflict of interests between the Parties that may affect their performance of the Clinical Study or adversely affect the Clinical Study's integrity. If a conflict of interest arises during their performance of the Clinical Study, Clinical Site or Principal Investigator must promptly notify GC India.

12.3 **Debarment**

Clinical Site warrants that to the best of its knowledge, it, the Principal Investigator and its other Personnel, are properly registered with appropriate medical registration bodies and have not been disqualified from practice or banned from conducting clinical studies by a regulatory authority. Clinical Site must notify GC India as soon as it becomes aware of any disqualification or ban. If Clinical Site, the Principal Investigator or any other Personnel is disqualified, or otherwise ineligible, GC India may terminate this Agreement immediately.

12.4 **Anti Bribery**

Clinical Site warrants that it:

(1) has not offered, promised or paid, directly or indirectly, a Benefit to a government official (including, but not limited to, a healthcare professional employed by a government-owned healthcare facility) to induce the government official to act in any way in connection with his or her official duties with respect to services performed under this Agreement or to otherwise obtain an improper advantage for the Clinical Site, Sponsor, or GC India (**Improper Payment**);

(2) has not received an Improper Payment; and

(3) will not offer, promise, pay, authorise or receive any Improper Payment in the future.

For the purposes of this clause, **Benefit** includes but is not limited to money, financial or other advantage, travel expenses, entertainment, business or investment opportunities, charitable donations or any other thing of value.

12.5 **Compliance with applicable law**

Clinical Site must not engage in any conduct on GC India's behalf or Sponsor's behalf or part of the Clinical Trial which violates, or potentially violates any applicable local or foreign laws or regulations.

MANAGEMENT OF TRIAL DRUG

13.1 Clinical Site must:

(1) supply and manage the Trial Drug following usual hospital supply, storage and disposal practices;
(2) ensure that all Trial Drug is used strictly according to the Protocol and is not used for any other purpose, unless agreed in writing by the Sponsor;
(3) provide a written explanation accounting for any missing Trial Drug;
(4) keep all Trial Drug under appropriate storage conditions (including any conditions specified in the Protocol) and in a secure area accessible only to authorised Personnel;

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(5) ensure that complete and current records are maintained of (i) the names of the Eligible Subjects who received the Trial Drug, including the date and the amount of Trial Drug dispensed; and (ii) the dates and amount of the Trial Drug broken, spilled or lost; and

(6) not charge Eligible Subjects or third parties for Trial Drug or for any services reimbursed by GC India under this Agreement.

13.2 At the completion or termination of the Clinical Study, Clinical Site must provide to GC India a written accounting of the quantities of the Trial Drug used in the Clinical Study. Clinical Site must return any unused Trial Drug to GC India, or if requested by GC India, destroy it and provide evidence of the destruction. If GC India requests, Clinical Site must give a copy of its drug destruction policy and procedure to GC India.

13.3 Clinical Site must not sell the Trial Drug, and guarantees that all the Trial Drug will only be administered to Eligible Subjects according the Protocol. The above mentioned procedure will be managed by one special entrusted person.

NOTICES

14.1 Any notice, consent, approval or other communication in connection with this Agreement (each, a Notice) must be in writing, in English, and be delivered or sent to the address or email of the recipient as follows (or as varied by notice):

(1) if to GC India and/or Sponsor:

Plot No. 5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road

Bangalore - 560 001, Karnataka, India

Telephone: +91 80 4942 1400

Name: Abby Abraham

Email: aabraham@georgeclinical.com

(2) if to CLINICAL SITE:

Address: Department of Nephrology C BLOCK Sanjay Gandhi Post Graduate Institute Of Medical Sciences Raebareli Road Lucknow, India.

Post Code: 226014

Telephone: +91 - 5222495187

Name: Prof R K Dhiman

Email: director@sgpgi.ac.in

(3) if to Principal Investigator: Dr. Narayan Prasad

Address: Professor & Head
Department of Nephrology C BLOCK Sanjay Gandhi Post Graduate Institute Of Medical Sciences Raebareli Road Lucknow – India.

Code: 226014

Telephone: +91 - 5222495187

Name: Dr.Narayan Prasad

Email: narayan.nephro@gmail.com

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14.2 A Notice takes effect from the time received and is taken to be received by the recipient:

(1) if delivered by hand, on the day of delivery;

(2) if sent by post, on the third (seventh, if sent to another country) Business Day after the date of posting;

(3) if sent by facsimile, on the day shown on the transmission report (from the machine which sent the facsimile) that the entire facsimile was sent to the recipient;

(4) if sent by email, on the day the machine (which sent the email) reports the email was successfully sent (provided no error or bounce back is received);

However, if received after 5:00pm or on a day that is not a Business Day, it is be taken to be received at 9:00am on the next Business Day. A **Business Day** is a day which is not a Saturday, Sunday, or public holiday in India.

ACCESS

15.1 Clinical Site must allow GC India, Sponsor, their respective employees and agents, and authorized representatives of any regulatory or governmental authorities access to the Clinical Site to examine the Clinical Site's facilities and its personnel and to inspect and copy all Clinical Study data, documents and records relating to the Clinical Study to monitor compliance with this Agreement and applicable laws, rules and regulations. Access must be with reasonable notice and during normal business hours. Clinical Site must ensure that the Principal Investigator and all relevant key Personnel are available during monitoring visits to the Clinical Site and assist with any audit of records as reasonably requested by GC India;

15.2 If Clinical Site is contacted by a regulatory authority in connection with the Clinical Study, Clinical Site must notify GC India immediately unless prevented by law and must give GC India and Sponsor copies of the notice and related documents, the right to review and comment on such documents, and allow GC India and Sponsor the right to be present at any such inspection or inspections. If the inspection or audit occurs without notice to the Clinical Site, then the Clinical Site must notify GC India immediately, and no later than 24 hours following the arrival of the inspector or auditor. GC India may request a meeting after the inspection with the Clinical Site, and Clinical Site must ensure that the Principal Investigator attends.

TRANSFERABILITY

16. GC India may transfer any rights under this Agreement to the Sponsor, without consent of the Clinical Site.

INDEPENDENT CONTRACTOR

17.1 Clinical Site acts as an independent contractor undertaking the Clinical Study. Nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the parties and no Party will hold itself out as an agent for another or Sponsor.

17.2 Neither the Clinical Site, nor any of its Personnel has authority directly or indirectly, to act on behalf of, or to commit or bind GC India or Sponsor or to incur any liabilities or

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expenses on behalf of GC India or Sponsor or to enter into any oral or written agreement in the name or on behalf of GC India or Sponsor.

17.3 Neither GC India nor Sponsor guarantees the salary of the Principal Investigator or any other Personnel. The Clinical Site is solely responsible for paying salaries and employment benefits to its Personnel, and as employer, will also be responsible for all other employer related obligations, including income and payroll taxes, insurances, and pension contributions and making all other deductions required by law.

TAXES

18. All amounts in this Agreement include all taxes, duties, fees, costs & expenses, unless expressly stated otherwise.

SEVERABILITY

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

WAIVER

20. A right or remedy created by this Agreement cannot be waived except in writing signed by the Party entitled to that right. Delay by a Party in exercising a right or remedy does not constitute a waiver of that right or remedy, nor does a waiver (either wholly or in part) by a Party operate as a subsequent waiver of the same right or of any other right of that Party.

COUNTERPARTS

21. This Agreement may be executed in a number of counterparts. All counterparts taken together constitute one instrument. A Party may sign any one counterpart. This Agreement may be delivered by email and the Parties may rely on an electronic signature as though it were an original signature

FORCE MAJEURE

22.1 A Party will not be liable for failure or delay in the performance of its obligations under this Agreement for the period and to the extent that its failure or delay was directly due to a **Force Majeure Event**.

22.2 A Party relying on **clause 22.1** must:

(1) Promptly notify the other Party of the circumstances and effect of the Force Majeure Event; and

(2) Take all steps reasonably necessary to mitigate the effects of the Force Majeure Event on the performance of its obligations.

22.3 If the Force Majeure Event persists for more than 3 months, the other Party may immediately terminate the Agreement by written notice, without any damages being due to the Party affected by the Force Majeure Event.

22.4 A **Force Majeure Event** means an event which is not within the reasonable control of a Party and not caused by its own act or omission, including (but not limited to) acts of God, natural events, fire, war, events of terrorism, embargo, strike, riot, or act of government or regulatory agency.

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ASSIGNMENT

23. The Clinical Site may not assign or transfer any of its rights or obligations under this Agreement without first obtaining GC India's and Sponsor's written consent. Sponsor may assign any of its rights or obligations under this Agreement without consent of the Clinical Site.

ENTIRE AGREEMENT

24. This Agreement constitutes the entire agreement between the parties in relation to the Clinical Study and supersedes all prior representations, agreements, statements and understandings, whether verbal or in writing in relation to the Clinical Study.

CONFLICT

25. If any terms of this Agreement are in conflict with any terms of the Protocol or the Budget, the Agreement and Budget will prevail with respect to legal terms and the Protocol will prevail with respect to clinical terms.

AMENDMENTS

26. This Agreement may only be amended by a written document signed by all Parties. The Protocol may only be amended in writing by the Parties and approved by the Ethics Committee.

INTEGRATION

27. The Protocol and any amendments to it and the Exhibits attached to this Agreement are an integral part of this Agreement and are incorporated in it by reference.

APPLICABLE LAW AND DISPUTES

28. The laws applicable in ~~Bangalore~~ Lucknow, India govern this Agreement. If any disputes arise in connection with this Agreement, and the dispute cannot be solved pursuant to clause 29, the parties submit to the non-exclusive jurisdiction of the courts in ~~Bangalore,~~ India.

29. DISPUTE RESOLUTION Lucknow

29.1 If a dispute arises in connection with this Agreement, the parties must first attempt to negotiate in good faith to resolve the dispute. However, nothing in this clause 29 prevents a party from obtaining urgent injunctive relief to protect their intellectual property rights.

29.2 If the dispute is not resolved within 14 days after good faith negotiations commence, either party may refer the dispute to mediation under the Arbitration and Conciliation Act 1996, in India.

29.3 If the dispute is not resolved within 21 days of the commencement of mediation, either party may commence proceedings in any court of competent jurisdiction.

29.4 Unless specifically provided otherwise, each party must continue to perform its obligations under this agreement, despite the existence of a dispute.

29.5 Nothing herein shall prevent either party from seeking equitable or injunctive relief through the court system.

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48

EXECUTED as an Agreement between the parties.

VISTERRA, INC.

By: David Oldach MD

24 FEB 2021

Initials: DWO

David Oldach, MD
Printed Name
Chief Medical Officer, Visterra
Title

On behalf of **George Clinical India Private Limited (GC India)**		On behalf of **CLINICAL SITE**	
Signed:		Signed:	
Name:	Abby Abraham	Name:	Prof R K Dhiman
Position:	Country Head, India	Position:	Director
Date:	15 / Feb / 2021	Date:	22/2/21

George Clinical India Private Limited

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

The Principal Investigator acknowledges this Agreement and understands the obligations it imposes

Acknowledged by the **Principal Investigator**

Signed: 3.3.21

(Prof. Narayan Prasad)
Professor & Head
Deptt. of Nephrology
S.G.P.G.I.M.S., Lucknow-226014
Reg. No. BR-27804/94

Name: Dr. Narayan Prasad – MBBS, MD, DM

Position: Professor & Head

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EXHIBIT A

PROTOCOL A Multicenter, Randomized, Double-Blind,Placebo-Controlled, Multiple Dose Study to Evaluate the Efficacy and Safety of VIS649 in Participants with Immunoglobulin A (IgA) Nephropathy

To be submitted separately

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EXHIBIT B – BUDGET

Per Subject Fee:
Site (PI) target to enrol 4 subjects during the enrolment period for the study.

GC India will pay the adjusted cost of **INR 663,685.00** per Eligible Subject randomised in accordance with the Protocol and who has completed the Clinical Study as per the payment schedule below

(NOTE: this payment is inclusive of the overhead, hospital administration and all miscellaneous e.g. printing fee, courier fee, and so on).

Such amount will be divided as follows: (INR)

Visit	Total Fees breakdown
Screening	34586.00
D1 Pre infusion (M0)	45400.00
D1 Post infusion (M0)	
D8 (M0)	14501.00
D18 (M0)	11533.00
D30 (M1)	44599.00
D60 (M2)	44599.00
D90 (M3)	44599.00
D120 (M4)	44599.00
D150 (M5)	44599.00
D180 (M6)	45019.00
D210 (M7)	44599.00
D240 (M8)	44599.00
D270 (M9)	44599.00
D300 (M10)	44599.00
D330 (M11)	45044.00
D360 (M12 - ET)	25174.00
D390 (M13)	12433.00
D420 (M14)	12433.00
D485 (M16 - EOS)	16171.00
Total	663,685.00

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SGPGIMS,Lucknow

Unscheduled Visit	13944.00

Conditional (Invoiced) Items	Max. qty per patient	Unit cost	Unit cost with O/H	Max. cost per Patient
Serious adverse event Report	all will be reimbursed	2,327	2,327	**N/A**
Re-consent	1	1,020	1,020	**1,244**
12-Lead ECG (Includes interpretation and report)	1	1,867	1,867	**1,867**
Initial Physcial examination(include Medical history,assement of Cardiovascular, respiratory, gastrointestinal, neurological, weight, height and Vital sign)	1	5,270	5,270	**6,430**
Serum Chemistry (Local Lab)	15	1,257	1,257	**18,855**
Hematology (Local Lab)	7	691	691	**4,837**
Colllection & shipping of archived biopsy slide (kits provided)	1	1,949	1,949	**1,949**
Pathology re read	1	3,689	3,689	**3,689**
Infusion supplies: Saline, infusion line and filter		Pass through		
Overnight facility charge, Simple	12	14,332	14,332	**171,984**
PK Blood Blood draw optinal sub-study M0, 2 hr & M11, 2 hr post infusion timepoint	2	356	356	**712**
Total cost for Invoiced Items per Patient				**₹211,567.00**

Screen Failures:	Max. Qty	Maximum cost
Screen Failure Visit	1 PER EVERY 1 ENROLLED PATIENTS	34,586
Re-screening	1 PER PATIENT	34,586

Site Costs (Invoiced Items)	Max Cost
Local Ethics Committee Fee, IRB Fee	25000 + 18% GST
Archival Fee (15 years)	60000
Study Start-Up Fee/Site Set-Up Fee	80000
Pharmacy: Set-Up Fee	60000
Study coordinator salary Rs.25,000(per month) X 30 Months	750,000
Pharmacist salary Rs.25,000(per month) X 30 Months	750,000

Equipment Cost	
Infusion Pump	63,000.00/- +Tax

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(A4)

In case of subjects included but not having completed the Clinical Study the amount to be paid will be calculated according to the fees of the visits actually performed by this subject. Where visits are conducted but not all per Protocol tests performed, GC India reserves the right to withhold partial payment at its discretion. No payment will be made for an ineligible subject incorrectly randomised into the Clinical Study or in case the subject did not complete the Clinical Study due to negligence, malpractice, breach of Protocol, or any wilfully wrong act or omission on the part of the Investigator or CLINICAL SITE.

In addition to the per subject payment, GC India will cover the following costs:

1. GC India will reimburse the CLINICAL SITE for Eligible Subject's reasonable travel and meal expenses up to a maximum of INR 1,500 per Eligible Subject visit ("**Subject Expenses**"), as agreed between GC India and Clinical Site. Reimbursement for Subject Expenses will be included in the per patient grant payable to the Investigator by GC India, which will be based on per Eligible Subject for each completed visit.

2. Reimbursement of the Subject Expenses to the CLINICAL SITE is subject to the CLINICAL SITE providing to GC India's nominated Clinical Study monitor and the monitor's approval of:
   (a) receipts or other supporting evidence of Subject Expenses; and
   (b) receipts or other satisfactory evidence that CLINICAL SITE has paid such Subject Expenses to the relevant Eligible Subjects.

3. Unless otherwise agreed by GC India in writing, GC India will not be liable for any other payment other than those specified in this Agreement.
   All payments to the CLINICAL SITE will be made according to the bank details provided in Exhibit C.

George Clinical India Private Limited

DWO

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

EXHIBIT C

1.	**CLINICAL SITE**	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Nephrology, C BLOCK , Raebareli, Road Lucknow 226014
2.	**CLINICAL SITE'S Payment Details:** Director SGPGIMS RESEARCH ACCOUNT	
3.	**CLINICAL SITE's**	Bank Name: State Bank Of India Bank Address: PGI Branch Raebareli Road Lucknow Name Account Holder: Director SGPGIMS RESEARCH ACCOUNT Account Number: 10095237491 PAN No.: AAAJS3913N GST No.: 09AAAJS3913N2ZN IFSC Code: SBIN0007789
4.	**Invoice Payment Notice Details**	Contact Name: George Clinical India Pvt Ltd. Address: Plot No. 5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road, Bangalore - 560 001, Karnataka, India
5.	**CLINICAL SITE Payment Notice Details**	Contact Name: Dr. Narayan Prasad – MBBS, MD, DM Email address: narayan.nephro@gmail.com Full Address: Department of Nephrology, C BLOCK Sanjay Gandhi Post Graduate Institute Of Medical Sciences Raebareli Road Lucknow 226014
6.	**Currency**	INR
7.	**VAT or GST**	(a) All amounts in this Agreement include all taxes, duties, fees, costs & expenses, unless expressly stated otherwise. (b) If any VAT/GST is payable by the Clinical Site and/or Principal Investigator on any amounts payable under this Agreement and this has been expressly agreed by GC India and Sponsor, the GST/VAT must be shown on a validly issued and accurate tax invoice at the local applicable GST/VAT rate. (c) If any VAT/GST may be refundable to the Clinical Site and/or Principal Investigator, the Clinical Site and/or Principal Investigator shall seek the appropriate refund and reimburse Sponsor for the VAT accordingly. (d) The Clinical Site and/or Principal Investigator (as payee) is solely liable for and will pay when due all GST/VAT, taxes, fees, duties, assessments and other governmental charges of any kind imposed by a taxing authority for the services performed under this Agreement. (e) Each Party will pay costs of bank transfers within its own country.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ 54AA 348725

Amendment #2
Clinical Study Agreement

This amendment dated 30 March 2023 to the Clinical Study Agreement (the "Amendment") is entered into by and between Sanjay Gandhi Postgraduate Institute of Medical Sciences, a clinical research site with its principal office and place of business at Raibareily Road, Lucknow - 226014, Uttar Pradesh, India ("**Institution**"), Dr. Jayantee Kalita, having an address at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareily Road, Lucknow - 226014, Uttar Pradesh, India ("**Principal Investigator**") and Medpace Clinical Research LLC, located at 5375, Medpace Way, Cincinnati, Ohio 45227 ("Medpace"), collectively, (the "Parties").

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(35)

WITNESSETH:

WHEREAS, the Parties entered into a Clinical Study Agreement as of 28 January 2021 (the "Agreement") pursuant to which Institution is conducting a Study based on Protocol No. VIB0551.P3.S1, entitled "A Randomized, Double-Blind, Multicenter, Placebo-Controlled Phase 3 Study With Open-Label Period To Evaluate The Efficacy And Safety Of Inebilizumab In Adults With Myasthenia Gravis", (the "Protocol"); and

WHEREAS, the Parties desire to amend the Agreement to amend the budget in Schedule A of the Agreement contained therein.

NOW THEREFORE, the Parties hereby agree as follows:

1. Schedule A of the Agreement shall be deleted in its entirety and replaced with the Schedule A appended to this Amendment.

2. All other provisions of the Agreement shall remain unchanged and in effect.

[SIGNATURE PAGE TO FOLLOW]

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(34)

IN WITNESS WHEREOF, the Parties hereto have executed this Amendment by proper persons thereunto duly authorized

FOR MEDPACE, ON ITS OWN BEHALF
AND AS PAYMENT AGENT OF SPONSOR

By: _____

Name: Taher Sadriwala

Title: Sr. Associate Director – Clinical Trial Management

Date: 01/Jun/2023

INSTITUTION

By: _____ 03/07/23

Name: _____

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

Title: _____

Date: _____

Read and Acknowledged by:
Principal Investigator

By: _____

Name: Prof. Jayantee Kalita

Date: 16/Jun/2023

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

VIELA BIO

PROTOCOL ID: VIB0551.P3.S1

// DR JAYANTEE KALITA //

PROTOCOL VERSION 6.0

SITE: //4105//

SCHEDULE A VERSION: VERSION #2.0

COUNTRY: INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SCHEDULE A

A1 STUDY BUDGET

Medpace, as Sponsor's payment agent, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. All fees listed include overhead, taxes, and subject stipend or travel reimbursement, as applicable. VAT is not applicable because Medpace Clinical Research, LLC is a US-based corporation. Should any changes to VAT law occur during the term of this Agreement, the party legally responsible shall be liable for VAT. Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject (Including 25% IOH and 18% GST)

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit 2/Day 1.

1.1.1	*Randomized Control Period-AcHR-Ab+ Population*	*INR 670,107.00*
1.1.2	*Randomized Control Period-MuSK-Ab+ Population*	*INR 473,031.00*
1.1.3	*Open Label Period*	*INR 554,746.03*

A2 SETUP FEES & VISIT PAYMENTS

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

A2.1 Setup Fees

2.1.1	*Administrative Fee*	*INR 40,000 + 18% GST*
2.1.2	*Pharmacy Start-Up Fee*	*INR 75,000 + 18% GST*

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

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

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Table 1 - Fees for Completed Clinical Visits for Randomized Control Period- AcHR-Ab+ Population

VISIT	VISIT FEE	25% IOH FEE	VISIT FEE INCLUDING 18% GST
Visit 1/Screening	INR 30,797	INR 7,699	INR 45,426
Visit 2/Day 1	INR 64,262	INR 16,066	INR 94,786
Visit 3/Day 15	INR 43,778	INR 10,945	INR 64,573
Visit 4/Day 29	INR 34,622	INR 8,656	INR 51,067
Visit 5/Day 57	INR 28,622	INR 7,156	INR 42,217
Visit 6/Day 85	INR 34,784	INR 8,696	INR 51,306
Visit 7/Day 126	INR 27,476	INR 6,869	INR 40,527
Visit 8/Day 183	INR 59,010	INR 14,753	INR 87,040
Visit 9/Day 225	INR 27,950	INR 6,988	INR 41,226
Visit 10/Day 267	INR 34,671	INR 8,668	INR 51,140
Visit 11/Day 309	INR 27,476	INR 6,869	INR 40,527
Visit 12/Day 365	INR 40,862	INR 10,216	INR 60,271
TOTAL PER PATIENT	**INR 4,54,310**	**INR 1,13,578**	**INR 6,70,107**
Remote Visit due to COVID-19	INR 17,592	INR 4,398	INR 25,948

Table 2 - Fees for Completed Clinical Visits for Randomized Control Period- MuSK-Ab+ Population

VISIT	VISIT FEE	25% IOH	VISIT FEE INCLUDING 18% GST
Visit 1/Screening	INR 30,797	INR 7,699.25	INR 45,425.58
Visit 2/Day 1	INR 64,262	INR 16,065.50	INR 94,786.45
Visit 3/Day 15	INR 43,778	INR 10,944.50	INR 64,572.55
Visit 4/Day 29	INR 34,622	INR 8,655.50	INR 51,067.45
Visit 5/Day 57	INR 28,622	INR 7,155.50	INR 42,217.45
Visit 6/Day 85	INR 34,784	INR 8,696.00	INR 51,306.40
Visit 7/Day 126	INR 27,476	INR 6,869.00	INR 40,527.10
Visit 8/Day 183	INR 56,358	INR 14,089.50	INR 83,128.05
TOTAL PER PATIENT	**INR 3,20,699**	**INR 80,175**	**INR 4,73,031**
Remote Visit due to COVID-19	INR 17,592	INR 4,398.00	INR 25,948.20

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Executive Registrar
SGPGIMS,Lucknow

30

Table 3- Fees for Completed Clinical Visits for Open Label Period

VISIT	FEE	25% IOH	FEE INCLUDING 18% GST
Visit 1/OLE Day 1	INR 27,505.00	INR 6,876.25	INR 40,569.88
Visit 2/OLE Day 15	INR 33,784.00	INR 8,446.00	INR 49,831.40
Visit 3/OLE Day 92	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 4/OLE Day 183	INR 55,018.00	INR 13,754.50	INR 81,151.55
Visit 5/OLE Day 275	INR 32,310.00	INR 8,077.50	INR 47,657.25
Visit 6/OLE Day 365	INR 36,810.00	INR 9,202.50	INR 54,294.75
Visit 7/OLE Day 456	INR 29,310.00	INR 7,327.50	INR 43,232.25
Visit 8/OLE Day 547	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 9/OLE Day 730	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 10/OLE Day 911	INR 32,013.00	INR 8,003.25	INR 47,219.18
Visit 11/OLE Day 1093/ET	INR 33,013.00	INR 8,253.25	INR 48,694.18
TOTAL PER PATIENT	**INR 3,76,099.00**	**INR 94,024.75**	**INR 5,54,746.03**
Safety Follow up	INR 22,199.00	INR 5,549.75	INR 32,743.53

A2.3 Screen Failures

Table 4 – Screen Failures

VISIT OF FAILURE	COST	25% IOH	COST INCLUDING 18% GST
Visit 1/Screening	INR 30,797	INR 7,699.25	INR 45,425.58

Payment for a max of 10 screen failures will be made for whom Medpace has received all appropriate documentation of procedures/visits completed with the next scheduled payment owed to the Payee. Eligible screen failure payment will be based on the order (by date) of when the subject is consented. Payment for additional screen failures must be pre-approve by Medpace/Sponsor.

A2.4 Final Payment

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

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

A2.5 Archiving Fee — 350,000 plus 18% GST

Payable with final payment. The expectation is that the study site will be responsible to maintain study documents for 25 years after site closure unless notified by the sponsor.

The final payment shall be reconfirmed and paid as per the quotation submitted and on receipt of sponsor's approval.

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SGPGIMS,Lucknow

A2.6 Unscheduled Visit Due to Worsening MG Symptoms (Including 25% IOH) INR +18% GST — 21,118.00

Payable with final payment. An unscheduled visit should be performed if a patient complains of worsening MG symptoms and use of rescue therapy is being considered. This should be performed before the rescue therapy is initiated. This Unscheduled visit should follow the procedures as outlined in the protocol. If an Unscheduled Visit is performed for a different reason, then it is only necessary to perform those specific procedures. Unscheduled Visit must be entered into EDC prior to database lock and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit.

Total includes Adverse Events Assessment, Patient Daily Reimbursement, Study Coordinator Fee, and Physician's Fee. All other procedures should be invoiced at cost if completed

A3 INVOICEABLE ITEMS

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

A3.1 Additional Procedures

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

Table 5 – Unitized Procedures

FEES	COST	COST INCLUDING 18% GST
Optional B-cell Repertoire Profiling Substudy	INR 800	INR 944
Optional DNA Sample	INR 800	INR 944

A3.2 OLE - Day 1 Visit — INR 70,848 + 18% GST, if applicable

Payable if the OLE - Day 1 visit occurs on a separate date from the Day 365 visit.

A3.3 Rescue Medication

Rescue Medications to be paid at actual cost upon receipt of invoice and supporting documentation, if not covered by a third party as standard of care and costs are reasonable and customary.

A3.4 Additional Study-necessitated Fees

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

A3.5 Nominal equipment

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

A4 MEDPACE RIGHTS

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

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SGPGIMS,Lucknow

A5 MEDPACE INVOICING

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

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

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

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

A6 PAYEE INFORMATION

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

Table 6 - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name	Director SGPGIMS Research Scheme
Payee Mailing Address	Administrative Building, SGPGIMS, Raebareli Road, Lucknow
Contact Name	Dr. Jayantee Kalita
Email Address	jayanteek@yahoo.com
Bank	State Bank of India
Account №	10095237491
IBAN №	N/A
BIC Code/Swift Code	SBININBB500
IFSC Code (India)	SBIN0007789
Tax ID#**	AAAJS3913N

**Requested for Medpace Accounting tracking purposes only

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Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Uttar Pradesh

e-Stamp

DILIP SINGH
SHCIL ACC CODE U.P.14243404 L.No.-85
11/671, INDIRA NAGAR, LUCKNOW

Base Certificate No.	:	IN-UP03136416437070T
Certificate No.	:	**IN-UP03137310303929T**
Certificate Issued Date	:	08-Jul-2021 04:39 PM
Account Reference	:	NEWIMPACC (SV)/ up14243404/ LUCKNOW SADAR/ UP-LKN
Unique Doc. Reference	:	SUBIN-UPUP142434049439918869249 3T
Purchased by	:	Dr Anshika Srivastava
Description of Document	:	Article 5 Agreement or Memorandum of an agreement
Property Description	:	MOU
Consideration Price (Rs.)	:	
First Party	:	Dr Anshika Srivastava
Second Party	:	DBT SGPGI
Stamp Duty Paid By	:	Dr Anshika Srivastava
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made onTwenty July day of Two thousand and twenty one BY AND BETWEEN President of India, acting through …Secretary……, Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India a society under the Societies Registration Act–1860, having its registered office in/at **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road,Lucknow-226014, Uttar Pradesh, India** hereinafter referred to as **SGPGIMS** (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous of **human genetics and developmental genetics** decided to support a project submitted by **Dr. Anshika Srivastava, Assistant Professor & PI, Department Of Medical Genetics, SGPGIMS, Lucknow** for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **Probing the dynamic balance of histone H2AUb1 regulatory axis in hypertrophic cardiomyopathy and early heart development.**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs. 60.61600 (Rupees Sixty Lakh Sixty One Thousand Six Hundred Only)(Sanction Letter no- No. BT/12/IYBA/2019/13)** over a period of three years from March 2, 2020, to March 01, 2023 for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF Sanjay Gandhi Post Graduate Institute of Medical Sciences (Institute/NGO)

2.1. To provide their contribution of NIL for3 years from date of sanction of the project as detailed in Annexure–II. *(If a jointly supported project)*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be threeyears from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by **Dr. Anshika Srivastava** will be the joint property of **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** and DBT, Government of India. It shall be the responsibility of **Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road,Lucknow-226014, Uttar Pradesh, India** to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.3 All the assets including the equipment and produce acquired will be the property of DBT and shall not be utilized for purposes other than those for which the grant has been sanctioned. The rights of **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** under this MoA shall not be transferred to any other party without prior approval in writing of DBT.

4.4 It shall be the responsibility of **Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** to ensure that support of DBT is suitably acknowledged in the publications (papers, reports, etc.) arising out of the PROJECT.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

5. SECRECY

It is hereby agreed that the participating agencies shall keep information and data collected completely secret provided that the right to transfer the technology shall rest with the DBT.

6. MONITORING

6.1 The progress of implementation of the project and proper utilization of grant shall be reviewed by the DBT and by the Monitoring Committee set up by DBT.

6.2 The periodic progress of physical achievements and the utilization of funds, statement of expenditure shall be evaluated by the Monitoring Committee.

6.3 The Comptroller and Auditor General of India, at his discretion shall have the right of access to the books and accounts of **Sanjay Gandhi Post Graduate Institute of Medical Sciences(SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India** for the grants received from DBT for this project.

6.4 The DBT may terminate the grant at any stage if it is convinced that the grant has not been properly utilized or appropriate progress has not been made. In the event, DBT terminates the grant, **Dr. Anshika Srivastava** shall hand over all documents including technical details and equipment purchased related to the project.

7.0 DURATION OF MEMORANDUM OF AGREEMENT

This MoA will remain inforce for the duration of the project and until all claims are settled between DBT and **Sanjay Gandhi Post Graduate Institute of Medical Sciences(SGPGIMS), Raibareli Road, Lucknow-226014, Uttar Pradesh, India.**

8.0 ARBITRATION

In the event of any question, dispute or difference whatsoever arising between the parties to this Agreement out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity of the breach thereof shall be referred to an Arbitrator to be appointed by mutual consent of both the parties herein. If the parties cannot agree on the appointment of the Arbitrator within a period of one month from the notification by one party to the other of existence of such dispute, then the Arbitrator shall be nominated by the Secretary, Department of Legal Affairs, Ministry of Law & Justice,

Anshika

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Government of India. The provisions of the Arbitration and Conciliation Act, 1996 will be applicable and the award made thereunder shall be final and binding upon the parties hereto, subject to legal remedies available under the law. Such differences shall be deemed to be a submission to arbitration under the Indian Arbitration and Conciliation Act, 1996, or of any modifications or reenactments thereof.

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9.0. GOVERNING LAW

This Contract shall be governed by the Law of India for the time being in force.

IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

1. Vandana Sc 'C'

2. Sc 'C'

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

Deo Prakash Chaturvedi
Scientist 'C'
Department of Biotechnology
Govt. of India
C.G.O. Complex, Lodhi Road
New Delhi-110003

For and on behalf of The President of India

Witnesses:

1. (SMT. SUNITA AGARWAL)
Professor
Deptt. of Genetics
SANJAY GANDHI POST GRADUATE
INSTITUTE OF MEDICAL SCIENCES
LUCKNOW-226 014 (INDIA)

2. Dr. Moin Saleem Ansari
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences,
LUCKNOW-226014, INDIA

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

Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, INDIA

(Designation)

For and on behalf of

...

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Annexure - I

Detailed Project Activities

Detailed Methodology

Below is the objective-wise description of detailed methodology and overall experimental approach as shown in figure 3.

Objective 1: Determine the pathogenic mechanism of ASXL3-dependent histone H2A deubiquitination in cardiogenesis:hESCs ASXL3-mutation models and successful cardiac directed differentiation: I willcreate BRS patient specific mutations (c.1448dupT; T484NfsX5 and c.1897_1898delCA;Q633VfsX13) in human embryonic stem cells (HUES9) using CRISPR/Cas9. As shown in our previous studies performed in patient fibroblasts that heterozygous mutations in ASXL3results in nonsense mediated decay and both the mutations are associated with congenitalHCM as evident through our Asxl3-/- mice (Figure 2). hESCs will undergo cardiac-directed differentiation using sequential application of a highly efficient protocol relying onapplication of cytokines at specific time points hESCs.[14]

Immunohistochemistry (IHC): A hypertrophic phenotype will be validated using cell sizequantification with immunofluorescence imaging and with a qRT-PCR assay of NPPA. I will quantify the human cardiomyocytes diameter with WGA. Ki67 and PH3 staining willquantify proliferation and cells undergoing mitosis defects.

RNA-seq analysis: RNA will be isolated from five biologic replicates for each genotype(wildtype, heterozygous and homozygous). Random culture condition effects will beminimized by pooling samples from at least 3 different differentiation batches. Five biologic replicates will be obtained for each model to maximize the accuracy of RNA-Seq analysis at30M paired end reads per sample. I will employ an existing RNA-Seq processing pipeline tomap RNA-Seq reads (STAR) and quantify mRNA transcript abundance (RSEM).[15-17] I willassess differential expression for each target gene using the software package EBSeq andcontrol for false discovery rate (FDR) using established methods.[18] Enrichment of differential expression signals at the pathway level (gene set enrichment analysis, or GSEA) will beperformed using Fisher's exact test.

ATAC-seq: ATAC-seq will be performed on five biologic replicates for each genotype (wildtype, heterozygous and homozygous) in parallel with RNA-seq sample collection asabove. Nuclei will be isolated and a transposase reaction performed using protocol outlined by Scott LJ et al. [19] Analysis of ATAC-seq data will focus on quantification of

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availability oftranscription factor binding sites that are known recognition sequences for hypertrophicsignaling transcription factors and/or transcription factors that are differentially expressedbased on the RNA-seq data. For the former, quantification ofbinding site availability isimportant since the transcription factor may be activated through phosphorylation (or otherpost-translational modification) but may not necessarily be upregulated at the mRNA level –thus, the ATAC-seq methodology will be able to detect this level of activation that would bemissed by solely RNA-seq analysis.

Objective 2: Determine the pathogenic mechanism of TRIM37-dependent histone H2Aubiquitination in cardiogenesis: hESCs TRIM37-mutation models: I will create patient specific mutations usingCRISPR/Cas9 and will perform the cardiac differentiation as outlined in objective 1.

Immunohistochemistry: IHC analysis will be performed as outlined in objective 1.

RNA-seq: Experiments will be performed and analyzed as outlined in objective 1.

ATAC-seq: ATAC sequencing will be performed as outlined in objective 1.

Objective 3: Determine shared genetic mechanism and pathways in hypertrophiccardiomyopathy caused due to mutations in H2AUb1 regulatory axis members: This aim will directly compare two different genetic models of cardiac hypertrophy – one witha mutation in the histone H2A ubiquitin ligasegene TRIM37 and one with a mutation in thehistone H2A deubiquitinase ASXL3. Ihypothesize that there will be both shared anddistinct hypertrophic pathways activated betweenthe two models. Distinction of these pathwayswill have implications for therapeutic interventionfor cardiac hypertrophy.

The above-mentioned activities will be undertaken by Dr. Anshika Srivastava (PI) ***(Department of Medical Genetics, SGPGIMS, Lucknow)*** under the project entitled ***"Probing the dynamic balance of histone H2AUb1 regulatory axisin hypertrophic cardiomyopathy and early heart development."***

Objectives:

1. Determine the pathogenic mechanism of ASXL3-dependent histone H2A deubiquitination in cardiogenesis.
2. Determine the pathogenic mechanism of TRIM37-dependent histone H2A ubiquitination in cardiogenesis.
3. Determine shared genetic mechanism and pathways in hypertrophiccardiomyopathy caused due to mutations in H2AUb1 regulatory axis members.

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Annexure – II

Details of Funds

Dr. Anshika Srivastava

Assistant Professor

Department of Medical Genetics

Raebareli Road, SGPGIMS, Lucknow

(Rs in Lakhs)

Items	***I year***	***II year***	***III year***	**Total**
Non-recurring	10.00	0.00	0.00	10.00
Manpower	4.872	4.872	4.872	14.616
Consumables/Training/ Travel/ Contingencies	10.00	10.00	10.00	30.00
Overhead	1.00	1.00	1.00	3.00
Cash Award	1.00	1.00	1.00	3.00
Total	**26.872**	**16.872**	**16.872**	**60.616**

Anshika

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Annexure - IV

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further instalments of the grant.

7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure (**Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial

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Executive Registrar
SGPGIMS,Lucknow

year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest,the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: www.dbtindia.org / www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure – VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

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18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

Signature of Project Coordinator
(applicable only for multi-institutional projects)
Date :

Signature of Executive Authority of Institute/ University With seal

Date :

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

Signature of Principal Investigator :
Date :

Dr Anubha Srivastava
Assistant Professor
Dept. of Medical Genetics
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
LUCKNOW-226014, INDIA

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29

20

महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ UW 337558

Treasury Allotment Date and No. 18.04.2019 (UW 337558)	Serial No. **1598**/19 Date 26.04.2019
Nature of Document/Article No.	
Whether it is to be Registered -	If Registrable Name of S.R.O.-
Property Description in brief	As per the **Document**
Stamp Purchaser's Name	**Abbott India Limited,** 16, Godrej BKC, Bandra (E), Mumbai-51
if through other person then Name & Address	Anil Gonde,
Name of the Other Party	-
Stamp Duty Amount	Rs.100/-
Stamp Purchaser's Signature and Date	Shri **Jay R. Binwadkar,** Stamp Vendor, Ls. No. 1206030 Kumbhar Chawl, Netivali, Kalyan (E) 421 306 (M) 9890732173

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्या पासुन सहा महीन्यात वापरणे बंधनकारक आहे. अधिकारी

18 APR 2019

EPIDEMIOLOGICAL STUDY AGREEMENT

Abbott India Limited ("Abbott") desires to retain , **Sanjay Gandhi Post Graduate Institute of Medical Sciences**, at, **Raebarel Road, Lucknow, Uttar Pradesh-226014**,India ("Institution") to provide services in support of Institution's employee's **Dr. Usha Kant Misra** (the "Investigator"), conduct of a non-interventional, epidemiological study (the "Study") in relation to" **A Cross-Sectional, Multicenter Study To Determine The Sociodemographic Characteristics, Clinical Profile, And Usage Pattern Of Antiepileptic Drugs In Persons With Epilepsy In India"** effective as of the date this Epidemiological Study Agreement (the "Agreement") is fully executed (the "Effective Date"). In consideration of the mutual promises set forth herein, the parties agree as follows:

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1. Conduct of Study.

(a) Investigator will conduct the Study pursuant to the terms of this Agreement and in strict adherence to EPIDI066 study entitled "*A **Cross-Sectional, Multicenter Study To Determine The Sociodemographic Characteristics, Clinical Profile, And Usage Pattern Of Antiepileptic Drugs In Persons With Epilepsy In India***" (the "Protocol"), as the same may be amended from time to time in writing by Abbott, and with any other written instruction that may be provided by Abbott. The parties further agree that this Study is epidemiological and will not utilize any Abbott product(s) ("Abbott Product(s)"). Subjects may already be prescribed an Abbott Product prior to, during or after the Study however this is incidental to the conduct of the Study and any such decision to prescribe Abbott Product to any subject at any time shall be the sole decision of the relevant subject's doctor and unrelated to the Study.

(b) Investigator hereby represents and warrants that any and all personnel working by or on behalf of the Investigator, with respect to the Study, are employed by Investigator and will work under the supervision of the Investigator. Further, Investigator shall be responsible for making payments, if applicable, to such personnel upon receipt of funds from Abbott. Investigator will ensure that such personnel will comply with the terms and conditions of this Agreement and Investigator shall remain responsible and liable for the acts or omissions of such personnel as if such activities had been performed by Investigator.

(c) Investigator shall use best efforts to complete enrollment of 10 patients (hereinafter referred to as "subjects") within 03 months of Study initiation. The Investigator's site will be discontinued by the sponsor if there is no enrollment of patients within 01 month of site initiation. Abbott may terminate this Agreement immediately if (i) IRB or IEC (defined below) approval or NOC from Institutional Ethics Committee, if required, is not obtained after central Ethics committee approval within 5-8 weeks of receipt of all necessary materials for IRB/IEC submission; or (ii) all essential documents have not been executed and received by Abbott within 4 weeks of Investigator's receipt of IRB or IEC's written approval, if such approval is required.

Contacts. Investigator's contact(s) at Abbott will be **Sneha Nair-Head- Clinical Operations, Abbott India Limited ,16th Floor, Godrej BKC,Plot C – 68, "G" Block, Bandra Kurla Complex, Near MCA Club, Bandra (East),Mumbai 400 051, India, O:+91 22-38160910, M: 9970780488, Fax # 91-22 2871 7499**, or whomever Abbott may designate in writing. Abbott's contact(s) at Investigator will be retain, **Dr. Usha Kant Misra, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014, Phone: + 91- 8004904627.**

2. Compliance with Law.

(a) Investigator represents warrants and covenants that he/she will conduct the Study and perform his/her obligations under this Agreement in compliance with all applicable laws, regulations and guidelines. In furtherance of the foregoing obligations and as required by law, Investigator will further ensure that an Institutional Review Board ("IRB"), an Independent Ethics Committee ("IEC"), or both, as applicable, approves and oversees the conduct of the Study. Investigator will comply with the directives of the IRB or IEC, or both, as applicable, respecting the conduct of the Study, and will notify Abbott to the extent any such directives vary from the Protocol.

(b) Prior to the initiation of the Study, Investigator will and will ensure that any subinvestigator for the Study provides Abbott with all essential regulatory documents requested by Abbott including but not limited to current Curriculum Vitae and medical license, or equivalent, to ensure compliance with applicable regulations. Investigator will comply with all applicable requirements regarding reporting and management of conflicts of interest.

(c) Investigator agrees that if services are paid for or provided without charge by Abbott, neither Investigator, nor his/her agents shall separately bill or seek reimbursement for such services from any third party including, without limitation, the subject, any private provider of insurance, or any government program or other public provider of insurance.

3. Safety Reporting. Institution and Investigator shall comply with the safety reporting obligations attached hereto and incorporated herein as **Exhibit B** ("Safety Reporting Obligations").

Study Supplies. Due to the epidemiological nature of this Study, Abbott will not be providing any Abbott Product(s) or reimbursement for any Abbott Product(s). Abbott will provide to Investigator, at no cost, sufficient quantities of the case report forms or access to an electronic data capture system ("CRFs") as well as any other materials and information specified by the Protocol or that Abbott deems necessary to conduct the Study (together, the "Study Materials"). All Study Materials and other information provided by Abbott in connection with this Agreement will not be used for any purpose other than to conduct the Study pursuant to the Protocol and will remain the sole property of Abbott. Upon termination of the Study or at

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Executive Registrar
SGPGIMS,Lucknow

Abbott's request, the Study Materials will be returned or destroyed pursuant to the Protocol, and Institution will document such disposition, pursuant to Abbott's direction.

4. Delivery of Progress and Post-Study Reports. Upon request, Institution will submit oral or written reports on the progress of the Study to Abbott. Within forty-five (45) days following the completion or termination of the Study, Institution will furnish Abbott with the following, unless Abbott directs otherwise in writing:

   (a) the final IRB or IEC report on the Study prepared by the Investigator for the IRB or IEC or both, as applicable;
   (b) all completed, used and unused CRFs not previously delivered to Abbott; and
   (c) all data, reports and other information generated in relation to the Study.

5. Monitoring and Audits; Record Retention.

   (a) Institution will permit Abbott and/or any Abbott designee access to Study sites during normal business hours to monitor the conduct of the Study as well as to audit records, CRFs, source documents, and other data relating to the Study. Institution may redact such records as may be legally required to protect subject confidentiality consistent with **Section 9** (Subject Confidentiality and Data Protection) of this Agreement. If Abbott requests corrective and/or preventive action as a result of its monitoring or audit activities, Institution shall comply with the timely creation and implementation of a corrective action and/or preventive action plan. Abbott's right to audit shall survive the expiration of this Agreement.

   (b) Institution will ensure that subject data, as required in the Protocol, is entered into the CRFs (whether electronic or paper) within five (5) business days of subject visit.

   (c) Unless prohibited by law, Institution will notify Abbott immediately upon receiving any requests by any regulatory authority to inspect or have access to documents related to the Study and will promptly provide Abbott with a copy of any such request, to include copies of any documents received from or provided to regulatory authorities. In the event a regulatory citation or notice is issued which relates to the services under this Agreement, Institution agrees to produce a summary that includes an explanation of the issues identified by the regulatory authority, any response to the significant issues identified by the regulatory authority, and an explanation of the applicability of such regulatory citation or notice to the service(s) provided hereunder. Institution agrees to provide Abbott with such summary within fifteen (15) days of Institution's receipt of any regulatory citation or notice.

   (d) Institution shall retain the Study documents in accordance with applicable laws and regulations or the Protocol, whichever retention period is longer. At Abbott's request and expense, Institution shall retain the Study documents for an even longer period. Institution shall provide Abbott at least sixty (60) days' written notice before deleting any Study documents from its files.

6. Compensation.

   (a) Abbott shall pay Institution in accordance with the Study budget set forth in **Exhibit A** (the "Budget"). In addition, Institution's employees, including Investigator, may be reimbursed for reasonable and necessary expenses related to travel, consistent with Abbott's travel policy (including economy coach air travel, reasonable and customary lodging and meal rates based on the geographic region of travel), and may be provided meals as may be necessary for the publication/ presentation of study results/data or at investigator meetings or other Abbott required meetings. The parties agree that the amounts set forth in the Budget represent the fair market value for the services to be rendered and have not been determined in any manner that takes into account the volume or value of any referrals or business otherwise generated between or among Institution and Abbott.

   (b) The Budget is based on the full performance of services and compliance with the terms of this Agreement (including the Protocol). Abbott will not remit payments for CRFs containing incomplete or inaccurate data or data collected from subjects enrolled in violation of the Protocol ("Non-conforming CRFs"). If Abbott has paid for such Non-conforming CRFs such payment will be deducted from the next payment (or the final payment, as described in **Section 7(d)** below).

   (c) All payments shall be made in accordance with the terms of **Exhibit A** and only after all parties have signed this Agreement. If applicable, reimbursement of IRB/IEC fees is contingent upon completion of the IRB/IEC's review and final decision regarding all submitted Study documents including, but not limited to, the Protocol and/or Protocol revisions. Abbott will not be obligated to reimburse Institution for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

   (d) The final payment due to Institution under this Agreement shall be payable upon completion of all services contemplated hereunder, delivery to Abbott of all CRFs, and return to Abbott of all items described in **Section 5**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(17)

(Delivery of Progress and Post-Study Reports) and will be accompanied by a financial reconciliation performed by Abbott. If the total amount Abbott has paid is less than the amount to which Institution is entitled hereunder as revealed by the reconciliation, Abbott shall pay the outstanding amount due. If Abbott is due a refund for any unearned fees or overpayments, Institution shall remit the amount of such refund with supporting documentation to Abbott at: Clinical Operations, Abbott India Ltd,16th Floor, Godrej BKC,Plot C – 68, "G" Block Bandra Kurla Complex,Near MCA Club, Bandra (East),Mumbai 400 051, India. Any payments due from one party to the other under the reconciliation shall be made within forty-five (60) days of the notice and invoice of amount due.

(e) In the event of a payment dispute, Institution and Investigator shall not withhold Study data or information pending resolution of the dispute because such withholding may cause irreparable harm to the Study.

(f) Upon written notice, Abbott may delegate certain of its payment obligations to a contract research organization ("CRO"). In such event, Institution and Investigator agree that as to any payments delegated by Abbott to a CRO, Institution and Investigator shall first seek redress from the CRO for compensation.

(g) Investigator shall be responsible for direct compensation of Investigator, including any subinvestigators, from funds paid by Abbott to Institution under the Study Budget. Neither Investigator nor any subinvestigators shall receive any separate compensation from Abbott.

(h) In this study; Abbott has delegated its Fee payment obligations under this Agreement to **JSS Medical Research India Pvt Ltd.** The Investigator will hence approach Site Management Organization (SMO) for queries or concerns in relation to compensation under this Agreement.

7. Confidentiality.

(a) During the Term of this Agreement, including any extensions thereof, and for a period of ten (10) years after the expiration or termination of this Agreement, Institution, its employees (including Investigator), agents, subcontractors and affiliates (collectively, "Receiving Party") shall not disclose Confidential Information without Abbott's prior written consent. Notwithstanding the foregoing, obligations of confidentiality and non-use with respect to any Confidential Information identified as a trade secret by Abbott shall remain in place for so long as the applicable Confidential Information retains its status as a trade secret under applicable law. "Confidential Information" shall include any information provided to Receiving Party by or on behalf of Abbott, including but not limited to the Protocol, Abbott Product, Study Materials, and all materials and information concerning Abbott or the Study or developed as a result of conducting the Study, except any portion thereof which:

(i) is known to the Receiving Party prior to receipt, as evidenced by its written records;
(ii) is disclosed to the Receiving Party by a third party who has a right to make such disclosure in a non-confidential manner; or
(iii) is or becomes part of the public domain through no fault of the Receiving Party.

(b) The Receiving Party shall not use Confidential Information for any purpose other than as indicated in this Agreement without Abbott's prior written approval.

(c) Nothing in this Agreement will be construed to restrict Receiving Party from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Receiving Party shall give Abbott prompt written notice (and in any case at least five (5) business days notice) to allow Abbott to take action to protect its Confidential Information. In the event that no protective order or other remedy is obtained, or Abbott waives compliance with the terms of this **Section 8**, Receiving Party shall furnish only that portion of the Confidential Information which is legally required based on the written opinion of legal counsel.

(d) Receiving Party will not disclose to Abbott any information which is confidential or proprietary to a third party unless Institution has first obtained the prior written approval of such third party and Abbott.

8. Subject Confidentiality and Data Protection.

(a) The parties will comply with all applicable laws and regulations regarding Study subject confidentiality and data protection. Investigator will be responsible on behalf of the Institution for obtaining a signed subject authorization document for the use and disclosure of data and an Informed Consent Form, if required (collectively, "ICF") from each Study subject prior to the subject's participation in the Study. The ICF must permit Abbott and its representatives involved with or evaluating the Study to access, process, obtain copies, transfer and retain Study data. Each ICF must conform with the Protocol and be compliant with: International Conference on Harmonisation, Harmonised

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(16)

Tripartite Guidelines for Good Clinical Practice ("ICH"); all applicable laws and regulatory requirements; and must be approved in writing by Abbott, and if applicable by the IRB/IEC. A Study subject's participation in the Study will be contingent upon the execution of a proper ICF.

(b) Where Institution and/or Investigator collects, retains, processes or discloses information identifying or, in combination with other information, identifiable to a living individual, including Study subjects and others participating in or associated with the Study (the "Personal Data") it shall only do so in accordance with this Agreement, with all applicable laws and with Abbott's written instructions. Institution and Investigator shall maintain appropriate safeguards to ensure the confidentiality and security of the Personal Data. Institution and Investigator shall promptly inform Abbott of any unauthorized access to or disclosure of Personal Data (the "Security Breach"), including the timing and nature of the Security Breach. Institution and Investigator shall take all reasonable measures to remedy the Security Breach. Where applicable data protection laws require that the parties enter into additional agreements or undertakings, including international data transfer agreements, Institution will undertake to ensure that all necessary agreements are implemented and in place.

(c) Investigator acknowledges and consents to, and shall cause all subinvestigators for the Study to acknowledge and consent to, Abbott's collection, use, processing, and disclosure of Investigator's and sub-investigator's Personal Data including details of his/her name, address, qualifications and clinical trial experience. Additional uses or disclosures may include financial information (including compensation and reimbursement payments), public registration of the Study on web sites designed for this purpose such as www.clinicaltrials.gov, assessments by Abbott of Investigator's suitability for future studies, and for purposes of complying with applicable laws. Investigator understands and expressly agrees and shall cause all subinvestigators for the Study to expressly agree that this information may, if necessary for these purposes, be made available to ethics committees, government authorities and other companies within the Abbott group of companies located both in the country in which the Study is carried out and in other countries, including in the United States or elsewhere as required by applicable law or as necessary for the purposes of Good Clinical Practice or data protection audits or inspections.

9. Publicity. Institution shall not and shall ensure Receiving Party shall not disclose the existence or terms of this Agreement or use the name, trademark, servicemark or logo of Abbott in any publicity, advertising or information, which is disseminated to any third person or to the general public without Abbott's prior written approval. Institution understands that the terms and conditions of this Agreement, including the amount of any payment made hereunder, may be disclosed and made public by Abbott as required by law or regulation or where Abbott deems appropriate.

10. Inventions. Any information, invention, data or discovery (whether patentable or copyrightable or not), innovation, communication or report, conceived, reduced to practice, made, generated or developed by the Receiving Party that either results from use of Abbott Product(s) or results from conduct of the Study will be promptly disclosed to Abbott, assigned to Abbott and will be the sole property of Abbott. Institution and Investigator each agree, upon Abbott's request and at Abbott's expense, to execute or cause to have executed such documents and to take such other actions as Abbott deems necessary or appropriate to obtain patent or other proprietary protection in Abbott's name covering any of the foregoing.

11. Publications and Presentations.

(a) Publication Requirements. To foster the highest standards of conduct related to scientific publications, including manuscripts, abstracts, and poster/oral presentations (collectively, "Publication(s)"), Abbott is committed to transparency and ethical publication practices. If Investigator serves as an author on any Publication emanating from the Study, Investigator must comply with the Requirements for Scientific Publications attached hereto as **Exhibit B**.

(b) Procedures. As the Study sponsor, Abbott retains the first right to disclose the results of the Study through a Publication or any other public disclosure (collectively, a "Study Results Disclosure"). Accordingly, following the earliest of: (i) Abbott's Study Results Disclosure; or (ii) twelve (12) months after completion or termination of the Study at all Study sites, Institution and Investigator shall have the right to prepare and submit for Publication a Study Result Disclosure in appropriate scientific journals or other professional publications. If Institution or Investigator prepares a Study Results Disclosure, Institution shall provide or shall require Investigator to provide Abbott, at least sixty (60) days prior to any submission of a work for a Study Results Disclosure, with a draft of the same for Abbott's review and comment to ascertain whether any patentable subject matter or Abbott Confidential Information (other than the results of the Study generated hereunder) are disclosed therein. Abbott shall return comments to Institution or Investigator within sixty (60) days after receipt of the draft Study Results Disclosure (the "Review Period"). In addition, Institution or Investigator shall delay any proposed Study Results Disclosure an additional sixty (60) days in addition to the Review Period in the event Abbott so requests to enable Abbott to secure patent or other proprietary protection (the "Delay Period"). Institution agrees and shall require Investigator to agree to keep the proposed Study Results Disclosure confidential until the Review Period and, if elected by Abbott, the Delay Period has expired. Institution agrees and shall require Investigator to agree that due consideration will be given to Abbott comments; and further, Abbott Confidential Information (other than the results of the Study generated hereunder) shall be deleted from any

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(15)

Study Results Disclosure. In the event that Institution or Investigator and Abbott differ in their opinion or interpretation of data in the Study Results Disclosure, the parties shall resolve such differences in good faith through appropriate scientific debate.

12. Representations and Warranties. Institution represents and warrants that:

(a) the terms of this Agreement are valid and binding obligations of Institution, and are not inconsistent with any other contractual or legal obligation it or Investigator may have or with Institution's policies and procedures or the policies and procedures of any institution or company with which each of Institution or Investigator is associated;

(b) Institution's performance of the services and acceptance of compensation, including the acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator or Institution (including its employees and agents) hereunder, is in compliance with all policies and procedures of Institution, and that Investigator's performance of such services does not present a conflict of interest with Investigator's official duties;

(c) Investigator has received any required authorization, written or otherwise, from Institution for Investigator's performance of the services and acceptance of any meals and/or reimbursement of reasonable expenses for investigator meetings or other Abbott required meetings, which may be provided to Investigator hereunder;

(d) If Investigator leaves Institution's employment during the Term, then Institution will promptly notify Abbott in writing and will obtain a written acknowledgement by Investigator's new employer that Investigator is participating in the Study under the terms of this Agreement;

(e) Institution and Investigator have the experience, capabilities, adequate subject population, and resources, including but not limited to sufficient personnel and equipment, to efficiently and expeditiously perform the Study in a professional and competent manner;

(f) any subinvestigators used by Institution for the Study will be selected based upon a consideration of the following: (i) training and expertise in relevant fields; (ii) appropriate research facilities; (iii) experience with the relevant subject population so that the subinvestigator has a reasonably high likelihood of recruiting the appropriate research participants and following through to the completion of the Study; (iv) prior scientific research or clinical experience; and (v) ability to conduct the Study in accordance with applicable legal and regulatory requirements;

(g) Investigator is not under investigation or subject to any disciplinary action by any medical board, and Investigator has a medical license, or equivalent, that has not been restricted or suspended by any medical board in any way. In the event that any of foregoing occurs, Investigator shall immediately notify Abbott, and Abbott shall have the right to immediately terminate this Agreement;

(h) Institution shall ensure that Investigator does not alter in any way Investigator's normal practice for prescribing medications to patients or be influenced in any way to prescribe an Abbott product in place of any other therapy due to the conduct of this Study or payment to Institution of any compensation from Abbott for conducting this Study; and

(i) if any significant changes occur during the Term with regard to the circumstances surrounding this Agreement (e.g., there is a change in a policy or procedure that could reasonably be interpreted to affect the propriety of Institution or Investigator's involvement in this Agreement), Institution agrees to immediately notify Abbott in writing of any such changes.

13. Term and Termination.

(a) This Agreement will be effective on the Effective Date and shall expire on the later of: (i) one (1) year from the Effective Date; (ii) the date of Study database lock if there is subject enrollment under this Agreement; or (iii) the date of completion of all the obligations of the parties hereunder (the "Term"), unless terminated earlier as provided below.

(b) Abbott may terminate this Agreement at any time upon written notice. Either party may terminate this Agreement upon written notice if (i) the other party has breached a material term of the Agreement, or (ii) if the Study is terminated by any governmental or regulatory authority.

(c) Termination or expiration of this Agreement will not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Institution will discontinue all then-enrolled subjects from the Study.

14. Insurance. Each party agrees to maintain a policy or policies of insurance or self-insurance sufficient to satisfy its respective duties and obligations under this Agreement to the extent such duties and obligations are commercially

(N)

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SGPGIMS,Lucknow

insurable. Each party further agrees to provide written evidence of such insurance (including certificates of insurance or other evidence providing reasonable assurances) to the other party within seven (7) business days following receipt of written request by the other party therefore.

15. Debarment and Exclusion. Institution represents and warrants that none of Institution, any Institution employees, including Investigator, agents and subcontractors performing services hereunder, including any subinvestigators, have ever been, are currently, or are the subject of a proceeding that could lead to Institution or such employees, agents or subcontractors becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual, nor are they listed on the United States Food and Drug Administrations (the "FDA") Disqualified/Restricted List for clinical investigators. Institution further covenants, represents and warrants that if, during the Term, Institution, or any of Institution's employees, including Investigator, agents or subcontractors, including any subinvestigators, performing services hereunder, becomes or is the subject of a proceeding that could lead to that party becoming, as applicable, a Debarred, Excluded or Convicted Entity or Individual or added to FDA's Disqualified/Restricted List for clinical investigators, Institution will immediately notify Abbott, and Abbott will have the right to immediately terminate this Agreement. The provision of this paragraph regarding notice of acts occurring during the Term will survive termination or expiration of this Agreement. For purposes of this provision, the following definitions will apply:

    (a) A "Debarred Individual" is an individual who has been debarred by the FDA pursuant to Title 21 of the United States Code ("USC") Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from providing services in any capacity to a person that has an approved or pending drug product application.

    (b) A "Debarred Entity" is a corporation, partnership or association that has been debarred by the FDA pursuant to Title 21 of USC Section 335a (a) or (b) by any other competent authority, including, without limitation, any local competent authority from submitting or assisting in the submission of any abbreviated drug application, or a subsidiary or affiliate of a Debarred Entity.

    (c) An "Excluded Individual" or "Excluded Entity" is (i) an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal health care programs such as Medicare or Medicaid by the Office of the Inspector General of the U.S. Department of Health and Human Services; or (ii) is an individual or entity, as applicable, who has been excluded, debarred, suspended or is otherwise ineligible to participate in federal procurement and non-procurement programs, including those produced by the U.S. General Services Administration.

    (d) A "Convicted Individual" or "Convicted Entity" is an individual or entity, as applicable, who has been convicted of a criminal offense that falls within the ambit of Title 21 of USC Section 335a(a) or Title 42 of USC Section 1320a – 7(a), but has not yet been excluded, debarred, suspended or otherwise declared ineligible.

    (e) "FDA's Disqualified/Restricted List" is the list of clinical investigators restricted from receiving investigational drugs, biologics, or devices if FDA has determined that the investigators have repeatedly or deliberately failed to comply with regulatory requirements for studies or have submitted false information to the study sponsor or the FDA.

16. Independent Contractor. Each of Institution and Investigator's relationship to Abbott under this Agreement is that of an independent contractor, and neither Institution nor Investigator has authority to bind or act on behalf of Abbott.

17. Assignment. Institution may not assign this Agreement to any other party, or subcontract any of its services hereunder, without Abbott's prior written consent. Any attempted assignment without Abbott's prior written consent will be null and void and will constitute a material breach of this Agreement. Any permitted assignee shall assume all obligations of Institution under this Agreement. Assignment shall not relieve Institution of responsibility for the performance of any accrued obligation. Further, in the event that Institution is permitted to subcontract any duty hereunder to any third party, such subcontractor shall execute an agreement in a form acceptable to Abbott obligating such subcontractor to comply with the terms and conditions hereof, and Institution shall remain responsible and liable for the acts or omissions of such subcontractor activities as if such activities had been performed by Institution.

18. Subinvestigators. Institution will not use any subinvestigator for the Study without Abbott's prior written consent, and only upon Institution's agreement to ensure any subinvestigators compliance with the terms and conditions of this Agreement.

19. Notices. Any notice required or otherwise made pursuant to this Agreement shall be in writing, personally delivered or sent by certified mail, return receipt requested, or recognized courier service, properly addressed, or by facsimile with confirmed answer-back, to the other party at the address set forth below. Notices shall be deemed effective (a) on the date received if personally delivered or sent by certified mail or recognized courier, or (b) upon the date of confirmed answer-back if sent by facsimile.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(13)

If to Institution
Dr. Usha Kant Misra

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

Phone: +91- 8004904627.

If to Investigator:
Dr. Usha Kant Misra

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

Phone: + 91- 8004904627.

If to Abbott:
Sneha Nair,
Head- Clinical Operations,
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C- 68, BKC,Near MCA Club,
Bandra (E)
Maharashtra- 400051, India
Direct 91-22 38160910,
Mobile No : +91-9970780488

with a copy to:
Kaiyomarz Marfatia
Director- Legal & Secretarial
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C-68, BKC,Near MCA Club,
Bandra (E)
Mumbai-400051,
Maharashtra, India
Phone:91-022-28717488

20. Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination of the Agreement, will remain in full force and effect.

21. Severability. If any provision, right or remedy provided for herein is held to be unenforceable or inoperative by a court of competent jurisdiction, the validity and enforceability of the remaining provisions will not be affected thereby.

22. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same agreement. Each party acknowledges that an original signature or a copy thereof transmitted by facsimile or by PDF shall constitute an original signature for purposes of this Agreement.

23. Applicable Law, Place of Venue-The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof. The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, India will have sole jurisdiction over the litigation

24. Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the Parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Act. The arbitration shall take place in Mumbai and shall be conducted in the English language. The award of the arbitrator shall be final and binding on both parties.
The parties bind themselves to carry out the awards of the arbitrator. This Section shall survive termination or expiration of this Agreement.

25. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties. This Agreement is being signed in the English language only. If another language version is created, it shall not affect the interpretation of this Agreement and the English language version shall prevail.

26. Financial disclosure certification: Prior to the initiation of the study, institution will ensure that each investigator and any sub investigator(a) completes and returns to Abbot the financial disclosure certification. Investigator understands and will be required to certify that investigator and all sub investigator conducting the study, and their immediate families may not have a direct ownership interest(e.g., intellectual property rights) in the Abbott Product, nor may they be compensated with

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Executive Registrar
SGPGIMS,Lucknow

(12)

If to Institution
Dr. Usha Kant Misra

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

Phone: + 91- 8004904627.

If to Investigator:
Dr. Usha Kant Misra

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

Phone: + 91- 8004904627.

If to Abbott:
Sneha Nair,
Head- Clinical Operations,
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C- 68, BKC,Near MCA Club,
Bandra (E)
Maharashtra- 400051, India
Direct 91-22 38160910,
Mobile No : +91-9970780488

with a copy to:
Kaiyomarz Marfatia
Director- Legal & Secretarial
Abbott India Limited,
Floor 16, Godrej BKC,
Plot No.C-68, BKC,Near MCA Club,
Bandra (E)
Mumbai-400051,
Maharashtra, India
Phone:91-022-28717488

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23. Applicable Law, Place of Venue-The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof. The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, India will have sole jurisdiction over the litigation

24. Arbitration. Any dispute, controversy or claim arising out of or relating to this Agreement which cannot be resolved within thirty (30) days by mutual consent of the Parties, shall be settled by arbitration in accordance with the Indian Arbitration and Conciliation Act, 1996, as amended from time to time, by one arbitrator appointed in accordance with the said Act. The arbitration shall take place in Lucknow and shall be conducted in the English language. The award of the arbitrator shall be final and binding on both parties.
The parties bind themselves to carry out the awards of the arbitrator. This Section shall survive termination or expiration of this Agreement.

25. Entire Agreement. This Agreement, including all exhibits hereto, contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties. This Agreement is being signed in the English language only. If another language version is created, it shall not affect the interpretation of this Agreement and the English language version shall prevail.

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Abbott securities in exchange for being an Investigator or subinvestigator in the Study. Investigator and any subinve... will promptly notify Abbott of any change in the accuracy of the Financial Disclosure Certification during the Term and for one (1) year following completion of the Study.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives.

ABBOTT INDIA LIMITED

By: _____

Name: Sneha Nair

Title: Head-Clinical Operations

Date: 25/07/2019

INVESTIGATOR NAME

By: _____

Name: Dr. Usha Kant Misra

Title _____

Date: _____

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES

By: _____

Name: Prof. Rakesh Kapoor

Title: Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Date: 03.09.2019

Exhibit A - Budget
Attachment 1 to Exhibit A
Exhibit B - Safety Reporting Obligations
Exhibit C- Requirements for Scientific Publications

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SGPGIMS,Lucknow

(10)

EXHIBIT A
BUDGET

INVESTIGATOR	Dr. Usha Kant Misra
ADDRESS	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014
PHONE	+ 91- 8004904627

DISEASE BEING STUDIED: Epilepsy	PROTOCOL: EPIDI066	Visits: Baseline
Number of subjects required per Protocol/Study by Investigator		80
Total per subject cost (see **Attachment 1**, per subject breakdown; payments to be made per the Subject Visit Payments schedule, described below, every 3 months)		INR 1000(Visit) = 1000*
Total cost for all CRFs for all subjects		INR 80,000**
ADDITIONAL STUDY FEES: Payments will be made as follows, in accordance with Compensation Section of the Agreement.		
TOTAL COMPENSATION)		INR 80000

*** On completion of visit 1(Baseline)**
**** depends on the total no of patients enrolled / CRF completed**

SUBJECT VISIT PAYMENT SCHEDULE: Payments will be made as follows, in accordance with the Compensation Section of the Agreement:

Subject Visit Payments: Payments for subject visits will be made quarterly following enrollment of the first subject. Payments will be made after data is entered by Investigator into the CRFs and reviewed by Abbott, and will correspond to amounts listed in **Attachment 1 to Exhibit A**. Investigator understands that such payments are subject to subsequent verification by Abbott and will be adjusted per Section 7(d) (Compensation) of the Agreement if necessary. Total payment mentioned in the agreement is for a recruitment of 20 patients.
A CRO, JSS Medical Research India Private Limited has been contracted to provide the site with a CRC for subject recruitment, source documentation& data entry purpose. The cost of the CRC will be paid by Abbott India Limited to JSS Medical Research India Private Limited.

A final payment shall be made following termination of the Study, delivery to Abbott of the remaining Completed CRF(s), final reconciliation of any remaining amounts due, and the return to Abbott of all items described in Section 4 (Study Supplies) of the Agreement. Abbott will not be obligated to reimburse Investigator for pass-through expenses invoiced to Abbott more than one hundred eighty (180) days after the termination date of this Agreement.

CHECQUE PAYMENT INFORMATION:

Cheque shall be made payable to:	**DIRECTOR SGPGIMS RESEARCH ACCOUNT**
Individual's name and address	Dr. Usha Kant Misra Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow, Uttar Pradesh-226014
Individual's name and e-mail address at site to receive detailed payment information:	Dr. Usha Kant Misra drukmisra@rediffmail.com
Individual's name and address to receive Invoices at Abbott:	Dr. Prachi Sudhir Bhoyer Site Management, JSS Medical Research India Private Limited
Pan Card Number of Institute:	**AAAJS3913N**

(Information must be accurate for FDA purposes)

(N)

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SGPGIMS,Lucknow

(9)

NEFT payment Information:

Payee Name:	**DIRECTOR SGPGIMS RESEARCH ACCOUNT**
Bank Account No.	**10095237491**
IFSC Code:	**SBIN0007789**
Bank Name, Branch & address:	**STATE BANK OF INDIA** **SGPGIMS, LUCKNOW.**
GSTN, If applicable:	**09AAAJS3913N2ZN**

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(8)

ATTACHMENT 1 TO EXHIBIT A

Study Budget Breakdown

- **For participation as Principal investigator**

  1. Scope of work

  Table 1: Subject grant

  Fee Per completed CRF per Subject- 1000

  Other Payment terms:

- **Cost for minimum 80 patients completing the study = 80*1000**
- **Total Investigator Grant = INR 80,000/-**
- **Per patient grant as outlined in table 1, is inclusive of overheads**
- **With reference to clause 8/g towards compensation: Abbott India Limited has delegated its payment obligation towards the investigators to a service provider (i.e. JSS Medical Research India Private Limited). Thus payment shall be made from Abbott to Investigator through (JSS Research).**
- **An invoice addressed to Abbott India Limited will have to be provided by the investigator (on institution letterhead) to the personnel from JSS Research India Private Limited prior to release payment. A template for the same will be shared by JSS Research. Any and all invoices raised by the institution/ site under the agreement shall be paid by the Abbott within 60 days from the date of the receipt of the invoice from the institution/ site to the Abbott.**
- **Travel Expenses: Expenses towards domestic travels, hotel stay, meal and car rental for any of the study related meeting would be done by Abbott with prior written approval from Abbott.**
- **All payments under this agreement are subject to applicable taxes including service tax and the same shall be borne by Abbott. As per the Indian Tax Laws TDS would be applicable. A TDS certificate would be provided to your site before the end of the financial year.**
- **Payment will be released within 60 days of receipt of the invoice.**

(N)

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SGPGIMS,Lucknow

(9)

EXHIBIT B

SAFETY REPORTING OBLIGATIONS

(a) Institution and Investigator shall comply with all applicable adverse event reporting and other regulatory obligations applicable for investigators and Abbott shall comply with all applicable adverse event reporting and other regulatory obligations applicable for sponsors. In addition, Institution and Investigator shall report to Abbott the following Pharmacovigilance-relevant information if spontaneously reported to Institution or Investigator and only in case relating to an Abbott product(s):

(i) adverse reactions (a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility);

(ii) product exposure (including maternal, paternal or fetal exposure) associated with a pregnancy;

(iii) trans-mammary exposure of an infant (transmission via breast milk) to a product;

(iv) overdose (i.e. administration of a quantity of a medicinal product given per administration or cumulatively which is above the maximum recommended dose according to the authorized product information (Note: Clinical judgment should always be applied));

(v) abuse (i.e. persistent or sporadic, intentional non-therapeutic excessive use of a product by patient/consumer which is accompanied by harmful physical or psychological effects)

(vi) misuse (i.e. intentional and therapeutic but inappropriate use of a product by patient/consumer not in accordance with the authorized product information);

(vii) off-label use (i.e. intentional prescribed therapeutic use of a product not in accordance with the authorized product information);

(viii) occupational exposure (i.e. exposure to a product as a result of one's professional or non-professional occupation);

(ix) medication errors (i.e. unintended failure by patient/consumer or health care professional in the drug treatment process that leads to, or has the potential to lead to, harm to the patient);

(x) lack of therapeutic efficacy (i.e., "lack of effect" reports), which will be handled as a serious adverse reaction if associated with vaccine or contraceptive product or drugs used for critical conditions or for the treatment of life-threatening diseases;

(xi) suspected transmission of an infectious agent, which will be classified as a serious adverse reaction;

(xii) an unexpected therapeutic or clinical benefit from use of the product.

(b) Such information shall be reported by Institution and/or Investigator to Abbott within 24 hours of becoming aware of such occurrences. Institution and Investigator shall promptly make available to Abbott such records as may be necessary and pertinent to investigate such occurrences.

(N)

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Executive Registrar
SGPGIMS,Lucknow

Exhibit C

REQUIREMENTS FOR SCIENTIFIC PUBLICATIONS

1. Criteria for Authorship. Based on the October 2007 guidelines of the International Committee of Medical Journal Editors (ICMJE), authorship credit must be based on:

   (a) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and
   (b) Drafting or revising the article for important intellectual content; and
   (c) Final approval of the version to be published.

   A person must meet all three of the above criteria to warrant authorship.

2. Acknowledgement of Medical Writers and Other Contributors. Those individuals who have made a significant contribution to the Study or Publication, but do not meet the criteria for authorship noted above, must be listed in an acknowledgments section, including disclosure of the source of any financial support given to such contributors. All persons must give written permission to be acknowledged.

3. Conflict of Interest. In the interest of transparency and maintaining the highest possible standards of conduct, authors will comply with each journal's or congress's requirements for conflict of interest disclosure in the Publication. Such conflict of interest disclosure requirements may include, but are not limited to, disclosure of an author's receipt of research grants, author's receipt of payments for consultant or speaker services, and/or author's ownership of stock.

4. Sponsorship. Authors must acknowledge Abbott as the funding source of a Study, and must also comply with additional sponsorship-related disclosures required by the journal or congress.

5. Access to Data. Abbott will provide all authors with the final Protocol, statistical analysis plan, relevant statistical tables generated from the plan, figures, and reports needed to prepare the planned Publication. Abbott will provide a copy of the Protocol and plan for statistical analysis when requested by a medical journal considering a submitted manuscript for publication, with the understanding that the documents are confidential, the property of Abbott, and should not be disclosed to any third party without Abbott's prior written permission.

6. Redundant Publication. Duplicate or redundant publication of the Study results in peer-reviewed journals is not permitted. Secondary Publications that present significant and scientifically sound additional analyses or groupings of data are permitted. Publication of foreign language translations of the original manuscript, in accordance with the policies of the journals involved is permitted. Encore presentation of data, when permitted by scientific congress policy, is permitted.

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Executive Registrar
SGPGIMS,Lucknow

महाराष्ट्र शासन
GOVERNMENT OF MAHARASHTRA
ई-सुरक्षित बँक व कोषागार पावती
e-SECURED BANK & TREASURY RECEIPT (e-SBTR)

16256323503175

Bank/Branch: IBKL - 6910820/BANDRA KURLA COMPLEX, MUMBAI
Pmt Txn id : 216266650 Stationery No: 16256323503175
Pmt DtTime : 23-MAY-2019@18:01:43 Print DtTime : 23-MAY-2019 20:11:19
ChallanIdNo: 69103332019052350892 GRAS GRN : MH001849764201920S
District : 7101-MUMBAI Office Name : IGR182-BOM1_MUMBAI CITY
GRN Date : 23-May-2019@18:01:42

StDuty Schm: 0030045501-75/STAMP DUTY
StDuty Amt : R 5,000/- (Rs Five, Zero Zero Zero only)

RgnFee Schm: 0030063301-70/Registration Fees
RgnFee Amt : R 0/- (Rs Zero only)

Article : 13-Bond
Prop Mvblty: N.A. Consideration: R 25,00,000/-
Prop Descr : 101AWINGFULCRUMHIRANANDANIBUSINESSPARKSAHARROADANDHERIEMUM400099

Duty Payer: PAN-AADCP2043E,PPD PHARMACEUTICAL DEVELOPMENT INDIA PVT LTD

Other Party: PAN-AAAJS3913N,DIRECTOR SGPGIMS RESEARCH ACCOUNTS

Bank official1 Name & Signature

Bank official2 Name & Signature

आईडीबीआई बैंक लि. IDBI BANK LTD.

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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("Agreement"), is entered into as of _____ day of _____, ("Effective Date") by and between PPD Pharmaceutical Development India Private Limited, 101-A Wing, 'Fulcrum', Hiranandani Business Park, Sahar Road, Andheri East Mumbai 400 099, India ("PPD"), and Sanjay Gandhi Postgraduate Institute of Medical Sciences ("Institution"), with its principal place of business at Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India, represented by Dr. Rakesh Kapoor, a duly authorized representative with authority to contract on behalf of the Institution and Dr.Narayan Prasad ("Principal Investigator"), with his/her offices located at Sanjay Gandhi Postgraduate Institute of Medical Sciences Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India.

PPD, Institution and Principal Investigator are herein referred to each as a "Party" and, collectively, as the "Parties".

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

e-SBTR IS VALID UPTO SIX MONTHS FROM THE DATE

41

WHEREAS

I. PPD is a global contract research organization that is currently assisting GlaxoSmithKline Research & Development Limited,980 Great West Road Brentford, Middlesex TW8 9GS,United Kingdom ("GSK") or one of its Affiliates in the conduct of the clinical trial in accordance with the protocol entitled "A Phase 3 randomized, open-label, active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of GSK1278863 compared to darbepoetin alfa" ("Clinical Trial"), Protocol Number: "PHI200808" and any amendments thereto ("Protocol"). GSK is the Sponsor of the Clinical Trial. PPD is an Affiliate of PPD International Holdings Inc and has been engaged by PPD International Holdings Inc to support the performance of the Clinical Trial;

II. The Institution and Principal Investigator desire to participate in the conduct of the Clinical Trial, in accordance with the Protocol, herein attached as **Schedule 1**;

III. The Parties agree to conduct the Clinical Trial in accordance with the terms and conditions hereinafter set forth.

THEREFORE, IT IS AGREED AS FOLLOWS:

1. Clinical Trial Performance

1.1 Institution and Principal Investigator shall provide certain services ("Services") related to the conduct of the Clinical Trial, in accordance with the Protocol, hereto attached as **Schedule 1** (and any subsequent amendments made thereto in accordance with this Agreement, and with all applicable laws, rules and regulations relating to the Clinical Trial. The Protocol is subject to approval by the appropriate Institutional Review Board or Ethics Committee or equivalent body (collectively "IRB"). The informed consent ("Informed Consent") is subject to approval by the IRB. If there is any discrepancy or conflict between the terms contained in the Protocol and this Agreement, the terms of the Protocol shall govern and control with respect to clinical matters and the terms of the Agreement shall govern and control with respect to all other matters.

1.2 Prior to the commencement of the Services, Institution and Principal Investigator shall review the Protocol and notify PPD if they cannot comply with any of the terms contained therein. If in the course of performing the Services, in accordance with generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the subjects ("Subject(s)") a deviation from the Protocol is required, such standards will be followed. In such case, the Party aware of the need for a deviation shall immediately notify PPD and GSK of the facts supporting such deviation as soon as the facts are known to such Party. The notification shall also be confirmed in writing within three (3) working days of the original notification being made to PPD and GSK.

1.3 The Institution and Principal Investigator agree to carry out the Services in strict compliance with:

(a) all specifications and timelines established in this Agreement;

(b) the Protocol and any amendments to the Protocol;

(c) the provisions of the current version of the World Medical Association's Declaration of Helsinki, in particular, neither the Institution nor the Principal Investigator must at any time jeopardise the health or well-being of any patient by unwarranted continuation of the Clinical Trial;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

40

(d) applicable national laws, regulations and guidelines including without limitation the "Ethical Guidelines for Biomedical Research on Human Subjects" based on the ICH-GCP laid down by Indian Council of Medical Research (ICMR), and the Guideline for Good Clinical Practice (GCP) of the International Conference on Harmonisation (ICH) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Institution and Principal Investigator. (ICH Topic E6, Consolidated Guideline 1.5.96);

(e) (if the Trial is conducted under an Investigational New Drug (IND) the conditions specified in the Statement of Agreement and in accordance with Rule 122DA(3) of the Drugs and Cosmetics Rules under the Drugs and Cosmetics Act, 1945 (the "Act"); and

(f) Indian GCP and Schedule Y of the Drugs and Cosmetics Act and its amendments.

(g) If the Clinical Trial includes the collection by Institution of human biological materials from Subjects for research use, Institution will comply with all applicable laws, rules, regulations and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Study and with respect to any such human biological materials from the Clinical Trial retained in Institution's possession. Institution and GSK will mutually agree to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Clinical Trial and for research use of any human biological materials, with ethics approval. Institution agrees that any human biological materials collected as part of the Clinical Trial that are transferred to GSK or a GSK contractor, or held by Institution for GSK, will be under the custodianship and control of GSK.

1.4 The Clinical Trial shall be conducted only at the following location: Sanjay Gandhi Postgraduate Institute of Medical Sciences,Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India

1.5 The Institution agrees that the Clinical Trial will be conducted under the direction of the Principal Investigator in accordance with the Protocol and this Agreement.

1.6 The Principal Investigator will perform Services as agreed under this Agreement personally. In the event the Principal Investigator can no longer function in such capacity, then PPD and the Institution shall attempt to agree on a replacement. PPD shall have the right to approve any new principal investigator designated by the Institution. The new principal investigator shall be required to agree to the terms and conditions of this Agreement. If a mutually acceptable replacement cannot be agreed upon, PPD may terminate this Agreement in accordance with Clause 16.

1.7 The Institution and the Principal Investigator shall not subcontract any Services to another person or entity without PPD's prior written approval.

1.8 Notwithstanding anything herein to the contrary, if during the term of this Agreement, information that becomes available to PPD or GSK which affects the safety or efficacy of the Clinical Trial Product (as that term is defined at Clause 3.1 below), or if the Clinical Trial Product is approved by any regulatory agency, the Parties shall negotiate, in good faith, a modification of this Agreement to either (i) reduce the number of Subjects to be studied; and/or (ii) terminate the Clinical Trial, and/or (iii) modify any other relevant provision of this Agreement.

2. Term of Clinical Trial

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Executive Registrar
SGPGIMS,Lucknow

2.1 This Agreement shall take effect on the Effective Date and shall continue until 20 May 2021 ("Expiration Period"), unless terminated in accordance with Clause 16.

2.2 In the event that the Clinical Trial is extended beyond the Expiration Period, the Parties agree that such an extension will be covered by this Agreement and shall not necessitate any amendment to this Agreement. Any continuation of the Services under this Agreement shall be confirmed in writing by PPD, prior to the Expiration Period.

2.3 Notwithstanding the above, the Services will not commence until PPD is granted appropriate IRB and regulatory approval and the Institution has received copies of said approvals.

2.4 Patient recruitment at the Institution is scheduled to start in April 2017 and to be completed by 12 Nov 2019. The Institution shall use its best efforts to complete Subject enrolment by 12 Nov 2019. The Institution shall enroll 15 Subjects in the Clinical Trial ("Enrolment Maximum"). The Institution will not enroll more Subjects than the Enrolment Maximum and neither PPD nor GSK will be obligated to make any payment with respect to any Subject enrolled in excess of the Enrolment Maximum. If, during the Clinical Trial, it becomes apparent that Institution and/or Principal Investigator are not able to complete the Clinical Trial on schedule, they will notify PPD immediately.

2.5 In the event the Institution is unable to complete the enrolment by such date, PPD may reassign the Institution's enrolment slots, thereby reducing the number of Subjects enrolling at the Institution in the Clinical Trial. The Institution acknowledges that the Clinical Trial is part of a multi-center clinical trial. When the enrolment goal of 4500 Subjects for the Clinical Trial as a whole is reached, enrolment will be closed at all institutions, including the Institution, regardless of whether the Institution or any other institution has reached its individual enrolment goal.

2.6 All Subject visits will be completed no later than 25 Feb 2021 ("Visits Completed Date"). All case report form ("CRF") information associated with a Subject's visit must be satisfactorily completed within seven (7) calendar days after the Subject's visit or, if applicable, receipt of the Subject's test results. All final CRF data will be entered into the CRF and submitted to PPD no later than 20 May 2021. All data queries from PPD must be completed and returned to PPD within seven (7) calendar days or, if during final clean up, one (1) calendar day, or such other time set by PPD.

3. Supply of the Clinical Trial Product and Equipment

3.1 During the course of the Clinical Trial, PPD shall procure that GSK will provide the Institution with Daprodustat (GSK1278863) ("Clinical Trial Product") and Placebo and related devices, or other materials as GSK determines necessary for the conduct of the Clinical Trial (collectively, the "Materials").

3.2 The Parties acknowledge that GSK shall be responsible for packaging, labelling and shipping the Clinical Trial Product supplies to the Institution at GSK's own expense and in full compliance with all applicable laws.

3.3 The Clinical Trial Product will be distributed by GSK directly to the Institution's pharmacy, which should already be aware of storage and conservation conditions required for the Clinical Trial Product.

3.4 The Principal Investigator and the Institution: (i) shall use the Materials only to conduct the Clinical Trial in accordance with the Protocol; (ii) shall not chemically, physically, or otherwise modify the Materials, except if specifically required by the Protocol; and (iii) shall handle, store, and ship or dispose of the Materials with appropriate care in compliance with all applicable local, state, and federal laws, rules, and regulations including, but not limited to, those governing hazardous substances.

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3.5 Upon termination of the Clinical Trial or this Agreement, all unused Materials provided by GSK shall be promptly returned at GSK's expense, to an address provided by GSK or, at GSK's option and expense, destroyed with the destruction certified in writing.

3.6 Any Materials provided by GSK or by PPD in the course of the Clinical Trial may not be transferred to any other location or to any third party without the prior written consent of PPD.

3.7 Equipment

(a)Loaned Equipment ("Loaned Equipment") means any equipment temporarily provided to Institution by PPD or Sponsor pursuant to this Agreement only for use in the Study, including, but not limited to computer hardware and software if provided for the Principal Investigator and other staff to use, collect, enter, and report Study data to Sponsor.

b. Transferred Equipment ("Transferred Equipment") means any equipment permanently transferred to Institution by Sponsor or a Sponsor Affiliate pursuant to this Agreement, including, but not limited to computer hardware and software if provided for the Principal Investigator and Study Staff to use, collect, enter, and report Study data to Sponsor.

c. If applicable, with respect to Loaned Equipment provided by Sponsor for use in the Study, Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by PPD or Sponsor, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of Sponsor, and that, at the completion of the Study or at Sponsor's request, Institution will return the Loaned Equipment and all related training materials and documentation to Sponsor or to a vendor designated by PPD or Sponsor.

d. Investigator and Study Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will be responsible for arranging and paying for any required internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. If Institution fails to return the Loaned Equipment within the timeframe specified by PPD or Sponsor, Institution will be responsible for reimbursing PPD for any penalties, late fees, and/or replacement costs.

e. Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights;

(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment; or

(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

4. Obligations of the Parties

4.1 *Institution obligations*

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Institution shall:

(a) be responsible for providing, at its sole cost and expense, the premises, adequate personnel, equipment (subject to Clause 3.7) and other resources necessary to conduct the Clinical Trial, in accordance with this Agreement, the Protocol and the conditions imposed by the IRB;

(b) ensure that the Principal Investigator observes current legislation, strictly complies with this Agreement, the Protocol, ethical regulations on clinical trials with medicines and collaborates in the performance of monitoring visits by PPD, audits by auditors appointed by PPD/GSK or its Affiliates and inspections by competent health authorities;

(c) promptly advise PPD as soon as possible if Institution observes or becomes aware of: (i) material non-compliance with the Protocol, ICH Good Clinical Practice guidelines, or any applicable laws, rules or regulations, (ii) incomplete or inaccurate recording of data or any significant misconduct, (iii) any changes of personnel, facilities or clinical research methods at the Institution that may affect the Clinical Trial, or (iv) any other matters, events, conditions or difficulties that may jeopardize the proper conduct of the Clinical Trial;

(d) notify PPD and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product, in accordance with Clause 11 below and the procedures set forth in the Protocol (**Schedule 1**);

(e) maintain adequate records with respect to Clinical Trial Subject identification, clinical observations, laboratory tests, and Clinical Trial Product receipt and disposition;

(f) cooperate with PPD and GSK or its Affiliates in their efforts to monitor the Clinical Trial at the Institution premises;

(g) use the data obtained from the Clinical Trial Subjects only for the purposes and in connection with the Clinical Trial and as outlined in the Protocol; and

(h) obtain written consent from all individuals providing services on behalf of Institution with respect to the Clinical Trial, including (without limitation) sub-investigators, study coordinators and other Institution employees, agents or subcontractors ("Study Staff") that allows GSK, GSK's Affiliates, and third party suppliers working for GSK or its Affiliates to hold and process personal data provided with respect to Study Staff anywhere in the world, both manually and electronically, for all purposes relating to the performance of this Agreement, for the purposes of administering and managing the business activities of any company in the GSK's group, and for compliance with applicable procedures, laws, and regulations.

4.2 *Principal Investigator Obligations*

Principal Investigator shall:

(a) be responsible for overseeing all medical aspects of the Clinical Trial;

(b) ensure that the Clinical Trial activities are performed in accordance with the Protocol, the guidelines provided by the correspondent IRB, the terms of this Agreement and any other local applicable legislation to the performance of clinical trials in human subjects;

(c) oversee the submission of IRB and Ethical Approval;

(d) oversee the enrolment of patients at the Institution, in accordance with the inclusion/exclusion criteria defined in the Protocol;

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SGPGIMS,Lucknow

(e) inform all individuals to be enrolled in the Clinical Trial before they agree to participate in the Clinical Trial about the purpose(s), methods and conditions of conducting the Clinical Trial, its expected therapeutic benefit and Clinical Trial-related risk;

(f) oversee and review all case report forms ("CRFs") for accuracy and completeness and to provide these forms and any other Clinical Trial data or samples to PPD in accordance with Clause 2.6 and in the format and manner agreed upon by the Parties and in an anonymised form;

(g) obtain a signed Informed Consent from each Subject recruited for the Clinical Trial (or if permitted, their legal representative), in accordance with this Agreement, applicable local laws and regulations. The form of such Informed Consent must be the most current form approved by the IRB, GSK and PPD, and must contain language necessary to permit regulatory agencies, the IRB, GSK and its Affiliates and PPD to have full access to and use of personally identifiable information, including patient health information, as defined in applicable privacy laws, rules and regulations and according to internationally recognized standards and data protection principles;

(h) not allow a Clinical Trial Subject to be enrolled simultaneously in this Clinical Trial and another clinical trial without PPD and GSK prior written approval;

(i) ensure that all Clinical Trial data, Clinical Trial records and CRFs, including any documents which identify and link each Clinical Trial Subject to their CRF, are stored securely, such that they are accessible only with the knowledge of the Institution and the Principal Investigator;

(j) promptly report (in writing) any serious or unexpected adverse events to the GSK, PPD and the IRB; in accordance with Clause 11 below and following the procedures set forth in the Protocol;

(k) notify GSK, PPD, and the IRB, in writing, of any deviations from the Protocol;

(l) engage with GSK in the collaboration of the final report of the Clinical Trial, granting approval thereto upon signing it;

(m) report on the progress of the Clinical Trial to the IRB (as appropriate);

(n) perform the Services in accordance with the highest professional standards of skill, care and diligence and in compliance with all applicable laws and regulations;

(o) notify PPD of any provisions in its local law, or of any changes in that law, which do or could affect the Principal Investigator's ability to conduct the Clinical Trial or to perform his/her duties as defined in this Agreement;

(p) provide PPD with the complete results of the tests and all of the data obtained during the Clinical Trial;

(q) submit all data and other information related to the Clinical Trial in a timely manner;

(r) cooperate with PPD, GSK and its Affiliates and regulatory authorities in all their efforts to monitor the Clinical Trial and conduct audits and inspections;

(s) within twenty four (24) hours of first knowledge of any SAE (as that term is defined at Clause 11.1 below), notify PPD, and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product and follow the procedures set forth in the Protocol and Clause 11;

(t) if he/she is not able to continue as Principal Investigator by reason of retirement, transfer or similar reasons, he/she shall provide written notice to PPD as soon as possible and at least within three (3) weeks of such departure; and

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(u) inform the patients involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file whose ownership correspond solely to GSK. Principal Investigator shall collect and process all personal data in accordance with applicable local regulation on personal data on behalf of GSK and only throughout the duration of the agreement signed with GSK and only for the purposes established in the said agreement.

4.3 PPD Obligations

PPD shall:

(a) be responsible for obtaining regulatory approval for the Clinical Trial;

(b) be responsible for the submission to the IRB and any competent regulatory authority.

(c) be responsible for the monitoring of the Clinical Trial;

(d) provide to the Institution the Protocol, Informed Consent forms and required number of CRFs; and

(e) inform the Institution and the Principal Investigator of chemical/pharmaceutical, toxicological, pharmacological and clinical data and results to justify the design and duration of the Clinical Trial.

5. Funding of the Clinical Trial and Payments

5.1 As consideration for the performance under the terms and conditions of this Agreement, PPD will pay the Institution in accordance with **Schedule 2.** Institution will not be compensated for any Subjects who were enrolled without a properly executed informed consent form or who do not meet the inclusion/exclusion criteria for the Clinical Trial. The Institution shall be responsible for compensating all other entities and individuals who were involved in the conduct of the Clinical Trial, including (without limitation) the Principal Investigator and the Study Staff.

5.2 Payments under this Agreement are pass-through payments from GSK. PPD shall make payment to the Institution, in accordance with **Schedule 2**.

5.3 Payments are dependent upon the reports and other information pursuant to Clauses 4.1 and 4.2 being submitted in a timely and satisfactory manner. Payment for partially completed Services, e.g, early withdrawal of Subject, shall be made on a pro-rata basis for Services performed according to **Schedule 2**. No payment will be due or paid for Services performed that are deemed violations of or deviations from the Protocol or this Agreement.

5.4 Invoices are payable within sixty (60) days following receipt of a valid invoice, as described in Section 2 of **Schedule 2**, but Institution hereby acknowledges and agree that payments due under this Agreement shall be made by PPD once said payments are received by PPD from GSK. PPD shall exercise reasonable efforts to ensure timely receipt of pass-through payments from GSK.

5.5 Payments for Services rendered under this Agreement shall be made in full in accordance with the Agreement, without deductions for taxes of any kind. Any taxes due and payable as a result of the payments by PPD to the Institution shall be Institution's sole responsibility and Institution shall pay all such taxes for which it is liable in a timely manner.

5.6 PPD will reimburse the Institution for travel costs incurred by Subjects in accordance with **Schedule 2**.

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5.7 The Institution acknowledges and agrees that it shall be solely responsible for paying the appropriate amount of all federal and local taxes/including VAT with respect to all fees and compensation paid pursuant to this Agreement.

5.8 Institution and Principal Investigator agree that GSK or its Affiliates may make public the amount of funding provided to the Institution by PPD for the conduct of the Clinical Trial and may identify the Institution and the Principal Investigator as part of this disclosure. Institution has obtained the Principal Investigator's consent to this disclosure.

5.9 The amounts paid under this agreement are bona fide fair market value compensation for the work conducted under this Agreement. The parties agrees that no payments by GSK pursuant to this agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of GSK products. Notwithstanding the foregoing, commercially reasonable payments to a subcontractor who is performing services under the terms of this agreement that meet the criteria for bona fide services are not considered to be a pass-through rebate or discount payments (even if the subcontractor is a GSK customer).

5.10 Statement of Investigator Financial Interest form

The Principal Investigator hereby acknowledges the requirements of the FDA Financial Disclosure Rule and agrees to fill in and return to PPD, upon PPD or PPD representative's request, the Statement of Investigator Financial Interest form before the start of the Study. The Principal Investigator also consents to the disclosure of the so filled Form to the FDA if necessary.

5.11 Institution and Principal Investigator shall not charge any Subject or third-party payor for Clinical Trial procedures required by the Protocol that are paid for by PPD or GSK under this Agreement or for any Clinical Trial Product that is provided or paid for by PPD or GSK under this Agreement.

5.12 All of Sponsor's payment obligations are conditioned upon Institution reporting to PPD and/or Sponsor all data required by the Protocol and other governing documents for the Study, including all adverse events, and upon Institution's compliance with standards identified in this Agreement

6. Clinical Trial Subject

6.1 Informed Consent of each of the Subjects participating in the Clinical Trial shall be obtained in accordance with applicable local laws and regulations in India, including completion of the approved Informed Consent form, which has been approved by the IRB. The Institution/Principal Investigator shall administer the Clinical Trial Product only to Subjects from whom Informed Consent has been properly obtained by the Principal Investigator under Clause 4.2(g) and this Clause 6. The Institution/Principal Investigator shall maintain adequate documentation of its obtainment of the Informed Consent of each Subject.

6.2 PPD, the Institution and the Principal Investigator shall hold in confidence the identity of the Subjects and shall comply with all applicable laws regarding the confidentiality of their identities and their individual medical records.

6.3 The method of explanation to the patient and the obtaining of consent should be conducted in accordance with the directions of the IRB and is a Principal Investigator responsibility. Each Subject shall be provided with their own copy of the patient information sheet which they can retain for their own records.

7. Clinical Trial Results and Intellectual Property

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Executive Registrar
SGPGIMS,Lucknow

7.1 The Parties are in agreement that all of the Materials and data gained through the conduct of the Services shall be the property of GSK.

7.2 GSK shall exclusively own all rights, title ("Rights") in and to any invention, and interest in and to inventions (in any clinical specimens or samples obtained from the Subject), discoveries, know-how, patents (whether patentable or not), copyright, trade secrets and other intellectual rights, including but not limited to inventions, discoveries and technology relating to the Clinical Trial Product or otherwise generated by the Clinical Trial (collectively, "Inventions"). The Institution and Principal Investigator hereby irrevocably transfer and assign any and all their Rights in any Invention to GSK. The Inventions will be the sole property of GSK.

7.3 The Institution and Principal Investigator agree to: (i) immediately notify in writing to PPD of any Invention, and (ii) to cooperate and assist GSK to apply for and to execute applications, assignments, affidavits, or other documents, reasonably necessary to obtain any patent, copyright, trademark or other statutory protection for the Inventions, as GSK deems appropriate, and (iii) to treat all Inventions as confidential information in accordance with Clause 8.

7.4 Neither the Institution nor the Principal Investigator shall acquire any rights of any kind with respect to the Inventions or to the Clinical Trial Product.

7.5 The obligations of this Clause shall survive after the term or termination of this Agreement.

8. Confidential Information

8.1 Institution/Principal Investigator and their employees and agents and third parties involved in the study by the Principal Investigator and/or Institution shall not disclose to any third party or use for any purposes other than for the performance of the Clinical Trial any data, records or other information (hereinafter, collectively "Information") disclosed to Institution/Principal Investigator by GSK or PPD or generated as a result of this Clinical Trial without the prior written consent of GSK and shall sign a written non-disclosure agreement. Such Information shall remain the confidential and proprietary property of GSK and shall be disclosed only to Institution/Principal Investigator and their employees or agents who have a "need to know". The obligation of nondisclosure shall not apply to the following Information:

(a) that is generally known to the public or that becomes publicly available through no act or omission on the part of Institution/Principal Investigator;

(b) that is disclosed to Institution/Principal Investigator by a third party legally entitled to disclose such information;

(c) which the Institution/Principal Investigator, as applicable, can demonstrate that it possessed prior to, or developed independently from, disclosure or development of this Agreement;

(d) that is required by law to a government authority or by order of a court of competent jurisdiction, provided that (i) such disclosure is subject to all applicable governmental or judicial protection available for like material; (ii) reasonable advance notice is given to GSK; and (iii) all reasonable steps to limit the scope of such disclosure have been taken.

8.2 The obligations of this Clause shall survive after the term or termination of this Agreement.

9. Publications

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9.1 SPONSOR will post a Study Protocol summary on a publicly available protocol register prior to the enrollment of Study subjects.

9.2 SPONSOR will post a Study results summary on a publicly available results register no later than twelve (12) months following completion of the Study at all Study sites. Posting of summary Study results may occur prior to publication of Study results in the peer-reviewed literature.

9.3 SPONSOR will seek to publish the Study results in the searchable, peer reviewed scientific literature in the form of a publication or presentation of Study results from all Study sites (a "Multicenter Publication"). In the event a proposed manuscript is not accepted for publication or publication is otherwise not feasible (e.g., early-stage studies of a terminated product), SPONSOR will include results conclusions and context on the SPONSOR's Clinical Study Register to supplement the Study results summary.

9.4 Any participation of Principal Investigator or other representatives of Institution as a named author of this Multicentre Publication will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts, and Institution and Principal Investigator acknowledge that the enrollment of Study subjects alone is not a qualification for authorship. If the Principal Investigator or other representative of Institution is a named author of the Multicenter Publication SPONSOR and Institution (on behalf of such authors at Institution) agree that authors: (a) will have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication; (b) will adhere to ICMJE requirements regarding authorship; (c) will disclose as part of the Multicenter Publication that SPONSOR financially supported the Study and any personal financial relationship with SPONSOR; that SPONSOR has made substantial contributions to the study and that SPONSOR has given or will give final approval to the version of the Multicenter Publication ultimately published; and (d) upon completion of author activities will certify in writing to the foregoing and that the authored publication is fair, accurate, and balanced.

9.5 Institution and Principal Investigator agree that SPONSOR may make public the names of the Principal Investigator and the Institution as part of a list of investigators and institutions conducting the Study when making either protocol or results summary register postings. Institution and Principal Investigator agree that SPONSOR may make public the amount of funding provided to Institution by SPONSOR for the conduct of the Study and may identify Institution and Principal Investigator as part of this disclosure. Principal Investigator agrees that, if Principal Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Drug or that otherwise relates to SPONSOR, Principal Investigator will disclose that he/she was an investigator for the Study.

9.6 Site, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Site's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any SPONSOR Confidential Information other than the Study results from Institution's Study data. Institution shall submit to SPONSOR for review and comment any proposed Institution Publication at least sixty (60) days prior to submitting the Institution Publication to any third party. If SPONSOR requests a delay in order to enable intellectual property rights to be secured, Institution agrees to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after SPONSOR's request. Institution also agrees that any Institutional Publication shall only be made after the Multicenter Publication, provided that the Multicenter Publication is submitted within twelve (12) months after conclusion of the Study at all sites. Institution agrees that SPONSOR's financial support of the Study will be disclosed in any Institution Publication and will require all authors of such Institution Publication to disclose any financial relationship with SPONSOR. Institution shall ensure that Principal Investigator complies with the obligations identified in this subsection.

Lt Col Varun Bajpai VSM
Executive Registrar
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9.7 The obligations of this Section shall survive termination of this Agreement.

(31)

10. Data Protection

10.1 Institution and Principal Investigator shall comply and shall require any of the persons or entities performing the Services on their behalf to comply, with all applicable laws, rules, regulations, and guidelines governing the privacy of personally identifiable information and patient health information in India.

10.2 PPD guarantees that the Protocol establishes the mechanisms that allow the disassociation of data with a personal nature of the Subjects participating in the Clinical Trial.

10.3 Institution assures PPD and GSK that the Principal Investigator shall inform the Subjects involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file which is owned by GSK. All personal data collected shall be treated with the privacy, confidentiality and safety measures established by the relevant applicable regulation.

11. Adverse Events Reporting

11.1 For the purposes of this Agreement an Adverse Event ("AE") shall mean any untoward medical occurrence whether thought to have been caused by the Materials or the Clinical Trial or not and Serious Adverse Event ("SAE") shall mean any adverse event which is fatal, life threatening, disabling or incapacitating, requires in-patient treatment or prolongs existing hospitalization, is a congenital anomaly in the off-spring of the patient or which may require intervention to prevent the previously stated outcomes.

11.2 Any SAE must be reported as defined in the Protocol within twenty four (24) hours of first knowledge of any SAE and using the electronic Case Report Form ("eCRF"). This applies also for any event that could affect the safety of the study participants or the conduct of the Clinical Trial.

11.3 The Institution is responsible for ensuring that the Principal Investigator notifies GSK, the Institution and the Responsible Ethics Committee of any Adverse Events (including Serious Adverse Events) that occur during the course of the Clinical Trial in accordance with the Protocol, and relevant ethical and regulatory guidelines, and in the case of the Institution and the Responsible Ethics Committee with their policies and procedures.

11.4 Nothing in this Agreement shall remove or restrict any obligation on Institution and/or Principal Investigator to report clinical safety information arising during the Clinical Trial to the regulatory authorities in India, in accordance with the local requirements or comply with any other legal or administrative obligation in connection with the Clinical Trial.

11.5 The Institution shall monitor the Subjects in accordance with the Protocol. The Institution shall require the Principal Investigator to promptly (within twenty-four (24) hours of the occurrence of any SAE) report via the electronic eCRF all SAEs that may be associated with the administration of the Clinical Trial Product that occurs during the course of the Clinical Trial. Failure to comply with this Clause shall constitute reasonable grounds for PPD to terminate this Agreement as provided in Clause 16.

11.6 In the event that GSK maintains its own Investigator Brochure(s) ("IB(s)") for the Clinical Trial Product(s) being investigated under the Clinical Trial, regardless of the indication under study, GSK will provide these IB(s), and any updates and/or supplements to these IB(s), to the Institution during the course of the Clinical Trial for information purposes.

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SGPGIMS,Lucknow

11.7 Outputs from the Clinical Trial Independent Data Monitoring Committee ("IDMC") (including, but not limited to, meeting minutes, interim analyses and any recommendations or requests made by the IDMC to Institution, which address the safety of the Clinical Trial Subjects) and other pertinent data will be provided by Institution to PPD as they become available.

11.8 Sponsor agrees to reimburse the Institution/Principal Investigator for reasonable and necessary medical expenses incurred as a direct result of diagnosing and treating of an SAE related to the Trial Product and study related procedure and incurred during the course of the Clinical Trial, provided that the Trial Product was administered in accordance with the Protocol and the SAE did not occur as a direct result of the Institution or Principal Investigator's negligence or misconduct. The Institution/Principal Investigator agrees to treat any such illness or injury. Payments will be made following an invoice per treatment and confirmation by Sponsor or PPD that the treatment has been performed as a result of such SAE. Institution or Principal Investigator will provide all information reasonably requested by Sponsor or PPD to confirm such treatment.

11.9 Without prejudice to the foregoing if injury is suffered by a Clinical Trial Subject while participating in the Clinical Trial, the Sponsor agrees to operate in good faith in accordance with the guidelines entitled "GlaxoSmithKline's – Clinical Trial Compensation Guidelines" (refer **Schedule 5**) and Indian GCP, and the Principal Investigator shall make clear to the Clinical Trial Subjects that the Clinical Trial is being conducted subject to these Guidelines.

12. Recordkeeping and Audits

12.1 The Institution and Principal Investigator shall keep complete and systematic data related to the Clinical Trial and the Services performed and any other records generated as a part of this Agreement for a minimum period of twenty five (25) years, or as agreed by the Parties, or as required by applicable local regulation.

12.2 Upon the expiration of the above time period, prior to disposing of such records the Institution/Principal Investigator shall notify GSK and if GSK requests, shall deliver such records to GSK rather than dispose of them.

12.3 During the Institution's regular business hours and with reasonable advance notice, PPD, GSK or its Affiliates or their designee may audit the Institution's records, facilities, equipment, or procedures related to Institution's obligations under this Agreement. Such audits may include, without limitation, Institution's records related to the Clinical Trial and the performance of the Services, in order to verify Institution's compliance.

12.4 If any governmental or regulatory authority notifies the Institution/Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Clinical Trial and/or the Services under this Agreement, Institution/Principal Investigator shall co-operate with the authority and notify PPD and GSK as soon as is practicable (to the extent possible, within two (2) business days and prior to the inspection or action), allow the authority to conduct an inspection or take other legal action, allow PPD and GSK to be present at the inspection or participate in any response to the action, and provide PPD with copies of any reports issued by the authority and Institution's proposed response for GSK's prior review and approval (such approval not to be unreasonably withheld).

13. Insurance

13.1 PPD declares that an insurance policy to cover the conduct of the Clinical Trial, in pursuance of current national laws, is in place and hereto attached as **Schedule 3**. Said policy shall be maintained and updated throughout the duration of the Clinical Trial.

13.2 The insurance of the Sponsor does not relieve the Investigator, Institution and/or their agents participating in the Clinical Trial from their obligation to be liable and responsible to GSK and

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Executive Registrar
SGPGIMS,Lucknow

PPD for their own negligence and wilful misconduct, or their failure to adhere to the terms of the Protocol or any laws or regulation applicable to the Clinical Trial. The Principal Investigator and Institution each represent and warrant that they possess, through insurance or otherwise sufficient financial resources to meet their obligations under this Agreement. The Institution shall provide evidence of its insurance upon request by PPD.

14. Representations and Warranties

14.1 Institution and Principal Investigator represent and warrant to the best of their knowledge, that the Institution and the Principal Investigator are not bound by any other agreement which could prevent, or be violated by, or under which there would be a default as a result of, the execution and performance of this Agreement, and that each will not enter into any such conflicting agreements during the term of this Agreement.

14.2 Institution represents and warrants that all persons involved in the Clinical Trial and the Principal Investigator (i) have not been debarred or convicted of a crime which could lead to debarment under any applicable law, rule or regulation; (ii) have not been disqualified as a testing facility under applicable local regulation; or (iii) are not disqualified as a clinical investigator under applicable local regulation. If such persons later become debarred or receive notice of any action or threat of action with respect to debarment and Institution/Principal Investigator gain knowledge thereof, PPD will immediately be notified.

14.3 Institution represents to Sponsor that medical care for the disease or condition to which the Study relates is available to Study subjects following the Study in accordance with local standard of care through the usual operations of the local healthcare system, and that upon completion of the Study, Institution will appropriate transition Study subjects from the Study to such medical care or refer Study subjects to a health care provider for such medical care.

14.4 Institution shall indemnify GSK and PPD against all direct losses, damages, liabilities and expenses (including legal expenses) incurred by PPD and/or GSK as a result of any breach of the warranties contained in this Clause.

14.5 Principal Investigator hereby warrants that he is authorized to perform the Services at the Institution premises under his/her own name and that the performance of the correspondent agreement and the acceptance of any payments is not in violation of legal or internal regulations of the Institution or other entity to which Principal Investigator is associated or any agreement to which Principal Investigator is bound. Likewise, Principal Investigator further warrants that he/she has obtained all required consents from and/ or filed all required notifications to/from the Institution board or other regulatory or self-regulatory authority, board or committee.

15. Limitation of Liability and Indemnification

15.1 Institution and Principal Investigator shall indemnify, defend and hold harmless PPD and GSK and its Affiliates from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by PPD or GSK or its Affiliates as a result of the negligence or willful misconduct of Institution and/or Principal Investigator.

15.2 A Party shall give written notice to the other Parties as soon as is practicable of the details of any claim or proceedings brought or threatened against it by a third party in respect of which a claim will or may be made under Clause 15.1 above.

15.3 Upon request by Institution and/or Principal Investigator, indemnification of Institution and Principal Investigator by GSK shall be governed by a separate letter agreement between GSK, Institution and Principal Investigator.

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Executive Registrar
SGPGIMS,Lucknow

(28)

15.4 Nothing in this Clause 15 or otherwise in this Agreement shall exclude or in any way limit Institution' liability for (i) fraud, (ii) death or personal injury caused by its negligence; and (iii) any liability to the extent the same may not be excluded or limited as a matter of law.

15.5 No Party shall be liable to the other Parties for any punitive, exemplary damages or for an indirect or consequential loss or damage resulting from any breach of this Agreement even if the other Parties have been advised of the possibility of such damages.

15.6 Each Party's agreement to indemnify and hold the other Party or Parties harmless is conditional on the indemnified Party (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within ten (10) days after the indemnified Party has knowledge of such claim, demand or action, (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand, and (iv) not compromising or settling such claim or demand without the indemnifying Party's written consent.

15.7 The obligations of this Clause shall survive termination of this Agreement.

16. Termination

16.1 PPD may terminate this Agreement at any time, without cause, by giving thirty (30) days written notice to the Institution and Principal Investigator if any of the following conditions occur:

(a) the authorization and approval to perform the Clinical Trial in India is withdrawn by the IRB or any other competent authority;

(b) if PPD's agreement with GSK is terminated;

(c) if available data indicate that it is not safe to continue to administer the Clinical Trial Product to Subjects;

(d) if overall Clinical Trial enrolment has not been met, even if the enrolment at the Institution has not been completed;

(e) the Principal Investigator is unable to continue and an acceptable successor is not agreed upon;

(f) adherence to the Protocol is poor, or Clinical Trial data recording is chronically inaccurate or incomplete;

(g) the Clinical Trial is terminated;

(h) material breach of this Agreement; or

(i) by mutual agreement of the Parties.

16.2 In the event this Agreement is terminated for any reason prior to the end of the Clinical Trial, the Institution shall take all reasonable steps required by PPD, including communicating with the Subjects, to facilitate completion of the Clinical Trial at an alternative clinical site designated by PPD. In such event, PPD will (except where the termination was as a result of the breach by the Institution of its obligation under this Agreement) reimburse the Institution for its reasonable direct costs incurred in connection with such transfer, as well as for reasonable non-reimbursed costs incurred and non-cancellable commitments made prior to the receipt by the Institution that the Agreement will be terminated.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

16.3 Termination of this Agreement by any Party shall not affect the rights and obligations of the Parties that have accrued prior to the effective date of the termination.

17. Effect of Termination

17.1 In the event of termination, the sum payable under this Agreement shall be limited to prorated fees based on actual Services performed pursuant to the Protocol as determined in accordance with **Schedule 2**.

17.2 Upon completion of the Clinical Trial or earlier termination thereof, Institution and/or Principal Investigator shall ensure that all data, information, reports and Clinical Trial results are properly recorded in eCRFs and submitted to PPD, and shall return to PPD all Information.

17.3 Upon completion of the Clinical Trial or early termination thereof, all unused Clinical Trial Product, and/or Materials furnished to Institution and/or Principal Investigator by or on behalf of GSK or PPD shall be returned to PPD, as described in Clause 3.

17.4 Immediately upon receipt of a notice of termination, Institution and Principal Investigator shall cease entering Subjects into the Clinical Trial, cease conducting procedures to the extent medically permissible on Subjects already entered into the Protocol, and refrain from incurring additional costs and expenses to the extent possible

17.5 All provisions of this Agreement that by their nature would be expected to survive termination of this Agreement shall survive such termination, including - but not limited to – Clauses 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18, 19 and 20.

18. Compliance with Laws and Human Rights

18.1 Each Party shall perform its obligations under this Agreement in a manner that complies with all applicable international, national and local laws in relation to, or otherwise relevant to, its obligations under this Agreement and shall promptly notify the other Parties if it receives a written allegation of non-compliance with any such law by any person which relates to its performance of such obligations.

18.2 Institution and the Principal Investigator (the "Site") agree to the terms of **Schedule 4**.

18.3 Each Party expressly agrees that this Agreement is the result of arms-length negotiations, and that neither Party has entered into this Agreement with a corrupt motive to obtain or retain business or to secure an unfair business advantage.

18.4 Each Party hereby warrants and undertake that they shall at all material times keep and maintain accurate and up to date accounting records to ensure that all transactions relating to this Agreement are sufficiently documented.

18.5 Institution represents that, with respect to employment and conducting the Clinical Trial under this Agreement, Institution will:

(a) not use child labor in circumstances that could cause physical or emotional impairment to the child;

(b) not use forced labor (prison, indentured, bonded or otherwise);

(c) provide a safe and healthy workplace; safe housing (if housing is provided by Institution to its employees); and access to clean water, food, and emergency healthcare in the event of accidents in the workplace;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(d) not discriminate against employees on any grounds (including race, religion, disability or gender);

(e) not use corporal punishment or cruel or abusive disciplinary practices;

(f) pay at least the minimum wage and provide any legally mandated benefits;

(g) comply with laws on working hours and employment rights;

(h) respect employees' right to join and form independent trade unions;

(i) encourage subcontractors under this Agreement to comply with these standards;

(j) maintain a complaints process to address any breach of these standards.

19. Applicable law and competent jurisdiction

19.1 This Agreement shall be governed by and interpreted in accordance with the laws of India.

19.2 The Parties, expressly waiving any other jurisdiction to which they might be entitled, agree to submit any disputes arising out or in connection with this Agreement (whether of a contractual or non-contractual nature) to the Courts of Lucknow.

20. Miscellaneous

20.1 Independent Contractor

The Institution, including its agents and employees, shall be an independent contractor at all times, and shall not be an agent of PPD or GSK and shall have no actual, apparent or implied authority to bind PPD or GSK in any manner or to any obligation whatsoever. The Principal Investigator shall not be or be deemed to be an employee of PPD or GSK and shall not be entitled to any benefits available to employees of PPD or GSK.

20.2 Assignment

Institution shall not assign this Agreement in whole or in part to any other Party and shall not appoint any other person as Principal Investigator without PPD's written consent. PPD may assign this Agreement in whole or in part, including to any corporate parent, affiliate or subsidiary of PPD, without the Principal Investigator's/Institution's consent.

This Agreement shall be binding upon the Parties, their legal representatives, successors and permitted assigns. Institution and Principal Investigator acknowledge and agree that GSK and each of its Affiliates is a third party beneficiary to this Agreement and shall be entitled to enforce all of the rights and benefits of this Agreement at all times as if it were a party to this Agreement.

20.3 Use of Name

No Party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement which uses the other Parties names, symbols, or trademarks without the other Parties prior written approval.

20.4 Notices

(a) All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices may be sent by facsimile or e-mail, if confirmed by also sending as described above.

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Executive Registrar
SGPGIMS,Lucknow

(b) Notices pertaining to this Agreement shall be sent to:

If to Institution:
Attn:Dr. Rakesh Kapoor
Address: Sanjay Gandhi Postgraduate Institute of Medical Sciences,Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India.

Tel.: 8004263199
Fax: NA
E-mail address: narayan@sgpgi.ac.in

If to PPD:
Attn.: Rashmi Chitgupi
Title: Associate Director , Clinical Management
PPD Pharmaceutical Development India Private Limited
101-A Wing, 'Fulcrum'
Hiranandani Business Park,Sahar Road
Andheri East Mumbai 400 099 India
Tel.: +91 22 4247 2900
Fax: +91 22 4248 6900
E-mail address: Rashmi.Chitgupi@ppdi.com

If to the Principal Investigator:
Attn: Dr Narayan Prasad
Address: Sanjay Gandhi Postgraduate Institute of Medical Sciences,Raibareli road, Department of Nephrology, C Block, ground floor, Lucknow, Uttar Pradesh - 226014,India.
Tel.: 8004263199
Fax: NA
E-mail address: narayan@sgpgi.ac.in

20.5 Severability

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not in any way be affected.

20.6 Waiver; Modification of Agreement

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by any Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by any Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

20.7 Force Majeure

If any Party is delayed in performing an obligation under this Agreement by strike, lockout, or other labor troubles of a third party; by restrictive governmental or judicial order not directly related to this Agreement; or by riots, insurrection, war, inclement weather, or Acts of God; performance is excused for the period of such delay. The delayed Party shall promptly notify the other Parties in writing of the delaying event.

20.8 Entire Agreement

This Agreement and its exhibits constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes any prior agreement, understanding or arrangement between the Parties, whether oral or in writing. No

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Executive Registrar
SGPGIMS,Lucknow

representation, undertaking or promise shall be taken to have been given or be implied from anything said or written in negotiations between the Parties prior to this Agreement except as expressly stated in this Agreement.

20.9 Miscellaneous

(a) For the purposes of this Agreement, "Affiliate" means any entity that controls, is controlled by, or is under common control with, a party to this Agreement. In this context, "control" shall mean (i) ownership by one entity, directly or indirectly, of at least forty percent (40%) of the voting stock of another entity; (ii) power of one entity to direct the management or policies of another entity, by contract or otherwise; or (iii) any other relationship between GSK or Institution and an entity which GSK and Institution have agreed in writing may be considered an "Affiliate" of GSK or Institution (as the case may be).

(b) PPD or GSK may provide the following supportive measures to strengthen the Institution's research capacity for the benefit of the community. Site will be provided with Handicam for AV recording of informed consent process and thermohygrometer for 2-8 degree and room temperature (2 in quantity).PPD, GSK and the Institution agree that any of these measures that may be provided by PPD or GSK are not intended to be for the exclusive benefit of the Clinical Trial or of GSK studies generally, or to induce the Institution to participate in the Clinical Trial or to induce or reward any use, purchase, recommendation, or prescription of GSK products. GSK and the Institution also agree that any of these measures that may be provided by PPD or GSK are intended to be sustainable by the Institution and the local community following the Clinical Trial.

(c) GSK and the Institution have sought agreement with key interested external parties, including ethics committees, research investigators, national government, health ministry, local health authorities, ethics groups, non-governmental organisations, or representatives of the communities who might participate in the Clinical Trial, that it is appropriate to conduct the Clinical Trial at the Institution, including discussion of the standard of care to be provided during the study, the scientific rationale for interventions (including placebo), the provision of healthcare for subjects after the study, and the fate of any capacity built for the conduct of the study.

(d) The Institution agrees that any nationally-licensed medicinal products that are not the subject of the Clinical Trial but are required for the routine care of a Clinical Trial subject during and after the Clinical Trial for the disease or condition to which the Clinical Trial relates are expected to be available to the Clinical Trial subject and funded through the usual operations of the local healthcare system independently from the Clinical Trial and without expectation of GSK support.

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Executive Registrar
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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

Sanjay Gandhi Postgraduate Institute of Medical Science

DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA

Name:
Position:
Date: 03.09.2019

Dr. Narayan Prasad

Narayan Prasad

Name:
Position: Professor
Date: 2-8-19

(Prof. Narayan Prasad)
Department of Nephrology
S.G.P.G.I.M.S., Lucknow-226014
Reg. No. BR-27804/94

PPD Pharmaceutical Development India Private Limited

27MAY2019

Name:
Position:
Date:

Reshmi Chitgupi
Associate Director - Clinical Management
PPD Pharmaceutical Development India Pvt. Ltd.
101-A Wing, Fulcrum, Hiranandani Business Park
Sahar Road, Andheri East
Mumbai – 400 099, India.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

22

SCHEDULE 1

PROTOCOL

TITLE PAGE

Division: Worldwide Development
Information Type: Protocol Amendment

Title:	A phase 3 randomized, open-label (sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa.

Compound Number: GSK1278863

Development Phase: IIIA

Effective Date: 12-OCT-2016

Protocol Amendment Number: 02

Author (s): Meadowcroft, Amy; Kler, Lata; Davies, Rich; Barnes, Allison; Waterhouse, Brian; Mahar, Kelly; Cizman, Borut; Sikirica, Vanja; Marquita, West; Miller, Maria; Cobitz, Alexander

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SCHEDULE 2

FUNDING OF CLINICAL TRIAL AND PAYMENTS

1. Financial Support

a) PPD will pay a sum of INR 4,49,136.00 plus GST where applicable for every complete and evaluable Subject as defined below.

b) A complete and evaluable Subject is defined as follows:

- all procedures must be performed according to the Protocol and ICH GCP guidelines;
- a Subject will only be included according to the inclusion/exclusion criteria set out in the Protocol;
- all data are documented accurately, completely.

c) All payments will be on a *pro rata* basis. For Subjects who do not complete, the payment schedule will be evaluated according to the number of visits performed (see attachment).

d) Payments will be made quarterly according to the actual Services performed (after source data verification and CRF retrieval by PPD). The final payment will be made after resolution of all queries to the following bank account:

Bank account holder: Sanjay Gandhi Postgraduate Institute of Medical Sciences
PAN No: AAAJS3913N

e) All costs should be invoiced within one (1) month of termination of the Clinical Trial to ensure payment.

f) Central Laboratory costs will be paid by the GSK.

g) Institution shall reimburse Subjects for their travel expenses up to a value of 1000.00 INR per visit. PPD shall reimburse the Institution for the travel expenses on receipt of a valid invoice together with supporting documentation of the expense being incurred.

2. Invoicing Instructions

PPD's payment obligation is also conditioned upon Institution submitting valid invoices. The Institution shall submit valid invoices at end of every six (6) months for Services performed during that six (6) month period to the attention of;

PPD Pharmaceutical Development India Private Limited

101-A Wing, 'Fulcrum',
Hiranandani Business Park,
Sahar Road, Andheri East
Mumbai 400 099
INDIA
Telephone: +91 22 4247 2900
Facsimile: +91 22 4248 6900

The following information must be indicated on each invoice:

(i) Invoice number

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(20)

(ii) Invoice date
(iii) Protocol number
(iv) Institution contact details (address, GST number, telephone, fax and contact person)
(v) Dates on which Services were performed.
(vi) Total amount of fees for the Services

Failure to provide the required information will delay approval and the invoice may be returned for revisions. All invoices shall become payable sixty (60) days following receipt and approval by PPD.

All fees payable by PPD will be exclusive of GST, VAT, and similar indirect taxes as per the existing rules in India. PPD will pay the vendor on receipt of a legal tax invoice raised according to the terms of this agreement and the indirect tax / GST laws applicable in India.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(19)

Exhibit A
Payment Schedule
200808

Payment by PPD shall be made payable to the payee and at the address indicated on the PAF or other applicable form provided to PPD prior to the execution of this Agreement ("Payee") as follows:

Bank account holder: Sanjay Gandhi Postgraduate Institute of Medical Sciences
PAN No: AAAJS3913N

Institution may request to revise the payee details provided herein during the course of the Study. In such cases, the parties agree that no amendment to this Agreement shall be required provided that Institution provides written notification to PPD with the revised payee details and, if applicable, a revised PAF The parties further agree that PPD assumes no liability for incorrect payee details provided by Institution.

Cost per Subject: The Institution will be paid, **in accordance with the rate set forth in the budget, per** completed subject and as outlined on the Exhibit A, less 10% percent withholding. Payments will be made on a quarterly basis in US dollars and will be based on completed visits and applicable data entered into the subject electronic case report forms (eCRFs).

Screen Failures: The Institution will be paid for six (6) Screen Failures (as defined below) without pre-approval from Sponsor and to a maximum of fifteen (15) with express pre-approval from GSK.. Additional Screen Failures may be considered upon sponsor approval. Institution will be reimbursed in accordance with the rates set forth for the Screen Run-in visit in the Budget, as verified in the CRF. For purposes of this Agreement, a Screen Failure shall mean any subject, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the Initial screen, Full Screen, Run In and/or Day 1 visit but does not randomize into the Study.

IRB Fees: Central IRB is defined as the IRB selected by the Sponsor. Local IRB Fees will be submitted by the Institution and reimbursable directly to the Institution upon the receipt of correct and itemized invoices by PPD.

Pharmacy Start-Up Fees: Payee will receive a one-time fee **in accordance with the rate set forth in the budget** to cover set-up of the pharmacy services on this Study. The pharmacy start-up fees will be payable upon PPD's receipt of a correct and itemized invoice from Payee

Patient Stipend/Compensation: Patient stipend/compensation is included in the costs per subject and will be paid to Institution at the rate stated in the attached budget on a quarterly basis based on completed visits. In the event that any patient stipend/compensation is paid by PPD to the Institution but not actually paid to the Study subject by the Institution, Institution will promptly refund that amount to PPD.

Invoices: All correct invoices pertaining to this Study should be addressed to PPD and submitted for reimbursement to the following:

PPD Pharmaceutical Development India Private Limited
101-A Wing Fulcrum,
Hiranandani Business Park,Sahar Road
Anderi East,Mumbai – 400 099
InvestigatorPayments@ppdi.com

All invoices for Study payments, as outlined in this payment schedule, must be submitted to PPD within 90 days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.

GST: All fees payable by PPD will be exclusive of GST and similar indirect taxes as per the existing rules

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

in India. PPD will pay the vendor on receipt of a legal tax invoice raised according to the terms of this agreement and the indirect tax / GST laws applicable in India.

Unscheduled Visits: An Unscheduled Visit indicates a subject visit which is not expressly set forth in the Protocol, but is otherwise required for the study. Unscheduled Visits will be reimbursed on a per procedure basis in accordance with the rates set forth in the Budget. In the event a medically necessary procedure is not included in the Budget, Institution must receive prior written approval before procedure is performed. Amount of compensation for a procedure not included in Budget will be approved at the time written approval is provided.

Final Payment: The final payment, which corresponds to the remaining 10% of costs, shall be made upon completion of the close-out visit and upon receipt of (i) all completed and corrected case report forms and queries, of (ii) all Study documentation, of (iii) all unused Study drug has been accounted for and (iv) all study equipment and supplies returned as specified by PPD and Sponsor.

If at the completion of the Study, PPD has advanced sums under the terms of this Agreement that exceed the earned amount for all Study subject visits completed, Payee shall reimburse to PPD any amount by which amounts advanced by PPD exceed the fees earned within ninety (90) days.

No other additional funding requests will be considered without the prior written consent of PPD.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Sponsor:	GSK									
Protocol:	GSK200808	Day 1 through Week 52								
Site:	Dr. Narayan Prasad									
PI:	Sanjay Gandhi Postgraduate Institute of Medical Sciences	Initial Screen (Week -8)	Full Screen (Week -8)	Run-in (Week -4)	Day 1	Abbreviated Study visit	Full Study Visit	Abbreviated Study visit	Abbreviated Study visit
Date:									
Currency:	Indian Rupee					Week 2	Week 4	Week 8	Week 12
Procedures	**Unit Cost**								
IWRS call	INR 716.00	INR 716.00		INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00
Informed Consent	INR 1,006.00	INR 1,006.00							
Entry Criteria	INR 1,076.00		INR 1,076.00		INR 1,076.00				
History: medical, hospitalization, transfusion; demography, height, weight	INR 4,153.00		INR 4,153.00						
Vital Signs (SBP/DBP, HR)	INR 492.00		INR 492.00	INR 492.00	INR 1,476.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00
Kt/Vurea for dialysis adequacy	Invoice				Invoice		Invoice		
ECG	INR 1,538.00				INR 1,538.00				
HemoCue HgB	INR 802.00	INR 802.00		INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00
Iron Therapy Transfusions	Invoice		Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
Rescue Medications	Invoice						Invoice	Invoice	Invoice
Central Laboratory Collection (hematology, clinical chemistry, ferritin, total iron, UIBC, Hepcidin, Lipids (non-fasting), HbA1c, hsCRP, IPTH,estradiol and FSH (if required) Storage biomarkers)	INR 973.00		INR 973.00	INR 973.00	INR 973.00		INR 973.00	INR 973.00	INR 973.00
Pregnancy Test (FRP only)	Invoice			Invoice	Invoice		Invoice		
Adverse Events	INR 500.00		INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00
Concomitant Medications	INR 700.00		INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00
Symptoms of ACKD questionnare	INR 749.00		INR 749.00		INR 749.00			INR 749.00	INR 749.00
Patient Global Impression of Change (PGI-C)	INR 430.00							INR 430.00	INR 430.00
Patient Global Impressions of Severity (PGI-S)	INR 716.00		INR 716.00		INR 716.00			INR 716.00	INR 716.00
Kidney Ultrasound	INR 10,353.00			Invoice					
SF-36	INR 716.00				INR 716.00			INR 716.00	INR 716.00
Work Productivity and Activity Impairment Questionnaire (WPAI-ANS-CPV)	INR 716.00				INR 716.00			INR 716.00	INR 716.00
Non-Procedures									
Study Coordinator	INR 2,297.00	INR 2,297.00		INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00
Physician	INR 4,700.00	INR 4,700.00		INR 4,700.00	INR 4,700.00		INR 4,700.00	INR 4,700.00	INR 4,700.00
Pharmacy Dispensing	INR 529.00			INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00
Patient Compensation	INR 1,000.00	INR 1,000.00		INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00
Total Per Visit		INR 10,521.00	INR 9,359.00	INR 12,709.00	INR 19,204.00	INR 7,036.00	INR 12,709.00	INR 16,036.00	INR 16,036.00
Total OH Per Visit	25%	INR 2,630.25	INR 2,339.75	INR 3,177.25	INR 4,801.00	INR 1,759.00	INR 3,177.25	INR 4,009.00	INR 4,009.00
Total Per Visit (with OH)		INR 13,151.25	INR 11,698.75	INR 15,886.25	INR 24,005.00	INR 8,795.00	INR 15,886.25	INR 20,045.00	INR 20,045.00
Total Costs Per Repeat Visit: (with OH)		INR 13,151.25	INR 11,698.75	INR 15,886.25	INR 24,005.00	INR 8,795.00	INR 15,886.25	INR 20,045.00	INR 20,045.00
Total Cost Per Patient (with OH) (To include, Screening, Run-in, Day 1 through 52 Week Treatment Period, Year 2, 3, and 4 , End of Study Visit and 1 Follow up Visit)									

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Full Study Visit	Abbreviated Study visit	Abbreviated Study visit	Full Study Visit	Abbreviated Study visit	Abbreviated Study visit	Full Study Visit	Abbreviated Study visit	Abbreviated Study visit	Week 52
Week 16	Week 20	Week 24	Week 28	Week 32	Week 36	Week 40	Week 44	Week 48	
INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00
INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 1,476.00
Invoice			Invoice			Invoice			
									INR 1,538.00
INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice
INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00
Invoice			Invoice			Invoice			Invoice
INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00
INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00
			INR 749.00						INR 749.00
			INR 430.00						INR 430.00
			INR 716.00						INR 716.00
			INR 716.00						
			INR 716.00						INR 716.00
									INR 716.00
INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00
INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00
INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00
INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00
INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 16,036.00	INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 12,709.00	INR 18,558.00
INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 4,009.00	INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 3,177.25	INR 4,639.50
INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 20,045.00	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 23,197.50
INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 20,045.00	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 15,886.25	INR 23,197.50

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Year 2			Year 3			Year 4					
Week 64 and Week 88	Week 76	Week 100	Week 112 and Week 136	Week 124	Week 148	Week 160 and Week 184	Week 172 and Week 196	Week 208	Unscheduled Visit	End of Study	Follow-up* (4-6 weeks after stopping study treatment)
INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00	INR 716.00
INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 492.00	INR 1,476.00	INR 492.00
Invoice			Invoice			Invoice		Invoice			
		INR 1,538.00			INR 1,538.00			INR 1,538.00			
INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00	INR 802.00		
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice			
INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00	INR 973.00
Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice	Invoice		Invoice	Invoice
INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00	INR 500.00
INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00	INR 700.00
		INR 716.00			INR 716.00			INR 716.00		INR 716.00	
INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00	INR 2,297.00
INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00	INR 4,700.00
INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00	INR 529.00		
INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00	INR 1,000.00
INR 12,709.00	INR 12,709.00	INR 14,963.00	INR 12,709.00	INR 12,709.00	INR 14,963.00	INR 12,709.00	INR 12,709.00	INR 14,963.00	INR 12,709.00	INR 13,078.00	INR 11,378.00
INR 3,177.25	INR 3,177.25	INR 3,740.75	INR 3,177.25	INR 3,177.25	INR 3,740.75	INR 3,177.25	INR 3,177.25	INR 3,740.75	INR 3,177.25	INR 3,269.50	INR 2,844.50
INR 15,886.25	INR 15,886.25	INR 18,703.75	INR 15,886.25	INR 15,886.25	INR 18,703.75	INR 15,886.25	INR 15,886.25	INR 18,703.75	INR 15,886.25	INR 16,347.50	INR 14,222.50
INR 31,772.50	INR 15,886.25	INR 18,703.75	INR 31,772.50	INR 15,886.25	INR 18,703.75	INR 31,772.50	INR 31,772.50	INR 18,703.75	INR 15,886.25	INR 16,347.50	INR 14,222.50
										INR	5,45,388.75

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Study Treatment Discontinuation Visit (within 2 weeks of discontinuing study treatment)	Study Treatment Discontinuation In-Clinic Follow up Visit to study end	Study Treatment Discontinuation Phone Follow Up Call to study end
INR 716.00		
INR 1,476.00	INR 492.00	
INR 1,538.00		
INR 802.00	INR 802.00	
Invoice	Invoice	
INR 973.00	INR 973.00	
Invoice (Urine Pregnancy Test for FRP only)		
INR 500.00	INR 500.00	INR 500.00
INR 700.00	INR 700.00	INR 700.00
INR 749.00		
INR 430.00		
INR 716.00		
INR 716.00		
INR 716.00		
INR 2,297.00	INR 2,297.00	INR 2,297.00
INR 4,700.00	INR 4,700.00	
INR 1,000.00	INR 1,000.00	
INR 18,029.00	INR 11,464.00	INR 3,497.00
INR 4,507.25	INR 2,866.00	INR 874.25
INR 45,073.00	INR 14,330.00	INR 4,371.25
INR 45,073.00	INR 2,57,940.00	INR 78,682.50
INR 45,073.00	INR 2,57,940.00	INR 78,682.50

Hemocue Visit Year 2+	Retention Activities	Phone/Third Party medical records follow up visit
INR 4,280.91	INR 9,418.00	INR 9,418.00
INR 4,280.91	INR 9,418.00	INR 9,418.00
INR 4,280.91	INR 9,418.00	INR 9,418.00
INR 4,280.91	INR 9,418.00	INR 9,418.00

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Executive Registrar
SGPGIMS,Lucknow

Invoiced Items	Base Rate		OH		Total w/OH	
Urine Pregnancy Test	INR	334.00	INR	83.50	INR	417.50
Serum Pregnancy Test	INR	300.00	INR	75.00	INR	375.00
Kt/V urea for patients transitioning into dialysis(adequecy)	INR	3,040.00	INR	760.00	INR	3,800.00
Kidney Ultrasound	INR	10,353.00	INR	2,588.25	INR	12,941.25
Optional Genetic Consent	INR	1,432.00	INR	358.00	INR	1,790.00
Iron Therapy Transfusions	INR	12,710.00	INR	3,177.50	INR	15,887.50
Rescue Medications	INR	1,350.00	INR	337.50	INR	1,687.50

* Additional follow up visits will be paid based on the rates set forth above and in accordance with the protocol.

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SCHEDULE 3

GSK INSURANCE POLICY

CERTIFICATE OF INSURANCE

MAGMA HDI General Insurance Company Ltd

Name of the Insured	GlaxoSmithKline Consumer Healthcare Ltd
Address of the Insured	R&D Centre, Plot no.-67, Sector-32,Gurgaon - 122001
Additional Insured Name	1.GlaxoSmithKline Consumer Healthcare Ltd 2.GlaxoSmithKline Asia Pvt Ltd 3 GlaxoSmithKline Pharmaceuticals Ltd 4.Chiron Panacea Vaccines Private Limited 5.Chiron Behring Vaccines Private Limited

Insured: All subsidiaries and affiliated engaged in clinical trials in the name of the named insured including the CRO's (Contract Research Organisations) and investigators.

This is to certify that policies of insurance listed below have been issued to the insured named above and are in force at this time. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this certificate may be issued or may pertain, the insurance afforded by the policies describes herein is subject to all terms , exclusions and conditions of such policies.

1. Type of Insurance:	CLINICAL TRIALS Insurance Cover
2. Country:	Clinical Trials in India
3. Policy No.:	P0016200001/9999/100203
4. Policy Inception Date:	January 1 2016
5. Policy Expiration Date:	December 31 2016
6. No.of Subjects:	Number of Patients-301
7. Study Title:	A Phase 3 randomized, open-label (Sponsor-blind), active-controlled, parallel-group, multi-center, event driven study in non-dialysis subjects with anemia associated with chronic kidney disease to evaluate the safety and efficacy of daprodustat compared to darbepoetin alfa.
8. Protocol Number:	200308
9. Study Start Date:	30-Jun-16
10.Study End Date:	15-May-21
11.Limits of Liability:	INR 100'135'162 any one occurrence & in the annual aggregate
12.Deductible:	INR 2'503'379 each occurrence
13. Sponsor:	GlaxoSmithKline Research & Development Limited,980 Great West Road,Brentford,Middlesex, TW8 9GS,UK
14. Claims Handling	Claims payable by MAGMA HDI GENERAL INSURANCE CO. LTD
List of Investigators:	NA
Special Remarks if any	"The coverage provided by this policy covers the trial for its entire duration. Coverage is therefore given for the entire life of the trial. No amendment or renewal is required with regard to the policy period"

This Certificate is issued as a matter of information only and confers no rights upon the certificate holder. This certificate does not named, extend or alter the coverage afforded by the policies listed above.

for MAGMA HDI GENERAL INSURANCE CO. LTD

Authorised Signatory
PLACE : Mumbai
03/08/2016

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Executive Registrar
SGPGIMS,Lucknow

(11)

SCHEDULE 4

GSK ANTI-BRIBERY AND ANTI-CORRUPTION TERMS

1. Site acknowledges that it has received and read GSK's 'Prevention of Corruption – Third Party Guidelines' (either in hard copy or at http://www.gsk.com/policies/Prevention-of-Corruption-Third-Party-Guidelines.pdf) and agrees to perform its obligations under the Agreement in accordance with the principles set out therein.

2. Site shall comply fully at all time with all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which the Site conducts business with GSK.

3. Site agrees that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery.

4. Site shall not contact, or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative.

   For the purpose of this Agreement "Government Official" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organisation such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision making role, has responsibility for performing regulatory inspections, government authorisations or licenses, or otherwise has the capacity to take decisions with the potential to affect GSK business.

5. Site represents that except as disclosed to GSK in writing prior to the commencement of this Agreement, it has not been convicted of or pleaded guilty to a criminal offence, including one involving fraud or corruption, that it is not now, to the best of its knowledge, the subject of any government investigation for such offenses, and that it is not now listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

6. Site represents and warrants that except as disclosed to GSK in writing prior to the commencement of this Agreement: (1) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (2) it shall maintain arms length relations with all third parties with which it deals for or on behalf of GSK in performance of this Agreement.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

7. GSK shall have the right during the term of this Agreement to conduct an investigation and audit of Site's activities under this Agreement to monitor compliance with the terms of this Agreement. Site shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSK.

8. Site shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Site must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

9. Site agrees that in the event that GSK believes that there has been a possible violation of the terms of this Agreement, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.

10. GSK shall be entitled to terminate this Agreement with immediately on written notice to Site, if Site fails to perform its obligations in accordance with this Schedule 4. Site shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Schedule 4. To the extent (and only to the extent) that the laws of the territory provide for any such compensation to be paid to Site upon the termination of this Agreement, Site hereby expressly agrees (to the extent possible under the laws of the territory) to waive or to repay to GSK any such compensation or indemnity.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(9)

SCHEDULE 5

GLAXOSMITHKLINE'S – CLINICAL TRIAL COMPENSATION GUIDELINES

GlaxoSmithKline (GSK) will adhere to the following broad guidelines in the event of injury caused to the patient attributable to participation in the trial in question.

1. **Basic Principles**

1.1 Notwithstanding the absence of legal commitment, GSK will pay compensation to the patient-volunteers suffering study related injury (including death) in accordance with these guidelines.

1.2 Compensation will be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under trial or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the patient in the trial.

1.3 Compensation will be paid to the child injured in utero through the participation of the subject's mother in a clinical trial as if the child were a patient-volunteer with the full benefit of these guidelines.

1.4 Compensation will only be paid for the more serious injuries of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.

1.5 Where there is an adverse reaction to a medicinal product under trial and injury is caused by the procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it were caused directly by the medicinal product under trial.

1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the trial should exclude a patient from consideration for compensation under these guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.

1.7 For the avoidance of doubt, compensation will be paid regardless of whether the patient is able to prove that GSK has been negligent in relation to research or development of the medicinal product under trial or that the product is defective and therefore, as the producer, GSK is subject to strict liability in relation of injuries caused by it.

2. **Types of Clinical Research Covered**

2.1 These guidelines apply to injury caused to patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended to treat but for which the product license does not exist or does not authorize supply for administration under the conditions of the trial.

2.2 These guidelines do not apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital, for which separate guidelines for compensation already exist at the facility where the study is carried out

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

2.3 These guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply of administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial. These guidelines do not apply to post-marketing surveillance and ancillary care.

2.4 These guidelines do not apply to clinical trials which have not been initiated or directly sponsored by GSK. Where trials of products are initiated independently by doctors, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).

3. Limitations

3.1 Compensation will not be paid to research participants receiving placebo in consideration of its failure to provide a therapeutic benefit.

3.2 Compensation will not be paid for natural progression of an underlying disease.

3.3 Compensation will not be available for adverse effects due to concomitant medications allowed as per protocol/routine procedures as part of standard of care.

3.4 No compensation should be paid for the failure of a medicinal product to have its intended effect or to provide any other benefit to the patient.

3.5 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.

3.6 No compensation should be paid (or it should be abated as the case may be) to the extent that the injury has arisen:

(a) through a significant departure from the agreed protocol;

(b) through a wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction;

(c) through a contributory negligence by the patient.

3.7 Compensation may not be provided if it is determined (by the Investigator and the IEC) that the injury has arisen through:

(a) wrongful act or default of a third party;

(b) contributory negligence by the research participant (e.g. willful or reckless non-adherence to protocol procedures/instructions by the research participants as described in the ICDs).

4. Assessment of Compensation

4.1 The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by the Indian Courts in cases where legal liability is admitted.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(7)

4.2 Compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):

(a) the seriousness of the disease being treated, the degree of probability that adverse reaction will occur and any warnings given;

(b) the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given a particular patient's circumstances. As an extreme example, there may be patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

4.3 In any case where GSK concedes that a payment should be made to a patient but there exists a difference of opinion between GSK and patient as to the appropriate level of compensation, GSK shall seek at its own cost (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his/her opinion should be given substantial weight by GSK in reaching its decision on the appropriate payment to be made.

5. Miscellaneous

5.1 Claims pursuant to the guidelines should be made by the patient to GSK, preferably via the investigator, setting out details of the nature and background of the claim and, subject to the patient providing on request an authority for GSK to review any medical records relevant to the claim. GSK should consider the claim expeditiously.

5.2 The undertaking given by GSK extends to injury arising (at whatever time) from all administration, clinical interventions or procedures occurring during the course of the trial but not to treatment extended beyond the end of the trial at the request of the investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor.

5.3 The fact that GSK has agreed to abide by these guidelines in respect of a trial does not affect the right of a patient to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, patients will normally be asked to accept that any payment made under the guidelines will be in full settlement of their claims.

5.4 GSK should encourage the investigator to make clear to participating patients that the trial is being conducted subject to GSK's guidelines relating to compensation for injury arising in the course of clinical trials and the copy of these guidelines should be made available to the participating patients.

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

EN 049307

Rajendra Kumar Notary Mohanlalganj Lucknow Reg.No. 31(05)2009

I identified the deponent who has signed before me

Sworn & Verified Before Me

SUBCONTRACT AGREEMENT

This is a subcontract under a grant from **Malaysian Palm Oil Board,** No. 6, Persiaran Institusi, Bandar Baru Bangi, 43000 Kajang, Selangor Malaysia, to **Wayne State University**, 5057 Woodward Avenue, Detroit, Michigan 48202 entitled *"Palm Tocotrienol in Hemodialysis Patients Study (PATCH STUDY)"*. The parties under this subcontract are **Wayne State University**, hereinafter referred to as THE UNIVERSITY, and **Sanjay Gandhi Post-Graduate Institute of Medical Sciences, Raebarely Road, Lucknow 226014, India,** hereinafter referred to as THE SUBCONTRACTOR.

This subcontract sets forth the terms for the performance and administration of work under the above grant and consists of:

Subcontract Document
Attachment I - Statement of Work
Attachment II - Approved Budget
Attachment III – Memorandum of Agreement

EXECUTION AND MODIFICATION

An agreement shall exist when this document has been signed by duly authorized representatives of the parties. Modifications shall be made by written agreement of the authorized representatives of the parties.

09/10/2019

Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Mohanlalganj. Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

PERIOD OF PERFORMANCE

The period of performance of this contract shall begin on **November 15, 2018** and shall not extend beyond **December 14, 2019** unless agreed to in writing by both parties hereto.

SCOPE OF WORK

The work to be done under this subcontract is specified in **Attachment I**.

TOTAL ESTIMATED COST

As compensation THE UNIVERSITY agrees to reimburse THE SUBCONTRACTOR for performance of the work described in Attachment I in an amount not to exceed **$30,000 USD (Attachment II)**.

WAYNE STATE UNIVERSITY PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR

Dr. Pramod Khosla
Wayne State University
School of Liberal Arts and Science
3009 Science Hall
Detroit, MI 48202
313 577-0448
aa0987@wayne.edu

The Principal Investigator/Project Director shall be responsible for the technical, scientific and programmatic aspects of the subcontract.

WAYNE STATE UNIVERSITY AUTHORIZED SUBCONTRACTING REPRESENTATIVE

Patty Yuhas Kieleszewski
Associate Director, Contract Administration
Sponsored Programs Administration
5057 Woodward Avenue Suite 13200
Detroit, Michigan 48202, USA
+1 (313) 577-3726

The Authorized Subcontracting Representative shall be responsible for the business management aspects of the subcontract as the Wayne State University official empowered to execute agreements and modifications thereto.

SUBCONTRACTOR PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR

09/01/2019
Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Mohanlalganj Lucknow

Dr Anita Saxena
Professor
Sanjay Gandhi Post-Graduate Institute of Medical Sciences (SGPGIMS)
Department of Nephrology
Raebareli Road, Lucknow 226014,
India
Tel +91 9453019812

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

anitimmy@yahoo.com

The Subcontractor Principal Investigator/Project Director shall direct the subcontract project and is responsible to the subcontracting institution for the proper management and conduct of the grant program. The above named person may not be changed without approval by THE UNIVERSITY.

1. PAYMENT

Invoices are to be submitted according to **PAYMENT SCHEDULE** on Attachment II. Two (2) copies of all invoices, detailing current charges and total-to-date charges, should be sent to the **Wayne State University Sponsored Program Administration at 5057 Woodward Avenue Suite 13200 Detroit, MI 48202** or emailed to subkinvoices@wayne.edu. Please indicate project **#4-22508** on all invoices. The final invoice, clearly marked **FINAL**, must be submitted within **45 days** after the expiration date of this subcontract.

2. ALLOWABLE COSTS

THE SUBCONTRACTOR'S normal policies governing salaries, wages and fringe benefits shall apply to all THE SUBCONTRACTOR'S employees paid from this subcontract. THE SUBCONTRACTOR'S standard policy on travel and travel reimbursement shall apply to all costs for travel and transportation charged to this subcontract.

3. REBUDGETING OF FUNDS

It is understood that THE SUBCONTRACTOR'S budget as attached hereto (Attachment II) is an estimate and that there may be a need to depart from it to cover certain unanticipated requirements of the work. Any rebudget requires prior approval from THE UNIVERSITY.

4. RELATION TO THE PRIME GRANT

This subcontract is subject to all terms and conditions stated in the Memorandum of Agreement for Research and Development awarded by the Malaysian Palm Oil Board to THE UNIVERSITY which is incorporated herein by reference (see Attachment III), and THE SUBCONTRACTOR hereby agrees to accept and does accept as binding upon THE SUBCONTRACTOR each and every provision of said grant that is binding upon THE UNIVERSITY. THE SUBCONTRACTOR agrees to assume and does assume all the responsibility of THE UNIVERSITY to the Malaysian Palm Oil Board for the terms of the said referenced grant so far as they relate to services to be performed by THE SUBCONTRACTOR. This paragraph shall not be construed so as to require THE SUBCONTRACTOR to furnish or perform any services other than those expressly specified in this subcontract or amendments hereto.

5. ACCOUNTS, AUDITS AND RECORDS

(A) THE SUBCONTRACTOR shall maintain books, records, documents and other evidence, accounting procedures and practices, sufficient to reflect properly all direct and indirect costs of whatever nature it claims to have been incurred for the performance of this subcontract. The foregoing constitutes "records" for the purpose of this subcontract.

(B) THE SUBCONTRACTOR'S facilities, or such part thereof as may be engaged in the performance of this subcontract, and its records shall be subject at reasonable, mutually agreeable times during normal business hours and upon reasonable advance notice to inspection and audit by THE UNIVERSITY'S financial officer or its authorized representatives.

NOTARY Rajendra Kumar Adv. & Notary Reg.No. 3[illegible]2004

09/01/2019

Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankahi
Mohanlalganj, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(C) THE SUBCONTRACTOR shall preserve and make available its records until the expiration of three (3) years after submission of the final report for the budget period which they cover or until audit is completed and all resulting questions are resolved, whichever occurs first.

6. INDEMNITY

THE SUBCONTRACTOR will save, indemnify, defend and hold harmless THE UNIVERSITY, its agents, directors, and employees from any and all liability that may arise as a result of the negligent actions and/or omissions of THE SUBCONTRACTOR, its agents, and employees under the performance of this subcontract.

THE UNIVERSITY will save, indemnify, defend and hold harmless THE SUBCONTRACTOR, its agents, and employees from any and all liability that may arise as a result of the negligent actions or omissions of THE UNIVERSITY, its agents, and employees to the extent allowed under Michigan law.

7. EQUAL OPPORTUNITY

During the performance of this subcontract, THE SUBCONTRACTOR agrees as follows:

(A) THE SUBCONTRACTOR will not discriminate against any employee or applicant for employment because of race, color, religion, sex, age, marital status or national origin or because of handicap except where a bona fide occupational qualification exists.

(B) THE SUBCONTRACTOR will comply with all provisions of Executive Order No. 11246 of September 24, 1965, and of the rules, regulations and relevant orders of the Secretary of Labor.

(C) In the event of THE SUBCONTRACTOR'S noncompliance with this Equal Opportunity Provision this contract may be cancelled, terminated, or suspended in whole or in part, as deemed appropriate by THE UNIVERSITY.

8. AUTHORITY AND RELATIONSHIP OF PARTIES

The nature of the relationship which THE SUBCONTRACTOR shall have to THE UNIVERSITY shall be that of an independent contractor. This subcontract shall not be construed to contain any authority, either express or implied, enabling THE SUBCONTRACTOR to incur any expense or perform any act on behalf of THE UNIVERSITY. Nothing in this subcontract shall prevent or impair the right of THE UNIVERSITY to apply for, receive, administer or perform the conditions of any public or private grant or contract. Nothing in this agreement shall operate to impair the tax-exempt status of THE UNIVERSITY.

9. ASSIGNMENT

THE SUBCONTRACTOR shall not assign, transfer, or convey this subcontract or any part hereof, or any interest herein, nor shall THE SUBCONTRACTOR subcontract for the performance of any of its obligations hereunder, without the prior written consent of THE UNIVERSITY.

Rajendra Kumar
Adv. & Notary
Teh. Mohanlalganj
Lucknow
Reg.No. 31(53)2009

09/01/2019

Rajendra Kumar
Adv. & Notary
Vill. ... Post-Kankar...

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

10. INTEGRATION CLAUSE

This subcontract represents and embodies all the agreements and negotiations between the parties hereto and no oral agreements, representations, or correspondence shall be held to vary the provisions hereof.

11. STATE OF GOVERNING LAW

THE UNIVERSITY and The SUBCONTRACTOR agree to remain silent.

12. TERMINATION

THE UNIVERSITY may terminate this subcontract upon written notice to THE SUBCONTRACTOR at any time prior to the completion of this subcontract. In addition, either party may terminate this subcontract for any reason upon thirty (30) days written notice. THE SUBCONTRACTOR shall be reimbursed for uncancellable obligations properly incurred prior to the date of notice of termination.

13. PUBLICATIONS

THE SUBCONTRACTOR agrees to acknowledge the support of THE UNIVERSITY and/or the awarding Sponsor whenever activities funded in whole or in part by this subcontract are published in any news media. All major publications resulting from this work will be prepared jointly by the parties with major responsibility assigned as per specifics of the particular publication. The terms and conditions in Section 7- PUBLICATIONS in the Memorandum of Agreement for Research and Development (Attachment III) shall remain in full effect for twelve months after the expiration of the Memorandum of Agreement for Research and Development.

NOTARY Rajendra Kumar Adv. & Notary Teh. Mohanlalganj Lucknow Reg.No. 31/1992

IN WITNESS WHEREOF, the parties have caused this contract to be effective as of **Nov 15, 2018**, with signatory approval of their duly authorized representatives.

WAYNE STATE UNIVERSITY

SIGNED:_____

09/1/2019

Rajendra Kumar Adv. & Notary Vill. Garhi Post-Kankaha Mohanlalganj, Lucknow

DATE: 09.01.2019

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS)

SIGNED

Title:_____

DATE:_____

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WSU18xxx

PROFESSOR DR ANITA SAXENA
PRINCIPAL INVESTIGATOR
SANJAY GANDHI POST-GRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS)

SIGNED _____

NOTARY
Rajendra Kumar
Adv. & Notary
Teh. Mohanlalganj
Lucknow
Reg.No. 31(39)2009

DATE 09.01.2019

09/01/2019
Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

WSU18xxx

ATTACHMENT I

STATEMENT OF WORK

The Bangladesh arm of the multi-centered PATCH study will be a randomized, double blind, placebo-controlled, parallel design study involving the Sanjay Gandhi post-Graduate Institute of Medical Sciences (SGPGIMS) in Lucknow, India. The protocols to be followed have been detailed in our previous intervention studies with TT (Daud et al, 2013) and omega-3- supplements (Daud et al, 2012). The protocol is also in line with the procedures used in the recent tocopherol and lipoic acid intervention trial (Himmelfarb et al, 2014). SGPGIMS will recruit upto 75 eligible patients undergoing thrice weekly or twice weekly dialysis. Patients will be administered 300mg TRF per hemodialysis session under direct supervision and 300mg TRF during non-dialysis days as a take home supplement. The administrations of TRF/placebo will last for up to 12 months. Compliance will be monitored by capsule counting method as well as by direct observation during regular thrice-weekly dialysis sessions. Changes in diet will be monitored via multiple 24-hr diet recalls at baseline and at 3–month intervals. Blood will be collected at t=0 (baseline), 3, 6, and if needed at 9 and 12 months, plasma will be isolated and stored at SGPGIMS at -80 degrees until subsequent analyses by Wayne State. SGPGIMS will also provide us with the results from routine blood measurements that they undertake as part of the patients' standard care. No blood samples will be collected for the study which is not part of the patient's routine care. An additional sample will be collected 3 months after the study finishes (documenting any residual effects of the supplement).

NOTARY
Rajendra Kumar
Adv. & Notary
Teh. Mohanlalganj
Lucknow
Reg.No. 31[illegible]2009

09/01/2019
Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Mohanlalganj Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ATTACHMENT II-APPROVED BUDGET
FOR THE PERIOD 11/1/18 TO 12/14/19

PERSONNEL	- U$	6,000.00
PATIENT CARE	- U$	5,000.00
MEDICAL INSURANCE	- U$	5,000.00
RESEARCH SUPPLIES	- U$	6,000.00
STUDY MEASURES	- U$	3,000.00
MAINTENANCE	- U$	2,000.00
SAMPLE SHIPMENT	- U$	1, 000.00
TRAVEL	- U$	2, 000.00
TOTAL DIRECT COSTS	- $	30,000.00
OVERHEAD/SERVICE TAX		
TOTAL COST	- $	30,000.00

PAYMENT SCHEDULE

Invoice for $5,000 USD upon full execution of Subcontract WSU18059.

Invoice for $10,000 USD on June 1, 2019.

Invoice (marked FINAL) for $15,000 USD upon completion of project.

Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ATTACHMENT III

Memorandum of Agreement for Research and Development

(see attached)

NOTARY
Rajendra Kumar
Adv. & Notary
Teh. Mohanlalganj
Lucknow
Reg.No. 31(65)2009

09/01/2019
Rajendra Kumar
Adv. & Notary
Vill. Garhi Post-Kankaha
Teh. Mohanlalganj. Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ VL 053892

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००००९
- 5 JUL 2019
सक्षम अधिकारी

E-Track Number : 116566
Center Number : 235925
Reference for Payment : PO.....

श्री. दि. क. गवई

AGREEMENT FOR CLINICAL TRIALS

This Agreement for Clinical Trials (the "Agreement") is effective on **11-July-2019**, (the "Effective Date") between

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, Raebareli Road Lucknow - 226014, Uttar Pradesh, India (hereinafter referred to as "**Institution**")

and

GLAXOSMITHKLINE PHARMACEUTICALS LIMITED, a company registered under the Companies Act, 1956 and having its registered office at Dr. Annie Besant Road, Worli, Mumbai 400030 (hereinafter referred to as "**GSK**").

WHEREAS GSK is a pharmaceutical company involved in the research, distribution and sale of vaccines for use in humans;

WHEREAS GlaxoSmithKline Biologicals S.A., rue de l'Institut 89, B – 1330 Rixensart, Belgium (hereinafter referred to as "**GSK Bio**" or "**Sponsor**") is the sponsor of the Study (as

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Executive Registrar
SGPGIMS,Lucknow

defined below) and has subcontracted the conduct of the Study to its affiliated local company, GSK;

WHEREAS Institution is concerned with the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare

WHEREAS GSK is willing to contract with Institution to undertake the conduct of a sponsored study on the investigational Vaccine (as defined later) entitled "A phase ***III***, randomized, open study to assess the immunogenicity, reactogenicity and safety of two different formulations of GlaxoSmithKline (GSK) Biologicals' oral live attenuated human rotavirus (HRV) vaccine, *Rotarix,* when given as a two-dose primary vaccination, in healthy infants with no previous history of rotavirus illness or vaccination." (hereinafter referred to as the "**Study**"). Such Study will be conducted under the oversight and responsibility of Investigator at Institution; and

WHEREAS Investigator shall conduct the Study and Institution is willing to provide certain resources in furtherance thereof.

NOW, THEREFORE, in consideration of the promises and the mutual covenants and conditions hereinafter recited, the parties do hereby agree as follows:

I. INSTITUTION AND PRINCIPAL INVESTIGATOR

a) Institution represents and warrants that it holds the necessary registrations and authorisations to perform the Study under this Agreement.

b) Save as may be agreed from time to time by GSK and Institution, Principal Investigator shall take primary responsibility for the conduct of the Study at the Study site on behalf of Institution.

c) The Institution represents that it is entitled to procure the services of Dr. Piyali Bhattacharya to act as principal investigator for the Study ("**Principal Investigator**" or "**Investigator**") and shall be responsible for the performance of the obligations of the Principal Investigator and other Study staff set out in this Agreement. Institution represents that Investigator and other Study staff holds the necessary registration and has the necessary expertise, time and resources to perform the Study.

d) Institution shall procure and shall ensure that Principal Investigator procures the performance of the obligations of the Study staff as set out in this Agreement with all due skill, care and diligence. Institution shall provide qualified personnel, facilities and resources, as required, to perform this Agreement.

e) Where Institution is not the principal employer of Principal Investigator, Investigator represents that Principal Investigator has notified his/her principal employer of his/her proposed participation in the Study and, where relevant, his/her supervision of the Study staff and that his/her principal employer has consented to his participation in the Study. Any financial or other arrangement relating to the Investigator's involvement in the Study will be agreed directly between Institution and the principal employer of Investigator.

f) The Institution and the Principal Investigator represent that the Principal Investigator has the necessary expertise to perform the Study, that the Principal

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Executive Registrar
SGPGIMS,Lucknow

Investigator is not involved in any litigation or investigation conducted by any public authority, and that no data produced by him in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

g) The Institution shall forthwith notify GSK if Dr. Piyali Bhattacharya ceases to be employed by or associated with the Institution or is disqualified or barred from performing obligations herein, or any conflict of interest arises which has not been previously disclosed to GSK or is otherwise unavailable to perform his/her obligations under this Agreement and shall use its best endeavors to find a replacement acceptable to both GSK and the Institution. If no mutually acceptable replacement can be found GSK may terminate this Agreement pursuant to clause XV below.

h) Principal Investigator represents he/she is free to participate in the Study and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict Principal Investigator's performance of the obligations detailed in this Agreement.

i) Principal Investigator is not involved in any regulatory or misconduct litigation or investigation by the DCGI, Medical Council of India, US Food and Drug Administration, the Medicines and Healthcare products Regulatory Agency, the European Medicines Agency, the General Medical Council or other regulatory authorities. No data produced by Principal Investigator in any previous study / clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

j) Principal Investigator has considered, and is satisfied that, facilities appropriate to the Study are available to Investigator at the Study Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the Institution to perform the Study efficiently and in accordance with its obligations under the Agreement.

k) Principal Investigator carries medical liability insurance (or the Institution carries medical liability insurance covering him) and details and evidence of the coverage (including violation of approved protocol, scientific misconduct or negligence) will be provided to GSK upon request.

l) During the Study, Principal Investigator will not serve as an investigator or other significant participant in any study / clinical trial for another sponsor if such activity might adversely affect his ability to perform his obligations under this Agreement.

m) Neither Principal Investigator, nor his spouse nor any dependent children, have entered into and will not enter into any financial arrangements with GSK to hold financial interests in GSK namely (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Study could be influenced by the outcome of the Study, (ii) any proprietary interest in the product being tested, (iii) any significant equity interest in GSK and (iv) any significant payments from GSK such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria. In the case of subparagraphs (iii) and (iv) the Investigator

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Executive Registrar
SGPGIMS,Lucknow

understands that such prohibitions relate to the period that the Investigator is carrying out the Study and for one (1) year following completion of the Study.

II. STUDY CONDUCT

a) GSK Bio is the Sponsor of the Study. The Study shall be carried out under the strict supervision of the Principal Investigator and in accordance with the protocol reference ***Amendment 3 Final: 31*** October 2017 set out in Schedule A attached hereto (**"the Protocol"**). The Principal Investigator undertakes to comply with all rules in force within the Institution and represent that such rules are not in conflict with this Agreement.

b) The Principal Investigator shall be responsible for obtaining and maintaining all approvals from the relevant local ethics committee for the conduct of the Study and the Principal Investigator shall keep GSK fully appraised of the progress of ethics committee submissions and shall upon request provide GSK with all correspondence relating to such submissions. The Principal Investigator shall not consent to any change in the Protocol requested by a relevant ethics committee without the prior written consent of GSK.

c) It is further agreed by the Institution and the Principal Investigator that the Study shall be carried out by scientifically qualified staff in accordance with:

i) the principles that have their origin in the World Medical Association Declaration of Helsinki entitled "Ethical Principles for Medical Research Involving Human Subjects" (latest version), the ICH Harmonised Tripartite Guideline for Good Clinical Practice (GCP);

ii) all applicable laws, including without limitation: the Drugs & Cosmetics Act 1940 and Rules, notifications, circulars, office orders and any other directives thereunder or issued by office of the Drugs Controller General of India (DCGI) or similar such administrative body, Information Technology Act 2000 and Rules pertaining to sensitive personal information thereunder, Electronic Health Record (EHR) Standards for India, 2016, other medical privacy laws or regulations, as well as by obtaining any required subject consent or authorization to allow GSK access to Study subject's personal and medical information as may be necessary to monitor the Study and to receive and use Study data and all legal and ethics requirements of the country in which the Study is performed (collectively herein **"Applicable Laws"**;

iii) the Protocol;

iv) and in strict compliance with the terms of this Agreement.

Should there be any inconsistency between the Protocol and the other terms of the Agreement, the terms of the Protocol shall prevail to the extent of such inconsistency.

d) Prior to commencing the Study, the Principal Investigator or a person designated by the Principal Investigator shall inform each subject of the nature of the Study and obtain the subject's or the subject's legal representative's written signed

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Executive Registrar
SGPGIMS,Lucknow

consent whenever possible, or failing that, oral witnessed informed consent of that subject to undergo the Study.

e) The Principal Investigator agrees to exercise his/her due diligence to complete the Study according to the timing agreed upon in the Protocol.

f) Neither the Institution nor the Principal Investigator shall during the term of this Agreement conduct any other trial which might adversely affect the Institution or Principal Investigator's ability to perform their obligations under this Agreement.

g) Neither the Institution nor the Principal Investigator shall have the right to sub-contract all or part of the Study conduct to any third party without the prior written consent of GSK. The Institution shall enter into written agreements with any approved subcontractor with terms and conditions required by and consistent with this Agreement. The Institution and the Principal Investigator shall be completely responsible for the satisfactory performance of all services assigned to sub-contractors, and the Institution and the Investigator acknowledge that the acts or omissions of any subcontractors shall be deemed to be the acts or omissions of the Institution and/or the Principal Investigator with respect to the performance of any obligation of either the Institution or the Principal Investigator under this Agreement.

h) In the event Institution/Principal Investigator observes or becomes aware of material non-compliance with the Protocol, the GCPs or any Applicable Laws, incomplete or inaccurate recording of data, or any significant misconduct or other matters of concern relating to the performance of the Study, Institution/Principal Investigator shall promptly inform GSK, and shall cooperate with GSK to take appropriate and timely measures to remedy such non-compliance or other matter of concern.

i) The Institution must have adequate security measures to ensure the safety and integrity of the investigational Vaccine, and Study records and reports, equipment and any Study related materials held or located at the Study Site.

III. SUPPLY OF MATERIALS

a) GSK shall supply the Institution / Principal Investigator with approximate 45 Vaccines each of HRV lyophilized vaccine and HRV liquid vaccine ("**the Vaccine**") as shall be required for the purpose of the Study and the Principal Investigator acknowledges that he/she has no claim to the Vaccine so supplied and that it shall remain the sole and exclusive property of GSK and shall be used by the Principal Investigator and/or the Institution solely for the purposes of this Study and in accordance with the terms of this Agreement or other Study related documents. Further Vaccine supplies may be made based on subject recruitment.

b) The Institution represents to have complete facilities and infrastructure required for storage for the Vaccine.

c) The Principal Investigator and the Institution shall use the Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify the Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, and ship or dispose of Vaccine in compliance with all Applicable Laws and instructions as may be mentioned on the Vaccine label/pack or communicated by GSK from to time, including, but not limited to, those governing

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

hazardous substances. The Principal Investigator and the Institution shall not charge any Study subject or third-party payor for any Vaccine, or for Study procedures for which payment by GSK has or will be made under this Agreement.

d) The Vaccine shall be returned to GSK/ the Sponsor or drug depot working under Sponsor's responsibility in case of:
   - Recall intimation by GSK/ Sponsor
   - Complaint from the Institution/PI
   - As and when required by GSK/Sponsor

   The Vaccine can be also returned for destruction to the GSK/Sponsor or drug depot working under the Sponsor's responsibility.

   The Vaccines to be returned must be identified and stored in a dedicated area within the Institution's premises at the label storage temperature conditions unless otherwise authorized.

IV. ELECTRONIC CASE REPORT FORMS AND EQUIPMENT / SYSTEMS

a) GSK might lend computer equipment and, where appropriate, software systems or other materials or equipment to the Institution for the sole purpose of performing the Study. Any equipment or material that is not part of the compensation paid to the Institution for the performance of the Study, as referenced under section XI b) 6. of this Agreement, shall be returned to GSK as provided for in section IV b) (viii) below.

b) In the event GSK provides computer equipment and/or software systems; (including but not limited to the web-based case report from system for Study staff to use to collect, enter and report Study data to GSK electronically, the Institution hereby agrees that:

   i) Study staff will make themselves available for training in using the systems;

   ii) the systems will be used only for the Study and only as described in written directions provided by GSK;

   iii) the computer equipment and if appropriate the systems and other equipment will be kept in a safe and secure location, and will be used only by Study staff designated by Site Principal Investigator as responsible for entering Study data;

   iv) Case Report Forms (CRFs") information associated with a study subject's visit must be satisfactorily completed within three (3) days after the subject's visit or, if applicable, receipt of the study subject's test results;

   v) All data queries from GSK must be completed and returned to GSK within seven (7) days or, if during final clean up, one (1) day, or such other time set by GSK;

   vi) Institution will take suitable precautions and measures to prevent theft, damage or loss to the computer equipment;

   vii) Institution will be responsible for arranging and paying for any required internet connection as necessary to use the systems; and

Lt Col Varun Bajpai VSM
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viii) at the completion or early termination of the Study or at GSK's request, Institution will return to GSK the computer and all system related training materials and documentation provided to the Institution and/or Study staff, as well as other materials or equipment lend to the Institution for the purposes of the Study.

V. CONFIDENTIALITY

a) "GSK Confidential Information" means: (1) all information (including, without limitation, Study protocols, case report forms, clinical data, other data, reports, specifications, Study budget, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of GSK or GSK's affiliates that are provided to Institution in connection with this Agreement or the Study; (2) Study data, results, information fixed in any tangible medium, or reports created by Institution, Investigators, or Study staff in connection with the Study (except for Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

b) GSK Confidential Information and all tangible expressions, in any media, of GSK Confidential Information are the sole property of GSK.

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

d) The contents of this Agreement shall not be disclosed to third parties unless agreed to by both parties.

e) The obligations of confidentiality and non-use shall not apply to information:

i) which at the time of receipt by the Principal Investigator and/or the Institution is in the public domain;

ii) which after receipt by the Principal Investigator and/or the Institution becomes part of the public domain by publication or otherwise by lawful and proper means;

iii) which the Principal Investigator and/or the Institution can establish by competent proof was in their possession before receipt from us and was acquired with free rights of disposal directly or indirectly from a source wholly independent of us;

iv) which the Principal Investigator and/or the Institution subsequently receive from a third party with good legal title thereto or which had the right to disclose or transfer such information.

In the event that the Principal Investigator and/or the Institution hereto are required by applicable statute or regulation or by judicial or administrative process

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Executive Registrar
SGPGIMS,Lucknow

to disclose any part of the GSK Confidential Information which is disclosed to them hereunder, the Principal Investigator and/or the Institution shall (i) promptly notify GSK of each such requirement and identify the Information so required thereby, so that GSK may seek an appropriate protective order or other remedy and/or waive compliance by the Principal Investigator and/or the Institution with the provisions of this Agreement and (ii) consult with GSK on the advisability of taking legally available steps to resist or narrow the scope of such requirement.

f) Notwithstanding anything to the contrary contained in this Agreement, it is agreed between the Parties and the Principal Investigator and/or the Institution hereby acknowledges that GSK, its group companies and/or its or their authorized third parties shall have access to the contents of this Agreement including personal information and sensitive personal data or information of Principal Investigator and/or the Institution as contained in this Agreement (but not of the Study subjects) . The Principal Investigator and/or the Institution hereby expressly permits such disclosure and waives any right to object in future.

g) The obligations of this Section shall survive termination or expiration of this Agreement.

VI. STUDY TRANSPARENCY AND PUBLICATION

a) GSK will post a Study Protocol summary on a publicly available protocol register prior to the enrollment of Study subjects.

b) Post Study completion, GSK will post a Study results summary on a publicly available results register. Posting of summary Study results may occur prior to publication of Study results in the peer-reviewed literature.

c) GSK will seek to publish the Study results from all Study sites (a "Multicenter Publication") in the searchable, peer reviewed scientific literature in the form of journal manuscripts and in some cases, in the form of presentations of Study results at international congresses. Where publication in the searchable, peer reviewed scientific literature is not feasible, the Study results summary shall be posted on publicly available register(s).

d) First publication(s) ("Primary Publication") and all consequent Multicenter Publication(s) or disclosure(s) of the Study results shall be coordinated by GSK in order to ensure compliance with GSK policies and SOPs. The Primary Publication shall disclose at least the primary and secondary efficacy endpoints and safety results, and when medically informative, exploratory analyses. For a multicentre Study, the Primary Publication(s) or disclosure(s) of Study results shall be a complete joint Multicenter Publication(s) or disclosure(s). Thereafter, any other publications will reference the original publication(s). Primary Publication(s) of Study results shall be accompanied by public disclosure(s) of the full Study Protocol in publicly available registers.

e) Any participation of Principal Investigator or other representatives of Institution as a named author of a Multicenter Publication will be determined in accordance with the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for Manuscripts, and Institution and Principal Investigator acknowledge that the enrollment of Study subjects alone is not a qualification for

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

authorship. Institution, Principal Investigator and GSK who are involved as authors in preparing a publication are responsible for ensuring that authorship in such publications is attributed appropriately in accordance with the criteria for authorship described in the Uniform Requirements of the International Committee of Medical Journal Editors (ICMJE) (http://www.icmje.org/) (or, if more stringent, the authorship criteria of the specific journal) and that the publication is developed according to the recommendation from the International Society for Medical Publication Professionals (ISMPP) about Good Publication Practice for Communicating Company Sponsored Medical Research (C Graf et al. Good Publication Practice for Communicating Company Sponsored Medical Research: the GPP2 guidelines. BMJ 2009;339:b4330).

f) Institution and Principal Investigator agree that all significant contributions made by individuals and organizations shall be acknowledged. The contributions of writers and individuals not listed as authors, the role and involvement of GSK in the Study and any writing and/or coordination support to develop Primary Publications, as well as Institution Publications or Written Materials shall also be described and disclosed.

g) If the Principal Investigator or other representative of Institution is a named author of the Multicenter Publication, GSK and Institution (on behalf of such authors at Institution) agree that authors:

i) Will enter a written agreement with GSK confirming the key principles of obligations related to development of publications and agreement thereto prior to starting the work on the development of the Multicenter Publication

ii) will have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication;

iii) will adhere to ICMJE requirements regarding authorship;

iv) will disclose as part of the Multicenter Publication that GSK financially supported the Study and any personal financial relationship with GSK;

v) will disclose that they have made substantial contributions to the Study and have given or will give final approval to the version of the Multicenter Publication ultimately published;

vi) and upon completion of author activities will certify in writing to the foregoing and that the authored publication is fair, accurate, and balanced.

h) Institution, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution's Study data (an "Institution Publication"), provided that the Institution Publication does not also disclose any GSK Confidential Information other than the Study results from Institution's Study data.

i) Institution and Principal Investigator shall, and shall ensure that any other persons under their control submit to GSK for review and comment any proposed publication, presentation, poster, abstract, material for use for teaching purposes

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

or otherwise disclosing the Study results (hereinafter jointly referred to as the "Written Material") at least sixty (60) days prior to disclosing such Written Material to any third party and shall allow GSK a period to review the same not to be shorter than 60 days for manuscripts, posters, presentations and material for use for teaching purposes or otherwise disclosing the Study results or 21 working days for abstracts. If GSK requests a delay in order to file patent applications or seek similar protection of any inventions, know-how or other intellectual or industrial property rights disclosed in the proposed Written Material, Institution and the Principal Investigator agree to delay submitting such Written Material to any third party for up to one hundred twenty (120) days after GSK's request. Institution and Principal Investigator agree to incorporate in the Written Material any and all reasonable comments made by GSK.

j) Institution also agrees that any Institution Publication shall only be made after the Multicenter Publication. Institution agrees that GSK's financial support of the Study will be disclosed in any Institution Publication and will require all authors of such Institution Publication to disclose any financial relationship with GSK. Institution shall ensure that Investigator complies with the obligations identified in this subsection.

k) Study subjects' Personal Information, such as name or initials, shall not be publicly disclosed at any time.

l) Institution and Principal Investigator acknowledge that GSK may be required by Applicable Laws or industry codes of practice or GSK policy to disclose specific information, including but not limited to, the fact that GSK has funded the conduct of the Study, the names and address of the Principal Investigator and the Institution as well as details of any payment or benefit in kind made to or for the benefit of the Institution or the Principal Investigator. By executing this Agreement, the Institution agrees that GSK or its affiliates may publicly disclose such information as required under any Applicable Laws or industry codes of practice or GSK policy and that it has obtained the consent of the Principal Investigator to such disclosure. Moreover, Institution shall ensure that Principal Investigator agrees that, if Principal Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Drug or that otherwise relates to GSK, Principal Investigator will disclose that he/she was an investigator for the Study.

m) In order to achieve an optimal scientific outcome of publication activities if considered appropriate, GSK, Principal Investigator or other Institution personnel involved with the Study may participate in the Publication Steering Committee ("PSC") for the Study or core writing team(s) and may, if requested by GSK in writing, present the Study results at congresses or conferences identified by GSK. Institution agrees that Principal Investigator or other Institution personnel involved with the Study are allowed to participate in such PSC, core writing team(s) and speaking engagements at peer-reviewed plenary sessions of scientific congresses. Participation will consist as appropriate of: (1) attending either in person or via teleconference the various meetings of the PSC which will be called from time to time to develop the publication plan for the Study, review proposals for publications submitted to the PSC, define publication timelines, endorse the scientific meetings at which and medical journals in which results from the Study should be presented, recommend and endorse authorship. Members of the PSC, will be expected to participate in a minimum of two (2) and a maximum of twelve (12) meetings of the PSC; (2) attending either in person or via teleconference the various meetings or otherwise participating in activities of core writing teams for

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

any publications as approved in the publication plan with an aim to review the progress of any such publications; (3) if requested by GSK in writing, present the Study results on congress(es) or conference(s) identified by GSK for any publication as approved in the plan as author on such publication.

n) Persons participating as a member of a PSC, in core writing team(s) activities or presenting Study results at conferences or congresses will not receive any payment, honorarium or other fee for participation in such activities nor ownership to nor other title or interest in work product arising out of such activities. However, GSK will reimburse such persons or the Institution (as the case may be and as advised by such persons) for their reasonable travelling and lodging expenses while travelling at GSK's request, provided that travel and lodging expenses have been authorized by GSK in writing in advance and that GSK receives proper original receipts.

o) The obligations of this Section shall survive termination of this Agreement.

VII. RESULTS AND INTELLECTUAL PROPERTY

a) The Principal Investigator and the Institution agree to communicate the results of the Study promptly to GSK in such format as GSK shall require. The Principal Investigator and the Institution shall immediately assign to GSK all Intellectual Property rights (including know-how and copyright) and interests in all countries in any inventions or developments arising from the Study and agree to assist GSK in connection with any application for Letters Patent or other forms of protection and do all such other things and execute all such documents and authorizations as may be necessary in connection with any such applications. GSK will have the sole rights to decide in which countries to apply for and obtain Letters Patent or other forms of protection and shall be liable for all expenses incurred in filing, prosecuting to grant and maintaining in force such Letters Patent or other forms of protection.

b) All background IP owned or controlled by a Party hereto shall remain the property of such Party.

c) The obligations of this Section shall survive termination or expiration of this Agreement.

VIII. INDEPENDENT CONTRACTOR

a) The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind, which purports to bind the other without the other's prior written authorization. It is hereby expressly understood that GSK shall not be responsible for any aspects of the employment of the Institution personnel involved in the conduct of the Study, unless otherwise specifically agreed upon in writing by GSK, and neither the Principal Investigator nor any other member of the Institution staff shall at any time be or be deemed to be, or to act as, employees of GSK.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(28)

IX. INDEMNIFICATION – INSURANCE

a) GSK shall through its insurance program provide free medical management and compensation for damages in relation to bodily injury (including death) attributable to the administration of the Vaccine in accordance with the Protocol or the participation in the Study as envisaged in Schedule Y of the Drugs & Cosmetics Rules, 1945 (collectively referred as "**Study Related Injury**").

b) Subject to sub-clause (d) and (e) of this clause IX, GSK will:

i) hold the Principal Investigator, his/her Study-staff (who are identified to be working on the Study), the Institution harmless and indemnify the same against damages and legal costs and expenses arising out of any legal action in relation with such Study Related Injury;

ii) cover the costs of treatment of Study subjects for Study Related Injury;

PROVIDED HOWEVER THAT GSK shall not be liable if such injury results from any wrongful act, omission or negligence or failure to conduct the Study in accordance with the Protocol on the part of Institution, Investigator, Study staff any person undertaking or involved in the conduct of the Study AND PROVIDED FURTHER THAT no admissions or settlements are made without the prior written approval of GSK, GSK is promptly informed of any claims or prospective claims and is given full conduct and control of any defence proceedings/negotiations.

c) Institution shall maintain all appropriate insurance including medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study, or require that each medical professional maintain such insurance. Upon GSK's request, Institution shall have its insurance carrier (or shall cause the medical professional to have his or her insurance carrier) furnish to GSK certificates that all insurance required under this Agreement is in force.

d) In no event will GSK be liable on any theory of liability, whether in an equitable, legal, or common law action arising hereunder for contract, strict liability, indemnity, tort (including negligence), or otherwise, for damages which, in the aggregate, exceed the amount GSK has paid under the Agreement as fees which gave rise to the cause of action, provided this limitation excludes any liability imposed by any authority and calculated under any Applicable Law.

e) GSK will be not liable for any indirect, or incidental or consequential damages of any type, including lost profits, arising out of or in connection with this Agreement or its termination or suspension.

f) Institution shall indemnify and hold harmless GSK, its affiliates, and each of their respective officers, directors, employees, agents and contractors (collectively, the "GSK Indemnitees") from and against any and all costs, charges, damages, expenses, fees (including without limitation reasonable attorneys' fees) and losses (including, without limitation fees and costs incurred in recovering the same) incurred by any GSK Indemnitee that arises from Institution's or Principal Investigator's breach, negligence, gross negligence or wilful misconduct or a breach by Institution or any of its agents, contractors or subcontractors of this Agreement.

Dr. Piyali

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

X. COMPENSATION

a) GSK agrees to pay for up to a maximum of 90 subjects included in the screening sequence, (at a cost of 11400/- per screened subject).

b) GSK also agrees to pay, for each subject enrolled and properly documented as detailed in the Protocol, the following fees, in INR and this up to a maximum of 90 subjects included in the Study:

Total study budget	**Unit cost**	**No. of subjects**	**Amount**
Study assessments	6300	90	567000
Investigator's fees	3600	90	324000
Study personnel's fees	1500	90	135000
Total			1026000
Overheads (to specify	25%		256500
Travel reimbursement	1500	90	135000
Others (to specify) Archival costs (for 25 years)	100000		100000
Miscellaneous	20000		20000
Total study budget			1537500

(hereinafter referred to as the "Study Budget")

Visit Activities	Cost in INR		
	Visit 1	2	3
Informed consent	800	0	0
Check Inclusion/Exclusion Criteria	700	0	0
Physical Examination – General	800	700	0
Vaccine/Treatment Administration	400	400	0
Record, Concomitant Medication/Vaccine	300	300	300
Blood Draw, Complex	800	0	800
Study Coordinator, Complex - per visit	500	500	500
Physician, Complex - per visit	1200	1200	1200

c) The maximum Study Budget assigned to the Principal Investigator amounts to 1537500 (Study costs). The Principal Investigator shall be responsible for allocating and paying all costs of Study within the limit of the Study Budget to all co-investigators and sub-investigators working for the Study.

Payment of this Study Budget will be made upon achieving the following milestones:

Milestone payment	
I	First Payment: post site initiation visit: An amount of Rs.20000 will be released after site initiation visit.
II	Subsequent payments:
1	Towards subject visit: once in every two months based on subjects visits shown in eTRACK
2	Screen failure travel reimbursement payment: 10% of screen failures will be provided travel reimbursement.
3	Cost involved in medical management and additional costs: once in every

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Executive Registrar
SGPGIMS,Lucknow

	two months; shall be made on the receipt of the invoice and supporting documents
III	Post query resolution: An amount of Rs.50000 will be put on hold from the second last invoice. The said payment will be made after post query resolution.
IV	Post close out: archival payment will be made.

d) Payments shall be remitted by GSK in INR n a milestone-completion basis, within thirty (30) days after receipt of duly documented invoice or supporting documentation demonstrating completion of the milestone. If the number of the subjects is less than the then-current target number set forth in Section XI a), the Study Budget and the installments will be reduced accordingly.

The Study Budget shall cover all Study expenditure such as, but not limited to investigators fees, GE/IP surveillance fees, Study personnel's fees, laboratory costs, (including personal and material), travel costs linked to public disclosure activities (if and to the extent requested by GSK) such as Publication Steering Committee meetings, core writing team meetings and presentations of Study results at conferences or congresses, overheads and others (including but not limited to administrative costs, taxes, insurances, ERC submission costs, etc).

Such Study Budget has been agreed upon by the parties prior to start the Study, therefore GSK shall in no event accept any overspending and the Principal Investigator and the Institution undertakes to complete the Study within such Study Budget.

Payment instructions shall be specified in Schedule B attached hereto (please fill in the Schedule B – Payment Instructions Sheet).

Bank transfer costs shall be supported by GSK.

e) The Institution will receive the fees mentioned in sub-paragraphs (a) and (b) above for every subject evaluable according to the Protocol. The fee mentioned under (b) above shall be paid only with respect to evaluable subject and when the vaccination's calendar as foreseen in the Protocol has been scrupulously respected. In the event of non-evaluable subject(s), only the screening costs specified in sub-paragraph (a) will be paid. The non-evaluable subject's criteria are defined in the Protocol and include, but are not limited to, the following events:

i) subject or vaccine number not allocated;

ii) Study vaccine dose not administered but subject number allocated;

iii) administration of vaccine forbidden in the Protocol;

iv) wrong vaccine vial given;

v) deliberately breaking the randomization code at investigator site, violating the allowable reasons for breaking the code (i.e. SAE, etc.);

vi) Study vaccine dose not administered according to Protocol;

vii) Protocol violation;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

viii) non-compliance with vaccination schedule;

ix) non-compliance with blood sampling schedule;

(For points viii) and ix), if the rate for non-compliance exceeds 15%, the payment for these subset of subjects will not be made - example: if 30% of total subjects did not comply with vaccination and/or blood sampling schedule, 30% of volunteers fees will not be paid by GSK - The computation will be detailed on the last payment).

x) essential serological data missing when proven due to Principal Investigator's delinquency;

xi) other reasons due to Principal Investigator's shortcoming.

f) Institution/Principal Investigator agree to include at least 90 subjects within a period of 4-5 months after receipt of the Vaccine. After this period GSK reserves the right to terminate this Agreement without any obligation to pay compensation (except for actual expenses incurred with respect to the Study) in the event that such minimum number of subjects has not been included.

If Institution/Principal Investigator are able to find more subjects than are specified in the Protocol, and provided that GSK has agreed to the inclusion of any such additional subjects in the Study, GSK agrees to pay you the sum per subject referred to in sub-paragraphs XI (a), if applicable, and (b) above in respect of each extra subject so agreed.

g) The Principal Investigator hereby acknowledges the requirements of the FDA Financial Disclosure Rule and agrees to fill in and return to GSK, upon GSK representative's request, the Statement of Investigator Financial Interest form attached hereto as Schedule C before the start of the Study. The Principal Investigator also consents to the disclosure of the so filled Form to the FDA if necessary.

h) GSK will not make any payment, or, if payment has been made by GSK, Institution will repay to GSK any payments, for work associated with the Study if GSK determines that the Study results is not evaluable and/or is rejected by regulatory authorities because of a violation of the Protocol or any Applicable Laws and guidelines by Institution, Investigator, or Study staff.

i) All payments made by GSK to Institution shall be subject to applicable tax deduction(s) at source as required under Income Tax Act 1961.

j) As required under the Goods and Services Tax ("GST") laws as amended from time to time and any rules and regulations thereunder ("GST Laws"), it is agreed that the Institution will pass on any benefit due to reduction in rate of tax or from input tax credit by way of commensurate reduction in prices. Further, invoices shall be raised by the Institution in compliance with all Applicable Laws including but not limited to the GST Laws. The Institution warrants to comply with all required provisions of GST Laws including but not limited to invoice compliance, reporting compliance, payment of taxes and information and document compliance as well as provide GSK such support as may be required including but not limited to

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

providing information such as, its GSTIN, GST registered address, GST compliance rating, etc. amongst others and maintenance of appropriate level of GST compliance rating with a view to enable GSK to avail GST input tax credit for the taxes paid and such other requirements.

k) The Institution hereby acknowledges and agrees that if it fails to comply with the GST Laws, and any covenants as mentioned above and as such renders GSK ineligible for any GST input tax credit amongst other consequences, GSK shall have the right to (i) withhold entire invoice payment until the non-compliance so noticed is corrected and GSK is able to avail corresponding input tax credits; (ii) cause the Institution to rectify the said non-compliance during a the cure time given for the same; or (iii) terminate this Agreement; at the sole option and discretion of GSK, and it may exercise such other rights and remedies as per the terms of this Agreement.

l) The Institution hereby further acknowledges that if it receives any invoice from GSK, whether or not in full, or if it receives any advance payments from GSK, any subsequent alleged non-compliance of the GST Laws and/or requirements therein which renders GSK to lose the applicable input tax credit or any loss to GSK in any form, GSK will have the right to seek a financial refund or set-off such amounts against any payments payable (past, present or future payments) to the Institution.

XI. RECORDKEEPING – ACCESS - MONITORING

a) Institution shall make records regarding the Study as required by the Protocol, Applicable Laws, or ICH Good Clinical Practices, and in accordance with Institution's standard procedures. Institution will retain such records for a minimum of twenty-five (25) years from the issue date of the Clinical Study Report/Summary or equivalent, subject to a request from GSK/ Sponsor under sub-clause (d) below. GSK will inform the Institution / Principal Investigator of the date on which the GSK required retention period will expire. After the expiration of this period, Institution is responsible for complying with any remaining relevant local, organizational, state, national and/or regulatory guidelines for records retention.

b) GSK shall inform the Institution and the Principal Investigator of the name and telephone number of the person(s) appointed by GSK to monitor compliance of the Study with the ICH GCP and to conduct source data verification (hereinafter the "Monitor"). Authorized representatives of GSK, such as the Monitor, upon reasonable advance notice and during regular business hours, shall have the right to inspect Institution's facilities used in the conduct of the Study and to inspect and copy all records relating to the Study (including, without limitation, access to records as necessary for Study monitoring or to audit the conduct of the Study in accordance with GSK standards or Institution's business processes and practices that involve the Processing of Personal Information). GSK will maintain the confidentiality of any subject-identifiable medical records.

c) If any governmental or regulatory authority notifies Institution that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify GSK, allow GSK to be present at the inspection/action or participate in any response to the

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

inspection/action, and provide GSK with copies of any reports issued by the authority and Institution's proposed response.

d) Without prejudice to sub-clause (a), GSK / Sponsor may require Institution to return, delete or destroy portions of the Study records as follows: Institution shall return, delete or destroy all Personal Information provided by GSK / Sponsor and shall delete or destroy all Personal Information generated in performing the Study, including without limitation all originals and copies of such Personal Information in any medium, and any materials derived from or incorporating such Personal Information, within ten (10) days after GSK/ Sponsor's request for such return, deletion or destruction for any reason(the "Return Date").

e) In the event that Institution determines, in its reasonable discretion, that returning, deleting or destroying Personal Information is infeasible on the Return Date, or if Applicable Law prevents or precludes the return, deletion or destruction of any such Personal Information by Institution on the Return Date, Institution shall notify GSK in writing, in reasonable detail, of the reason for not returning, deleting or destroying such Personal Information on the Return Date. In such case, (i) Institution shall return, delete, or destroy the Personal Information as soon as possible after the Return Date, (ii) Institution shall extend the protections to Personal Information which is not returned, deleted or destroyed on the Return Date for as long as such Personal Information is retained by Institution, and (iii) Institution shall not Process such Personal Information without GSK's express prior written consent on or after the date occurring ten (10) days prior to the Return Date.

f) The obligations of this Section shall survive termination of this Agreement.

g) Monitoring and Audit

(i) GSK shall have the right during the terms of this Agreement to conduct an audit of the Institution and Principal Investigator's activities under this Agreement. Institution and Principal Investigator shall cooperate fully with such audit, the scope, method, nature and duration of which shall be at the reasonable discretion of GSK.

(ii) The Institution will allow regular monitoring visits, access for the purposes of audit to GSK and to regulatory authorities and as specified in the Protocol and permit access to the original Study records, reports, other Study related materials and its staff as soon as is reasonably possible upon request by GSK, or the Sponsor or regulatory authorities or any third party designated by the Sponsor or GSK. Any such access to take place at times mutually agreed during business hours and subject to such reasonable conditions relating to occupational health and safety, security, and confidentiality as the Institution may require.

(iii) The Institution will provide GSK with all reasonable assistance and cooperation to rectify any matter raised by a regulatory authority or as a result of an audit of the Institution or Study. This includes execution of any documents reasonably requested by GSK or regulatory authority in connection with the requirements of regulatory authority or GSK as a result of such an audit. The cost will be borne by the Sponsor unless such rectification is due to the default of the Institution or the Principal Investigator.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(22)

XII. ENTIRE AGREEMENT – MODIFICATION OF AGREEMENT

a) This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument.

b) No terms or provisions of this Agreement shall be varied or modified except that the parties may amend this Agreement by written instrument specifically referring to and executed in the same manner as this Agreement. The Principal Investigator will make sure and remain responsible for the compliance with the provisions hereof by any of the sub- or co-investigator(s) involved in the conduct of the Study.

XIII. FORCE MAJEURE

a) Neither Party shall be liable to the other Party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance ("a Delay") and shall perform its obligations to the extent possible to overcome the effect of such event. In the event of a Delay lasting for eight (8) weeks or more the non-affected party shall have the right to terminate this Agreement immediately by notice in writing to the other Party.

b) This section does not excuse either Party from performing its obligations in relation to confidentiality and protection of personal information.

XIV. TERM AND TERMINATION

a) This Agreement shall take effect on the Effective Date and shall continue to be valid for a period of three (03) years from the Effective Date or until completion or discontinuation of the Study in accordance with the Protocol, whichever is earlier, unless terminated as provided below. At the end of the term of the Agreement (unless determined earlier) if parties wish to and mutually agree to renew the arrangement herein, parties may enter into such documents as mutually agreed to effect the renewal. Notwithstanding the above, compensation of travel costs linked to public disclosure activities (if requested by GSK) such as presentations at congresses, core writing team meetings and Publication Steering Committee meetings shall be possible for 30 months from the termination of this Agreement.

b) GSK reserves the right to temporarily suspend or prematurely discontinue the Study (including terminating the Agreement) either at a single site or at all sites at any time for any reasons including, but not limited to, safety or ethical issues or severe non-compliance. GSK may also terminate this Agreement if the Principal Investigator is no longer able (for whatever reason) to act as Principal Investigator and no replacement mutually acceptable to the Institution and GSK can be found. Reasons for suspension or early termination will be documented in the Study file at GSK.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

c) If GSK determines such suspension or early termination is needed, GSK shall discuss the reasons for taking such action with the Principal Investigator and/or the Institution. When feasible, GSK shall provide advance notification to the Principal Investigator of the impending action prior to it taking effect.

d) In the event the Study is suspended or terminated for any reasons whatsoever, GSK will promptly inform the Principal Investigator with a written notification related thereto. Upon receipt of such written notification, the Principal Investigator will inform the appropriate regulatory authorities and all co-investigators or sub-investigator conducting this Study of the suspension or early termination of the Study as well as the reasons for such decision. In addition, if so required by Applicable Laws, the Principal Investigator shall inform the Institutional Review Board/Independent Ethics Committee ("IEC/IRB") promptly and provide the reason(s) for the suspension or early termination of the Study.

e) If a Study is prematurely discontinued, the Principal Investigator shall return to GSK all Study data. In addition, arrangements will be made for all unused quantities of Vaccine in accordance with the GSK procedures applicable to the Study.

f) In the case of a multicentre Study, which as the case may be will be confirmed in the attached Protocol, GSK will have the right to decide, at any time, during the duration of the present Agreement, to put an end to the recruitment of subjects, when the total number of required subjects for the multicentre Study has been reached, even if the number of subjects mentioned above has still not been reached. GSK will notify the Principal Investigator of its decision in writing and the Principal Investigator will have to stop the recruitment of subjects within a delay that will not exceed one (1) week.

XV. EFFECT OF TERMINATION

a) Upon notice of termination of this Agreement, Institution and the Principal Investigator shall cease enrolling subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

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

c) Upon termination of this Agreement, all unused Vaccines and all GSK Confidential Information (except for such records that Institution is required by Applicable Law to retain) in Institution's and Principal Investigator's possession shall be promptly delivered to GSK at GSK's expense, or, at GSK's option, destroyed with the destruction certified in writing.

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d) Upon termination or expiration of this Agreement for any reason, the Institution/ Principal Investigator agrees to transfer to GSK all paper or e-Case Report Forms duly completed (where applicable) within two (2) working days of the last contact with the subjects or receipt of the last data.

e) The obligations which by their nature extend beyond termination including but not limited to clauses III(d), IV, V, VI, VII, IX, XI and XV shall survive suspension or termination of this Agreement.

f) Termination shall not affect the rights or obligations of either party accrued as of such effective date of termination or that may arise subsequently with respect to transactions initiated or completed prior to the effective date of such termination.

XVI. USE OF PARTIES' NAMES

Neither party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement, or the Study, which uses the other party's name, symbols, or trademarks without the other party's prior written approval.

XVII. NOTICES

All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices pertaining to this Agreement shall be sent to:

If to Institution:
Name: Dr. Piyali Bhattacharya
Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road – Lucknow – 226014,
Uttar Pradesh, India

If to GSK:
Name: Dr. Sanjay Gandhi
Address: Glaxosmithkline Pharmaceuticals Ltd
Dr Annie Besant Road,
Mumbai – 400 030, Maharashtra, India

XVIII. ASSIGNMENT

GSK may assign its rights and duties under this Agreement without Institution's consent. Any assignment by Institution is valid only upon the prior written consent of GSK. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

XIX. SEVERABILITY

Any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected.

XX. GOVERNING LAW AND DISPUTE RESOLUTION

In case of a dispute or difference between the Parties arising out of, or touching upon the terms including effect, interpretation or scope of this Agreement, the Parties hereto shall make best endeavor to resolve the dispute by mutual discussions. This Agreement shall be governed by and interpreted in accordance with the laws of India, and any dispute under this Agreement shall be brought in the courts of Lucknow.

Piyali

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SGPGIMS,Lucknow

(19)

XXI. ANTI-BRIBERY ANTI-CORRUPTION AND ETHICAL STANDARDS AND HUMAN RIGHTS

A. ANTI-BRIBERY ANTI-CORRUPTION

a) Institution and Principal Investigator agree that, in connection with the performance of this Agreement, Institution and Principal Investigator shall comply and require Study staff to comply fully at all times with all Applicable Laws and regulations, including but not limited to anti-corruption laws, and that it has not, and covenants that it will not commit any act of bribery, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents or any other third parties, subject to its control or determining influence, from doing so. For the avoidance of doubt this includes facilitating payments, which are unofficial, improper, small payments or gifts offered or made to government officials to secure or expedite a routine or necessary action to which we are legally entitled.

b) In the event GSK has reasonable doubt that the Institution and Principal Investigator have failed to perform its obligations in accordance with this Clause XXI, GSK shall have a right to immediately suspend all operations under this Agreement with notice to the Institution and Principal Investigator in this regard, pending GSK's assessment of such failure, and to inter alia call upon the Institution and Principal Investigator to provide within 7 days of such notice, justifiable and satisfactory response thereto including furnishing any records /documentary proof /information in relation to the alleged doubt / failure. If the Institution and Principal Investigator fail to comply with this request of GSK within 30 days or if after reviewing the documents/information as provided by the Institution and Principal Investigator to GSK, GSK comes to a conclusion that that there has been a failure of Clause XXI by the Institution and Principal Investigator, GSK shall be entitled to terminate this Agreement immediately. Institution and Principal Investigator shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause XXI.

c) Institution and Principal Investigator shall not contact, or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative. For the purpose of this agreement "Government Official" (where 'government' means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means: (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organisation such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under applicable local laws (including anti-bribery and corruption laws) and not already covered by any of the above; and/or; (e) any person acting in an official capacity for or on behalf of any of the above.

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SGPGIMS,Lucknow

(18)

d) Institution and Principal Investigator shall inform GSK in writing, if, during the course of this Agreement, it is convicted of or pleads guilty to a criminal offence involving fraud or corruption, or becomes the subject of any government investigation for such offenses, or is listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

e) Institution and Principal Investigator represent and warrant that except as disclosed to GSK in writing prior to the commencement of this Agreement: (1) none of their significant shareholders (>25% shareholding) or senior management have influence over GSK's business; (2) no significant shareholders (>25% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services, are currently or have been in the past two years a Government Official with actual or perceived influence which could affect GSK business; (3) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed in the previous subsection (2) having a public or private role which involves making decisions which could affect GSK business or providing services or products to, or on behalf of GSK; (4) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; (5) it shall maintain arm's length relations with all third parties with which it deals for or on behalf of GSK in performance of this Agreement. Institution and Principal Investigator shall inform GSK in writing at the earliest possible opportunity of any conflict of interest as described in this Clause that arises during the performance of this Agreement.

f) Institution and Principal Investigator shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Institution and Principal Investigator must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

g) Institution and Principal Investigator agree that in the event that GSK believes that there has been a possible violation of the terms of this Agreement, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.

h) Institution and Principal Investigator shall provide anti-bribery and anti-corruption training to relevant personnel, including any relevant subcontractors, who act on behalf of GSK or interact with government officials during the course of any services provided to GSK. Institution and Principal Investigator shall provide GSK the opportunity to evaluate the training to determine whether it abides by GSK's standards and shall conduct additional training, as requested by GSK. Institution and Principal Investigator, upon request by GSK, shall certify that the anti-bribery and anti-corruption training has taken place.

B. ETHICAL STANDARDS AND HUMAN RIGHTS

a) Unless otherwise required or prohibited by law, the Institution and Principal Investigator warrant that in relation to its performance of this Agreement:

a. it does not employ engage or otherwise use any child labour in circumstances such that the tasks performed by any such child labour could reasonably be

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foreseen to cause either physical or emotional impairment to the development of such child

b. it does not use forced labour in any form (prison, indentured, bonded or otherwise) and its employees are not required to lodge papers or deposits on starting work;

c. it provides a safe and healthy workplace, presenting no immediate hazards to its employees. Any housing provided by the Institution and Principal Investigator to its employees is safe for habitation. The Institution and Principal Investigator provides access to clean water, food, and emergency healthcare to its employees in the event of accidents or incidents at the Institution and Principal Investigator 's workplace;

d. it does not discriminate against any employees on any ground (including race, religion, disability or gender);

e. it does not engage in or support the use of corporal punishment, mental, physical, sexual or verbal abuse and does not use cruel or abusive disciplinary practices in the workplace;

f. it pays each employee at least the minimum wage, or a fair representation of the prevailing industry wage, (whichever is the higher) and provides each employee with all legally mandated benefits;

g. it complies with the Applicable Laws on working hours and employment rights in the countries in which it operates;

h. it is respectful of its employees right to join and form independent trade unions and freedom of association; and

b) The Institution and Principal Investigator are responsible for controlling its own supply chain and shall encourage compliance with ethical standards and human rights by any subsequent supplier of goods and services that are used by the Institution and Principal Investigator when performing its obligations under this Agreement.

c) The Institution and Principal Investigator shall ensure that it has ethical and human rights policies and an appropriate complaints procedure to deal with any breaches of such policies. In the case of any complaints, the Institution and Principal Investigator shall report the alleged complaint and proposed remedy to GSK.

d) GSK reserves the right upon reasonable notice (unless inspection is for cause, in which case no notice shall be necessary) to enter upon the Institution and Principal Investigator's premises to monitor compliance with the provisions of this Clause XXI, and the Institution and Principal Investigator shall, subject to compliance with Applicable Laws, provide to GSK any relevant documents requested by GSK in relation thereto.

XXII. MEDICAL CONFIDENTIALITY, PRIVACY AND SECURITY OF PERSONAL INFORMATION

a) **Definitions**

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SGPGIMS,Lucknow

a. "**GSK Data**" means any data or information that is provided to or obtained by Supplier or Supplier personnel in connection with the negotiation and execution of the Agreement or the performance of Supplier's obligations under the Agreement, including any such data and information that either: (i) is created, generated, collected or Processed by Supplier personnel in the performance of Supplier's obligations under the Agreement, or (ii) resides in or is accessed through GSK's information systems or Supplier Information Systems, as well as any data and information derived from the foregoing.

b. "**Study Personal Information**" means any GSK Data that constitutes Personal Information (as defined below). Study Personal Information will relate to Study subjects, as required to be handled for conduct of Study in accordance with Protocol:

c. "**Personal Information**" shall mean any information or set of information relating to a person that identifies such person or could reasonably be used to identify such person.

d. **"Processing"** (and its conjugates, including without limitation "Process") means any operation or set of operations that is performed upon any information or data, including, without limitation, collection, recording, retention, alteration, use, disclosure, access, transfer, storage, or destruction of Personal Information

e. Study Personal Information will be Processed by Supplier as necessary for, and for the purposes of, the provision of services or other obligations set forth in the Agreement.

f. Unless stated otherwise in the Agreement, or agreed in writing between the parties, Study Personal Information will be Processed for the term of the Agreement, and any such additional period as may be stated therein.

g. "**Supplier**" for the purpose of this clause shall mean Institution and Principal Investigator

h. "**Supplier Information Systems**" (SIS) means all hardware, software, operating systems, database systems, software tools and network components used by or on behalf of Supplier to receive, maintain, Process, store, access or transmit GSK Data.

b) Retention and Return of GSK DATA.

a. **Retention.**

i. Subject to clause XII (Recordkeeping – Access – Monitoring) Supplier shall retain GSK Data only for as long as specified in the Agreement or as otherwise necessary to satisfy the purposes for which it was provided to Supplier, except only to the extent longer retention is required by Applicable Law.

b. **Return.**

i. Subject to clause XII (Recordkeeping – Access – Monitoring) Supplier shall (at its sole cost) return, delete or destroy, as specified by GSK, all GSK Data then in its possession or under its control, including without limitation all originals and copies of such GSK Data, upon GSK's request for any reason. Supplier shall certify compliance with this requirement by written notice to GSK received no later than thirty (30) days following such return, deletion or destruction of all GSK Data. Supplier will use

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destruction methods that meet or exceed current industry standards, to GSK's reasonable satisfaction. Unless otherwise agreed in writing with GSK, Supplier shall return any GSK owned physical assets.

c) Data Handling.

a. **Encryption.** When transferring GSK Data, and in communications between GSK and Supplier, Supplier will use encryption when transmitted over non-secure channels including email and remote connectivity. Supplier will use solutions that meet or exceed current industry standards, to GSK's reasonable satisfaction.

d) Data Security Breach Reporting and Incident Response.

a. Upon discovering any accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, GSK Data (a "Data Security Breach") or a potential compromise of Supplier systems that could result in a Data Security Breach, Supplier will send an e-mail to csir@gsk.com notifying GSK without undue delay, and in any case within (6) six hours. Supplier shall work with GSK in good faith to identify a root cause and remediate a Data Security Breach.

e) Information Protection Policies

a. The Supplier will implement mandatory security policies, standards, and procedures for staff and all subcontractors, vendors, or agents who have access to GSK Data, including Personal Information. These policies and procedures will cover:
b. measures, standards, procedures, rules and norms that will provide an industry-standard level of security;
c. staff functions and obligations relevant to the protection of GSK Data, including mandatory training;
d. procedures for reporting, managing and responding to security incidents relating to GSK Data; and
e. procedures for backup and restoration of GSK Data. Unless agreed otherwise in writing with GSK, Supplier will ensure that offline backup copies of GSK Data will be kept for thirty (30) days.
f. The Supplier will perform periodic risk assessment to ensure that these policies, standards and procedures are kept up to date, continue to be aligned with industry standards, and are revised as necessary whenever relevant changes are made to the SIS that uses or houses GSK Data, or to how that system is organised.

f) Physical and Environmental Security

a. Supplier must ensure that GSK Data is physically secured against unauthorised access.
b. Physical access to SIS must be restricted to authorized Supplier or approved sub-contractor personnel requiring access to perform their current role in line with access granting procedures and rules which provide security against unauthorized access, accidental or deliberate

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Executive Registrar
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damage and interference. Environmental controls will be established to detect, prevent and control destruction due to environmental hazard.

g) Disposal of media

a. When media or storage devices are to be disposed of or reused, Supplier will implement industry-standard procedures to prevent any subsequent retrieval of GSK Data before devices are withdrawn from the inventory. When media are to leave the physically secured premises (compliant with 3.5.1 above) as a result of maintenance operations, Supplier will implement encryption of GSK Data stored on the media.

h) Network Security

a. The Supplier will maintain industry-standard network security using equipment and techniques including firewalls, intrusion detection and prevention systems, access control lists and secure routing protocols.

i) Access Control

a. Supplier will ensure that:
   i. Technical mechanisms are designed and implemented to ensure that GSK Data within the SIS is logically segregated from other customers' data.
   ii. Procedures are implemented to define user roles and their privileges, how access is granted, changed and terminated; addresses appropriate segregation of duties; and to define the logging and monitoring requirements and mechanisms.
   iii. Access rights are implemented adhering to the "least privilege" approach (i.e., authorised staff will be granted the minimum access required to perform their roles).
   iv. All employees of the Supplier are assigned unique User-IDs that are not shared. Every account will be attributable to an individual.
   v. Access to SIS is controlled through a defined system of user administration, identification, authentication and authorisation where only appropriately authorized persons can grant, modify or revoke access. Administrators granting or modifying access credentials for IT Systems perform appropriate identity proofing to ensure that access is granted to the proper person.
   vi. A strong password policy is documented, established, operated, and enforced. Passwords, personal identifying numbers (PINs) or passphrases and any data that can be used to derive them must be encrypted in storage and transmission. Account credential secrets will be protected at all times from unauthorized disclosure, alteration, or use.
   vii. Intrusion detection and prevention mechanisms are implemented on SIS. This will include logging, monitoring or blocking of unauthorised access attempts, modification of data, and unusual network activity indicating malware, unauthorised access or access attempts, or other unauthorized activities. Supplier will appropriately monitor and escalate detected issues to ensure the security of GSK Data.

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Executive Registrar
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j) Virus and Malware Controls

a. Supplier will securely configure and maintain malware protection through use of network devices and software.
b. Supplier will apply security patches promptly following a change management process, with critical security patches implemented within thirty (30) days and non-critical security patches within ninety (90) days.
c. Supplier will maintain all hardware and software used to Process GSK Data at supported version levels.
d. Supplier will ensure that Independent Testing is performed at least annually to verify SIS is free of Known Vulnerabilities that may be used to gain unauthorized access to the SIS or GSK Data.
e. "Known Vulnerability" means those vulnerabilities documented and compiled by independent third parties, including the NIST National Vulnerability Database, a U.S. government repository of standards based vulnerability management data found at the nvd.nist.gov website, and other sites such as the Open Web Application Security Project (OWASP) found at the www.owasp.org website, United States Computer Emergency Readiness Team (US-CERT) found at the www.us-cert.gov website, and UK National Cyber Security Centre (NCSC) found at the www.ncsc.gov.uk website.
f. "Independent Testing" means testing via automated tools, by a qualified independent third party; or alternatively, by an internal group with expertise in security vulnerability assessment and independent from the development and support organization.
g. When the Supplier is providing application software, including web application or code, the Supplier will test for Known Vulnerabilities prior to each delivery and provide the results of Testing with the plan for remediation to GSK upon request.

k) Personnel

a. The Supplier will implement a mandatory security training program for personnel. This program will include data classification obligations; physical security controls; security practices and security incident reporting.
b. Supplier shall perform screening of Supplier Personnel at the time of hiring the Supplier Personnel that is, to the extent that permitted by such Applicable Laws in the country of hire, consistent with GSK's minimum required screening criteria:
c. An identity check.
d. A criminal record check.
e. Verification of education qualifications or other skills claimed.
f. A debarment check, where required.
g. Verification of entitlement to employment through the use of work permits or similar documents.
h. Verification of pertinent licenses including, motor vehicle licenses, certifications and operating documents that are required by law or required due to the nature of the position/job description and/or responsibilities.
i. Previous employment reference check.

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Executive Registrar
SGPGIMS,Lucknow

j. Verification of dates of employment claimed for the previous five (5) years.
k. Check on participation in animal rights activism. GSK reserves the right to perform these checks if Supplier cannot perform them.
l. Financial/credit check.

l) Business Continuity

a. Supplier will maintain and test at least annually a comprehensive business continuity plan which is designed to ensure availability of Supplier's critical business activities in the event of major failures or disasters, including the loss of an office facility or a data centre.
b. Supplier's business continuity plan will address the services provided to GSK and must aim to achieve recovery of services to GSK within an appropriate period acceptable to GSK. Unless otherwise agreed in writing with GSK, the Business Continuity Plans will provide for recovery of services within forty-five (45) days with no more than loss of one (1) day of updates to GSK Data.
c. **DATA PRIVACY**

m) Personal Information.

a. Before Processing any Study Personal Information Supplier shall ensure, taking into account industry good practice, the costs of implementation and the nature, scope, context and purpose of Processing, as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, that appropriate technical and organisational controls are in place to prevent unauthorised or unlawful Processing of any Study Personal Information it may hold and to protect any such Personal Information from accidental loss, damage or destruction.
b. Supplier shall:
c. only Process Study Personal Information in accordance with the documented instructions of GSK (including to the extent necessary to provide the Service and to comply with its obligations under this Agreement);
d. inform GSK if, in Supplier's opinion, any of GSK's instructions would breach data protection Laws; and
e. assist GSK with undertaking an assessment of the impact of Processing Study Personal Information, and with any consultations with a supervisory authority, if and to the extent an assessment or consultation is required to be carried out under data protection laws.

n) Data Subject Rights

a. Supplier shall:
   i. implement appropriate technical and organisational measures for the fulfilment of GSK's obligation to respond to requests by data subjects to exercise their rights of access, rectification or erasure, to restrict or object to Processing of Personal Information, or to data portability; and
   ii. if a data subject makes a written request to Supplier to exercise any of the rights referred to in clause 4.2.1, forward the request to GSK promptly, and in any event within five (5) days from the

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SGPGIMS,Lucknow

date on which Supplier received the request, and upon GSK's reasonable written request, provide GSK with all co-operation and assistance reasonably requested by GSK in relation to that request to enable GSK to respond to that request in compliance with applicable deadlines and information requirements.

o) Sharing of Personal Data

a. Supplier shall:

i. not engage another processor without prior specific or general written authorisation of GSK and in the case of general written authorisation, inform GSK of any intended changes concerning the addition or replacement of other processors, thereby giving GSK the opportunity to object to such changes;

ii. before disclosing Study Personal Information to any processor, enter into a contract with that processor under which the processor agrees to comply with obligations equivalent to those set out in the Agreement, including this Schedule; and

iii. before disclosing Study Personal Information to any of its employees and representatives, and the employees and representatives of each of its processors, in each case who have access to Study Personal Information, ensure that those persons:

iv. have undergone appropriate training in data protection and the care and handling of Personal Information; and

v. are bound to hold the information in confidence to at least the same standard as required under this Agreement (whether under a written agreement or otherwise).

p) No Transfer.

a. The Supplier shall not transfer any Study Personal Information to any jurisdiction not previously agreed in writing with GSK, or transfer any Study Personal Information to any third party, without the further prior written consent of GSK, which consent may be subject to the Supplier (or the relevant third party) entering into a data transfer agreement with GSK and entering into such other arrangements as GSK may reasonably require to satisfy the requirements that GSK or any of its affiliates may have as data controllers under any Applicable Law. Where GSK consents to any such transfer, Supplier shall comply with the Applicable Law governing the transfer of Personal Information to a jurisdiction different from that in which the data Processing is currently performed.

q) Third Party Data.

a. All or part of the GSK Data may contain Personal Information that is licensed to GSK by third parties. At GSK's request, Supplier shall enter into any agreements with such third parties as may reasonably be required to enable the Processing of such Personal Information.

r) Compliance with Laws.

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Executive Registrar
SGPGIMS,Lucknow

(10)

a. The Supplier will comply with all Applicable Laws as applicable to its business or the performance of its obligations under the Agreement, as such Laws may be revised from time to time.
b. Upon GSK's reasonable written request, Supplier shall provide all information necessary to demonstrate compliance with such Laws.
c. Supplier shall promptly notify GSK if it receives any complaint, notice or communication which relates directly or indirectly to the Processing of Personal Information, or to either party's compliance with data protection Laws, and shall fully co-operate and assist GSK in relation to any such complaint, notice, communication or non-compliance.

s) GSK Security Review Rights.

a. GSK and its agents, auditors (internal and external), regulators and other representatives as GSK may designate may inspect, examine and review the systems, records, data, practices and procedures of Supplier (and any subcontractors it may use) that are used in rendering the services under the Agreement to verify the integrity of GSK Data and compliance with the data privacy, confidentiality and security requirements of the Agreement.

t) Institution represents and warrants that it has completed the GSK assessment and Conflict of Interest process ("**Assessment**"). Institution further represents, warrants and covenants that:

i) the responses provided by Institution and Principal Investigator in the Assessment are true, accurate and complete as of the Effective Date of the Agreement;

ii) the privacy, security and data handling practices adopted and maintained by Institution shall be in effect and consistently applied as long as Institution conducts the Study in connection with, or otherwise retains, Personal Information for or on behalf of GSK; and

iii) Institution shall promptly notify GSK in writing within five (5) business days in the event of any material change in Institution 's privacy, security, or data handling practices.

u) The provisions contained in this Clause XXII shall survive the expiration or termination of this Agreement.

XXIII. TRANSPARENCY

a) Institution and Principal Investigator acknowledge GSK's ongoing commitment to transparency in its dealings with healthcare professionals worldwide. By signing this Agreement, Institution and Principal Investigator agree and consent that GSK or its affiliated company may disclose and publish specific information regarding this Agreement, including but not limited to the services provided by Institution and Principal Investigator, their names, location, affiliation with any institutions, any payment or benefit in kind that Institution and Principal Investigator receive pursuant to this Agreement.

b) If GSK or its affiliated company is required to report any payment, or other item or service of value provided to Institution and Principal Investigator under this

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SGPGIMS,Lucknow

Agreement, Institution and Principal Investigator acknowledge and agree that GSK or its affiliated company will report all such information to the applicable authority.

c) Institution and Principal Investigator agree and acknowledge that that this Agreement is not consideration for any understanding in relation to prescription, recommendation or other arrangement in relation to any GlaxoSmithKline group products.

IN WITNESS WHEREOF, the parties caused this Agreement to be executed, as of the date first written above, in multiple counterparts (each of which will be deemed to be an original, and all of which together will constitute one and the same Agreement) by their duly authorized representatives who, by signing, confirm their authority to bind their respective party.

For and on behalf of GLAXOSMITHKLINE PHARMACEUTICALS LIMITED By : Name : Dr. Sanjay Gandhi Title : Vice President – Vaccines Area Medical Lead (Gavi, Asia) & Lead LML (Clinical R&D, EM) GlaxoSmithKline Pharmaceuticals Ltd. Mumbai By : Name : Title :

For and on behalf of	By my signature I indicate my agreement to fulfill the role and obligations of Principal Investigator under this Agreement and consent to the disclosure of my name and Institution(s) with which I am affiliated as well as the details of any payment or benefit in kind made to me or for my benefit under this Agreement in publicly accessible worldwide registers.
Sanjay Gandhi Post Graduate Institute Of Medical Sciences, Uttar Pradesh	**Principal Investigator**
By : Name: PROF. RAKESH KAPOOR Title: DIRECTOR DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014	By : Piyali Bhattacharya Name: Dr. Piyali Bhattacharya Title:

Attachments to the present Agreement :

Schedule A : Protocol
Schedule B : Payment instructions sheet
Schedule C : Statement of Investigator Financial Interest Form

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SGPGIMS,Lucknow

(8)

SCHEDULE A

The Protocol
(Attached)

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SGPGIMS,Lucknow

(7)

SCHEDULE B
PAYMENT INSTRUCTIONS SHEET

PLEASE SELECT THE 'MODE OF PAYMENT' (BANK TRANSFER OR CHEQUE) AND COMPLETE ALL ITEMS.

o **Bank transfer**

Please give the EXACT name and address of the bank account holder.

Name of account holder	DIRECTOR SGPGI RESEARCH ACCOUNT
Address	Raebareli Road Lucknow – 226014, Uttar Pradesh, India
Account number	10095237491
Bank's name / branch name	State Bank Of India
Bank SWIFT code	SBIN0007789
	Telephone: NA Fax: NA
Bank Routing number (if any)	NA

NOTE:

TO AVOID PAYMENT ISSUES:

Please ask for the SWIFT code of the bank (8 or 11 characters)

Please ask for the ROUTING NUMBER of the bank.

SWIFT code: This code identifies each bank; using this code on any wire transfer, will avoid that a person in 'our' bank has to look for the beneficiary's bank address; this authorizes an immediate payment.

Routing number or Sort code: All banks identify their branches following rules that are different in each country; in Belgium, the first 3 digits of the account number identify the bank and branch (and 3 digits are enough), but other countries use other identifying systems (the RIB in France, the Sort Code in the UK, the Routing Number or ABA in the US, ...). With this additional information, there is no risk the beneficiary's bank takes time to find the beneficiary's account.

Piyali Bhattacharya

Principal Investigator's signature or Administrative Director signature

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Executive Registrar
SGPGIMS,Lucknow

SCHEDULE C

(6)

STATEMENT OF INVESTIGATOR FINANCIAL INTEREST IN GLAXOSMITHKLINE (TO BE ENCLOSED)

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Executive Registrar
SGPGIMS,Lucknow

35

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL62586797715625R
Certificate Issued Date	:	26-Mar-2019 03:49 PM
Account Reference	:	IMPACC (IV)/ dl732103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL73210330334234198919R
Purchased by	:	JSS Medical Research India Private Limited
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS Medical Research India Private Limited
Second Party	:	Not Applicable
Stamp Duty Paid By	:	JSS Medical Research India Private Limited
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

DATED 23 May 2019

12/2, 6th Floor, Tower-B, Vatika Mindscapes,
Sector- 27D, Faridabad-121003, Haryana
JSS MEDICAL RESEARCH INDIA PVT LIMITED
(AS THE CRO)
Dr. Gyan Chand
Professor, Department of Endocrine and Breast Surgery
(AS THE PRINCIPAL INVESTIGATOR)
AND
Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow -226014
(AS THE SITE/INSTITUTION)

CLINICAL TRIAL AGREEMENT

JSS Medical Research India Pvt. Ltd. Faridabad

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TABLE OF CONTENTS

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(33)

This Clinical Trial Agreement (the "**Agreement**") is dated: 23 May 2019

BETWEEN:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1. **JSS Medical Research India Pvt Ltd.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through its[Senior Vice President, Dr. Renu Razdan] being authorized to sign this Agreement (hereinafter referred to as "**JSS India**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

2. **Dr. Gyan Chand,** working as Professor at Sanjay Gandhi Postgraduate Institute, Lucknow. Centre having his residence at Lucknow (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

And

3. **Sanjay Gandhi Postgraduate Institute**, a [*hospital*] registered under the provisions of [Indian Companies Act, 1956 OR *any other relevant law*], having its registered office at Raebareli Road, Lucknow, Uttar Pradesh 226014 acting through its Director being authorized to sign this Agreement (hereinafter referred to as the "**Site**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

The Sponsor, JSS India, the PI, and the Site shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

Whereas:

A. The Sponsor is in the business of developing, manufacturing and/or distributing pharmaceutical products, in Chronic Ulcers.

B. JSS India is a CRO.

C. The Site is engaged in [Clinical Trial]and the PI is an [*Consultant*] at the Site.

D. The Sponsor desires to conduct a clinical trial in respect of the Drug, and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.

E. The Parties are now desirous of conducting the Clinical Trial in accordance with the terms and conditions hereof.

1. Definitions and Interpretations

1.1 In this Agreement:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(31)

"**Adverse Event**" shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject due to administration of the Clinical Trial Drug.

"**Applicable Laws**" shall mean any applicable statute, law ordnance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India

"**Budget**" shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

"**Case Report Form**" shall mean the case record form for each Subject in the form and manner provided by the Sponsor.

"**Clinical trial**" shall mean a clinical trial conducted as per the Protocol.

"**Clinical Trial Documents**" shall mean and include all documentation received from the Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Record Form; (v) Questionnaires; (vi) Patient Diaries and (vii) any other document as the Sponsor may, from time to time, provide.

"**Disability**" shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party's reasonable control.

"Dispute Notice" shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

"**Drug**" or "**Clinical Trial Drug**" shall mean the chemical compound invented by the Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

"**Drugs Act**" shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

"**Effective Date**" shall mean the date on which this Agreement shall come into effect.

"**Ethics Committee**" or "**Institutional Ethics Committee**" shall mean the ethics committee formed by the Site and the independent ethics committees formed in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and well being of all such actual and potential research participants.

"**Feasibility Study**" shall mean shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

"Fee" shall mean the fees and expenses, expenses and pass-through costs incurred in performing the Services payable by the Sponsor, or if so authorized by JSS India in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

"ICH GCP Guidelines" shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June, 1964 with applicable updates and amendments thereof.

"ICH" shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

"**Indian GCP**" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research. "**Information Brochure**" shall mean the information brochure of the Sponsor.

"**Informed Consent Form**" or "**ICF**" shall mean a written consent form provided by the Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.

"**Investigational Products**" shall mean the chemical compound invented by the Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by the Sponsor.

"**Invoice**" shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

"**Subject**" shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

"**Payment Milestone**" shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

"**Protocol**" shall mean Protocol No. [2015-DFU-301] as provided by the Sponsor.

"**Price**" shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule 'D' and in accordance with the milestones mentioned therein (the "Price and Payment Schedule"). The Price shall be the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

"**Screen Failure**" shall mean the screen failure as defined in the Protocol.

"**Serious Adverse Event**" or an "**SAE**" includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

"Services" shall mean the services detailed in Schedule 'A'.

"Site Indemnitee" shall mean the Site and its employees and its associated staff.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

"Sponsor Property" shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India.

"**Standard Operating Procedures**" or "**SOP**" shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

1.2 In this Agreement:

1.2.1 words denoting the plural number include the singular and vice versa;

1.2.2 references to Recitals, Clauses and Schedules are references to recitals, clauses and schedules to or of this Agreement;

1.2.3 references to this Agreement include the Recitals and the Schedules;

1.2.4 the headings and contents page(s) are for the purpose of reference only, have no legal or other significance, and shall be ignored in the interpretation of this Agreement;

1.2.5 references to any document (including, without limitation, to all or any of the Relevant Documents) are, unless the context otherwise requires, references to that document as amended, supplemented, novated or replaced from time to time;

1.2.6 references to statutes or provisions of statutes are references to those statutes, or those provisions, as from time to time amended, replaced or re-enacted; and

1.2.7 references to any Party include its successors, transferees and permitted assignees.

2. Scope of the Agreement

The PI agrees to perform the Clinical Trial for and on behalf of the Sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by the Sponsor.

3. Term

3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. Clinical Trial

4.1 Clinical Trial Initiation: JSS India and/or the Sponsor shall provide the PI all Clinical Trial Documents. The PI and/or the Site shall obtain the approval of the Ethics Committee in respect of the Clinical Trial. If the PI and/or the Site are unable to obtain the approval of the Ethics Committee within such duration, the Parties shall agree upon an alternative duration within which the PI and/or the Site shall obtain such approval. It is expressly agreed that the Sponsor and/or JSS India may

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

terminate this Agreement if such approval is not obtained by the PI and/or the Site within the time period prescribed hereunder.

4.2 Duration: The estimated duration for a Clinical Trial is [*as defined in the Protocol including follow-ups*]. The Site and the PI acknowledge that a Clinical Trial may be discontinued at any time, upon written instructions of the Sponsor and/or JSS India.

4.3 Completion of Subject related procedures: A Clinical Trial shall be considered to be completed when criteria for completion as specified in the Protocol are met.

5. Responsibilities and Obligations of the Parties

5.1 The Sponsor shall be responsible for the following:

5.1.1 Clinical Trial Documents and Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to JSS India and the PI.

5.1.2 Approvals and Consents: Procuring and providing any approvals and consents required to be taken by the Sponsor in [*the country of its jurisdiction and/or India*].

5.2 JSS India shall be responsible for the following:

5.2.1 Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of Sponsor.

5.3 The PI and/or the Site shall be responsible for the following:

a. The PI shall be responsible for the identification and documentation of any and all Adverse Events and/ or Serious Adverse Events.

b. Upon request by JSS India and/or the Sponsor, the PI will provide JSS India and / or the Sponsor all information needed by JSS India and/or the Sponsor in the clinical sections of regulatory submissions to any regulatory agency including but not limited to, the "Investigational New Drug", annual report and the NDA ("**New Drug Application**") safety update, as well as regulatory submissions to other such agencies, in accordance with the Applicable Laws.

c. The PI agrees that as soon as minimum essential information about an SAE becomes available to PI, it will immediately report such information to JSS India and/or the Sponsor, as directed in the Protocol. The PI will act reasonably to provide to the Sponsor and JSS India with at least the minimum essential information about an SAE, as identified in the Clinical Trial Documents at the earliest. The PI will not postpone or cause delay in reporting any such information to JSS India and/or the Sponsor irrespective of whether

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

more detailed information may become available at a later time, or because the available information is not yet confirmed.

d. The PI is responsible for making available any and all other safety information, as directed by JSS India and/or the Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.

5.4 Regulatory Agency Audit: The PI and the Site will inform JSS India and the Sponsor within twenty four (24) hours of being notified of a regulatory agency audit (if advance notice is given by any applicable regulatory agency) or within twenty four (24) hours of the beginning of any applicable regulatory agency audit (if no advance notice is given by the applicable regulatory agency). The PI and the Site shall provide JSS India and the Sponsor with a copy of all Clinical Trial specific observations made during a regulatory audit at the PI and/or the Site's facilities, immediately upon receipt of such information. The PI shall cooperate fully with JSS India and/or the Sponsor in any such investigation, and in the implementation of appropriate action plans for such observations.

6.Representations, Warranties and Covenants.

6.1 JSS India represents, warrants and covenants to the Sponsor as follows:

(a) Formation/Power and Authority: JSS India is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: JSS India represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Permits: JSS India will or it shall cause the Sponsor to identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of a Project.

(d) Freedom to Use: JSS India hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: JSS India certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

JSS India agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

6.2 The Sponsor represents, warrants and covenants to JSS India as follows.

(a) Formation/Power and Authority: The Sponsor is duly formed and validly existing under the laws of the country of its origin and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Sponsor represents and warrants that it is in full compliance at all times and will continue to be in compliance at all times with all Applicable Laws of the country of its origin and the laws of India.

(c) Permits: Prior to commencement of a Project, the Sponsor shall identify all permits and approvals necessary or helpful in connection with the conduct and successful completion of such Project, in accordance with the Applicable Laws, in the country of its origin and country where Clinical Trial has be undertaken. The Sponsor shall be solely responsible for procuring and maintaining each such permit and approval in the country of its origin. Unless impossible, expressly prohibited by Applicable Laws or otherwise requested by JSS India in writing, the Sponsor shall procure and maintain in the name of the Sponsor all permits and approvals for which it is responsible.

(d) Debar: The Sponsor certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial.

The Sponsor agrees that it will promptly notify JSS India in the event of any such debarment, conviction, threat or indictment occurring during the Term.

(e) Freedom to Use: The Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that JSS India, the PI and/or the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

6.3 The Site represents, warrants and covenants to JSS India and the Sponsor as follows:

(a) Formation/Power and Authority: The Site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance at all times and shall continue to be in compliance at all times with all Applicable Laws of India.

(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll up to [13] Subjects or such higher numbers as agreed upon with JSS India and the Sponsor in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Freedom to Use: The Site hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The Site agrees that it will promptly notify JSS India and/or the Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

ii. The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the PI and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

iii. Upon JSS India and/or the Sponsor's request from time to time, the Site will certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

6.4 The PI represents, warrants and covenants to JSS India and the Sponsor as follows:

(a) Power and Authority: The PI hereby represents that it is duly registered in accordance with the Applicable Laws, and it has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Ethics Committee: The PI representing that he is duly authorized by the Ethics Committee of the Site to do so, agrees to enroll up to [13] Subjects or such higher

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

numbers as agreed upon with [*JSS India/ the Sponsor*] in writing from time to time to meet the subject selection criteria described in the Protocol.

(c) Debar: The PI represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

i. The PI agrees that it will promptly notify JSS India and/or the Sponsor in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

ii. Upon JSS India and/or the Sponsor's request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7. Use of Name

No Party shall use the name of another Party either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that Party. Nothing herein shall be construed as prohibiting by JSS India and/or the Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights in accordance with Clause 10.

8. Ownership of Property and Data

The Sponsor shall have sole ownership and rights to any inventions or discoveries relating to the Drug, whether patentable or not, made in the performance of this Agreement.

9. Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the [Drug Controller General of India], and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH) region, (b) the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which the any applicable regulatory authorities are so notified.

b. JSS India and/or the Sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as JSS India and/or the Sponsor so elect, comprise: (a) inspection of the PI's and/or the Site's facilities and records relating to the rendering of services to or for a Clinical Trial; (b) review of the PI and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the PI's adherence to Applicable Laws, including in particular, but without limitation, Indian GCP and ICH GCP Guidelines.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

10. Publications

JSS India and/or the Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information to the Sponsor and/or JSS India. The PI and the Site agrees to delete any information that may be confidential or proprietary.

11. Fees

a. Budget: The Sponsor, PI and/or the Site shall provide an estimate of the budget to the other Parties on Site selection. The Parties shall negotiate and agree on the Budget. The Budget shall include Fees, the costs for conducting the Clinical Trial and any other incidental and/or overhead charges.

i. The Budget may only be modified in exigent circumstances, and only with the prior written consent of JSS India and/or the Sponsor. It is expressly agreed that tests or services not required by the Protocol or performed in excess of Protocol requirements shall not be compensated by the Sponsor and/ or JSS India unless the PI and/or the Site have taken the written consent of JSS India and/or the Sponsor before administration of such tests or services.

b. Payment of Fees and Expenses to the PI and/or the Site: The Sponsor, or if so authorized by the Sponsor, JSS India shall provide the PI and/or the Site the Fees in accordance with Schedule B.

The PI and/or the Site shall be paid for all patients, including any Screen Failure patients. In case the PI and/or the Site recruits more or less than the number of Subjects provided in the Protocol , the consideration for their services will be pro rated according to the actual number of Subjects enrolled and the agreed per Subject consideration. The PI and/or the Site will also be paid for Screen Failure patients. This consideration will be paid in addition to patients actually randomized, in accordance with Schedule C.

i. Unless otherwise agreed by the Parties, the following shall apply:

(a) the PI and/or the Site will issue its invoice for the Fees to the Sponsor and/or JSS India, if so authorized, [on reaching the Payment Milestone (as defined in Schedule B)] on a monthly basis; and

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(b) the Sponsor or JSS India, if so authorized, shall pay the invoiced amount within thirty (30) business days of the date of the invoice. The payment shall be made through wire transfer into the following account, or, through crossed cheque/DD, as applicable:

Payee details:

PAYEE NAME	Director, SGPGIMS RESEARCH SCHEME ACCOUNT, LUCKNOW
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAAJS3913N
BANK NAME & BRANCH ADDRESS	STATE BANK OF INDIA SGPGIMS BRANCH RAEBARELI ROAD, LUCKNOW 226014

ii. Taxes: Any goods and service tax, duty, value added tax, or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to the PI's and/or the Sponsor's account. The payment shall be made after deducting all applicable deductions as per Applicable Law, including tax deducted at source.

iii. Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to JSS India and/or the Sponsor that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

12. Insurance

a. The Sponsor shall maintain all adequate insurance coverage, which will include adequate clinical trial insurance of the study.

b. The Sponsor shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4.1 to the Site, the PI, the Clinical Trial and JSS India.

13. Indemnification

13.1 Indemnity: The Sponsor agrees to indemnify, defend and hold harmless the Site, the PI, the Site Indemnitees, the Clinical Trial, and JSS India and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("**Loss**") incurred by or imposed on the Site Indemnitees or the Site, the PI, the Clinical Trial or JSS India or any of the associated staff in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Clinical Trial and/or JSS India to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(21)

procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

13.2 Exclusions from Indemnification: The Sponsor's obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

(i) from malpractice, negligence, recklessness, intentional or willful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of any Site Indemnitee;

(ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to any Site Indemnitee in connection with the Study or the Study Drug, including, but not limited to information provided in the Investigator's Brochure;

(iii) from any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Drug;

(iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;

(v) due to any failure on the part of a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;

(vi) due to an omission by any Site Indemnitee to inform Study Subjects, to

a. inform PI and/or Site of any new diseases or medical conditions that have arisen during the Study;

b. immediately notify Investigator, PI and/or Site of a personal injury or other damage that may be the consequence of the Study;

c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and/ or JSS India and/ or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 13 above, directly or due to a third party claim shall give written notice to the Sponsor, against whom such indemnification rights are claimed.

Pursuant to Clause 13 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the Sponsor shall not relieve the Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the Sponsor or its defenses.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 13 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of the Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if the Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from the Sponsor; provided, however, that:

(i) the Indemnified Party shall obtain the prior written consent of the Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if

(A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against the Sponsor,

(B) such settlement does not expressly unconditionally release the Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or

(C) involves criminal or quasi-criminal allegations against the Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim;

(ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by the Sponsor in connection with such claim or legal proceeding;

(iii) the Sponsor shall be entitled to participate in the defense of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and

(iv) if the Indemnified Party abandons or fails to reasonably assume the defense of any such claim or legal proceeding, the Sponsor may assume control of the defense of such claim or legal proceeding at its own expense; provided, however, that if the Sponsor shall control the defense of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if

(A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party,

(B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or

(C) involves criminal or quasi-criminal allegations.

13.4.3 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site, the Clinical Trial and JSS India as contained in the Clinical Trial Agreement.

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13.5 Entire Obligation

The foregoing terms constitute the entire indemnification obligation of Sponsor in relation to the Study.

13.6 The Sponsor shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs. Sponsor shall also pay cash compensation, to subject or legal heirs of subject, awarded by ethics committee (or any court) in case of death or permanent disability. The Sponsor shall not be liable for payments for a Subjects' lost wages.

14 Confidentiality

a. All of the information disclosed by JSS India and/or the Sponsor or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and/or the Sponsor and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

b. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 Termination

15.1 JSS India may terminate the Clinical Trial by written notice of at least one (1) month in advance.

15.2 The Sponsor may terminate for any of following reasons:

a. Notification to any of the Parties from the local regulatory authorities to terminate Clinical Trial.

b. Determination by JSS India and/or the Sponsor that the PI and/or the Site is not performing the Clinical Trial as required in the Protocol or is not meeting any agreed requirements.

c. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial to provide access by JSS India and/or the Sponsor representatives to any and all original medical records necessary to verify entries on the Case Report Forms.

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d. Failure of the PI and/or the Site or its associated staff or any other person engaged in the Clinical Trial (excluding Subjects) to be available, upon reasonable notice by JSS India and/or the Sponsor, to meet with JSS India and/or the Sponsor or its representatives during the course of the Study as necessary to discuss information relevant to the Study.

e. Failure of the PI and/or the Site to comply with any regulatory requirements, under the Applicable Laws of India.

f. Unauthorized replacement of PI

g. Determination by JSS India and/or the Sponsor in writing that business or scientific considerations require termination.

h. Case Report Forms provided to the PI and/or the Site or its associated staff by JSS India and/or the Sponsor or its representatives for use in the Study, are not completed and forwarded to JSS India and/or the Sponsor or its designated representative, within the timelines prescribed by JSS India and/or the Sponsor.

15.2 In case PI is unable to continue as PI, he will propose the name of another investigator in writing to JSS India and/or the Sponsor. However JSS India and/or the Sponsor shall have the sole right to determine the acceptability of a new PI.

15.3 In the event that JSS India and/or the Sponsor exercise its right to terminate the Study based on any of the enumerated grounds above, written notice of its decision to exercise such right shall be given by registered mail delivered fifteen (15) business days before said termination.

15.4 Immediately upon receipt of any notice of termination, the PI and/or the Site shall stop recruiting patients into the Clinical Trial and shall cease treatment with the Drug, to the extent medically permissible, on the Subjects. In the event of termination, the payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. The PI and/or the Site shall cause to return to the Sponsor and/or JSS India (i) all documentation in respect of the Clinical Trial; and (ii) any funds not due under this calculation but already paid to the PI and/or the Site.

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(17)

16 Miscellaneous

16.1 Notices and Deliveries: Any notice required or permitted to be given hereunder by either Party shall be in writing and shall be deemed given on the date received if delivered by hand or by a reputable overnight delivery service, or three (3) business days after the date postmarked if sent by registered or certified mail, return receipt requested, postage prepaid to the following addresses:

If to JSS India:

JSS Medical Research India Pvt Ltd

12/2, 6th Floor, Vatika Mindscapes, Sector 27D, Faridabad-121003, Haryana, India

New Delhi—110020, India

Attention: Dr Renu Razdan

Designation: Senior Vice President-India

Telephone: +91 129 6613 500

E-mail: renu.razdan@jssresearch.com

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If to PI: Dr. Gyan Chand
Sanjay Gandhi Postgraduate Institute
Raebareli Road, Lucknow, Uttar Pradesh 226020
Designation: Professor
Telephone: +91- 9451546353

If to site: Sanjay Gandhi Postgraduate Institute of Medical Sciences
Raebareli Road, Lucknow, Uttar Pradesh 226020
Attention: Director, Institution
Telephone: +91-522-266800

If the Sponsor delivers, ships, or mails materials or documents to JSS India, or requests in writing that JSS India deliver, ship, or mail materials or documents to the Sponsor or to third parties, then the expense and risk of loss for such deliveries, shipments, or mailings shall be borne by the Sponsor. JSS India disclaims any liability for the actions or omissions of third-Party delivery services or carriers.

16.2 Amendment: No Party may amend any of the terms of this Agreement except by a written instrument signed by the Parties. In addition, any amendment to the Protocol must be approved in writing by JSS India and the Sponsor [and the appropriate Institutional Review Board (as per Indemnity Agreement Pg. 8)].

16.3 Independent Contractor Relationship: The Parties are independent contractors, and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint ventures. The Parties agree that all employees/ consultants of the PI and/or the Site shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to JSS India and/or the Sponsor.

16.4 Assignment: This Agreement may be assigned by JSS India and/or the Sponsor to any of its affiliates or to any third party without prior written confirmation of other parties. The PI and the Site shall not assign this Agreement without the prior written consent of JSS India and/or the Sponsor.

16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more

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than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

16.6 Survival: Sections 8,9, 13, 14, 15, 16.2, 16.3 and 16.11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive. No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date.

16.7 Severability: If any provisions herein are found to be unenforceable on the grounds that they are overly broad or in conflict with Applicable Laws, it is the intent of the parties that such provisions be replaced, reformed or narrowed so that their original business purpose can be accomplished to the extent permitted by law, and that the remaining provisions shall not in any way be affected or impaired thereby.

16.8 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument. Delivery of an executed signature page of this Agreement by facsimile transmission shall be as effective as delivery of an original executed counterpart of this Agreement.

16.9 Governing Law. This Agreement shall be governed by the laws of India, and the courts of Lucknow alone shall have exclusive jurisdiction in respect thereof.

16.10 Dispute Resolution: The Parties shall endeavor to resolve all disputes amicably by meetings caused between designated officials of each Party, within fifteen (15) days of receipt of a Dispute Notice. If the Parties are unable to resolve any dispute within the above referred fifteen (15) days, then the dispute shall be resolved by arbitration through a sole arbitrator jointly appointed by all Parties as per the provisions of the (Indian) Arbitration and Conciliation Act, 1996, as amended from time to time. If the Parties are not able to agree on a sole arbitrator, within fifteen (15) days of referral of a dispute to arbitration, the dispute shall be resolved by a panel of three (3) arbitrators. The Site and the PI shall appoint one (1) arbitrator, and JSS India and the Sponsor shall appoint one arbitrator. The two (2) arbitrators so appointed shall jointly appoint the third arbitrator which shall be the presiding arbitrator. The venue of arbitration will be Lucknow, India. Cost of arbitration including but not limited to fees of arbitrator(s) shall be shared equally by all Parties or as per the award of the arbitrator(s).

16.11 Interim Relief: Nothing shall preclude either Party from seeking an interim, from a court having jurisdiction to grant such relief. The pursuit of interim relief shall not be a waiver of the duty of any of the Parties to pursue any remedy (including for monetary damages) through the arbitration as more specifically described in Clause 16.10 above.

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IN WITNESS WHEREOF, this Agreement has been executed by the Parties hereto through their duly authorized officers on the date(s) set forth below.

JSS India

By: _____

Print Name: Dr. Renu Razdan

Title: Senior Vice-President

Date: May 23, 2019

Medical Research India Pvt. Ltd. Faridabad

The Principal Investigator

By: _____

Print Name: Dr. Gyan Chand

Print Title: Professor, Endocrine Surgery

Date: 29 July 2019

Dr. Gyan Chand
Professor
Dept. of Endocrine Surgeon
S.G.P.G.I. M.S., Lucknow

The Site

By: _____

Print Name: Prof. Rakesh Kapoor

Print Title: Director

Date: 08. 08. 2019

DIRECTOR
Sanjay Gandhi Post Gradu
Institute of Medical Scienc
LUCKNOW-226 014, INDI

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(13)

Schedule A

[List of services to be provided by the PI and/or the Site]

Sl. No.	Activities	JSS India	PI/Site
1.	Execution of Clinical Trial Agreement	☒	☒
2.	Sharing Essential Documents	☒	
3.	Review of Site Specific Informed Consent Document	☒	(☒)
4.	IEC Submission of Dossier, IEC notifications of updates/documents		☒
5.	Execution of Informed Consent Form from subjects		☒
6.	Inclusion/Exclusion Assessment		☒
7.	Medical Management		☒
8.	IP Handling, Accountability & Storage		☒
9.	IP Administration/dispensing		☒
10.	Glucometer, test strips and lancets accountability and dispensing		☒
11.	Laboratory Sample Collection and Centrifuge		☒
12.	Telephonic Contact & Follow-up with patients as per study protocol		☒
13.	eCRF Entries/ Completion on time (within 3 days of subject visit)		☒
14.	eCRF Signatures		☒
15.	Safety Reporting (e.g. AES/SAEs)		☒
16.	Randomization		☒
17.	Query Resolution (During the study; Post close-out, if any)		☒
18.	Query Signatures (During the study; Post close-out, if any)		☒
19.	Source Documentation		☒
20.	Documentation of ICF procedure including AV consenting as applicable		☒

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21.	Patient diary retrieval and review		☒
22.	12-Lead ECG, X ray, MRI, CT, neurological assessment for DFU, Doppler etc.		☒
23.	Providing Clinical Supplies and Non-Clinical Supplies	☒	
24.	Archival of study documents		☒

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(11)

Schedule B

I. Budget for Clinical Trial – Break Up

Visit 1/Screening	8,000
Visit 2/ Baseline/ Day 0	5,000
Visit3/ Day 3	5,000
Visit 4/Day 7	5,000
Visit 5/ Week 2	5,000
Visit 6/ Week 3	5,000
Visit 7/ Week 4	5,000
Visit 8/ Week 5	5,000
Visit 9/ Week 6	5,000
Visit 10/ Week 7	5,000
Visit 11/ Week 8	5,000
Visit 12/ Week 9	5,000
Visit 13/ Week 10	5,000
Visit 14/ Week 11	7,000
Visit 15/ Week 12	5,000
Visit 16/ Week 14	5,000
Visit 17/ Week 16	5,000
Visit 18/ Month 2	5,000
Visit 19/ Month 3	5,000
Visit 20/Week 52/53	5,000
Total	**105,000**

Total for 13 patients (a)	**1,365,000**
Miscellaneous (Phone & fax bills, stationery, Scan etc.) (b)	**60,000**
Administrative @ 25% of the total budget (c)	3,41,250
Total PI Grant (d)	**17,66,250**
Per patient Grant (e)	**1,35,865 INR**

PASS THROUGH	**Cost in INR**	Comments
EC Fee	**25,000 INR**	Excluding Tax
EC Fees for renewal of study approval	**NOT APPLICABLE**	
EC fees for protocol amendment	**NOT APPLICABLE**	
EC Fees of SAE review	**NOT APPLICABLE**	
All the Investigation Charges as mentioned in the Protocol	**On actuals**	

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will be on actual at various visits:-		(ABI, Neurological Assessment, X-ray, Doppler, CT/MRI, ECG)
Offloading Shoes & Wound Dressing Protector	-	Will be provided by the CRO
Temperature Logger 2/site	-	Will be provided by the CRO
Patient Travel reimbursement per visits	**1000 per visit*19 visits= 19000**	247000
CRC Salary	**25,000 INR per month for 2 CRC (1Blinded & 1 Unblinded)**	Study coordinator fee of INR 25,000/- per month will be paid from the day of site initiation to site closeout.
	Total	INR 2,72,000

Expenses for AE/SAE management will be billed on actuals. SAE Compensations for related SAEs including Trial related Injury/Deaths	Applicable Taxes Present GST rate (18%) are not included in the pass-through budget	INR 1000/- per year (Archival of document post study not included in the budget)	INR 1,00,000 Startup Fee (will be adjusted from the future invoices)

NOTE:

II. Payment Schedule

A. Ongoing Payments:

- Invoice will be raised monthly for the completed visits of the enrolled subjects, after confirmation of CRA about the EDC entries completion of these visits.
- The payment schedule should be as per the SCHEDULE D
- All the payments made to site under investigator grant will be subject to TDS deduction.
- Pass through cost (ECG & Subject reimbursement) shall be based upon actuals. Site has to submit separate invoice for pass-through charges accompanying ECG bills.
- CRC Fees of INR 25,000/- will be paid monthly (includes both Blinded & Unblinded CRC)

B. Last Payment: 20% of last invoice will be retained & will be released at the time of the Close Out visit. This payment will be made when all the subjects for Clinical Trial have been recruited, all data have been entered in the Case Report Form and all queries resolved. In addition, any additional expense pending to be paid will be paid at this time.
In the event of any excess payment from the Sponsor/CRO to the Trial Site, the Trial Site must promptly return the excess amount to the Sponsor.

SCHEDULE C

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(9)

Estimated Budget for Screen Failure

INR 8,000/- per Screen failed subject will be reimbursed. The cap for screen failure patient is 5.

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SCHEDULE D

Price and Payment Schedule

The payment to the sites shall be made as per below listed schedule:

Sr. No.	Item	Price	Payment
1	Total subject visits performed in a Month (V1-V20)	Refer per subject cost from Schedule B	*100%

*20% of last invoice will be retained and will be released at the time of the Close-Out Visit

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महाराष्ट्र MAHARASHTRA ◐ 2018 ◐ UH 585469

TREASURY OFFICE THANE

जिल्हा कोषागार कार्यालय, ठाणे
1-1 DEC 2018
मुद्रांक प्रमुख लिपीक / लिपीक

PRODUCT CODE:	**Sotagliflozin/SAR439954**
STUDY CODE:	**EFC14875**
STUDY NAME:	**THE SCORED TRIAL**

INVESTIGATOR/INSTITUTION CONTRACT

Site Name & City: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow

Study Code/ Name: EFC14875 / The SCORED Trial Effective Date: 30th January 2019

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This Contract (hereinafter "the Contract") is made on 21st day of January 2019, by and among:

DOCTOR SUSHIL KUMAR GUPTA, Professor, having his address at Endocrinology Department, 02nd floor, C-Block, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh 226014, India

Hereinafter the "**INVESTIGATOR**",

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES, having its address at Rae Bareli Road, Lucknow, Uttar Pradesh 226014, India represented for the purposes hereof by Prof. Rakesh Kapoor, Director

Hereinafter the "**INSTITUTION**"

AND

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, a private limited company having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented for the purposes hereof by Dr. Chirag Trivedi, Clinical Study Unit, Director

Hereinafter the "**SPONSOR**"

The INVESTIGATOR, the INSTITUTION and the SPONSOR are hereinafter individually referred to as a "Party "or collectively referred to as the "Parties".

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial "A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function" (hereinafter the « Study ») to evaluate Sanofi drug **Sotagliflozin/SAR439954** (hereafter the « Investigational Medicinal Product ») in accordance with a protocol entitled [The SCORED Trial, EFC14875] and its amendments (hereinafter collectively the « Protocol»), and

WHEREAS, the INSTITUTION is a Hospital known for its medical excellence, having the highest caliber faculty, high class education, research and patient care, and

WHEREAS the INVESTIGATOR is a doctor attached to the INSTITUTION and is specialized in the field of Endocrinology, and

WHEREAS, the INSTITUTION and the INVESTIGATOR having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Medicinal Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study, and

WHEREAS the INVESTIGATOR is responsible for ensuring that the Ethics Committee is registered before starting the Study;

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

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Executive Registrar
SGPGIMS,Lucknow

ARTICLE 1. PROTOCOL.

INVESTIGATOR/INSTITUTION shall perform the Study in strict compliance with the Protocol and a copy of the same has been provided and signed by the INVESTIGATOR and is submitted to the relevant Independent Ethic Committee («IEC/IRB»)/Health Authority («HA»)/Competent Authority

(«CA») for favorable opinion/approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB/HA/CA according to local regulations. All of the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters, for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE.

The Study shall be performed at the INSTITUTION **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh 226014, India** (hereafter the «Study Site»). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTION include global compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

For the purpose of the Contract, the term «Collaborators» shall mean any person involved in the Study including but not limited to associates, sub-investigators, biologists, assistants and nurses.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

ARTICLE 3. COMPLIANCE.

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the «ICH– GCP»), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR and the INSTITUTION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF) / electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/eCRFs to the SPONSOR.

The INVESTIGATOR and any Collaborator (as such term is defined at Article 5.2) will be trained by the SPONSOR with respect to the use of eCRFs.

The INVESTIGATOR and the INSTITUTION agree that any and all equipments if provided to the INVESTIGATOR's Study Site and or to the INSTITUTION to complete eCRFs shall remain the sole property of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall promptly return any such equipment when all eCRFs for the Study have been completed by the INVESTIGATOR and/or the INSTITUTION.

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Executive Registrar
SGPGIMS,Lucknow

ARTICLE 4. TERM.

This Contract is being entered into force from **30th January 2019** ("the Effective Date") and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately 51 (fifty one) months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR.

5.1 The SPONSOR shall provide directly or indirectly the INVESTIGATOR and/or the INSTITUTION with all necessary information, documents and materials, including but not limited to :

- the Investigator Brochure (IB) / SmPC data
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Medicinal Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators and the INSTITUTION shall use the information, documents and Investigational Medicinal Product provided by the SPONSOR, solely for the purpose of the Study as per Protocol requirements, or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

5.3 Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Medicinal Product shall be returned or made available to the SPONSOR upon completion of the Study.

The Investigational Medicinal Product will not be made available to the investigator until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB/HA/CA.

5.4 Should the Study require the use of a specific material, the SPONSOR (or its designee) may provide such material to the INVESTIGATOR and/or the INSTITUTION under conditions (reference of the material, quantities, conditions of restitution, etc.) detailed in a separate agreement.

5.5 The INVESTIGATOR / INSTITUTION or its designee shall ensure that an accurate record of the quantity of Investigational Medicinal Product received and dispensed to each Subject is maintained. The INVESTIGATOR/INSTITUTION shall ensure that the Investigational Medicinal Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.6 The INVESTIGATOR/INSTITUTION agree to take responsibility for the safeguarding of such materials and to notify the SPONSOR promptly in case of any loss damage, or failure of these materials.

5.7 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION by or on behalf of the SPONSOR shall be returned to the SPONSOR.

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ARTICLE 6. SUBJECTS RECRUITMENT.

6.1 The INVESTIGATOR has estimated that he/she can recruit a maximum of **30 (thirty) Subjects** (the «Subjects »), within **approximately 15 (fifteen) months**. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, the SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g., __x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of one (1) Subject must be enrolled within two (2) months of initiating the Study at the Study SITE. Subsequently, if no Subjects are enrolled over a period of three (3) months, or if the INVESTIGATOR cannot begin the Study at the STUDY Site, the SPONSOR may decide at its discretion to discontinue the Study at the Study SITE.

6.3 Especially in case of multicenter studies, the SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the global recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed the informed consent. The INVESTIGATOR shall upon receipt of the notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS.

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1). The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Study.

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and /or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

ARTICLE 8. MONITORING OF THE STUDY.

8.1 The SPONSOR shall appoint monitor(s), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR and the INSTITUTION to ensure proper conduct of the Study (hereinafter the «Monitor(s)»). The INVESTIGATOR and the INSTITUTION agrees to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information.

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION.

The INVESTIGATOR and/or the INSTITUTION shall immediately inform the SPONSOR of any serious adverse event («SAE») or other events as defined in the Protocol.

Lt Col Varun Bajpai VSM
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ARTICLE 10. FINANCIAL TERMS AND CONDITIONS.

10.1 As consideration for the proper performance by the INVESTIGATOR and the INSTITUTION of their obligations under the Contract, the SPONSOR shall pay the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

10.2 Out of pocket expenses authorized in advance by the SPONSOR that have been provided for in Exhibit 1 shall be reimbursed to the PAYEE as directed by the INVESTIGATOR and/or the INSTITUTION (without any mark-up) within 30 (thirty) days on receipt by the SPONSOR of an itemized invoice on the Letter Head of the PAYEE.

10.3 The PAYEE will bear the responsibility for the declaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

10.4 Fees/reimbursement of costs to the INVESTIGATOR and/or the INSTITUTION by the PAYEE will be an internal arrangement among themselves and the SPONSOR will not be liable to pay/reimburse any amount to the INVESTIGATOR and/or the INSTITUTION.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE.

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the « Confidential Information »), is confidential. The INVESTIGATOR and the INSTITUTION, agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR and the INSTITUTION, shall use the Confidential Information solely for the purposes of the Study.

Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the information that is strictly necessary for the accomplishment of their acts.

11.2 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or the INSTITUTION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION gives the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.3 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination, whether by expiration or by early termination.

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Executive Registrar
SGPGIMS,Lucknow

ARTICLE 12. RECORD RETENTION.

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) copy only of all data generated in the course of the Study for the longest of those two time periods:

- fifteen (15) years or,
- such longer period as required by applicable regulatory requirements, (the « Retention Period »).

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send to the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. PERSONAL DATA PROTECTION.

13.1 The Subject data and specific data regarding the INVESTIGATOR, the INSTITUTION and Collaborators which may be collected by the SPONSOR and included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the SPONSOR or its representative to Health Authorities or to the SPONSOR's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

13.2 As data controller, when processing or archiving data pertaining to the INVESTIGATOR, the INSTITUTION, the Collaborators and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

13.3 The INVESTIGATOR, the INSTITUTION, the Collaborators and/or the Subjects have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the SPONSOR, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS.

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

As the Study is being conducted at multiple sites, the SPONSOR agrees that, consistent with scientific standards, first presentation or publication of the results of the Study shall be made only as part of a publication of the results obtained by all sites performing the Study.

However, if no multicenter publication has occurred within twelve (12) months following the completion of the Study at all sites, the INVESTIGATOR shall have the right to publish or present independently the results of the Study subject to the review procedure set forth herein.

The INVESTIGATOR shall provide the SPONSOR with a copy of any such presentation or publication derived from the Study for review and comment at least thirty (30) days in advance of any presentation or submission for publication. In addition, if requested by the

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Executive Registrar
SGPGIMS,Lucknow

SPONSOR, any presentation or submission for publication shall be delayed for a limited time, not to exceed ninety (90) days, to allow for filing of a patent application or such other measures as the SPONSOR deems appropriate to establish and preserve its proprietary rights.

14.2 The INVESTIGATOR and the INSTITUTION shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS.

15.1 All information, documents, materials (hereinafter collectively «Information») and Investigational Medicinal Product provided by the SPONSOR are and shall remain the sole and exclusive property of the SPONSOR or its designee.

15.2 The INVESTIGATOR and the INSTITUTION shall not themselves and/or shall not permit any of its Collaborators to mention any Information or the Investigational Medicinal Product in any application for a patent or any other intellectual property rights whatsoever.

15.3 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.4 The SPONSOR may use or exploit all the results at its own discretion, without any limitation to its property right (territory, field, continuance...), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study, issued under this Contract.

15.5 As the case may be, the INVESTIGATOR, the INSTITUTION and/or the Collaborators shall provide all assistance required by the SPONSOR, at the SPONSOR's expense, for obtaining and defending any patent, including signature of all legal documents.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE.

16.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

In case, there is no permanent injury, the quantum of compensation shall be commensurate with the nature of the non-permanent injury and loss of wages of the subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

Lt Col Varun Baipai VSM
Executive Registrar
SGPGIMS,Lucknow

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the SPONSOR;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death :

(a) adverse effect of the Investigational Medicinal Product;

(b) violation of the Protocol, scientific misconduct or negligence by the SPONSOR or the INVESTIGATOR, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the INVESTIGATOR, then the INVESTIGATOR will be liable to reimburse to the SPONSOR the expenses on such medical management and financial compensation that the SPONSOR shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) failure of the Investigational Medicinal Product to provide intended therapeutic effect; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

(d) use of placebo in a placebo-controlled trial; where the standard care, though available, was not provided to the subject as per the clinical trial protocol;

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

(f) for injury to a child in-utero because of the participation of parent in the Study;

(g) any clinical trial procedures involved in the Study.

16.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

16.3 The insurance subscribed by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policy.

16.4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Medicinal Product or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Medicinal Product or the performance of any required procedure; or

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or willful malfeasance of the Indemnities.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

Lt Col Varun Baipai VSM
Executive Registrar
SGPGIMS,Lucknow

ARTICLE 17. AUDITS AND INSPECTIONS.

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and/or the INSTITUTION / PAYEE shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR and the INSTITUTION shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR or the INSTITUTION is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate in this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR and/or the INSTITUTION to the SPONSOR.

17.4 The INVESTIGATOR and the INSTITUTION shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR and/or the INSTITUTION for the audits and inspections and that the assistance and availability of the INVESTIGATOR or the INSTITUTION for the audits and inspections is included in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT.

18.1 This Contract may be terminated: (1) by a joint decision of the INVESTIGATOR and the INSTITUTION upon thirty (30) days prior written notice if the Study Site or the INVESTIGATOR for any reason becomes unable to perform or complete this Study; or (2) by the SPONSOR upon thirty (30) days prior written notice.

18.2 In the event this Contract is terminated, the SPONSOR will be responsible for compensating the INVESTIGATOR and/or the INSTITUTION for actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 3; 11; 12; 13; 14; 15; 16; 17; 19; 20, 21 and 22 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE.

19.1 The INVESTIGATOR and the INSTITUTION represent and warrant that neither the INVESTIGATOR/INSTITUTION nor any Collaborators involved in conducting the Study or any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial/studies, or

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Executive Registrar
SGPGIMS,Lucknow

Parties waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original, as of the Effective Date.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED (SPONSOR)		**INVESTIGATOR**	
[Signature]		**[Signature]**	
[Name]	**Dr. Chirag Trivedi**	**[Name]**	**Dr. Sushil Gupta**
[Title]	**Clinical Study Unit Director**	**[Title]**	**Professor, Department of Endocrinology**
In presence of		In presence of	
[Signature]		**[Signature]**	
[Name]	**Y. J. Cama**	**[Name]**	

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (INSTITUTION)	
[Signature]	DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
[Name]	**Prof. Rakesh Kapoor**
[Title]	**Director**
In presence of	
[Signature]	
[Name]	

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SGPGIMS,Lucknow

EXHIBIT 1

CONDITIONS OF PAYMENT

Agreement Effective Date: - 30th January 2019

1) The SPONSOR will pay **Rs.4,51,700/- (Rupees Four Lakhs Fifty One Thousand Seven Hundred Only)** per Subject included in accordance with the Protocol and who has completed the Study. The said amount is inclusive of audits and inspections compensation as referred to under Article 17.5.

Such amount is divided as follows:

EFC14875 (Per Subject Cost Details)			
Visits	**Investigator Fees (in INR)**	**Site Coordinator Fees*(in INR)**	**Subject reimbursement (for travel, meals during site visit) (in INR)**
Screening (V1)	17,000	3,300	1,500
Week 0 Randomization (V2)	22,500	3,500	1,500
Week 4 (V3)	14,000	3,800	1,500
Week 8 (V4)	14,000	3,800	1,500
Week 26 (V5)	14,500	4,400	1,500
Week 35 (V6) Phone Visit	3,700	2,600	-
Week 44 (V7) Phone Visit	3,700	2,600	-
Week 52 (V8)	17,500	4,300	1,500
Week 61 (V9) phone visit	3,700	2,600	-
Week 70 (V10) Phone visit	3,700	2,600	-
Week 78 (V11)	17,200	4,400	1,500
Week 87 (V12) Phone Visit	3,700	2,600	-
Week 96 (V13) Phone visit	3,700	2,600	-
Week 104 (V14)	17,500	4,300	1,500
week 113 (V15) Phone Visit	3,700	2,600	-
week 122 (V16) phone visit	3,700	2,600	-
week 130 (V17)	17,200	4,400	1,500
week 139 (V18) phone visit	3,700	2,600	-
week 148 (V19) phone visit	3,700	2,600	-
week 156 (V20)	17,500	4,300	1,500
week 165 (V21) phone visit	3,700	2,600	-
week 174 (V22) phone visit	3,700	2,600	-
week 182 (V23)	17,200	4,400	1,500
week 191 (V24) phone visit	3,700	2,600	-
week 200 (V25) phone visit	3,700	2,600	-
week 208 (V26)	17,500	4,300	1,500
week 217 (V27) phone visit	3,700	2,600	-
week 226 (V28) phone visit	3,700	2,600	-
pEOT visit	14,900	3,100	1,500
Close-out visit	14,900	3,100	1,500

Lt Col Varun Baipai VSM
Executive Registrar
SGPGIMS,Lucknow

EFC14875 (Per Subject Cost Details)			
Visits	**Investigator Fees (in INR)**	**Site Coordinator Fees*(in INR)**	**Subject reimbursement (for travel, meals during site visit) (in INR)**
Follow-up visit	11,800	4,600	1,500
Unscheduled Visit (if done)**	17,000	4,700	1,500
Total Per Subject Cost	**321,400**	**106,300**	**24,000**

*In case, the Study Coordinator is to be provided by the SPONSOR, the study coordinator Fees will not be payable to the INSTITUTION/INVESTIGATOR and the same shall not be applicable.

**Unscheduled Visit- This cost does not apply to unscheduled phone calls made to the patients. Also, the unscheduled visit cost listed in table above is the maximum payable amount when all tests/procedures are done during unscheduled visit. In case all tests/procedures are not done, the payment will be commensurate to the actual work done by the site during patient's unscheduled visit.

2) Cost of local lab tests, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice. Additional investigations apart from protocol specified investigations will be reimbursed based on proper rational provided by the INVESTIGATOR and based on verification provided by the SPONSOR.

3) For screen failure, the SPONSOR will pay Rs.20,000/- (Rupees Twenty Thousand only) per screen failed subject (this is as per the expectation that the screen failure rate is in line with the country screen failure rate).

4) Ethics committee's fees, if any, shall be paid based on actuals and shall be payable on receipt by the SPONSOR of an itemized invoice, on the Letter Head of the Ethics Committee and/or the PAYEE.

5) 25% Institutional overheads on aforesaid Point 1 (except Subject reimbursement) & Point 3.

6) Sponsor will pay one time lump sum of Rs.50,000/- (Rupees Fifty Thousand only) after the Study Closure to PAYEE for archival and document storage for a period of 15 years from the date of site closure.

7) A close out fee of Rs.10,000/- (Rupees Ten Thousand only) will be paid towards close out efforts once the site close out visit has been conducted.

8) A onetime start-up fee of Rs.50,000/- (Rupees Fifty Thousand only) shall be paid for the time spent for Health Authority documentation, undertaking study specific training, patient identification, Ethics Committee submission, approval activities and shall cover the cost of any study related infrastructure if required. The payment shall be made on the receipt of Ethics Committee approval unless discontinued due to regulatory obligations.

9) Concomitant medications that are standard of care for the underlying diseases are not reimbursable.

10) All the devices or instruments provided by the SPONSOR will be returned to SPONSOR at the time of closeout.

11) Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Contract.

12) Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the Sponsor to the Payee against presentation by the Payee of all relevant documentation.

The party who makes a taxable service under or in connection with this Contract shall be entitled to recover such taxes that it is required by law to collect from the other party to

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Executive Registrar
SGPGIMS,Lucknow

whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law. Notwithstanding anything contrary stated herein in this Contract, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the Payee shall indemnify the Sponsor such GST amount along with applicable interest.

A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.

In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

The payment for recruited Subjects will be made to the INVESTIGATOR/INSTITUTION on quarterly basis upon presentation of the invoices in Indian Rupees by a cheque/ bankwire transfer within 30 days (from the receipt of correct Invoice) on the following PAYEE account:

•	Bank Name & Branch:	State Bank of India , SGPGIMS, Rai Bareilly Road
•	Bank IFSC	SBIN0007789
•	Account No.:	10095237491
•	PAYEE:	Director SGPGI-Research Scheme A/C
•	PAN No.:	AAAJS3913N
•	GST No.:	09AAAJS3913N2ZN

The final payment will occur only after:

- the delivery and review of the final data of the Study, provided that they shall be ready for statistical analysis;
- the completion of all CRF/e-CRF, including resolution of all DRF/e-DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- the INVESTIGATOR has returned all remaining Investigational Medicinal Product and applicable study material, if any, in compliance with Article 5).

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