Ref.

To,

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital,

Rae Bareli Road, Lucknow - 226014,

Uttar Pradesh, India

Attn: Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital

Attn: Dr. Soniya Nityanand, HOD, Department of Haematology

Subject: Terms of Donation by Cuddles Foundation.

Dear Sir / Madam,

1. Cuddles Foundation (Cuddles) is a non-government charitable organisation, registered under the Mumbai Public Trusts act, 1950 with its registered office at 17/17H, 1st Floor, Bahubali Building, Cawasji Patel Street, Fort, Mumbai – 400 001. Cuddles is primarily engaged in providing nutrition related aid for paediatric oncology patients and related activities. Cuddles currently provides such aid to hospitals across India. Ms. Purnota Bahl (Founder and Trustee) of Cuddles, is the authorised signatory on behalf of Cuddles.

2. Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital is a government medical hospital which provides treatment to paediatric oncology patients.

3. Pursuant to discussions with the Hospital, Cuddles undertakes to make reasonable efforts to provide aid to the Hospital on the terms and conditions set out in this Letter.

a. Cuddles shall bear the cost, not exceeding such amount as may be mutually agreed between Cuddles and the Hospital from time to time: (i) of the Hospital retaining minimum 1 full time trained nutritionists having the requisite qualifications mandated by law (including any guidelines applicable to the Hospital) (Nutritionist); (ii) in relation to meals and other perishable food items procured by the Hospital for out-patients (Meals), (collectively Donation). The Donation shall be paid by Cuddles directly to the Nutritionist and provider of Meals, for and on behalf of the Hospital; and

b. Cuddles shall donate the products set out in Annexure 1 to the Hospital in such quantities and per a schedule as may be mutually agreed between Cuddles and the Hospital from time to time (Products).

4. The Hospital understands that Cuddles mandate is to provide nutrition related aid for paediatric oncology patients and the Hospital undertakes that it shall utilize the Donation and Products only for the treatment of in-patient and out-patient oncology patients aged 18 years or less.

5. The Hospital acknowledges that Cuddles, the persons named as trustees under its trust deed dated 3 October 2013, as amended from time to time (**Trustees**) or its employees are not experts and do not

Cuddles Foundation Mumbai

S. Nityanand

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

have any nutrition related experience and confirms that Cuddles is merely acting as a donor to the Hospital of the Donation and Products.

6. The Hospital confirms that it is the responsibility of the Hospital to verify the credentials of the Nutritionist(s). The Nutritionist shall operate under the control and supervision of the doctors at the Hospital and the Hospital acknowledges that Cuddles will not supervise or control the work of the Nutritionist(s).

7. The Hospital confirms to provide space to store Meals and Products appropriately and that it is its responsibility to check that the Meals and Products are in good condition prior to their usage and Cuddles will have no role to play in determining which, if any, of the Meals paid for or Products donated will be utilized by the Hospital.

8. This Letter and the arrangement set out herein shall be deemed to have come into effect from 1st March, 2019 and shall continue to be in force till 28th February, 2022. Either Party can terminate this Letter by providing 1 (one) month's prior written notice.

9. The terms set out herein, including the Annexures, shall be governed by Indian law and may be amended only with the prior written approval of the Trustees of Cuddles and the Hospital.

We request you to kindly execute this Letter in acceptance of the aforesaid terms.

With regards,

Cuddles Foundation

Cuddles Foundation Mumbai

Agreed and confirmed

26/2

Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital

S. Nityanand 26.2.19

Dr. Soniya Nityanand, HOD, Department of Haematology, Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI) Hospital

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Memorandum of Understanding (MOU)

Agreement to Establish a

Canada-India Neonatal Centre of Excellence in Research & Education (CINCERE)

Between

The Department of Medical Education of Uttar Pradesh

And

आत्मना सर्गो जितः

Sanjay Gandhi Postgraduate Institute of Medical Sciences

And

Sinai Health System

Each a "Party" and together "Parties"

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

In Support of

Sinai Health Foundation

Sinai Health System

Sanjay Gandhi Postgraduate Institute of Medical Science
Lucknow (India)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

उत्तर प्रदेश UTTAR PRADESH

ET 321593

Agreement to establish a

Canada-India Neonatal Centre of Excellence in Research & Education (CINCERE)

Between

The Department of Medical Education of Uttar Pradesh

And

The Sanjay Gandhi Postgraduate Institute of Medical Sciences

And

Sinai Health System

Each a "Party" and together "Parties".

1. Whereas the Department of Medical Education of Uttar Pradesh (hereafter known as "UP"), and the Sanjay Gandhi Postgraduate Institute of Medical Sciences (hereafter known as "SGPGIMS") and Sinai Health System (hereafter known as "Sinai") have common goals to improve the health of infants through clinical care, training and research, and
2. Whereas UP, SGPGIMS, and Sinai under the direction of Dr. Shoo Lee desire to strengthen their international relationship in clinical care, training and research, and
3. Whereas UP and SGPGIMS wish to establish a neonatal research and training center based on excellence to serve the needs of India, and

4. Whereas Sinai agrees to partner with UP and SGPGIMS in this endeavor,

The UP, SGPGIMS, Sinai agree to establish a Canada-India Neonatal Centre of Excellence in Research & Education (hereafter known as "CINCERE") at Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS).

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

This Agreement is signed at SGPGIMS on 6th Mar 2019 in Lucknow, India. With the signing of this agreement, UP, SGPGIMS, and Sinai agree to the following:

1. This Agreement is non-binding and no other legally binding obligations will be created until definitive agreements are executed and delivered by all Parties.

2. CINCEREis national in scope and SGPGIMSwill undertake to accept trainees from all across India.

3. The Parties will develop a statement of work which will document the details of the training program and the responsibilities of all the Parties based on the following components of the CINCERE programs("Statement of Work"):

(a) Clinical collaboration

Sinai will adviseSGPGIMS colleagues in clinical care of patients to facilitate mutual learning and share experience about care of patients. This will include ward rounds, clinical case discussion, discussion about the published literature and use of evidence-based methods and teaching. The aim is to enable Sinai and SGPGIMS faculty to share their expertise and upgrade neonatal care at SGPGIMS. A continuous quality improvement program will be introduced, and SGPGIMS staff will be trained in Evidence-based Practice for Improving Quality (EPIQ) methods.

(b) Research collaboration

SGPGIMS researchers will explore opportunities for joint research in neonatal-perinatal research, including training of new and young researchers.A clinical and outcomes database will be established to facilitate research, audit and quality improvement.Research initiatives will include quality improvement, simulation, developmental and family integrated care, point of care technologies and telemedicine. The ethical issues if any, shall be dealt in accordance with existing procedures.

(c) Joint neonatal training program

A neonatal training curriculumwill be developed for SGPGIMS and associated community health providers, including doctors, nurses and others as deemed appropriate. The curriculum will include objectives, course duration, course content, course methods and evaluation criteria and will be jointly developed and taught by SGPGIMS faculty at SGPGIMS. Training will be conducted in English.Trainees will learn the fundamentals of neonatal-perinatal medicine, participate in daily NICU ward rounds, and engage in discussions about clinical cases, published literature and evidence-based practice. They will develop critical thinking

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Executive Registrar
SGPGIMS,Lucknow

skills and learn about different neonatal care approaches and research.

(d) *Facilitation for Canadian Fellowship programs*
Sinai will facilitate applications of deserving doctors who have passed PDCC or DM Neonatology from SGPGIMS in future, in desired neonatal fellowship programs of Canada.

(e) *Neonatal nurse training program*
A joint needs assessment will be performed and a nurse training program will be established to upgrade the skills of SGPGIMS nurses to an appropriate level. Canadian nurse educators may participate in the training program as deemed appropriate by the needs assessment.SGPGIMS will nominate at least two nurse educators to be part of the instruction cadre that will sustain the training program going forward.

(f) *Visiting Scholar Exchange*
SGPGIMSmay arrange for Visiting Scholars from SGPGIMS faculty members to visit NICUs in Canada& SGPGIMS. Visiting Scholars may choose their desired location in Canadafor postings subject to availability. In most cases, Visiting Scholars will be observers but practical experience may be available on an individually arranged basis. Visiting scholars will be responsible for their own expenses.

(g) *Neonatal Advanced Simulation Training and Research Center (NASTARC)*
Sinai will assist SGPGIMS to establish an advanced simulation center at SGPGIMS, and provide advice and training to SGPGIMS staff. Sinai will provide core equipment(Appendix A) to establish NASTARC. SGPGIMS will provide the physical facilities necessary for NASTARC and provide infrastructureand staff for its continued operation.

(h) *Telemedicine Program*
A telemedicine program will be established to enable on-going teaching and collaboration between SGPGIMS and Canadian faculty, and between SGPGIMS, state medical colleges and community health institutions.SGPGIMS will provide the telemedicine infrastructure and services in Lucknow.

(i) *Infant Transport System*
Sinai will assist SGPGIMS to establish an infant transport system at SGPGIMS, including providing advice and training to SGPGIMS staff. SGPGIMS will source funding and provide the staff and equipment necessary for the transport system. SGPGIMS will decide on the appropriate time for establishing the infant transport system.

4. Establish a joint committee (hereafter called the "Joint Committee") to oversee CINCERE and its programs, including to establish the goals, standards,

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Executive Registrar
SGPGIMS,Lucknow

curriculum and other aspects of the training program, including establishing selection and graduating criteria, selection of trainees and approving graduation of trainees, and approving any fees necessary. The Joint Committee will have equal representation from SGPGIMS, to be selected by the SGPGIMS leadership Board respectively, and be co-chaired by representatives from both organizations. An evaluation and progress review system will be jointly established.

5. SGPGIMS will:

(a) provide logistical support to organize the programs, including establishing the clinical database, making classrooms and teaching aids available for teaching, arranging for course materials, collection of necessary fees etc.;
(b) agree that clinical work is not required of Canadian faculty;
(c) agree that SGPGIMS faculty will work together to upgrade skills of NICU staff at SGPGIMS;
(d) provide housing, food and program related ground travel within India for Sinai (and partners) in Lucknow;
(e) beyond the first three years, the joint committee will explore alternate mechanisms for funding Sinai faculty visiting SGPGIMS;
(g) provide physical facilities, staff; establish and operate NASTARC, the telemedicine facility andother agreed joint programs;
(h) will be responsible for operation & maintenance of the equipment supplied for NASTARC as per Appendix A;
(h) nominateat least two nurse educators to teach neonatal nurses in collaboration with a nurse educator from Canada;
(i) prepare and submit an annual report within 3 months of each calendar year end to the joint committee;
(j) provide support for all other activities as decided by the Joint Committee.

6. Sinaiwill:

(a) organize participation of Sinaifaculty at SGPGIMS;
(b) endeavor to provide6 qualified faculty members each year to teach in SGPGIMS. Each will stay for up to a month duration;
(c) provide faculty trainingpersonnel with the understanding that faculty may include neonatologists, nurses, respiratory therapists, dieticians, physiotherapists, occupational therapists, neonatal follow-up experts and others as determined appropriate by the Joint Committee;
(d) ensure that SGPGIMS is not responsible for salaries of Canadianfaculty;
(e) facilitate the applications of SGPGIMS trainees and visiting faculty to Canadian programs;
(f) endeavor to establish scholarships for selected trainees in Canada;
(g) endeavor to provide a nurse educator to train counterparts in SGPGIMS to provide training for neonatal nurses in India;
(h) provide core simulation equipment (Appendix A) for establishing NASTARCand related research programs; and to fund air travel to Lucknow, visa, research, training and other related activities of participating Canadian faculty, as decided by the Joint Committee, for the first three years, up to C$250,000.

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Executive Registrar
SGPGIMS,Lucknow

7. This agreement will remain in effect for a period of three (3) years, or until it is terminated by mutual agreement or by either party with three (3) months' notice.

8. The Joint Committee will meet at least once a year, at a mutually agreed upon time, to review the progress of the partnership and agree on future directions.

9. The Joint Committee will review the program annually & will prepare report for perusal of apex authorities of respective institutions /organizations, and make recommendations for change.

Signed by xxxx
On behalf of the Department of Medical Education, UP
Dates:

(Dr. K. K. Gupta)
Director
Medical Education & Training
Lucknow

Signed by xxxx
On Behalf of SGPGIMS
Dated: 6/3/2019

Prof. Rakesh Kapoor
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signed by xxxx
On Behalf of Sinai Health System
Dated:

Acknowledged by Shoo K. Lee
Dated: March 6, 2019

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Appendix A

1. PremieNatalie & Mamabreast x12
2. Neonate SimNewB Advanced trainer in neonatal resuscitation x1
3. Premature Anne x2
4. NeoNatalie (dark) x12
5. Pneumothorax Trainer x1
6. Baby Stap for lumbar puncture x1
7. Vetspeed Neonatal Echocardiography simulator x1
8. Ultrasound Neonatal Head Phantom GEORGE x1
9. Neonatal and Pediatric Multi-Venous IV Training Arm Kit x6
10. Arterial arm stick kit x3
11. Medtronic Video laryngoscope x1
12. HeartSim 200 x1
13. Newborn ANNIE x2
14. Neonatal Intubation Trainer x6

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

DD 348124

MEMORANDUM OF UNDERSTANDING

1. This MoU made on this.....day of ..... Two Thousand Seventeen between Council of Scientific and Industrial Research, a Society registered under the Societies Registration Act XXI of 1860 having its registered office at Anusandhan Bhawan, 2 Rafi Marg, New Delhi-110 001 (hereinafter called CSIR which expression shall where the context so admits, include its successors and permitted assigns) through its CSIR-Central Drug Research Institute having its office at B.S. 10/1, Sector 10, Jankipuram Extension, Sitapur Road, Lucknow-226031, India, (hereinafter called CSIR-CDRI) of the one part.

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

   Each CSIR-CDRI and SGPGIMS here under are also referred to separately as the ("Party"), or together as the ("Parties")

DIRECTOR
Institute of Medical Sciences
LUCKNOW-226 014, INDIA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(16)

2. Preamble

2.1 WHEREAS CSIR-CDRI is a Pioneer Drug Research Institute having all the infrastructure facilities for and development of new drug from conceptual to commercialization stage.

2.2 WHEREAS SGPGIMS is one of the Premier Medical Institute providing Medical education and health services in India.

3. Objective of the Program

The objectives of the Program are to promote institutional linkage between CSIR-CDRI and SGPGIMS and to explore other avenues for possible collaboration where expertise exists and can be mentored by either or both of them and also to provide higher education opportunities for faculty, support staff and students of CSIR-CDRI and SGPGIMS .

4. Scope of the Program

The Program is established to provide collaborative cooperation through:

i) **Collaborative Research Programs in specific fields of interest** - CSIR-CDRI and SGPGIMS will jointly identify specific fields to conduct collaborative research programs of mutual interest and benefit to both parties. It should also include technical inputs for development of protocols for collaborative projects.

ii) **Submission of Joint projects-** Project proposals may be jointly submitted to DBT, CSIR, DST, ICMR, or any other funding agencies for extramural funding for carrying out further studies of selected project/molecules.

iii) **Faculty Exchange Programs**- Exchange programs for faculty will be explored and conducted accordingly which will be mutually beneficial for both the parties.

iv) **Student Exchange Programs-** Exchange programs for students will be explored and conducted accordingly which will be mutually beneficial for both parties.

v) **Joint Programs**: Organizing joint scientific conferences, workshops symposia, meetings in the areas of mutual interest. Societal Health awareness programs, etc.

vi) **Sharing of Instrumentation Facility:** Sharing of Instrumentation facility for discovery of new biomarkers in various human diseases.

vii) Any other areas/programs of mutual interest.

5. General Provisions

(i) The MoU shall remain valid for a period of five (5) years from the last date of signing of the MoU.

(ii) The collaborators shall initiate the work after obtaining necessary approval of the research project from Institutional Animal Ethics Committee of CSIR-CDRI and SGPGIMS respectively.

M. Sinha

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(iii) The collaborators shall initiate the work after obtaining necessary approval of the research project from Institutional Human Ethics Committee of CSIR-CDRI and SGPGIMS respectively.

(iv) Both parties acknowledge the importance of protection of human and animal subjects in any research activity. Matters related to the transfer of biological material should receive prior approval on each side by the competent authority according to the existing rules and regulations of each party.

(v) The progress of implementation of the program shall be reviewed by SGPGIMS and CSIR-CDRI, as mutually decided and the benefits of the collaboration shall be shared mutually.

(vi) Both parties shall take necessary financial approvals from the competent authority for fulfilling the objectives of the program under clause 4 on case to case basis.

(vii) Incase, If any molecule shows promising activity, it may be considered for further development by CSIR-CDRI and SGPGIMS on mutually acceptable terms and conditions.

(viii) Both parties and their student can visit the collaborating institutes as per requirements of the project, and shall have adequate insurance coverage without any financial liability on each other.

(ix) During the tenure of the MoU and thereafter parties undertake on its behalf and on behalf of its affiliates, employees, associates, consultants, professional advisors (collectively referred to as "Permitted Users") to whom information under the scope of the MoU is disclosed shall maintain its confidentiality and shall also prevent any disclosure of the information to any third party. PARTY shall allow access to the information to only Permitted Users who are evaluating the data and information and they shall maintain the confidentiality of the same as their own data.

(x) The parties shall consult each other for any publication in respect of research work. These publications (papers, reports etc.) shall be in the names of actual research workers, wherein it will be duly acknowledged that the work has been carried out under the collaborative research program of CSIR-CDRI and SGPGIMS . As a part of collaboration, the outcomes of the research under this Agreement shall develop joint publication.

(xi) Any publication, document and/or paper arising out of joint work conducted by the participants pursuant to this MoU will be jointly owned. The use of the name, logo and/or official emblem of the participants on any publication, document and/or paper will require prior permission of both the participants. It may however be ensured that the official emblem and logo is not misused.

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(xii) Applications for joint Patents will be filed in the name of institutions namely CSIR-CDRI, Lucknow and SGPGIMS, Lucknow.

(xiii) Both parties agree to ensure appropriate protection of Intellectual Property Rights generated from such cooperation consistent with their respective laws, rules and regulations and other international agreements to which both parties are signatories.

(xiv) In case research is carried out solely and separately by the Party or the research results are obtained through the sole and separate effort of the Party the Party concerned alone will apply for grant of IPR and once granted the IPR will be solely owned by the concerned Party.

(xv) In case of research results obtained through joint activities, the grant of intellectual property rights will be sought by both the parties jointly and once granted these rights will jointly owned by the parties on mutually acceptable terms and conditions.

(xvi) In case of research results obtained through joint activities under this MoU both parties will apply as co-applicants for the protection of intellectual property rights subject to exclusive rights of both the Parties to commercialize the technology jointly on mutually acceptable terms and conditions.

(xvii) Any expenditure towards filing, maintaing and securing of IPR, development of the product and revenue towards license fee and royalty shall be shared on case to case basis in mutual consultation between Director, CSIR-CDRI and Director, SGPGIMS under a separate agreement.

(xviii) Any product generated under the program shall be licensed to any industry by CSIR-CDRI and/or SGPGIMS under a separate agreement after mutual consultation between Director, CSIR-CDRI and Director, SGPGIMS.

(xix) The annual maintenance of the facility including all the instruments shall be the responsibility of each party without any financial liability on each other.

(xx) Nothing contained herein shall constitute this a partnership or joint venture agreement or constitute either party as the partner, principal or agent of the other, this being a MoU between independent contracting entities.

(xxi) No amendment or modification of this MoU shall be valid unless the same is made in writing by all the parties or their authorized representatives and specifically stating the same to be an amendment of this MoU. The modifications shall be effective from the date on which they are made, unless otherwise agreed to.

(xxii) Both parties shall do their utmost to ensure the smooth and efficient implementation of the program.

M. Sinha

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(13)

(xxiii) This MoU can be terminated by either party by providing thirty (30) days notice of termination however; no termination should adversely interrupt or impair a program or course of study or its participants, commenced prior to such termination.

(xxiv) The parties will use their best efforts to settle all matters in dispute amicably. All disputes and differences of any kind related to this MoU shall be jointly settled between Director, CSIR-CDRI and Director, SGPGIMS.

For & on behalf of CSIR-CDRI	**For & on behalf of SGPGIMS**
Signature M. Siddiqui	**Signature**
Name निदेशक Director	Name DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
Designation केन्द्रीय औषधि अनुसंधान संस्थान Central Drug Research Institute लखनऊ / Lucknow	Designation
Seal	Seal
Witnesses	**Witnesses**
1- Naseem Ahmad Siddiqui CSIR-CDRI, LKO	1- Surendra Srivastava. SGPGIMS LKO
2- Neelima (Neelima Srivastava) BD-IP Unit, CSIR-CDRI, LKO	2- Amita Aggarwal SGPGI Amita

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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उत्तर प्रदेश UTTAR PRADESH

DL 880879

MEMORANDUM OF UNDERSTANDING

BETWEEN

INDIAN INSTITUTE OF TECHNOLOGY KANPUR

AND

(SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES)

FOR IMPLEMENTATION OF SCHEME NATIONAL INITIATIVE FOR SETTING UP OF DESIGN INNOVATION CENTRES

THIS MEMORANDUM OF UNDERSTANDING is made on this 04 day of July 2016 between Prof. Indranil Mannathe Director, Indian Institute of Technology Kanpur (hereinafter called the 'THE FIRST PARTY') and Prof. Rakesh Kapoor, Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences) (here in after called the 'THE SECOND PARTY').

WHEREAS it has been the concern of the Government of India to establish Design Innovation Centers to promote a culture of innovation and creative problem solving, to promote knowledge sharing and to enhance interdisciplinary design-focused education, research & entrepreneurial activities.

AND WHEREAS in pursuance of this concern, the Project objectives are:

- To promote a culture of innovation and creative problem solving.
- To serve as a place that imparts design based education and practice systematic design through projects.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ION B:

E FIRST PARTY'agrees to:

- Release the Grant as described at Section C.
- Render or arrange to render such technical assistance and guidance as may be needed by 'THE SECOND PARTY', from time to time for an effective and efficient implementation of the Scheme.
- Supervise the Scheme in the concerned Institutions.
- Select and review the project proposals of the faculty as well as students of the Second Party through Project Review Body (PRB) consisting of design experts.
- Assist or arrange to assist such academic assistance as required in forming a curriculum on design innovation within the Spoke institute
- Review the findings of audits and maintain the policy reforms and conduct evaluation studies.

SECTION C:

THE FIRST PARTY'will release funds as mentioned in Annexure A towards the approved scheme of the Institution in instalments on the basis of

- Fund requirement of the selected project proposals submitted by the faculty and students of the Second party by the 'Project Review Body'set up by the First party and satisfactory progress and performance against eligible activities by the Second Party,
- Unspent balance lying with the Spoke.
- Submission of Fund Utilization Certificates by the Second Party and The financial as well as academic support is subject to receiving continuous grants for the same from the Ministry of Human Resource Development to meet expenditures to the First Party. The funding of DIC-Spoke Institutions will be limited to XII Five Year Plan.

SECTION D:

- Each DIC-Spoke Centre will have a Head or Director, who will be leader in the profession. He / She will be an eminent person in the field.
- IIT Kanpur: Prof. Nachiketa Tiwari
- Spoke: Director, SGPGIMS

SECTION E:

The Project implementation schedule:

- The Project became effective on 26th Aug 2016.
- The Project is expected to proceed at uniform rate over three years, extension and funding can be considered by the FIRST PARTY on the basis of outcome of the DIC and the approval of the same by the Ministry of Human Resource Development.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4-7-16

उत्तर प्रदेश UTTAR PRADESH

DZ 016386

30 JAN

This MoU is entered into and between CSIR-Indian Institute of Toxicology Research (CSIR-IITR), a constituent Laboratory of Council of Scientific and Industrial Research, New Delhi situated at Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow-226001, Uttar Pradesh, hereinafter called "CSIR-IITR".

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, situated at Rae Bareli Road, Lucknow-226014, Uttar Pradesh, hereinafter called "SGPGIMS".

Sharing a common desire to extend and strengthen the functional relationship between CSIR-IITR and SGPGIMS, we the undersigned, mutually agree to share existing facilities and available expertise at our respective institutions. CSIR-IITR and SGPGIMS signed to this effect a Memorandum of Understanding (MoU) on 23rd day of February, 2018 which reads as follows:

- The major objective is to establish a close linkage and functional coordination between CSIR-IITR and SGPGIMS for mutual

23.2.18

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

continuance will be subject to review after expiry of the agreed period of five years.

- Any disputes arising will be settled by mutual negotiation between the two parties.

In witness thereof the parties have jointly signed/executed this Memorandum of Understanding in two copies on the date and year written above.

For and on behalf of:

23.2.18

(प्रोफेसर आलोक धावन)
(Professor Alok Dhawan)
निदेशक/Director
सीएसआईआर–भारतीय विषविज्ञान अनुसंधान संस्थान
CSIR-Indian Institute of Toxicology Research
लखनऊ/Lucknow-226001

CSIR-Indian Institute of Toxicology Research, Vishvigyan Bhawan 31, Mahatma Gandhi Marg Lucknow-226001, Uttar Pradesh

23/2/18

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

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow-226014, Uttar Pradesh

Witness:

1. .....डॉ0 के0 सी0. खुलबे/Dr. KC Khulbe
प्रमुख, अनुसंधान योजना एवं व्यापार विकास विभाग
Head, Research Planning & Business Development Division
सी.एस.आई.आर.–भारतीय विषविज्ञान अनुसंधान संस्थान
CSIR-Indian Institute of Toxicology Research
विज्ञान भवन 31, महात्मा गांधी मार्ग, लखनऊ–226001 भारत
Bhawan 31, Mahatma Gandhi Marg, Lucknow-226001 India

2. Prem Prakash
(PREM PRAKASH)

Witness:

1. .....
Prof. Girish Gupta
Faculty Incharge (Research)
S.G.P.G.I.M.S.
Lucknow-226014

2. .....
Dr. S. SRIVASTAVA
SCIENTIST-IV
Research Cell
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Lucknow - 226014

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Memorandum of Understanding

Between

सी.एस.आई.आर.-भारतीय विषविज्ञान अनुसंधान संस्थान

CSIR-Indian Institute of Toxicology Research, Lucknow

Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow-226001

And

संजय गांधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ

Sanjay Gandhi Post Graduate Institute of Medical Sciences

Rae Bareli Road, Lucknow-226014

On

23rd day of February, 2018

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

DZ 016386

30 JAN

This MoU is entered into and between CSIR-Indian Institute of Toxicology Research (CSIR-IITR), a constituent Laboratory of Council of Scientific and Industrial Research, New Delhi situated at Vishvigyan Bhawan, 31, Mahatma Gandhi Marg, Lucknow-226001, Uttar Pradesh, hereinafter called "CSIR-IITR".

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, situated at Rae Bareli Road, Lucknow-226014, Uttar Pradesh, hereinafter called "SGPGIMS".

Sharing a common desire to extend and strengthen the functional relationship between CSIR-IITR and SGPGIMS, we the undersigned, mutually agree to share existing facilities and available expertise at our respective institutions. CSIR-IITR and SGPGIMS signed to this effect a Memorandum of Understanding (MoU) on 23rd day of February, 2018 which reads as follows:

- The major objective is to establish a close linkage and functional coordination between CSIR-IITR and SGPGIMS for mutual

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cooperation towards the advancement of knowledge of the employees, faculty, scholars and students of both the institutions.

- CSIR-IITR and SGPGIMS will both provide intellectual and infrastructure support for carrying out collaborative /academic research in the areas of mutual interest. A prior approval of each research activity under such collaboration is required from the competent authorities of both the organizations. Mutually approved research projects will be executed without any financial liabilities on each other for recurring expenses after assessing the priority. The outcomes of the studies in terms of research papers, patents, products, etc will be jointly shared by the individuals from both the organizations.

- CSIR-IITR and SGPGIMS will encourage and provide facilities to explore and prepare joint proposals on thrust areas for funding. The technical activities and grant sharing between CSIR-IITR and SGPGIMS shall be mutually agreed while submitting such proposals to funding agencies. The outcomes of the joint research in terms of research papers, patents, products, etc will be jointly shared by both the organizations.

- The research orientation programme for the early and mid career faculty members of SGPGIMS may be conducted at CSIR-IITR and vice versa. The duration, frequency, adequacy and other modalities of such orientation programme can be decided on mutually agreeable basis.

- For ethically approved studies, SGPGIMS will provide the demographic data and biological materials including the tissues from human volunteers.

- CSIR-IITR and SGPGIMS may jointly organize Seminars/Workshops/ Conferences and short term training programme on the topics of mutual interest.

- SGPGIMS may offer honorary positions of Visiting Professors to the Scientists of CSIR-IITR as per the norms of SGPGIMS.

- These arrangements shall be valid for a period of five years commencing from the date of signing of this MoU and its

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continuance will be subject to review after expiry of the agreed period of five years.

- Any disputes arising will be settled by mutual negotiation between the two parties.

In witness thereof the parties have jointly signed/executed this Memorandum of Understanding in two copies on the date and year written above.

For and on behalf of:

23.2.18

(प्रोफेसर आलोक धावन)
(Professor Alok Dhawan)
निदेशक/Director
सीएसआईआर-भारतीय विषविज्ञान अनुसंधान संस्थान
CSIR-Indian Institute of Toxicology Research
31, महात्मा गांधी मार्ग, लखनऊ-226001

CSIR-Indian Institute of Toxicology Research, Vishvigyan Bhawan
31, Mahatma Gandhi Marg
Lucknow-226001, Uttar Pradesh

23/2/18

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

Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Rae Bareli Road, Lucknow-226014, Uttar Pradesh

Witness:

1. ..... 23/2/2018
..... डॉ. के.सी. खुलबे/Dr. KC Khulbe
..... Head, Research Planning & Business Development Division
..... CSIR-Indian Institute of Toxicology Research
2. Prem Prakash
(PREM PRAKASH)

Witness:

1. .....
..... Prof. Girish Gupta
Faculty Incharge (Research)
S.G.P.G.I.M.S.
Lucknow-226014

2. .....
..... Dr. S. SRIVASTAVA
SCIENTIST-IV
Research Cell
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Lucknow - 226014

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

DT 962699

MEMORANDUM OF UNDERSTANDING

BETWEEN

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES

AND

WAYNE STATE UNIVERSITY

SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, (hereinafter referred to as SGPGIMS"), an institution of higher learning, a tertiary care hospital established under the Government of Uttar Pradesh Act 30 year 1983 whose address is at SGPGIMS, Raebarelly Road, Lucknow 226014 India and shall include its lawful representatives and permitted assigns; **WAYNE STATE UNIVERSITY** (hereinafter referred to as "WSU"), a public institution of higher education established in 1868 whose address is at 4092 FACULTY/ADMINISTRATION BUILDING, 656 W. KIRBY, DETROIT, MICHIGAN, 48202, UNITED STATES OF AMERICA and shall include its lawful representatives and permitted assigns; hereinafter referred to singularly as "the Party" and collectively as "the Parties"),

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

The Parties are desirous of entering into this Memorandum of Understanding to declare their respective intentions and to establish a basis of co-operation and collaboration between the Parties upon the terms as contained herein.

HAVE REACHED AN UNDERSTANDING as follows:

ARTICLE I
OBJECTIVE

The Parties, subject to the terms of this Memorandum of Understanding and the laws, rules, regulations and national policies from time to time in force in each Party's country, will endeavour to strengthen, promote and develop co-operation between the Parties on the basis of equality and mutual benefit.

ARTICLE II
AREAS OF CO-OPERATION

1. Each Party will, subject to the laws, rules, regulations and national policies from time to time in force, governing the subject matter in their respective countries, endeavour to take necessary steps to encourage and promote co-operation in the following areas:

   a) Exchange of students for the purposes of value-added study, learning and research;
   b) Exchange of academicians for the purposes of value-added study, training and research;
   c) Joint research and teaching activities; and
   d) any other areas of co-operation to be mutually agreed upon by the Parties.

   The lists of activities are not exhaustive and may be added from time to time with mutual agreement of the Parties.

2. For the purpose of implementing the co-operation in respect of any areas stated in paragraph 1 the Parties will enter into a legally binding agreement subject to terms and conditions as mutually agreed upon by the Parties including clauses on "confidentiality",

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Executive Registrar
SGPGIMS Lucknow

renewed unless either institution informs the other in writing of its intention to terminate it at least six (6) months in advance.

2. This Memorandum of Understanding may be extended for a further period as may be agreed in writing by the Parties.

ARTICLE VII
NOTICES

Any communication under this Memorandum of Understanding will be in writing in the English language and delivered by registered mail to the address or sent to the electronic mail address or facsimile number of **SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW** or WAYNE STATE UNIVERSITY, as the case may be, shown below or to such other address or electronic mail address of facsimile as either Party may have notified the sender and shall, unless other wise provided herein, be deemed to be duly given or made when delivered to the recipient at such address or electronic mail address or facsimile number which is duly acknowledged:

To : SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES, LUCKNOW Raebarelly Road
Lucknow 2226014
India
(Attn: Director)
Tel : + 91 522 2668112
Fax : + 91 522 2668129
E-mail: director@sgpgi.ac.in

To : WAYNE STATE UNIVERSITY (WSU)
Ahmad Ezzeddine, PhD
Associate Vice President for Educational Outreach and International Programs
Office of the Provost
Wayne State University
656 W. Kirby, Detroit, MI 48202
UNITED STATES OF AMERICA
Tel: +1 (313) 577-8968

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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उत्तर प्रदेश UTTAR PRADESH

DH 041389

MEMORANDUM OF UNDERSTANDING

This MoU made on this Friday day July 7th of 2017 between National Institute of Pharmaceutical Education and Research (an autonomous institution under Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Govt. of India), Shree Bhawani Paper Mill Road, ITI Compound, Raebareli-229010, India (hereinafter called NIPER, Raebareli) of the one part.

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014, India (hereinafter called SGPGIMS, Lucknow which expression shall where the context so admits, include its successors and permitted assigns) of the second part.

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

Background

i. NIPER, Raebareli and SGPGIMS, Lucknow will share interests in basic sciences and research in the areas of Cardiovascular, Drug Metabolism, Renal Physiology, Anticancer Research and Diabetes.

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

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1. Commencement and Duration

1.1. This Memorandum of Understanding ("MoU") shall take effect on the date of signing and shall continue for a period of 5 years unless terminated earlier in accordance with the provisions of Clause 7.

2. Force of this MOU

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

3. Broad Areas for Cooperation

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

(a) Joint Research projects
(b) Training of Post Graduate students of NIPER at SGPGIMS as per the norms of the Institute.
(c) Organising joint seminars and conferences
(d) Joint publications as a result of collaborative research
(e) Faculty interaction between two organisations
(f) Any collaborative efforts that both may deem fit from time to time.

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

4. Joint Contributions

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

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

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

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

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

5. **Confidentiality and Privacy**

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

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

6. **Intellectual Property**

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

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

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

7. **Termination**

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

7.2. The termination of this MoU shall not affect the implementation of activities that have been undertaken prior to such termination,

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unless agreements pertaining to such activities explicitly provide for such termination.

8. Amendments and Supplementary Agreements

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

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

9. Use of Name and Logo

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

For and on behalf of NIPER, Raebareli

Signature

Name : **Dr. S. J. S. Flora**

Designation : **Director**

Seal **Dr. S.J.S. Flora Director NIPER, Raebareli**

Date

Witnesses

1. (KESHRI NATH TIWARI)
2. NIPER, RAEBARELI (ANUJ GARG) NIPER, RAEBARELI

For and on behalf of SGPGIMS, Lucknow

Signature

Name : **Prof. Rakesh Kapoor**

Designation : **Director**

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

Date 2/7/2017

Witnesses

1. (DR. S. SRIVASTAVA) Scientist - IV, SGPGI
2. (DR. K. Ganesh)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

उत्तर प्रदेश UTTAR PRADESH

DZ 090167

Memorandum of understanding

By and between

Foundation of Primary Immunodeficiency Diseases, USA

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow.

The Memorandum of understanding ("MOU") describes the terms and conditions under which Foundation of Primary Immunodeficiency Diseases, USA ("FPID") will provide funding and assistance under its grant program to Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow (the "Recipient") in connection with the project described below (annexure).

Background regarding the Foundation of Primary Immunodeficiency Diseases, USA

This is a non-government organization co-founded by Dr Sudhir Gupta and Dr Abha Gupta and managed by board of directors comprising of luminaries in the field of immunology and primary immunodeficiencies. The aim is to support education, diagnosis, treatment, and research in primary immunodeficiency diseases (PIDs) in India and the U.S. The broad objectives among each head are:

Education:

1. Broaden public awareness of PID via lectures, seminars, and print, online, and broadcast media.
2. Educating general and specialty practicing clinicians about diagnosis and therapy for PID via lectures, seminars, and conferences.
3. Training of immunologists/hematologists in molecular diagnosis, hematopoietic stem cell transplantation, and gene therapy via an exchange program among various institutions.

Diagnosis:

1. **To support the establishment of centers/laboratories for the diagnosis of PID (in India).**
2. Routine immunology laboratory diagnosis
3. Molecular diagnosis

Contd....2..

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Treatment:

1. Treatment with immunoglobulin via different routes (e.g., subcutaneous and intravenous)
2. Hematopoietic stem cell transplantation (cord blood and bone marrow)
3. Gene therapy

Research:

Research projects to understand the pathogenesis of PID (Basic and Translational). Both fellowships and individual research projects may be funded.

More information on FPID is available at www.fpid.org

Terms and conditions:

Purpose: To set up an SGPGI-FPID Center for diagnosis of PID that will provide free of cost tests for patients with suspected PID

Support: Rs. 5,00,000/annually will be provided to run the laboratory for consumables and manpower . This amount may be increased based upon the need and satisfactory progress report.

Reports: The Recipient will provide 6 monthly report on the progress made

Confidentiality: FPID will protect the confidentiality of information and data provided by the recipient.

Payments: The payments will be made by electronic wire-transfer to SGPGI in the name of **Director, SGPGI (research account).**

Return of unused funds: Any grant that remains unutilized may be carried over for following year and adjusted into following year budget.

Compliance: The FPID reserves the right, in its sole discretion to discontinue the project grant program if the foundation is not satisfied with the progress of the grant or the information reported by the recipient.

Prohibited activities: The money provided by FPID will be used for the sole purpose for which it is to be used and in no circumstances will it be used for any other purpose.

Dispute Resolution: All disputes will be resolved by mutualdiscussion.

Duration of MOU: 5 years

Project commencement:
This MOU will become effective on the date that it is fully executed by both **FPID** and the **Recipient**. The FPID reserves the right, in its sole discretion to discontinue the project grant program if the foundation is not satisfied with the progress of the grant or the information reported by the recipient. In the event of such termination the FPID will provide recipient with written notice of termination documenting the reason for termination.

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Executive Registrar
SGPGIMS,Lucknow

Other elements of this agreement

Any notice required by the MOU shall be sent in writing by certified mail addressed in the case of FPID to:
Dr Sudhir Gupta
2 Geneve, Newport Beach, CA 92660, USA

And in the case of recipient by courier mail to the address below:
The Director, SGPGI, Lucknow 226014, India

This MOU represents the complete agreement between the parties regarding its subject matter and supersedes all prior written or oral communications, representations and agreements regarding the same subject matter. This MOU may be amended or modified only in a written document signed by duly authorized representatives of FPID and recipient. This MOU may be executed in two or three counterparts, each of which will be deemed an original. If any provision of this MOU is held unenforceable for any reason, than unenforceability shall not affect the enforceability of any other provision of this MOU and the parties will negotiate in good faith to substitute an enforceable provision with similar aims.
Executed by the parties hereto as of the date set forth

FPID

Prof Sudhir Gupta
Co-founder and Chairman, Board of Directors
Date_____

Recipient

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

Date_____

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Executive Registrar
SGPGIMS,Lucknow

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL75113360813084Q
Certificate Issued Date	:	12-Jan-2018 12:11 PM
Account Reference	:	IMPACC (IV)/ dl982203/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL98220353284573996806Q
Purchased by	:	PHARMAZZ INDIA PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PHARMAZZ INDIA PRIVATE LIMITED
Second Party	:	SGPGI AND DR U K MISRA
Stamp Duty Paid By	:	PHARMAZZ INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Institution)

And

Dr. U.K. Misra (Principal Investigator)

PHARMAZZ INDIA PVT. LTD.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(27)

FOR THE STUDY

Title of Study:	A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke.
Protocol Number:	PMZ-01
Version Number:	02
Date of Protocol:	18 April 2016

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on **23 Mar 2018** ("**Effective Date**") at New Delhi **BY AND BETWEEN**:

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Office at B-4 Sarita Vihar New Delhi 110076, (hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institution having its office at Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014, (hereinafter referred to as **"Sanjay Gandhi Post Graduate Institute of Medical Sciences**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART**;

AND

Dr. U.K. Misra a registered medical practitioner holding MCI registration number-18599 , is the Professor at Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014 (hereinafter referred to as "**Principal Investigator**"), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART**;

Pharmazz, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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RECITALS

1. WHERE (**Sanjay Gandhi Post Graduate Institute of Medical Sciences**) is a pioneering institution of world-class investigator sites in India. It is a chain of investigator sites having an exclusive set up for conducting Phase II to Phase IV clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related toPMZ-1620 is a lyophilized IRL-1620 Injection, proposed to act as a Treatment agent in Acute Ischemic Stroke.

3. Principal Investigator **Dr. U.K Misra, DM (Neurology)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement with **Dr. U.K. Misra** for conducting Clinical Trial Phase II study titled **"A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke"."**at Sanjay Gandhi Post Graduate Institute of Medical Sciences Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the proposed Study. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions**

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

a) **"AGREEMENT"** shall mean this Clinical Trial Agreement;

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipments, samples, services, customer lists,

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marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) "**EFFECTIVE DATE**" shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled **"A Prospective, Multicentric, Randomized, Double Blind, Parallel, Saline Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of Acute Ischemic Stroke"**As defined in the Protocol.

g) "**PROTOCOL**" shall mean: The description of the Study contained in the Study protocol number **PMZ 01** (a copy of which is attached as Exhibit A) and all amendments thereto as the Parties may from time to time agree in writing.

h) "**STUDY DRUG**" or "**Investigational Drug**" shall mean: IRL-1620 For Injection 30 µg/vial

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Executive Registrar
SGPGIMS,Lucknow

i) **"ETHICS COMMITTEE"** shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

j) **"DCGI"** Drug Controller Government of India.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

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2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator to complete the following -

Responsibility of the Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator

The **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees to provide full support to the Principal Investigator **at Sanjay Gandhi Post Graduate Institute of Medical Sciences Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014** to conduct the Clinical Trial in **Sanjay Gandhi Post Graduate Institute of Medical Sciences** premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the said hospital for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be jointly and severally responsible

a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**");

c) to fulfill all other terms and conditions stipulated herein and in the Exhibits hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

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2.2 The Principal Investigator shall personally review all case report forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/eCRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new

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principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethical committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** throughout the period of the Clinical Trial and **with third party vendor or sponsor** for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall obtain written approval from Pharmazz before destruction of such data.

2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

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Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz will provide the Study Drug to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the Safety and Efficacy of PMZ-1620 therapy along with standard supportive care in subjects of acute ischemic stroke.

3 VISIT AND INSEPECTION

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

a. examine and inspect the **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study, and audit all

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reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

c. Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 RECORDS AND REPORTING

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 PAYMENT, PRICING TERMS

5.1 Pharmazz agrees that in consideration of the Principal Investigator's and Sanjay Gandhi Post Graduate Institute of Medical Sciences carrying out the Clinical Trial in accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in Exhibit B, to the **Director SGPGI, Research Account** in accordance with the payment schedule set forth therein which shall include the remuneration and all other related cost.

5.2 The Parties agree that the payment of the amount set forth in Exhibit B will be paid by the Pharmazz to the **Director SGPGI, Research Account** to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the insurance program nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in Exhibit B is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in Exhibit B to be paid to **Director SGPGI, Research Account** shall be paid by Pharmazz. This amount is based on the estimated number of subjects in the time duration as agreed by Principal Investigator as per site feasibility report Exhibit D. Any change in the estimated number of subjects will proportionally affect the amount of payment.

5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to **Director SGPGI, Research Account** under this Agreement. The Budget as reflected in Exhibit B is exclusive of taxes.

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5.5 Site will raise GST invoices visit wise as mentioned in Exhibit B. All payments under this Agreement will be made within 15 days from the date of receipt of Invoice.

6 REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect)

The Second Party i.e. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be solely liable to pay all costs of such compliance. In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement.

Sanjay Gandhi Post Graduate Institute of Medical Sciences and PI are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

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The Second Party and PI will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of one year from the Effective date of this Agreement. This agreement can be extended with mutual understanding, if the trial is not complete.

8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90 day written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the Principal Investigator shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

9.1 Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for any of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI

b) **Sanjay Gandhi Post Graduate Institute of Medical Sciences** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters upon enrollment and as per his undertaking and site feasibility report provided **(Exhibit D);**

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the Principal Investigator **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to provide access by the Pharmazz's representatives all

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original medical records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and PI's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be effected by written notice to the Second Party and PI, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phase down costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and PI, whichever is later. The Second Party and PI shall be given reasonable opportunity to present to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and PI will be provided an additional period of time, specified and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party and PI to meet the deadline of (30) days for corrective measures then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

11.2 Upon termination or completion of the Study, the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were

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furnished to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees that it shall indemnify, defend and hold harmless the Principal Investigator, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

The indemnity granted in this Article shall apply separately to each Indemnity in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

12.2 It is a condition precedent to the Pharmazz's indemnification obligations under above mentioned clause 12.1 that:

a) Whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Pharmazz of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 12.1 above must (i) promptly notify the Pharmazz of the assertion of any such claims (ii) authorize and permit Pharmazz to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Pharmazz regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Pharmazz's obligations hereunder. Subject to the foregoing, Principal

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Investigator may also participate with prior consent of the Pharmazz in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Pharmazz to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Pharmazz.

The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** hereby irrevocably agree that they shall indemnify and hold harmless the Pharmazz, its present and future directors, officers and or employees against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Pharmazz by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences**; or (v) failure of the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines. The Institution and the Principal Investigator however shall in no event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof if the same is due to negligence and / or misconduct on the part of Pharmazz.

Sponsor warrant that they shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. Sponsor shall have the right to settle claims at its sole expense.

12.3 Sponsor shall provide the cost of medical management and compensation as per Rule 122-DAB-Compensation in case of injury or death due to study drug during the conduct of clinical trial.

a) In case of an injury occurring to the clinical trial subjects, he or she shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

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b) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expense incurred on the medical management of such subject.

c) The expense on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

12.4 **Insurance**

The Pharmazz undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the DCGI rules. This Insurance covers the Clinical Trial to be conducted for the Study at **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Insurance policy is attached at Exhibit E.

13. PUBLICATION OF RESULTS

It is the general policy of the Pharmazz to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Pharmazz for its perusal, comments and approval. The Pharmazz may at its discretion may either refuse the publication or forward it to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** along with its comments or modifications which shall be final and binding on the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences.**

14. PUBLICITY AND PRODUCT PROMOTING ACTIVITY

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Pharmazz shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Pharmazz and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Pharmazz.

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15. INTELLECTUAL PROPERTY RIGHTS

Sanjay Gandhi Post Graduate Institute of Medical Sciences agrees that all the Intellectual Property Rights with regard to **PMZ-1620** are and shall remain Pharmazz's exclusive property, and understands that **Sanjay Gandhi Post Graduate Institute of Medical Sciences** acquires no right, title, or interest in the Intellectual Property and the know-how used/created for the purpose of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees that all rights that may be created by the use of the Intellectual Property under this Agreement by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall inure to the sole benefit of Pharmazz and shall be the exclusive property of Pharmazz. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not at any time do or suffer to be done any act which would impair materially Pharmazz's proprietary rights in or to, or infringe, any Intellectual Property Rights of Pharmazz.

Pharmazz will be exclusively responsible if any dispute or claim arises regarding the ownership of the patent rights, copy rights & trade mark rights used by Pharmazz.

16. CONFIDENTIALITY

a) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree to keep confidential and secret all materials, documents and confidential information that the Pharmazz discloses to the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Pharmazz whether in written, electronic, oral, visual or other form (**"Confidential Information"**).

b) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Pharmazz to any third party except as required by law provided that the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall:

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First give prompt notice of such disclosure requirement to the Pharmazz so as to seek any limitations on or exemptions from such disclosure requirement; and

Reasonably co-operate with the Pharmazz in any such efforts of defense in the confidential and proprietary information to be made before appropriate authority.

c) Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** can prove and produces credible written evidence to establish that such information or material:

i. at the time of disclosure or after disclosure to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** or their successors or assigns;

ii. by written records were in the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences**'s possession at the time of disclosure by the Pharmazz were not acquired directly or indirectly from the Pharmazz;

iii. subsequent to disclosure hereunder, the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences** receives from a third party legally in a position to provide with information to the Principal Investigator/**Sanjay Gandhi Post Graduate Institute of Medical Sciences,** provided, however, that such was not obtained by said third party directly or indirectly from the Pharmazz under an obligation of confidentiality.

d) All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property

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of the Pharmazz and will be treated as "Confidential Information" by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and may be used by the Pharmazz in any manner. Further, Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall assign to the Pharmazz all of their rights, title, and interest in such Inventions.

e) All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Pharmazz by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** forthwith upon written request or upon termination of this Agreement, whichever is earlier.

f) Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Pharmazz, and that if there is a breach (either actual or **threatened) by the Principal Investigator/ Sanjay Gandhi Post Graduate Institute of Medical Sciences** or co-investigator or a party in receipt of Confidential Information under this Agreement, the Pharmazz would have complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Pharmazz shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

g) Institution Information. During performance of this Agreement, Sponsor representatives may gain access through site visits or otherwise to information relating to Institution's business or research operations, policies, or procedures that Institution identifies to Sponsor as proprietary and confidential or that is reasonably apparent to Sponsor to be so. Unless Institution provides written consent, Sponsor will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by law.

17. SEVERABILITY & WAIVER AND ASSIGNMENT

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

a) The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement. The parties agree that they negotiate in good faith or will permit a court/ Arbitration to replace any provision hereof so held invalid with a valid provision.

b) Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof but only by an instrument in writing..

c) This Agreement shall not be assigned as a whole or in part by any party without the prior written consent of the other parties except for the following types of general support services: communication, translation, photocopy of documents or similar services, failing which all actions taken will be null and void.

18. MISCELLANEOUS

a) It is agreed by the Parties that the Principal Investigator and Sanjay Gandhi Post Graduate Institute of Medical Sciences shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with any Parties including Pharmazz. Neither Principal Investigator nor **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall have any authority to represent, or bind the Pharmazz.

b) Principal Investigator shall comply with all the terms of the undertaking annexed hereto as **Exhibit C** and be read as part of this agreement, he has provided to the Pharmazz under this Agreement.

c) This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

d) If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

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Executive Registrar
SGPGIMS,Lucknow

e). The governing (applicable) language of this agreement shall be English, and all notices and other communications relating or pursuant to the provisions of the agreement (including, without limitation, those in connection with issues, disagreements and disputes) shall be in such language. This agreement, its formation and the facts and circumstances surrounding its making and performance, shall be interpreted in accordance with the following, and listed in order of precedence: (1) the express terms and conditions of the agreement; (2) the local laws of India

19. NOTICES

19.1. Unless otherwise provided herein, any communication, notice or notice of conditions interfering the performance of the agreement, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when received and acknowledged in case of electronic mode: Notifications shall be made to the following addresses:-

Pharmazz	**Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Mr. Sunil Gulati Chief Operating Officer	Dr. Rakesh Kapoor Director SGPGI	Dr. U.K Misra Principal Investigator
Pharmazz India Pvt. Ltd. B-4 Sarita Vihar New Delhi 110076 **Email**: sunil.gulati@pharmazz.com	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow- 226014 **Email:** director@sgpgi.ac.in	Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014 **Email:** ukmisra@rediffmail.com

19.2.1. Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration., which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed as per provisions of Arbitration and Conciliation Act, 1996 as amended from time to time. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto. Place of Arbitration shall be Delhi and both the parties shall bear the cost of arbitration in equal excluding counsel cost Parties agree that for claiming injunctive relief and for the enforcement of arbitral award only Delhi courts shall have exclusive jurisdiction

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Executive Registrar
SGPGIMS,Lucknow

in all matters arising out of or with this Agreement. This Agreement shall be governed by Laws of India.

20. RENEWAL CLAUSE

The agreement can be renewed by way of mutual consent of the parties in the event of requirement of further study of the protocol to complete the obligations enumerated herein above.

21. FORCE MAJEURE

Any delay or failure by the either party of required obligations shall be excused if and to the extent caused by acts of God, fire, storm, lockout, strike, terrorist act, flood, sabotage, Government Notification/ order, embargo, war (whether declared or not), riot, or other causes beyond the reasonable control of the said Party. If and when either party asserts Force Majeure as an excuse for failure to perform their obligations, then the said Party must notify the other Party in writing and upon the review of the said party's notice, the other Party shall determine whether the term of the agreement shall be extended for a reasonable time period to complete activities interrupted by the delays.

22. FURTHER ASSURANCES

Each party agrees that subsequent to the execution and delivery of this Agreement it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For **Pharmazz India Pvt. Ltd.**	For **Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Signature: ..... Name: Mr. Sunil Gulati Title: Chief Operating Officer	Signature: ..... Name: Dr. Rakesh Kapoor Title: Director, SGPGI	Signature: ..... Name: Dr. U.K. Misra Title: Principal Investigator

DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226014, INDIA

9c

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(6)

Exhibit-A

Clinical Trial Protocol

REFERENCE ENCLOSED

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SGPGIMS,Lucknow

(9)

Exhibit B

(Budget and Payment Schedule)

Budget

Total duration of Study	**9 months**		
Subject enrollment duration	**6 months**		
Total number of subjects	**15**		
Payment heads	**Total per subject**	**No. of Subjects**	**Amount per Head**
Investigator's Fees (In Rupees)	18000	15	270000
Study Coordinator Fees (In Rupees)	10000		150000
Protocol Procedures (Lab expenses) (In Rupees)	4425		66375
CT/ MRI cost (In Rupees)	4800		72000
Subject Travel (In Rupees)	2500		37500
Institutional Overhead on Investigator's & Coordinator's fees (In Rupees)			105000
Total Study Budget (In Rupees)			700875

- Protocol Procedures includes Lab expenses that is composed of cost of all the tests mentioned in protocol excluding Troponin T test, INR 55 shall be added to the Protocol procedures on Visit 1 (Baseline) for UPT if the subject is female.
- Recruitment of estimated number of trial subjects should be completed within 6 months.
- Archival fee will be paid on close out visit and it will be as per the institutional EC SOP.
- In addition to the above fee, Pharmazz shall pay for unscheduled visit (only if required) activities listed in Protocol.
- GST invoices required for release of payments visit wise.

Payee Details-

Payee Name	Director SGPGI, Research Account
Name of the Bank & Branch	State Bank Of India
A/C No:	10095237492
IFSC	SBIN0007789
MICR	226002034
PAN No./TAN No.	AAAJS3913N
GST No. (if applicable)	Not applicable

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Exhibit-C

Principal Investigator's Documents

REFERENCE ENCLOSED

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(3)

Exhibit-D

Site Feasibility Questionnaire Filled and Accepted by PI

REFERENCE ENCLOSED

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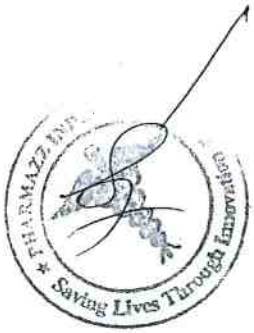
Executive Registrar
SGPGIMS,Lucknow

(2)

Exhibit-E

Insurance Policy for study

REFERENCE ENCLOSED



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SGPGIMS,Lucknow

Exhibit-F

Phase II Clinical Trial NOC

REFERENCE ENCLOSED

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

GOVT. OF KARNATAKA
DEPT. OF STAMP & REGISTRATION
28955
195333
भारत
INDIA
SEP 18 2018
14:1
R.0000100
PB6936
STAMP DUTY
KARNATAKA
Sub Registrar
Bommanahalli.

CLINICAL TRIAL/STUDY AGREEMENT

This agreement is made on this 18 Sep 2018 by and between **"Norwich Clinical Services"** a company incorporated under Companies Act, 1956 and having its registered office at No.147/F, 8th main, 3rd block, Koramangala, Bangalore-560034, (hereinafter referred to as **CRO/Sponsor Representative**), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the One Part;

AND

"Dr. Raghunandan Prasad" working at **Sanjay Gandhi Post Graduate Institute of Medical Sciences(SGPGI), Rae Bareli Road, Lucknow-226014** (Hereinafter referred to as "Principal Investigator" or "**P.I.**"), which expression unless repugnant to the context or meaning thereof shall include its successors and permitted assigns) being of the Second Part;

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI), Rae Bareli Road, Lucknow-226014 of the third part.

WHEREAS the purpose of this agreement is for conducting clinical study having Study Title:

"Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization- A Phase IV study." in accordance with applicable laws including but limited to Declaration of Helsinki, Schedule Y of Drugs and Cosmetics Act, 1940 and the rules framed there under, Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and ICMR Guideline 2017, on patients as stated in the protocol (hereinafter referred to as the subjects).

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1. The SPONSOR (GUERBET a company registered in France) is a pharmaceutical Company engaged inter alia in the business of manufacturing and/or marketing of various active pharmaceutical ingredients and pharmaceuticals in finished dosage forms;

1.1. **CRO/Sponsor representative** is a professional clinical research organization in India engaged in the business of undertaking bio studies, Clinical Trial Services and pharmacovigilance services in conformance to international standards.

1.2. The CRO has represented and warranted to sponsor that it has the necessary skill, experience, expertise and necessary facilities/infrastructure to provide the services contemplated under this agreement.

1.3. The CRO has also represented that all licenses, authorizations and permissions required under law for providing the services contemplated under this agreement will be obtained and that all such licenses, authorizations and permissions will be in full force and effect at the time of executing the services outlined in this agreement.

1.4. Whereas the CRO desires to enter into agreement with **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Dr. Raghunandan Prasad to conduct the study in the Sanjay Gandhi Post Graduate Institute of Medical Sciences.

1.5. The CRO has agreed to engage Dr. **Raghunandan Prasad** who is a Specialist in the therapeutic area required for the study, be a Principal Investigator for the study mentioned above.

1.6. The CRO has agreed to engage Sanjay Gandhi Post Graduate Institute of Medical Sciences & the Principal Investigator for providing the services contemplated under this agreement, subject to the terms and conditions contained herein.

1.7. Whereas during the term of this Agreement, the terms and conditions herein contained shall govern the services to be provided by the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator to CRO under any subsequent individual agreement for specific services to be rendered, referred to as a Specific Protocol

1.8. The Project shall be conducted as per the CRO/sponsor's confidentiality requirements.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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1.9. **Sanjay Gandhi Post Graduate Institute of Medical Sciences &** the Principal Investigator agree that the CRO/sponsor shall, subject to prior intimation to the Hospital and the P.I., have the right to enter their facility at reasonable times to inspect the facility, and the performance of the services hereunder. The CRO and the sponsor shall have the right to inspect and audit **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator records only to the extent they relate to services performed by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator hereunder for which the CRO is making payment to **Sanjay Gandhi Post Graduate Institute of Medical Sciences &** the Principal Investigator.

1.10. 1.10.1. Such rights shall, however, be only exercised by the CRO and the sponsor during **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & the Principal Investigator's normal business hours at a mutually agreed time and only following reasonable prior notice (48 hours prior notice being presumptively reasonable).

1.11. During the term of this Agreement, Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator agrees to diligently and conscientiously use its reasonable efforts to discharge its obligations in the Project as per the terms agreed hereunder, requested from time to time by the CRO/sponsor.

1.12. Responsibilities of **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator include providing such advice and information relating to the results of the studies subject matter of the Project as CRO/sponsor may reasonably request in writing from time to time to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** & Principal Investigator.

1.13. Notwithstanding the provisions of this clause, nothing in this Agreement shall preclude **Sanjay Gandhi Post Graduate Institute of Medical Sciences &** Principal Investigator from providing services to any other person or entity for such Project which is similar to the one undertaken in this Agreement.

1.14. The CRO expressly will have exclusive ownership interest in information, results; data developed or conceived under this Agreement and the studies covered by this agreement.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Branch - SGPGIMS, Lucknow

PAN No. - AAAJS3913N

- Limited within 45 days after the receipt of invoice from the Hospital.
- Investigator payments will be made after the receipt of completed CRFs.
- In case of patients not completing the study, payment of investigator fee will be made on prorate basis, up to the stage of study completion for that patient as per the calculation above.
- For SAE's if any, 20% of the fee payable to the Investigator will be withheld and released only on completion of reporting, follow-up and relevant documentation.
- The above payments will be subject to TDS at the applicable rates.

Note:

"In case of an injury occurring to the subject during the clinical trial, free medical management shall be given as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier." It is hereby clarified that the cost of the aforesaid medical management shall be borne by the Sponsor.

The following deductions will be made, if applicable:

- Tax deduction at source for all payments of fee unless a valid tax exemption certificate is provided by the investigator/ institution.
- Any capital expenses for the site incurred by the CRO on behalf of PI will be deducted from the fee payable to PI.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(10)

For NORWICH CLINICAL SERVICES

Signature:

Name: Dr. Saral Thangam

Title: Chief Executive Officer

Date:

NORWICH CLINICAL SERVICES PVT. LTD. BANGALORE

For Principal Investigator

Signature:

Name: Dr. Raghunandan Prasad

Title: Principal Investigator

Date: 25/09/18

For Sanjay Gandhi Post Graduate Institute of Medical Sciences.

Signature:

Name: PROF. RAKESH KAPOOR

Title: DIRECTOR

Date: 29.09.18

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Appendix E – Insurance

ICICI Lombard
GENERAL INSURANCE

CERTIFICATE OF INSURANCE [CLINICAL TRIALS LIABILITY INSURANCE]

Certificate Number:	4067/CT/GUERBET/16-17 – 001		Policy number: 4067/101887722/01/002
Insured Company:	GUERBET		
Mailing Address:	15 Rue Des Vanesses, VillepinteSeine-Saint-Denis, 93420 FRANCE		
Policy Period:	June 1, 2016 (00.01 hrs)	to	May 31, 2018 (23.59 hrs)
Coverage for the below mentioned trial is effective from:	March 1, 2017		
Retroactive date:	June 1, 2016		

Coverage

The Policy of Insurance listed herein have been issued to the Insured named above for the Policy period indicated. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this Certificate may be issued or may pertain, the Insurance afforded by this Policy is subject to all the terms, exclusions and conditions of such Policy. Aggregate Limit shown may have been reduced by paid claims.

Territorial Scope / Jurisdiction:	India	
Aggregate Limit of Indemnity*:	₹ 74,389,500	
Any One Accident Limit*:	₹ 74,389,500	
Deductible:	₹ 111,584	any one claim, including cost and expenses

* this is the total Limit applicable to the Policy and its shared by all the trials covered under this Policy

Limits and Deductibles if indicated in foreign currency are for the sake of convenience only. The policy will be issued in equivalent INR as on the date of inception of cover/ exchange rate agreed.

Study Protocol Number:	LUF-44-001
Study Title	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization - A Phase IV study
Clinical phase	as per the respective study protocol
Trial Start Date:	March 1, 2017
Estimated End:	June 30, 2018
Sponsor of the trial	GUERBET Address : 15 Rue Des Vanesses, Villepinte Seine-Saint-Denis, 93420 FRANCE

The Country in which the clinical trial take place: India **Number of Human Test Subjects: 125**

Certificate Holder: (optional)

■ "To whom it may concern."

☐ If to be named on the certificate, state name and address of person/institution to whom the certificate will be handed out:

Requested Language of the Certificate: (tick) **Number of Certificates requested:** one

English: (default) ■

Other: ☐

Date: February 6, 2017

Place: Mumbai Authorised Signatory

Important Notes:(A) This Certificate is issued as a matter of information only and confers no rights upon the certificate holder (B) This Certificate does not amend, extend or alter the coverage afforded by the Policy (C) Should above described Policy be cancelled before the expiration date thereof, the issuing Insurer will endeavor to mail 30days written notice to the Certificate Holder (if any name specified above), but failure to do so shall impose no obligation or liability of any kind upon the Insurer, its agents or representatives (D) Inception of the Policy is subject to full-filment of all subjectivities communicated by us and 100% premium received by us (as per Insurance Act of India - Section 64 VB) and the Policy shall stand cancelled ab initio in the event of non-realization of the premium.

ICICI Lombard General Insurance Company Ltd.
Address: # 414, Veer Savarkar Marg [Near Siddhi Vinayak Temple] Prabhadevi, Mumbai, India- 400 025

Prepared By:

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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ICICI Lombard
GENERAL INSURANCE

CERTIFICATE OF INSURANCE [CLINICAL TRIALS LIABILITY INSURANCE]

Certificate Number:	4067-18-19- Guerbet -1	Policy number:	4067/149576020/00/000
Insured Company:	GUERBET		
Mailing Address:	15 RUE DES VANESSES, VILLEPINTE SEINE-SAINT- DENIS, 93420 FRANCE ILE DE FRANCE PARIS PIN - 92654		
Policy Period:	1-Jun-18 (00.01 hrs)	to	31-Dec-18 (23.59 hrs)
Retroactive date:	June 1, 2016		

Coverage

The Policy of Insurance listed herein have been issued to the Insured named above for the Policy period indicated. Notwithstanding any requirement, term or condition of any contract or other document with respect to which this Certificate may be issued or may pertain, the Insurance afforded by this Policy is subject to all the terms, exclusions and conditions of such Policy. Aggregate Limit shown may have been reduced by paid claims.

Territorial Scope / Jurisdiction:	India	
Aggregate Limit of Indemnity*:	INR 74389500	Aggregate limit
Any One Accident Limit*:	INR 74389500	per occurrence limit
Deductible:	INR 111,584	

* this is the total Limit applicable to the Policy and its shared by all the trials covered under this Policy

Limits and Deductibles if indicated in foreign currency are for the sake of convenience only. The policy will be issued in INR and the exchnage rate noted on the policy will be the prevailing rate as on the date of inception of cover. All claims will be paid to the Insured in India in INR.

Study Project Number:	LUF-44-001
Title of the Study:	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study
Trial Start Date:	June 1,2016
Estimated End:	31 Dec 18
Sponsor of the trial:	GUERBET
Additional Insured:	All Sites and Investigators are Insured

The Country in which the clinical trial take place: India **Number of Human Test Subjects:** As per protocol

Certificate Holder: (optional)

■ "To whom it may concern."

☐ if to be named on the certificate, state name and address of person/institution to whom the certificate will be handed out:

Date: June 7, 2018

Place: Mumbai Authorised Signatory Prepared by Shreya

Important Notes:(A) This Certificate is issued as a matter of information only and confers no rights upon the certificate holder (B) This Certificate does not ammend, extend or alter the coverage afforded by the Policy (C) Should above described Policy be cancelled before the expiration date thereof, the issuing Insurer will endeavor to mail 30days written notice to the Certificate Holder (if any name specified above), but failure to do so shall impose no obligation or liability of any kind upon the Insurer, its agents or representatives (D) Inception of the Policy is subject to full-fillment of all subjectivities communicated by us and 100% premium received by us (as per Insurance Act of India - Section 64 VB) and the Policy shall stand cancelled ab initio in the event of non-realization of the premium.

ICICI Lombard General Insurance Company Ltd.
Address: # 414, Veer Savarkar Marg [Near Siddhi Vinayak Temple] Prabhadevi, Mumbai, India- 400 025

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Appendix F – Indemnity

Guerbet

Confidential

February 1st, 2018

Guerbet

Boîte postale 57400
95943 Roissy CdG Cedex France
Tél. : 33 (0)1 45 91 50 00
www.guerbet.com

Société Anonyme
au capital de 12 501 148 €
Siège social :
15, rue des Vanesses
93420 Villepinte
308 491 521 RCS Bobigny
Siret 308 491 521 00057

NAF 2120 Z

RE: Protocol No. LUF-44-001 "Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization - A Phase IV study" ("Protocol")

Dr. Raghunandan,

Sanjay Gandhi Post Graduate Institute of Medical Sciences (SGPGI),
Rae Bareli Road, Lucknow-226014

Dear Dr. Raghunandan,

This letter outlines the indemnification obligations that Guerbet ("Sponsor") agrees to assume as sponsor of the Study. The terms of the Study are set forth in the Clinical Trial Agreement executed between Norwich Clinical Services (CRO) and Institution ("Agreement"). CRO is providing clinical research organization services to Sponsor under a separate contract.

Sponsor shall indemnify, defend, and hold harmless "Institution" involved in the Study and their respective trustees, directors and personnel, including Investigator (collectively, the "Indemnitees") from and against any and all liabilities, damages, losses, claims, and expenses, including court costs and reasonable attorneys' fees ("Losses") resulting from or arising out of any third-party claims, actions or proceedings arising out of (i) personal injury to or death of any Study subject enrolled in the Study, which injury or death is caused by treatment of such Study subject in accordance with the Protocol, or (ii) Sponsor's use or publication of Study Data (as defined in the Agreement), in each case solely to the extent that such Losses do not arise out of or in connection with any Institution Indemnitee's (A) failure to comply with this Agreement, the Protocol, any written instructions of Sponsor or CRO concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority or (B) negligence or willful misconduct.

An Indemnitee claiming a right of indemnification or defense under this letter shall provide Sponsor prompt written notice (in all events within thirty (30) days) of any such claim, including a copy thereof, served upon it, and shall cooperate fully with Sponsor and its legal representatives in the investigation of any matter regarding the subject of indemnification, at Sponsor's expense; provided, however, that failure by an Indemnitee to provide prompt notice shall not relieve Sponsor of its obligations hereunder except to the extent that Sponsor is prejudiced by such failure. Sponsor shall have the right to exercise sole control over the defense and settlement of any such complaint or claims for which indemnification or defense is sought, including the sole right to select defense counsel and to direct the defense or settlement of any such claim or suit; provided that Sponsor shall not enter into any settlement or admit fault or liability on behalf of any Indemnitee without the prior written consent of such Indemnitee, which consent shall not be unreasonably withheld or delayed. An Indemnitee shall have the right to select and to obtain representation by separate legal counsel at the Indemnitee's sole expense.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

In addition to the above, Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study subject that is caused by treatment of the Study subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by (A) failure by Institution, Investigator or any of their respective personnel to comply with the Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority, or (B) negligence or willful misconduct by Institution, Investigator or any of their respective personnel.

Under no circumstances shall Sponsor be responsible to the Indemnitees for any lost profits, lost opportunities, or other incidental, consequential or special damages.

The Institution shall promptly notify CRO and Sponsor in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and cooperate with Sponsor in the handling of the adverse event.

Sincerely,

Pierre DESCHE
Senior VP, Development & Regulatory Affairs

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA70819968564369R
Certificate Issued Date	:	11-Mar-2019 01:15 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ VIJAYANAGAR2/ KA-BN
Unique Doc. Reference	:	SUBIN-KAKACRSFL0873327554761034R
Purchased by	:	MYLIN BIOTECH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CTA AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	MYLIN BIOTECH INDIA PVT LTD
Second Party	:	SGPGI LUCKNOW
Stamp Duty Paid By	:	MYLIN BIOTECH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

MYLIN BIOTECH INDIA PVT LTD IN-KA70819968564369R RS. 100 11-MAR-2019 01:15 PM

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CLINICAL TRIAL AGREEMENT

Protocol # NIZY-BYT-MB-18

This Clinical Trial Agreement ("Agreement") is made as on 07.03.2019 between

Mylin Biotech India Pvt Ltd, incorporated under the laws of India with its registered office located at at #40/11-1 2nd floor, Govindraj Nagar, Magadi Road Bangalore -560040 and having PAN:AAICM3171B, including its successors, assigns and Affiliates (hereinafter "**Mylin**");

Statutory Alert:

1. The authenticity of this Stamp Certificate should be verified at "www.shcilestamp.com". Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
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SGPGIMS,Lucknow

and

PROFESSOR Dr. ANITA SAXENA an Indian citizen/resident, with his address at Department of Nephology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Rae Bareli Road, Lucknow – 226014, Uttar Pradesh and having PAN : AAAJS3913N (hereinafter **"Principal Investigator");**

and

Sanjay Gandhi Post Graduate Institute of Medical Sciences, with its address at Rae Bareli Road, Lucknow 226014, Uttar Pradesh (hereinafter **"Institution").**

Mylin Biotech wishes to support a clinical trial entitled Protocol #**NIZY-BYT-MB-18 "A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients.**

The parties agree as follows:

1. **Definitions:**

1.1.1 **Affiliate:** means with respect to a Person, and other Person which, directly or indirectly through one or more intermediaries, Controls, is Controlled by or is under common Control with the first mentioned Person, "Control" shall mean with respect to any Party, the possession, directly or indirectly, of 50% or more of the voting securities and/or the power to direct or cause the direction of the board and/ or management and/or policies of that Person, whether through ownership of voting securities, contract or otherwise.

1.1.2 **Applicable Laws** means any statute, law, regulation, ordinance, rule, judgment, injunction, order, decree, ruling, license, permit, consent, approval, directive, agreement, guideline, policy or restriction, or any requirement or decision or interpretative, legislative or administrative action of, or determination by, any Authority having jurisdiction over the matter in question, or otherwise applicable to the Parties, whether in effect as of the date of this Agreement or at any time thereafter; and including all data protection, privacy, drug, anti-competitive, anti-corruption, anti-bribery as well as export and re-export laws and regulations, GCP and related United States Food Drug Administration ("FDA"), European Medicines Agency ("EMA") and India Food and Drugs Administration (or any other similar Authority), regulations and guidelines.

1.1.3 **Authority** means any constitutional, judicial, governmental, quasi-governmental, legislative, statutory, quasi-judicial, departmental, regulatory or public body constituted by any statute or ordinance or by a court of competent jurisdiction, or any authority having jurisdiction over the Parties or the subject matter of this Agreement.

1.1.4 **Intellectual Property Rights:** includes patents, trademarks, service marks, logos, trade names, internet domain names, copyright and moral rights, database rights, semi-conductor topography rights, rights in designs, rights in inventions, rights in know-how and other intellectual property rights, in each case whether registered or unregistered, and all rights or

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forms of protection having equivalent or similar effect anywhere in the world and the term "registered" includes registrations and applications for registration, rights to Study Results, economic copyrights and know-how therein conceived, generated or reduced to practice during the Study.

1.1.5 **Invention:** shall be understood in the widest sense of the word, in particular including but not limited to patentable and non-patentable technical inventions, discoveries, improvements, and innovations of any kind.

1.1.6 **Party:** means Mylin Biotech, Institution and Principal Investigator and "Parties" shall mean all of them.

1.1.7 **Person:** means any individual, corporation, company, partnership, trust, limited liability company, association or other entity.

1.1.8 **Study Site:** means the premises on which the Study will be carried out.

1.1.9 **Study:** means the investigation to be conducted at the Study Site in accordance with the Protocol.

1.10 **Study Team:** means the Principal Investigator, Sub-Investigator(s), Institution staff, employees Of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

1.11.1 **Regulatory Approval:** means any and all permits, consents, grants, approvals, authorizations, licenses, waivers, exemptions, concessions, sanctions, permissions, registrations, certificates, agreements, orders, declarations, filings, reports or notices of, with or to any Authority pursuant to Applicable Law.

1.11.2 **Research Staff:** Institution staff, employees of Institution's Affiliates or any person involved in the conduct of the Study at the Study Site.

2. **Investigators and Research Staff.**

2.1 **Principal Investigator.** The Principal Investigator is an employee of the Institution who will be responsible for the direction of the Trial in accordance with applicable Institution policies. The Principal Investigator commits himself and his Research Staff to conduct the Trial as per the Protocol and the Applicable Laws, against fair compensation.

2.2 **Sub-investigators and Research Staff.** Principal Investigator will ensure that only individuals who are appropriately trained and qualified assist in the conduct of that Trial as Sub-investigators or Research Staff.

2.3 **Obligations of Principal Investigator.** Principal Investigator shall be solely responsible for strict compliance by all Trial personnel, including the Sub-investigators and the Research Staff, with the terms of this Agreement. Principal Investigator shall ensure that any personnel who assist in the conduct of the Trial are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator will assume all those responsibilities assigned to all principal investigators under various Applicable Laws, rules, regulations, guidelines and standard including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards, and all Applicable Laws including those relating to the confidentiality, privacy and security of patient information.

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2.4 The Principal Investigator shall be solely responsible and liable for performance of the obligations under this Agreement by the Study Team. Any breach committed by the Sub-investigator or any other member of the Study Team shall be deemed to be a breach committed by the Principal Investigator. Nothing Contained herein shall discharge or relieve Principal Investigator from its obligations or liability hereunder.

2.5 **No Substitution.** Principal Investigator may not reassign the conduct of the Trial to a different principal investigator without prior written authorization from Mylin Biotech, In the event Mylin Biotech approves such replacement, such replacement principal investigator will be required to agree to the terms and conditions of this Agreement separately in writing. In the event Mylin Biotech does not approve a replacement principal investigator, Mylin Biotech will have the option to terminate this Agreement in accordance with the termination provisions below.

2.6 **Delegation of duties by Principal Investigator.** Principal Investigator may delegate duties and responsibilities to Sub-investigators or Research Staff only to the extent permitted by Applicable Law governing the Trial Conduct, as described below.

2.7 **Compliance with Institutional Policies.** Principal Investigator will comply with the policies and procedures of the Institution, with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Mylin Biotech promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the Parties will attempt to reach an appropriate accommodation.

3. **Protocol.** The Principal Investigator shall conduct the Trial in accordance with the Protocol.

3.1 **Amendments.** The Protocol may be modified only by a written Amendment, signed by both, Mylin Biotech and the Principal Investigator. The parties acknowledge that Protocol Amendments are also subject to approval by the responsible Institutional Ethics Committee ("IEC").

3.2 **Emergency Amendments.** If it is necessary to change the Protocol on an emergency basis for the safety of the Trial Subjects (hereinafter defined), Principal Investigator will notify Mylin Biotech and the responsible IEC as soon as practicable but, in any event, no later than three working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment duly executed by Mylin Biotech and the Principal Investigator.

3.3 **No Additional Research.** Principal Investigator represents and warrants that no additional research will be conducted on Trial Subjects during the conduct of the Trial, unless it is approved by Mylin Biotech in writing, and documented as a companion protocol or an Amendment to the original Protocol. Such prohibited research activities include analyses of biological samples from Trial Subjects for any non-therapeutic purpose.

4. **Institutional Ethics Committee.** Before the Trial is initiated, Principal Investigator will ensure that both the Trial and the informed consent form are approved by an IEC that complies with all applicable regulations. Principal Investigator will further ensure that the Trial is subject to continuing oversight by the IEC throughout its conduct.

4.1 **Trial Disapproval.** If, through no fault of Principal Investigator, the Trial is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Principal Investigator, as outlined below.

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5. **Trial Conduct.** Principal Investigator will conduct the Trial in accordance with the Protocol, Mylin's or its designee's written instructions and Applicable Law.

5.1 **Trial Initiation:** Prior to initiation of the Trial, Mylin Biotech shall organize an investigator meeting for all investigators who are taking part in the clinical trial for Mylin Biotech, at such place and time as finalized by Mylin Biotech **("Investigator Meeting")**. The purpose of the investigator Meeting will including but not limited to, to make the investigators aware about – (i) scientific aspect of the clinical trial; (ii) standard operating procedures including documentation process and adverse event reporting; (iii) Protocol and various regulatory guidelines within which the investigator needs to conduct clinical trial for Mylin Biotech. The Principal Investigator agrees to attend the said Investigator Meeting along with such member of its Research Staff, as approved by Mylin Biotech **("Attendees")**. Mylin Biotech agrees that it shall arrange for the travel and boarding and lodging of the Investigator Meeting Attendees.

6. **Mylin Biotech.** Mylin Biotech will provide the Principal Investigator with sufficient quantities of Mylin Biotech product that is being studied **("Mylin Biotech")** to conduct the Trial. If required by the Protocol and unless otherwise agreed in writing, Mylin Biotech will also provide placebo or comparator drug **("Comparator Drug")**.

6.1 **Custody and Dispensing.** Principal Investigator will adhere to Applicable Law and industry standards requiring careful custody and dispensing of Mylin Biotech or Comparator Drug, as well as appropriate documentation of such activities.

6.2 **Control.** Principal Investigator will maintain appropriate control of supplies of Mylin Biotech or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Principal Investigator, Sub-investigators, or Research Staff.

6.3 **Use.** Principal Investigator will use Mylin Biotech or Comparator Drug only as specified in the Protocol. Any other use of Mylin Biotech or Comparator Drug constitutes a material breach of this Agreement.

6.4 **Ownership of Mylin Biotech.** Mylin Biotech is and remains the sole and exclusive property of Mylin. Mylin Biotech grants or assigns Principal Investigator no express or implied intellectual property rights in Mylin Biotech or in any methods of making or using Mylin Biotech.

6.5 **Payment for Mylin Biotech or Comparator Drug.** Principal Investigator will not charge a Trial Subject or third-party payer for Mylin Biotech or Comparator Drug or for any services reimbursed by Mylin Biotech under this Agreement.

7. **Representation and Warranties:**

7.1 The Principal Investigator and Institution hereby jointly and severally represent and warrant to Mylin Biotech the following:

a. The Principal Investigator is trained and qualified to conduct clinical trials at the Study Site, and the Study Team working on the Study shall be appropriately trained in ICH GCP and the Protocol;

b. The Principal Investigator and the Study Team shall perform the Study in an efficient and professional manner and shall complete the Study within the time period as informed by Mylin Biotech from time to time;

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c. The Principal Investigator and Institution shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective Authority(ies) under the applicable Regulatory Approval. It shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study in any manner;

d. The Principal Investigator and the Study Team shall conduct the Study under the review and direct supervision of Mylin Biotech, the EC, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to co-ordinate, review and safeguard the rights, safety and well-being of the Trial Subject;

e. The representation, warranties set or hereunder may be relied upon in any applications of any Authority(ies);

f. The Principal Investigator and/or the Institution shall not, at all times during the term hereof, neither appoint nor utilize the services nor assign the activities of the Study contemplated under the Protocol to any Sub-investigator(s), who is debarred under any regulatory requirements/ Law or statutes from undertaking or performing the Study or the obligations hereunder;

g. The Principal Investigator shall ensure the safe custody of the Study Drug in accordance with the Protocol and shall not use the Study Drug for any purpose other than the purpose of this Agreement;

h. The Principal Investigator and/or the Institution shall publish any data in connection with the Study only in accordance with the Protocol;

i. The Principal Investigator and the Institution shall promptly notify Mylin Biotech in writing of any change in the truth of any of the aforesaid representations;

j. The Principal Investigator shall take necessary and appropriate steps to inform its Study Team of the terms and conditions of this Agreement and to ensure that such persons comply with the terms and conditions of this Agreement;

k. The Principal Investigator and the Institution shall at all times be accountable to Mylin Biotech for any and all breach, action, inaction or omission, committed by the Study Team, support staff and personnel provided by it for conducting the Study;

l. In the event the Study Site is inspected and the Study data are audited / examined by any Authority(ies) having competent jurisdiction under the regulatory requirements or Applicable Laws, the Principal Investigator and/or the Institution shall forthwith notify Mylin Biotech in writing of such inspection, inquiry, audit or examination conducted by such Authority(ies);

m. The Principal Investigator shall co-ordinate, co-operate with and assist in conducting the Study and shall perform such obligations and duties, as may be assigned or imposed upon him/her, in a timely manner, in accordance with the regulatory requirements and Applicable Law;

n. The Principal Investigator and/or the Institution shall not in any during the course of its business with any other party, breach directly or indirectly, any Applicable Law which may have an impact on the Study / Study Agreement in any manner;

o. The Principal Investigator and the Institution shall apply for, and obtain, maintain, renew all the applicable approvals including Regulatory Approvals, if any, during the term of the

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Agreement, Further, the Principal Investigator and the Institution shall during the term of this Agreement abide by all Applicable Laws, as amended from time to time;

p. The Principal Investigator and the Institution shall perform such other roles, responsibilities and duties related to the Trial, as may be reasonable required by Mylin Biotech from time to time; and

q. The Principal Investigator shall maintain true and complete financial records relating to the Study performed under this Agreement including costs and expenses incurred in connection with the Study.

7.2 Each Party hereby represents, warrants and undertakes as follows:

a. it has taken all necessary action on its part required to authorize the execution and delivery of this Agreement;

b. this Agreement constitutes a legal, valid and binding obligation of the Parties; and

c. Neither the execution nor the delivery of this Agreement nor its performance would violate any agreement nor constitute a default under any such agreements to which the Parties are a party.

7.3 Mylin Biotech hereby represents and warrants to the Institution that it will, during the term of this Agreement abide by all Applicable Laws Including provisions of the Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945, as amended from time to time.

8. Intellectual Property Rights

8.1 The Principal Investigator and/or the Institution shall duly notify Mylin Biotech, in a confidential written notification, of any Invention and/or Intellectual Property Rights arising as an incident to and/or during the conduct of the Study.

8.2 Principal Investigator and the Institution acknowledge and agree that any Intellectual Property Rights relating to the Study shall be deemed to be works for hire created for Mylin Biotech, who shall claim such Intellectual Property Rights through Mylin Biotech and shall hold sole title to such Intellectual Property Rights. All such Intellectual Property Rights shall be deemed assigned to Mylin Biotech, and the Principal Investigator and the Institution shall do or cause to be done all such things and deliver or cause to be delivered all such documents as are necessary to give effect to this provision. The Principal Investigator shall ensure that all members of the Study Team assign all Intellectual Property Rights to Mylin Biotech.

8.3 **Principal Investigator and the Institution hereby jointly undertake that:**

a. The Principal Investigator will unequivocally transfer to Mylin Biotech the right to obtain patent on Invention.

b. Principal Investigator shall take all steps necessary to secure Inventions and Intellectual Property Rights for the benefit of Mylin Biotech. To ensure the duties set forth in this Section are carried out, Mylin Biotech may, at its own cost, request that Principal Investigator prepares and signs appropriate documents and authorisations, as well as performs any other actions necessary for the rights to Inventions and Intellectual Property Rights to be vested fully and effectively in Mylin Biotech, Mylin Biotech has the exclusive right to choose the form of protection of intellectual property.

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c. Principal Investigator shall refrain from taking any actions that would prejudice the Intellectual Property Rights of Mylin Biotech in any way. Moreover, Principal Investigator agrees to inform Mylin Biotech of any known infringement of its Intellectual Property Rights, and to support Mylin, at Mylin's expense, in actions intended to protect Mylin's Intellectual Property Rights.

d. Mylin Biotech shall have exclusive and undisputed ownership of anything related to the Study, including without limitation, the Confidential Information, the Study Drug, the CRFs, the Protocol and the Study Results.

8.4 Any and all Intellectual Property Rights in relation to the foregoing in Section 8.3(d) shall vest exclusively in Mylin Biotech.

8.5 The provisions of this Section shall survive the expiration and/or termination of this Agreement indefinitely.

9. **Research Grant.** Funding will be made to the Principal Investigator by way of grant payments in accordance with **Attachment-B.** The grant represents Principal Investigator's costs of conducting the Trial. All amounts are inclusive of all direct, indirect, overhead and other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the parties, The Principal Investigator will not directly or indirectly seek or receive compensation from patient(s) participating in the Trial ("Trial Subject(s)") or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Mylin Biotech including, but not limited to, Mylin Biotech, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Mylin Biotech and/or Comparator Drug administration.

10. **Trial Subject Enrolment.** Principal Investigator has agreed to enrol Trial Subjects in the Trial in accordance with the Protocol. Mylin Biotech reserves the right, on written notice, to limit the number of Subjects to be included in the Study, including, but not limited to instances where the recruitment target has been reached.

10.1 **Multi-Center Studies.** Mylin Biotech may discontinue patient enrolment if the total enrolment needed for a multi-center Trial has been achieved.

11. **Informed Consent.** Principal Investigator undertakes that it will obtain a written Informed Consent Form ("ICF") for each Trial Subject explaining the Trial Subject's rights in connection with its relationship with the Institution and Principal Investigator. Principal Investigator will maintain a signed original of that ICF in the Trial Subject's record. Principal Investigator will provide Mylin Biotech an opportunity to review and approve the content of the ICF, including any revisions made during the course of the Trial, before it is used. Principal Investigator will allow Mylin Biotech or its designee to inspect signed ICF's or photocopies thereof during monitoring visits or audits. Principal Investigator will submit any modifications it may propose to the ICF to Mylin Biotech for review and written approval by Mylin Biotech before submitting the ICF for IEC approval. The Principal Investigator will ensure that every Trial Subject signs and ICF approved by Mylin Biotech and the IEC before the Trial Subject begins participating in the Trial. When required, the approved ICF will be modified to reflect amendments to the Protocol.

12. **Adverse Events.** Principal Investigator will report adverse events experienced by Trial Subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone. If the Trial Subject is physically

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injured by Mylin Biotech or properly performed Trial procedures and the Institution, Principal Investigator and other individuals participating in the conduct of the Trial have followed the Protocol, all Applicable Laws and regulations and all directions of Mylin Biotech, Mylin Biotech will reimburse the reasonable costs of medical expenses necessary to treat the injury.

13. **Protected Health Information.** The Parties recognize a common goal of securing all individually identifiable health information and holding such information in confidence and protecting if from unauthorized disclosure. Principal Investigator represents and warrants that he/she will comply with the provisions of any Applicable Laws relating to the confidentiality, privacy and security of such information.

13.1 **Authorization to Use and Disclose Health Information.** Principal Investigator will obtain a written privacy authorization, complying with Applicable Law, for each Trial Subject which will enable Principal Investigator to provide Mylin Biotech and other persons and entities designated by Mylin Biotech with completed Case Report Forms (**"CRFs"**), source documents and all other information required by the Protocol. Mylin Biotech, though not a covered entity, recognizes that, pursuant to this Agreement, it has the responsibility to protect all individually identifiable patient information and to restrict the use of such information to those persons and entities, including consultants, contractors, subcontractors and agents, who must have access to such information in order to fulfil their assigned duties with respect to the Trial, Such use also will be restricted to those uses permitted in the authorization forms and neither Mylin Biotech nor any party to whom Mylin Biotech may disclose individually identifiable health information may use such information to recruit research subjects to additional studies, to advertise additional studies or products, or to perform marketing or marketing research. Principal Investigator will provide Mylin Biotech an opportunity to review and approve the content of the authorization (including any revisions made during the course of the Trial) before it is used.

14. **Confidential Information.** During the course of the Trial, Principal Investigator and/or the Institution may receive or generate information that is confidential to Mylin Biotech Affiliate.

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

14.2 **Exclusions.** Confidential Information does not include information that is in the public domain prior to disclosure by Mylin Biotech; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Principal Investigator; is already known to Principal Investigator and the Institution at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Principal Investigator and the Institution, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

14.3 **Obligations of Confidentiality.** Unless Mylin Biotech provides prior written consent, Principal Investigator may not use Confidential Information for any purpose other than the authorized in this Agreement, not may Principal Investigator and the Institution disclose Confidential Information to any third party except as authorized in this Agreement or as required by law. Required disclosure of Confidential Information to the IEC or to an applicable Authority is specifically authorized.

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

14.5 **Survival of Obligations.** For Confidential Information other than Trial Data and Biological Sample Analysis Data, these obligations of nonuse and nondisclosure survive termination of this Agreement. Permitted uses and disclosures of Trial Date are described in Sections 18 (Publications) of this Agreement.

14.6 **Return of Confidential Information.** If requested by Mylin Biotech, Principal Investigator will return all Confidential Information, at Mylin's expense, except that required to be retained at the Study Site by Applicable Law. However, Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Trial Data, Biological Samples, and Records.

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

a. **Ownership of the Trial Data** Subject to Principal Investigator's right to publish, with prior written intimation to Mylin Biotech, the results of the Trial and the non-exclusive license that permits certain uses, Mylin Biotech is the exclusive owner of all the Trial Data.

b. **Non-Exclusive License.** Mylin Biotech grants Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal research or educational purposes.

c. **Medical Records.** Medical records relating to Trial Subjects that are not submitted to Mylin Biotech may include some of the same information as is included in Trial Data; however, Mylin Biotech makes no claim of ownership of those documents or the information they contain.

d. **Personal Information Protection.** Each party represents and warrants that procedures compatible with relevant personal information and data protection laws and regulations will be employed so that processing and transfer of such information and data identifiers will not be impeded.

15.2 **Biological Samples.** If so specified in the Protocol, Principal Investigator may collect and provide to Mylin Biotech or its designee biological samples (e.g., blood, urine, tissue, saliva, etc.) obtained from Trial Subjects for testing that is not directly related to patient care or safety monitoring, including pharmacokinetic, pharmacogenomics, or biomarker testing ("Biological Samples").

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

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

15.3 **Records.** Principal Investigator will ensure that Trial Subject's Trial records, which include that Principal Investigator's copies of all Trial Data as well as relevant source documents (collectively, "Records"), are kept up to date and maintained in accordance with Applicable Law.

a. **Retention.** Principal Investigator will retain all records and documents pertaining to the Trial for a period in accordance with Applicable Law and the Protocol. Principal Investigator will retain Records, under storage conditions conducive to their stability and protection, for a period of fifteen (15) years after termination of the Trial unless Mylin Biotech authorizes, in writing, earlier destruction. At the end of such required retention period, Principal Investigator will not destroy any such records until it has obtained Mylin's prior written permission to do so; provided, however, that if Mylin Biotech does not give written permission to Principal Investigator to destroy such records within thirty (30) days of Principal Investigator's request to Mylin Biotech, then Principal Investigator may forward all such records to Mylin Biotech, at Mylin's expense, or continue to retain such records. Principal Investigator further agrees to permit Mylin Biotech to ensure that the records are retained for a longer period if necessary, at Mylin's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16. Inspections and Audits.

16.1 **Access.** Upon reasonable request by Mylin Biotech, authorized representatives of Mylin Biotech, and/or authorized representatives of the applicable Authority, may during regular business hours examine and copy; all CRFs and other Trial records (including Trial Subject records and medical charts; Trial Subject consent documents; drug receipt and disposition logs); examine and inspect the facilities and other activities relating to the Trial or the IEC; and observe that conduct of the Trial.

16.2 **Notice.** Principal Investigator and/or the Institution will inform Mylin Biotech within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Principal Investigator or research staff with regard to the Trial; will provide Mylin Biotech with a copy of any communications sent by such persons; and will provide Mylin Biotech or Mylin Biotech the opportunity to participate in any proposed or actual responses by Principal Investigator to such communications.

16.3 **Cooperation.** Principal Investigator and the Institution will ensure the full cooperation of the researchers and IEC members with any such inspection and will ensure timely access to applicable records and data. Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records. Principal Investigator will promptly forward to Mylin Biotech copies of any inspection findings that Principal Investigator received from a regulatory agency in relation to the Trial. Whenever feasible, Principal Investigator will also provide Mylin Biotech with an opportunity to

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prospectively review and comment on any responses to regulatory agency inspections in regard to the Trial.

17. **Inventions.** If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Principal Investigator and/or the Institution will promptly inform Mylin Biotech. Principal Investigator will assign all interest in any such Invention to Mylin, free of any obligation or consideration beyond that provided for in this Agreement. Principal Investigator will provide reasonable assistance to Mylin Biotech in filling and prosecuting any patent applications relating to Invention, at Mylin's expense.

18. **Publications.** Principal Investigator acknowledges that Mylin Biotech has the right to use the Study Results in any manner deemed appropriate to Mylin's business interests, both during, and following termination/expiry of , this Agreement. Mylin Biotech shall have to sole right to retain the ownership of any and all data arising out of the conduct of clinical trials in relation to the Study. Upon completion of the Study, Mylin Biotech shall publish the results of the authorized clinical trial, either positive or negative, in scientific journals and with mention of the EC of clinical research that approved the study. Where Principal Investigator requires the use of the Study Results for publication, the Principal Investigator shall seek Mylin's written approval 90 (ninety) days in advance; such consent shall not be unreasonably withheld. If part of a multi-center trial. Principal Investigator agrees that the first publication is to be a joint publication involving all centers. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of Trial at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Agreement.

19. **Publicity.** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, Mylin Biotech reserves the right to identify the Principal Investigator in association with the listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

20. **Indemnification.**

20.1 Mylin Biotech agrees to indemnify and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses arising out of a Trial Subject injury, the design of the Trial, or the specifications of the Trial protocol. Trial Subject injury means a physical injury or drug-related psychiatric event caused by administration or use of Mylin Biotech required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial. Mylin Biotech further agrees to reimburse Principal Investigator for the reasonable cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject injury. Principal Investigator agrees to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Principal Investigator further agrees to promptly notify Mylin in writing of any such medical injury.

a. **Exclusions.** Excluded from this agreement to Indemnify are any claims for damages resulting from (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Mylin Biotech (b) failure of an Indemnified Party to comply with any Applicable Law

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and governmental regulations, or (c) fraud, negligence or withful misconduct by an Indemnified Party.

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

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

20.2 Principal Investigator and the Institution shall jointly and severally indemnify and hold harmless Mylin including its directors, employees; representatives, agents etc., and shall be fully liable for all claims, damages, losses, liabilities, costs or expenses (including reasonable legal fees) resulting or arising from:

a. failure by the Principal Investigator and the Study Team (Which shall include his/her employees, agents and representatives) to comply with the Applicable Law, the terms of this Agreement, ICH GCP and/or other nationally established guidelines, the approval of the IEC, Protocol or written instructions from Mylin Biotech;

b. any finding, requirement, determination or observation by any Authority (including but not limited to the FDA) which makes it necessary or desirable for Mylin Biotech to redo the Study;

c. failure by the Principal Investigator, the Study Team and/or the Institution to comply with Applicable Law;

d. any negligent act or omission or wilful misconduct or fraud by Principal Investigator, the Study Team and/or the Institution, fraud or misrepresentation.

20.3 Except in the case of fraud, willful misconduct, gross negligence or breach of any Applicable Law, neither Party shall be entitled to incidental, indirect, consequential nor special damages under any theory of Applicable Law arising in connection with such default or breach of the other Party's obligations under this Agreement, or any documents related thereto.

20.4 In the event of any act of Principal Investigator and/or the Institution, which renders the Study invalid, to the extent Principal Investigator and/or the Institution is liable, Mylin Biotech shall, in addition to any other right that Mylin Biotech may have under law or equity, have the option at its sole discretion to either (a) request Principal Investigator to repeat the Study at Principal Investigator's own cost, or (b) require Principal Investigator and/or the Institution to promptly refund Mylin Biotech the compensation received by Principal Investigator and/or the Institution under this Agreement and bear any additional costs that Mylin Biotech may incur for repeating the Study. Further without prejudice to any other rights that Mylin Biotech may have under law or equity, Mylin Biotech may, at its discretion, forthwith terminate this Agreement.

21. Termination.

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

a. **Disapproval by IEC.** If, through no fault of Principal Investigator, the Trial is never initiated because of IEC disapproval, this Agreement will terminate immediately.

b. **Trail Completion.** For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subject; receipt by Mylin Biotech of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either party.

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

(1) **Termination of Trial Upon Notice.** Mylin Biotech reserves the right to terminate the Trial for any reason upon thirty (30) days written notice to Principal Investigator.

(2) **Immediate Termination of Trial by Mylin Biotech.** Mylin Biotech further reserves that right to terminate the Trial immediately upon written notification to Principal Investigator and/or the Institution for causes that include – (i) failure to cure any breach within 15 days of written notice by Mylin Biotech notifying Principal Investigator of such breach; (ii) failure to enrol Trial Subjects at a rate sufficient to achieve Trial performance goals; (iii) material unauthorized deviations from the Protocol or reporting requirements; (iv) circumstances that in Mylin's opinion pose risks to the health or wellbeing of Trial Subjects; or (v) regulatory agency actions relating to the Trial or Mylin Biotech or Comparator Drug.

(3) **Immediate Termination of Trial by Principal Investigator.** Principal Investigator reserves the right to terminate the Trial immediately upon notification to Mylin Biotech or Mylin Biotech if requested to do so by the responsible IEC or if such termination is required to protect the health of Trial Subjects.

21.2 **Payment upon Termination.** If the Trial is terminated early in accordance with this Agreement, Mylin Biotech will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with **Attachment-B,** less payments already made. The termination payment will include any non-cancellable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by Mylin Biotech, and only to the extent such costs cannot reasonably be mitigated. If the Trial was never initiated because of disapproval by the IEC, Mylin Biotech will reimburse Principal Investigator for any other expenses that were prospectively approved, in writing, by Mylin Biotech.

21.3 **Return of Materials.** Unless Mylin Biotech instructs otherwise in writing, Principal Investigator will promptly return all materials supplied by Mylin Biotech, at Mylin's expense, for Trial conduct, and any Mylin-supplied Equipment. Principal Investigator will return and/or destroy, as required by Mylin Biotech, at Mylin's expense, unless otherwise specified by Mylin Biotech, any unused Mylin Biotech or Comparator Drug.

22. **Insurance.** The Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with local standards for all medical professionals conducting the Trial.

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23. **Debarment, Exclusion, Licensure and Response.** Principal Investigator and the Institution jointly and severally certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under Applicable Law with respect to services to be performed under this Agreement. Principal Investigator and the Institution also certifies that they are not excluded from any governmental health care program. Principal Investigator and the Institution further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and the Institution will notify Mylin Biotech promptly in writing to the extent possible, within two (2) business days if either of these certifications needs to be amended in light of new information or if Principal Investigator becomes aware of any material issues related to the medical licensure of any associated Trial researchers. Principal Investigator and the Institution will cooperate with Mylin Biotech regarding any responsive action necessary.

24. **Assignment and Delegation.** Mylin Biotech may at any time and upon written notice to Principal Investigator and/or the Institution assume the obligations and rights of Mylin Biotech or substitute Mylin Biotech with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Principal Investigator and/or the Institution to another without the prior written consent of Mylin Biotech, and the express agreement of Principal Investigator and/or the Institution, Mylin Biotech, and the requisite new assignee or subcontractor. Principal Investigator and the Institution must notify Mylin Biotech, at least 90 (ninety) days in advance, prior to moving to another location. This Agreement will bind and inure to the benefit of the successors and permitted assigns of Mylin Biotech.

25. **Equipment.** Mylin Biotech may provide, or arrange for a vendor to provide, certain equipment for use by Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C.

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

27. **Entire Agreement.** This Agreement contains the complete understanding of the parties and will, as of the Effective Date, supersede all other agreements between the parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the mutual consent of the parties. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

28. **Conflict with Attachments.** To the extent that terms or provisions of this Agreement conflict with terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in a writing between the parties.

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29. **Relationship of the Parties.** The relationship of Principal Investigator and/or the Institution to Mylin Biotech is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

30. **Force Majeure.** Neither party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) promptly notified to the other party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) days, then the parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

31. **Governing Law.** Subject to the terms of the Trial Conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions. The Parties agree to submit all their disputes arising out of or in connection with this Agreement to the exclusive jurisdiction of the courts of Lucknow.

32. **Notices.** All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

TO MYLIN BIOTECH INDIA PVT LTD:
Attention. To:

TO PRINCIPAL INVESTIGATOR:
Attention. To:

TO INSTITUTION:
Attention. To:

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In the event that the parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the parties agree that, upon being signed by both parties, this Agreement will become effective and binding and that facsimile copies and/or electronic signatures will constitute evidence and binding Agreement with the expectation that original documents may later be exchanged in good faith.

[INTENTIONALLY LEFT BLANK; SIGNATURE PAGE FOLLOWS]

ACCEPTED AND AGREED BY:
PRINCIPAL INVESTIGATOR

By:
Signature

Printed Name DR ANITA SAXENA

Title Professor

19/3/19
Date

ACCEPTED AND AGREED BY:
MYLIN BIOTECH

By: P. PRABHAKARAN
Signature

Printed Name

Title

Date

ACCEPTED AND AGREED BY:
INSTITUTION

By:
Signature

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

Printed Name

Title

Date 14.05.2019

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Attachment A

Protocol

The clinical Trial to be performed pursuant to this Agreement shall be that set forth in the Protocol dated 28/August/2018. and incorporated into this Agreement attached hereto by reference in addition to all current and future amendments thereto, which is incorporated into this Agreement by reference and entitled:

Protocol Number: NIZY-BYT-MB-18 A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients.

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Attachment B

RESEARCH GRANT PAYMENT TERMS

B-1. **General Terms.** Principal Investigator ("Payee") will be paid the per patient grant amount as outlined on **Attachment-D** (Research Grant Worksheet) per Trial Subject properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled or continuing in the Trial in violation of the Protocol.

B-2. **Payment Terms.** Research grant payments for each Trial Subject will be made in Indian Rupees (INR) quarterly and based on approval of invoices submitted. Invoices will be issued by Payee upon notice delivered by Mylin Biotech. Payments will be made in accordance with eCRFs submitted and monitored, and in accordance with Attachment D "Research Grant Worksheet". Monitoring will occur based on site enrolment and completion of data entry. Payments will be made in quarterly instalments on a pro-rata basis. Undisputed invoices will be paid by Mylin Biotech within 60 (sixty) days of such invoice issue date.

B-3. **Non-Procedural Costs.** Payee will be paid for additional non-procedural costs that are pre-approved by Mylin Biotech, as set forth in Attachment D. To request payment for such costs, Payee will remit an itemized invoice to Mylin Biotech or its designee with documentation and receipts substantiating agreed-upon pass-through expenses. Any non-procedural pass-through expenses will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment D.

B-4. **Final Payment.** At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Mylin's review. The final payment will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Mylin Biotech is returned; and all close out issues are resolved and procedures completed, including final IEC notification. All queries must be resolved within five (5) days of receipt by Payee any time during the Trial. Mylin Biotech or its designee will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any Payee will promptly reimburse Mylin Biotech amounts overpaid within thirty (30) days of notification by Mylin Biotech or designee.

B-5. **Taxes.**

(1) All payments to Payee by Mylin Biotech will be subject to deduction of TDS.

(2) The Payee shall comply with all its obligations under applicable tax laws in force at the time, including all laws, rules and regulations under the Goods and Services Tax ("GST") Regime ("GST"). In particular, the Payee shall pay its taxes and make all filings necessary under GST Law, including the GSTR-1 form, within the prescribed timelines. The Payee shall defend, indemnify and hold Mylin Biotech harmless against all losses, claims and liabilities arising out of any failure by the Payee to meet its obligations under GST Law, including any failure or error that results in denial of any tax credit under GST law to Mylin Biotech, The Payee shall full co-operate with Mylin Biotech to respond to

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the relevant tax authorities' demands, and to resolve any mismatch of Mylin Biotech and the Payee's GST filings within the timelines prescribed under the GST Law.

(3) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable Authority with respect to or measured by compensation paid to Payee under this Agreement. Mylin Biotech will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full responsibility for reporting all payments received, under this agreement, to the relevant taxation authorities as required by local regulations.

B-6. **Screen Failures.** A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrolment into the Trial. Screen Failures will be reimbursed, if at all, as outlined in Attachment D, based on work completed pursuant to the Protocol.

B-7. **Patient travel reimbursement.** Mylin Biotech, will reimburse reasonable patient travel related expenses per trial subject visit, up to the maximum amount listed in the Attachment D. Any reimbursement exceeding this limit will require prior written Mylin Biotech approval. Any payment will be based on the invoice together with supporting documentation (i.e. receipts) submitted to Mylin Biotech.

B-8. **Administrative Start-up Fees.** Within sixty (60) days of execution of this Agreement and receipt of a valid invoice, Mylin Biotech, will pay a non-refundable start-up payment in the amount listed in the Attachment D for the work performed to prepare for site activation and enrolment (including but not limited to, feasibility study, initial training of Protocol, briefings, advance talks, provisions of room for the monitoring, initiation of the Study at the Center, training of the future Members of the Study Team, participation in Investigator's meetings, contract review activities, the cost for purchasing small equipment, set-up costs for equipment and all other preparation).

B-9. **Necessary Procedures.** Payee will be reimbursed for valid necessary visits and procedures. Payment for any necessary procedure due to patient safety will be reimbursed at the agreed upon unit cost in the budget, or if there is no such unit cost in the budget, at the appropriate unit cost pre-approved by Mylin Biotech in writing, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Mylin's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Mylin Biotech will be notified as soon as practicable after the fact.

B-10. **Payee.**

The research grant payments will be made to the following payee and address:

Payee Name: Director, SGPGIMS Research Scheme Account, Lucknow
Payee Address: Raebareli Road, Lucknow, Uttar Pradesh 226014
Payee GST Number: 09AAAJS3913N2ZN
Payee PAN No: AAAJS3913N
Payee Bank Account Details: Saving account
Bank Name: State Bank of India
Bank Address: SGPGIMS Branch, Lucknow
Bank Account Number: 10095237491
IFSC Code: SBIN007789
Email address for remittance information: director@sgpgi.ac.in

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In cast of changes in the Payee's bank account details, Payee is obliged to inform Mylin Biotech in writing, but no amendment to this Agreement shall be required.

B-11. **Invoices.** All invoices must be issued and forwarded to the following as instructed:

MYLIN BIOTECH INDIA PVT LTD.
#40/11-1 2nd floor
Govindraj Nagar, Magadi Road
Bangalore - 560040

Each invoice must contain: (1) Mylin Biotech name, (2) Protocol Number, (3) Project Code, (4) a summary of the reimbursement to be made in compliance with the Research Grant Worksheet, and (5) the GST Registration number, (6) if GST reverse charges mechanism applies, the note "GST reverse charges applicable".

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation.

Any invoices submitted by the Payee more than 45 (forty five) days after the database lock will not be reimbursed.

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CLINICAL TRIAL AGREEMENT

Preamble:

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

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day 30/10/2018 **AMONG**

MYLIN BIOTECH INDIA PVT. LTD, a company originally incorporated in Bangalore and registered under section 592 of Companies act, 1956 as having place of Business and one of its office is located at #40/11-1 2nd floor, Govindraj Nagar, Magadi Road Bangalore -560040. through it **MYLIN BIOTECH INDIA PVT. LTD** "Sponsor"] of the First part.

AND

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

AND

Professor Dr. Anitha Saxena a, **Department of Nephrology, Sanjay Gandhi Post Graduate institute of Medical Sciences** [hereinafter referred to as **"Principal Investigator"**] of the Third Part.

WHEREAS The Sponsor, Institute and, Principal Investigator are willing to jointly carry out the Study Number:

NIZY-BYT-MB-18 Entitled **A prospective, double blind, multicentric randomized, placebo controlled Interventional study to evaluate the safety and efficacy of Enzobiotics (Synbiotics and Proteolytic Enzymes)in pre dialysis kidney disease patients. [Hereafter referred to as "Study"]** described in Study Protocol;

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

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

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1.0 Statement of work

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

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

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

2. Obligations and Responsibilities of Principal Investigator

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

2.2 The Principal Investigator will conduct the study in accordance with protocol, Schedule Y and ICMR Guidelines along with Helsinki and ICH Guidelines for international studies.

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

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

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

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

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

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

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2.9 The Principal Investigator will ensure enrolment of trial participants after obtaining informed consent including audiovisual recording and also informing the provisions of adequate treatment and compensation for SAE as per schedule Y.

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

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

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

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

2.14 The Principal Investigator will be responsible for obtaining IEC and sponsors permission for storage of blood or tissue samples for future use.

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

3.0 Obligation and Responsibilities of Institute:

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

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

3.3 Fulfillment of necessary obligations by IEC, PI and supporting staff.

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

3.5 Adequate treatment and compensation for SAE to trial participants.

3.6 Necessary infrastructure support to PI.

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

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

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

3.10 Safety reporting as per schedule Y and/or Sponsor policy.

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

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

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

3.14 Approval of study within 8 weeks of receipt of Investigator's brochure, protocol including PIS & CRF, regulatory approvals, draft CTA, Insurance policy and IEC fee from sponsor.

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

3.16 Review of progress report DSMB report & SAE from other centers and if necessary to recommend changes in protocol, termination of study or its extension beyond approved period.

3.17 Review of SAE at SGPGI and necessary action within the time frame decided by regulatory agencies.

3.18 Review of final report.

3.19 Approval of storage of blood or tissues for use in future studies.

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

3.21 Institutional clearance for sample to be sent abroad for non-pharmacogenetic studies.

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

3.23 Safeguarding IPR of sponsor and SGPGI.

3.24 Providing alternate PI if PI unable to continue.

3.25 Audited statement of utilization of Funds.

4.0 Obligation and Responsibilities of Sponsor

4.1 To provide investigator's brochure, Protocol, CRF draft CTA, Insurance policy from an Indian Insurance company and regulatory approvals.

4.2 To provide adequate supplies of trial drug, comparator and /or placebo prepared under proper quality control.

4.3 To provide Insurance cover for treatment and compensation of SAE and undertaking to supplement any amount not covered by the Insurance Company. Sponsor will also provide copy of Policy.

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

4.5 Not to send samples for Pharmacogenetic study abroad.

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4.6 To permit the storage of samples for future study if requested by Principle Investigator.

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

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

4.9 To define and follow procedure for premature termination.

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

5.0

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

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

(b) Violation of the approved Protocol;

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

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

(e) Use of placebo in a placebo-controlled Clinical Trial;

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

(g) For injury to a child in utero because of the participation of parent in Clinical Trial;

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

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

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

6.0 Undertaking and Representation of Principal Investigator

Principal Investigator hereby represents that he/she has furnished an undertaking to Licensing Authority in the format given in Appendix VII of Schedule-Y of Rules.

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SGPGIMS,Lucknow

7.0 Undertaking and Representation of Institute

Institute hereby represents that:-

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

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

(ii) It will ensure that IEC will discharge its responsibilities as per provisions of Schedule-Y

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that:-

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

9.0 Administration

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

9.2 The following Study plan will apply to the Study:

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

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

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

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

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

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

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

10.0 Trial Drug; Materials Transfer; Records Retention; Inspection

10.1 Trial drug:

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

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

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

(iv) Institute and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

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

(vi) Unless required by the Protocol, Institute will not modify the Trial Drug or its container. If the Institute policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Institute for use in a future study to be approved by IEC.

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

11.0 Representation and Warranties

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

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

12.0 Confidentiality

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

i. is or becomes publically available through no fault of Investigator or Institution.

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

iii. is disclosed to Principal Investigator or Institution by a third party without violation of law or any obligation of confidentiality; or

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

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

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

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

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

13.0 Return of Confidential Information

Upon either (i) the completion of the Trial or termination of this Agreement; or (ii) Sponsor's Request for any reason, Institute will immediately cease all use of all Confidential Information, and will promptly either return to Sponsor or if instructed by Sponsor destroy all Confidential Information, including any copies, extracts, summaries, or derivative works thereof, and certify in writing to Sponsor the completion of such return and/or destruction, provided, however, that Institute may retain one copy of Confidential Information in its legal archives solely for the purpose of monitoring its surviving obligations under this Agreement.

14.0 Trial Results and Inventions

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

14.2 All inventions, ideas, methods works of authorship, know-how or discoveries that are made, conceived, or reduced to practice by Institute, Principal Investigator or Trial Personnel: (i) as a result of or in connection with the conduct of the Trial (ii) that incorporate or use Confidential Information: or (iii) that are directly related to the Compound and in each case together will all intellectual property rights relating thereto (collectively, **Trial Inventions**"), will be the sole and exclusive property of Sponsor Or its designee. Institute and Principal Investigator will

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promptly disclose all Trial Investigations to sponsor in writing and interest in all Trial Investigations to sponsor or its designee. At sponsor's request and expense, Institute shall take and shall cause Principal Investigator and Trial Personnel to take, all additional actions as it deems necessary to perfect the interest of sponsor or its designee in Trial Investigations or to obtain patents or otherwise protect the interest of sponsor or its designee in Trial Investigations.

15.0 Payment

15.1 In consideration for conducting the Study Sponsor shall pay Institute and Principal Investigator as described in Annexure. All of Sponsor's payment obligations are conditioned upon Institute and Principal Investigator compliance with standards identified in this Agreement. Sponsor will not make payments, or, if payment has been made by Sponsor Institute and Principal Investigator will repay to Sponsor any payments, for Study visits, procedures, or other work associated with a Study subject if Sponsor determines that the Clinical Trial Subject's Data is not evaluable because of a violation of the Protocol by Principal Investigator or Study Staff.

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

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

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

-All Study related activities such as conduct of visit assessment and CRF completion -
Time and efforts of Principal Investigator/s and other Institute's Study personnel
-All manpower cost involved in the Study conduct
-All diagnostic test and other investigations
-Housing or hospital stay for patients including meals
-Patient reimbursement/ Compensation
-All over head costs
-Usage of Instruments/ equipments which during the Study should be having for proper

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-instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract

-Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of

-Institute infrastructure).

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

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

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

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

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

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

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

15.4 **Set-Up Fees:** Sponsor will pay the Institute an initial advance amount of **INR 25,000** (twenty five thousand only) within 15 days after obtaining the Ethics Committee and necessary regulatory approval. This up-front advance payment would be exclusive of Institutional overhead and service charges and shall be deducted/ adjusted on pro-rata basis from further subsequent payments.

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

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

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

Principal Investigator Fee/ Clinical Trial Subject Reimbursement and Hospitalization:

Payee Name (Account name)	**Director, SGPGIMS, Research a/c**
Account Number	**10095237491**
Bank Name	**State bank of India**
Branch Name	**SGPGI Branch, Lucknow**
Swift/IFSC Code	**SBIN0007789**
PAN Number*	**AAAJS3913N**
Send to	**Dr. ……..**

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<<Cheque Delivery Address>>	....., **Department of .....Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow-226014,U P, India**

15.8 Payments will be made **on monthly** basis according to actual work performed (CRF completion, source Data verification and CRF retrieval for completed visits). Advance payment will be adjusted against the 1st payment. Final payment will be made at the time of Investigation Site close-out visit or immediately after Investigation site close-out visit and payment will not be made until all queries are resolved.

15.9 Subject travel reimbursement is exclusive of Institutional overhead and will be done as mentioned in Annexure-A. However, Sponsor will release the funds to Institute and Principal Investigator for each Clinical Trial Subject, i.e., **Rs. .....**as per the Study schedule. However, it will be the obligation of Principal Investigator to pay the Clinical Trial Subject reimbursement on a pro rata basis (**Rs.....**- per visit). **Sponsor will provide an amount of .....N/A..... only for the future treatment Reimbursement to the Clinical Trial Subject who have completed the study.**

15.10 Payment will be made by Sponsor for Clinical Research coordinator salary per month **Rs. 20,000 (Twenty thousand rupees only)** for his/her efforts contribution to the Study. This payment would be inclusive of Institutional overhead and will be from the Investigation Site initiation visit to Investigation Site close out visit (until all the Data queries are resolved at the Institute's premises).

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

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

16.0 Use of other parties' names

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

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17.0 No joint venture etc.

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

18.0 Insurance and Indemnification

Insurance:

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

Indemnification:

Sponsor shall indemnify the Principal Investigator and Institute for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institute arising directly out of the performance of the Study pursuant to the Protocol and SOP; provided however

(i) Sponsor will not indemnify any Loss to the extent the Loss arises out of Indemnities' failure to conduct the Study in accordance with: (1) the Protocol except allowing for Protocol deviations which were medically necessary for a Clinical Trial Subject's safety or well-being and which were communicated to and accepted by Sponsor, (2) any other instructions by Sponsor, concerning the Study drug or device or a Study procedure, or (3) applicable local, state and central laws;

(ii) Sponsor will not indemnify any for Loss to the extent the Loss arose out of the negligence or wrongful acts or omissions of an Indemnity or any other person subject to an Indemnities' control;

(iii) The Sponsor will indemnify the subject suffering in any manner as a result of trial for any reason whatsoever including negligence or violation of the protocol by the Principal Investigator or any member of his team as per order of the incensing authority or the Institutional Ethics Committee.

19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

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

19.2 The Principal Investigator and Institute shall notify to the Sponsor immediately by telephone

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or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Principal Investigator and Institute s facilities or research records relating to this Study whenever and will provide in writing to the inspecting authority copies of all materials, correspondence, statements, forms and records which the

Principal Investigator and Institute receives, obtains, or generates pursuant to any such study.

19.3 The Principal Investigator and Institute will permit the Sponsor to

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

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

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

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

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

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

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

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

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

21.0 Effect of termination

(i). Upon notice of termination of this Agreement by either Institute or Sponsor or Principal

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Investigator, Institute shall cease enrolling Clinical Trial Subjects into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

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

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

22.0 Recordkeeping

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

Institute or Principal Investigator shall ensure the storage of Data related to Study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the agreement applicable laws and regulations in INDIA or until 5 years after completion of all regulatory activity, whichever period is longer, unless to the extent that Sponsor requires the return or destruction of this Data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such Data, Sponsor's written approval shall be obtained.

23.0 Publication

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result

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

24.0 Miscellaneous

24.1 Parties to this Agreement shall comply with the current provision of Drugs and Cosmetic Act 1940, Drugs and Cosmetic Rules 1945. For providing insurance to Clinical Trial Subjects in case of injuries or death, The parties to this Agreement have tied up with insurance company (The Oriental Insurance for 25,00000) which cover all patient enrolled in clinical trial. This insurance is valid from the period from 06.02.2019 to 05.09.2019. This insurance shall be extended from time to time till the expiry of Agreement.

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

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

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

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

25.0 Governing Law

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

26.0 Jurisdiction

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

27.0 Arbitration

All disputes or claims whatsoever arising out of or in respect of the terms and conditions of this agreement or relating to the admissibility or liability or quantity of compensation or damages payable to or by any of the parties to this agreement to the trial subject or his/her legal representative or the nominee shall be referred by the aggrieved party or person to the arbitration of a sole arbitrator to be appointed by the Chairman of the Institutional Ethics Committee of the Institute at the trial site within 30 days of the receipt of a written request by the aggrieved. The

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Indian Arbitration and conciliation Act 1996 as amended from time to time shall be applicable to such arbitration proceedings subject to the exception that the trial subject or his/her legal representative or the nominee shall not be liable to pay the cost of arbitration. The award of the arbitrator shall be final and binding on all the parties thereto.

28.0 Amendment

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

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

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

Signature and date: _____

Dr. ANITA SAXENA

(Name)

Title/Designation: Professor Department of Nephrology

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

Signature and date: _____

Dr. .....

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

(Name)

Title/Designation: .....

(Director/his nominee)

12/3/2019

3. Sponsor

Signature and date: _____

Mr. P.PRABHAKARAN **(Name)**

Title/Designation: G.M – SALES & MARKETING.

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ANNEXURE

It was agreed that the Site will receive INR ...../- (.....) per Satisfactory Completed Subject for the Study according to the schedule indicated below. This Satisfactory Completed Subject amount is intended to cover the following Study- related costs incurred by the Investigation Site which includes (costs related to the Clinical Trial Subject visits, tests etc. Study related Communications, Institute service charges and Overheads).As this Study required inpatient hospitalization, hospitalization fees of INR ..... (..... only) per completed Clinical Trial Subject will be reimbursed by ..... to Institution. Clinical Trial Subject will be paid INR .....(.....rupees only) as a reimbursement for loss of daily wages due to participation in Study. In case of early withdrawal of Clinical Trial Subjects, the reimbursement can be provided on Pro-rata basis.

Apart from the Principal Investigator grant as listed below, on successful completion of all the visits, sponsor will provide the Patient Future treatment Reimbursement of .....- (Rupees ..... only) to the patients (who have completed the Study).

Investigator/ Hospitalization/ Patient reimbursement Grant (Inclusive of Institutional overhead)

Grant Distribution	
Coordinator Payment	INR 20,000 per month (From Investigation Site Initiation to Investigation Site Closeout)
Investigational Cost	Company will pay to SRL
Hospitalization Cost	N/A
Stationary and Miscellaneous	Mylin will provide
Patient Travel convenience	INR 200
Patient Future treatment	N/A
Reimbursement	Study

All the above mentioned amount is inclusive of 25% Institutional overhead

Maybe not applicable as Trial is on OPD level

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SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA

15 FEB 2014

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धान मुद्रांक कार्यालय, मुंबई
मु वि क्र ६०००१०
13 FEB 2014
अधिकारी

Amgen Technology Pvt. Ltd.
Dynasty Business Park
A Wing
Andheri-Kurla Road
Andheri (East)
Mumbai - 400059

CLINICAL TRIAL AGREEMENT

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

1. SCOPE OF SERVICES

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

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

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Executive Registrar
SGPGIMS,Lucknow

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

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

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

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

2. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

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

3. COMPENSATION

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

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

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

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

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4. CONFIDENTIAL INFORMATION

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

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

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

5. PROPRIETARY RIGHTS

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

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

6. PUBLICATIONS

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

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

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

7. COMPANY-PROVIDED MATERIALS

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

8. REQUIRED EQUIPMENT AND SYSTEMS

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

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

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

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

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

9. COMPLIANCE WITH APPLICABLE LAWS AND ACCEPTED PRACTICE

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

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

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

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

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

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

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

(i) Notify Company thereof;

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

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

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

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

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

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

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

10. ANTI-CORRUPTION REPRESENTATION AND WARRANTY

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

11. INDEMNIFICATION

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

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

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

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

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

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

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

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

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

12. WAIVER OF CONSEQUENTIAL DAMAGES

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

13. SUBJECT INJURY

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

14. TERM AND TERMINATION

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

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

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

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

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

15. MISCELLANEOUS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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: Marisi Malkan

Title: Senior Country Manager

Date: 26th Feb '19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: Rakesh Kapoor
(print or type name)

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

Title:

Date: 14.02.2019

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT ORDER

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

1. GOVERNING TERMS AND EFFECTIVE DATE

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

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

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

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

2. STUDY CONDUCT

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

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

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

The Principal Investigator will direct and supervise the Study.

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

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

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

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

3. REAGENTS AND STUDY DRUG

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

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

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

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

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4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

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

5. REQUIRED EQUIPMENT

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

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

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

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

6. COMPENSATION

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

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

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

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

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

7. MISCELLANEOUS

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

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

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

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

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

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

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

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

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

AMGEN TECHNOLOGY PVT. LTD.

By: Mansi Malkan

Title: Senior Country Manager

Date: 26th Feb' 19

SANJAY GANDHI POST GRADUATE INSTITUTE

(signature)

By: 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

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Executive Registrar
SGPGIMS,Lucknow

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

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

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

SUBJECT FEES (Overheads 25%)

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

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

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

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

NON-SUBJECT FEES

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

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

PAYMENT TERMS

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

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

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

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

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

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

N/A

Invoices

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

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

Amgen Technology Pvt. Ltd. Mumbai

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CLINICAL TRIAL AGREEMENT – POISE-3

This **CLINICAL TRIAL AGREEMENT** ("**Agreement**"), effective as of the date of last signature ("**Effective Date**") is made between:

Hamilton Health Sciences Corporation ("**HHSC**"), through its **Population Health Research Institute** ("**PHRI**"), at 237 Barton Street East, Hamilton, Ontario, L8L 2X2, Canada, represented by its Director

-and-

CBCI Society for Medical Education, ("**CBCI**") established and registered under the Karnataka Societies Registration Act, 1980, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Secretary (hereafter referred as the "**Society**")

-and-

St. John's Research Institute, ("**SJRI**") a unit of the Society, having its address at St. John's National Academy of Health Sciences, John Nagar, Sarjapur Road, Koramangala, Bangalore-560034, Karnataka, India, represented by its Dean (hereafter referred as "**Institute**")

- and-

Division of Clinical Research and Training ("DCRT"), a Division of SJRI, with its administrative office at St. John's Research Institute, St. John's National Academy of Health Sciences, Bangalore-560 034 Karnataka; India, represented by, Dr. Denis Xavier, Vice Dean (PG), Professor, Dept. of Pharmacology, St. John's Medical College and Head DCRT (hereafter called "**National Leader**")

-and-

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, with its principal place of business at Department of Anaesthesiology, Raebareli Road, Lucknow, Uttar Pradesh, 226014, India (hereinafter the "**Institution**")

-and-

Dr. Sanjay Dhiraaj, as the principal investigator at the institution, with office at Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Department of Anaesthesiology, Raebareli Road, Lucknow, Uttar Pradesh, 226014, India (hereinafter the "**Investigator**")

WHEREAS:

A. PHRI is coordinating and is the sponsor of a multi-centre clinical trial entitled **P**eri**O**perative **I**Schemic **E**valuation-3 (**POISE-3**) ("**Project**"), the protocol including any amendments from time to time ("**Protocol**") is incorporated hereto by reference;

B. PHRI may also conduct substudies in conjunction with the Project ("**Substudy(ies)**"), and in the event that Site participates in any Substudies, all references to the Project shall include Substudy(ies), and the references to the Protocol shall include any protocols related to such Substudy(ies);

St. John's Research Institute Bangalore

Secretary CBCI BANGALORE-34 KOLAR

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C. PHRI has an agreement with SJRI to carry out national coordination activities in India for the Project;

D. DCRT, SJRI will be the National Leader Office ("**NLO**") Dr. Denis Xavier, Vice Dean (PG), Professor Dept. of Pharmacology, St. John's Medical College as its Head;

E. Investigator and Institution possess the resources and expertise to carry out a portion of the Project for a prescribed fee and wish to assist PHRI and NLO by acting as a site for the Project. The Investigators and Institution are hereinafter referred to jointly and severally as the "**Site**" and the activities carried out by the Site for the Project is referred to as the "**Study**";

F. The Study has been approved by the Institutional Ethics Committee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Luknow Ethics Committee (wherein such committee would approve the conducting of a clinical trial) at the Institution;

G. NLO obtained regulatory approval from Health Ministry Screen Committee (HMSC), Indian Council of Medical Research (ICMR) for conduct of a clinical trial in human subjects and has been registered on the Clinical Trials Registry of India (CTRI).

Each party is hereinafter referred to individually as a "**Party**" and collectively as the "**Parties**".

NOW THEREFORE, in consideration of the terms and conditions contained herein, the Parties agree as follows:

ARTICLE 1. PERFORMANCE OF THE STUDY

1.1 **Compliance:** The Parties agree to carry out the Study in conformance with the following: (a) all applicable requirements of any governmental, regulatory or other body that has authority with respect to the performance of the Study ("**Regulatory Authority(ies)**"); (b) generally accepted standards of good clinical practice, including but not limited to, to the extent adopted by the relevant Regulatory Authority, the Guidance for Good Clinical Practice of the International Conference on Harmonization, and all applicable laws, regulations and guidelines governing the conduct of human clinical research in the jurisdiction of the Institution (together with (a) as "**Applicable Laws**"); (c) the Protocol; and (d) this Agreement.

1.2 **Investigator:** The Study shall be carried out under the direction and supervision of the Investigator.

1.3 **Study Personnel:** Site represents that, during the course of the Study, all subinvestigators, employees, contractors, affiliates, agents and any other persons performing services for the Study (together as "**Personnel**") shall have the appropriate training, information, licenses, approvals, and certifications necessary to safely, adequately and lawfully perform the Study in accordance with this Agreement. Further, Site shall be responsible to ensure that the Personnel have read and understood the Protocol and shall perform their activities and fulfill their obligations in a timely and competent manner.

1.4 **Informed Consent Form:** PHRI shall provide Site with a template informed consent form ("**ICF**") for the Study. Site shall, prior to initiation of the Study and during the conduct of the Study, obtain and maintain written approval from its/his/her institutional review board or ethics review board ("**IRB**") for the Study. Any changes to the ICF require the prior written approval of both the IRB, NLO and PHRI.

1.5 **Subjects:** Site shall obtain a completed and signed ICF from each subject participating in the Study ("**Subject**") prior to enrolling the Subject into the Study, and keep the Subjects informed throughout the Study.

1.6 **Recruitment:** Site may commence recruitment of Subjects upon receipt of an authorization to do so from PHRI/NLO. Site will use diligent efforts to recruit Subjects in accordance with the Protocol. The Parties acknowledge that the Project is a multi-centre study and that recruitment is

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on a competitive basis. Once the Project recruitment goal has been reached, PHRI reserves the right to notify Site to limit or cease further recruitment, and Site shall immediately comply upon receipt of any such notice.

1.7 **Conflict:** Site represents and warrants that it/he/she is not presently, and shall not be at any time during the performance of the Study under any obligation to a third party or subject to any impediments which would: (a) prevent, inhibit or negatively affect their performance of the Study, (b) create a conflict of interest or (c) otherwise impair the acceptance by a Regulatory Authority of the data or results collected by Site.

1.8 **Debarment:** Site represents that neither it/he/she nor any of the Personnel has been or is under investigation by a Regulatory Authority for debarment, disqualification, or any similar regulatory action, and that it/he/she has no notice or knowledge of debarment, disqualification, or any similar regulatory action by any Regulatory Authority in another jurisdiction. Furthermore, Site shall, during the term of this Agreement and for three (3) years following its expiration or early termination, promptly notify PHRI in the event of such debarment or threat of debarment, conviction, disqualification, or indictment of Site or Personnel.

1.9 **Subject Safety:** PHRI/NLO agrees to notify Site promptly upon receipt of Study information that would directly affect the health or safety of Subjects. Site shall without delay inform all Subjects and the IRB, as applicable. PHRI shall not be liable for the failure of Site to immediately inform Subjects or IRB of such new information. Site shall promptly report all safety data and information, including but not limited to any failure to comply with or deviations from the Protocols, to PHRI/NLO in accordance with the requirements of the Protocol.

1.10 **Records:** Site shall prepare, maintain and store accurate and complete written records and supporting documentation for each Subject ("**Source Documents**") in accordance with the instructions provided by PHRI/NLO and Applicable Laws. Site shall prepare and submit accurate and complete case report forms and all additional documentation ("**CRFs**") for each Subject to PHRI as required by the Protocol. Site shall reasonably cooperate with PHRI/NLO to promptly resolve all data queries from PHRI/NLO and provide such Source Documents as may be required. In accordance with the obligations in **ARTICLE 5 (Privacy)**, Site and the Personnel shall ensure that any data or Source Documents disclosed to PHRI/NLO does not include any information that would personally identify a subject and/or any personal health information ("**PHI**") unless permitted by signed ICFs and/or other authorizations.

1.11 **Audit and Monitoring:** Site shall cooperate with and permit Regulatory Authorities or PHRI/NLO to examine and inspect the facilities and equipment required for performance of the Study and to inspect and copy all data, reports, work products and results relating to the Study. In relation to visits by PHRI/NLO and/or its representative, the Parties will mutually and reasonably agree upon dates and times taking into account the reason for such visit. For clarity, access to records for monitoring or audit does not entitle PHRI/NLO to make or retain a copy of any Subject's personal identification information or PHI, as more particularly specified in **ARTICLE 5 (Privacy)**, unless such copying is permitted in accordance with the ICF or any other authorizations. Site understands that clinical trial monitoring is essential to good clinical practices and agrees to cooperate with PHRI/NLO to enable its monitoring activities without undue restriction. If Site is notified of an inspection by a Regulatory Authority, Site shall forthwith inform PHRI/NLO about the pending inspection and permit PHRI/NLO, or any person designated by PHRI/NLO, to attend the inspection unless prohibited by Applicable Laws or court order. Site shall forthwith communicate the information that arises from such inspections to PHRI/NLO, unless prohibited by Applicable Laws or court order. The Parties agree that any consideration payable for the assistance of Site for any audits and inspections is included in the consideration payable hereunder, whether or not itemized as such.

1.12 **Change of Investigator:** Should Investigator leave the Institution or otherwise become unavailable during the term of this Agreement, PHRI/NLO shall cooperate with Institution to find a replacement investigator who is acceptable to both Institution and PHRI/NLO. Institution shall require the replacement investigator to agree to comply with and be bound by all the terms and conditions hereof. Notwithstanding this, PHRI/NLO may elect not to approve any person

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proposed as a replacement investigator, in which event PHRI/NLO shall have the right to terminate this Agreement in accordance with **ARTICLE 10 (Termination)**.

1.13 **Study Product:** Site shall obtain the drug product required for use in the Study ("**Product**") from its local pharmacy, the cost of which is included in the Payment Schedule attached herein as **Exhibit 1**. Investigator shall: (a) use the Product solely for the purposes of conducting the Study, and (b) ensure the Product is stored in accordance with all instructions provided by the local pharmacy and the Product labels. Site shall control and/or limit access to the Product to the Personnel, and provide up-to-date records showing receipt and dispensing of the Product in accordance the Protocol and Applicable Laws.

ARTICLE 2. TERM

2.1 This Agreement shall commence on the Effective Date specified above, and continue until 31st December 2022, unless otherwise terminated earlier in accordance with **ARTICLE 10 (Termination)** ("**Term**").

ARTICLE 3. COMPENSATION AND PAYMENT

3.1 In consideration for the work performed pursuant to this Agreement, PHRI agrees to pay Site in accordance with the Payment Schedule attached herein as **Exhibit 1** and Payment Rule Form attached as **Exhibit 2**.

3.2 Site shall review the details accompanying each payment and inform PHRI in writing of any discrepancies between the payment received and the payment expected. Site shall inform PHRI of any final discrepancies no later than four (4) months after the Project database is locked. Should PHRI not receive written notice of any final discrepancies within such four (4) month period, all payments required to be made hereunder shall be deemed to have been made in full.

3.3 Site represents and warrants that it/he/she is not a resident or citizen of Canada for tax purposes.

ARTICLE 4. CONFIDENTIAL INFORMATION

4.1 Site agrees to maintain or cause to be maintained in confidence all information received, resulting from and related to the Project, including but not limited to, the Protocol and CRFs ("**Confidential Information**"). This obligation shall be binding for a period of ten (10) years from the termination or completion of the Project. Site will not disclose the Confidential Information without the prior written approval of PHRI/NLO. Site may disclose Confidential Information to Personnel and the IRB to the extent required for the proper conduct of the Study, provided that each person to whom disclosure is made is fully informed of the confidential nature of the information and agrees to keep it confidential in accordance with this Agreement.

4.2 The obligations in **Section 4.1** will not apply to Confidential Information if and to the extent only that it: (a) is or later becomes known to the public or is in the public domain, other than by an act or omission of Site; (b) is previously known to Site, before the Effective Date or prior to Site having signed a confidentiality agreement with PHRI in connection with the Project, as evidenced by written records; (c) is lawfully obtained from a third party and such third party has a legal right to disclose the information; or (d) is independently developed by Site without the use of the Confidential Information, as evidenced by written records.

ARTICLE 5. PRIVACY

5.1 All Parties shall comply with Applicable Laws regarding the Confidential Information, including but not limited to protected or personal information, PHI and all data received or obtained in the course of the Project. Access to PHI and/or personal information shall be provided only to the extent permitted by the Subject's ICF or other authorization and Applicable Laws. Site shall de-identify all information, data and documents prior to providing access to PHRI/NLO, however in the event PHRI/NLO receives or otherwise has access to a Subject's PHI and/or personal

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information PHRI/NLO shall hold the PHI and/or personal information in confidence in accordance with all Applicable Laws, the signed ICF or other authorization.

ARTICLE 6. INTELLECTUAL PROPERTY

6.1 PHRI shall own and have all rights, title and interest in: (a) all Project information, documents and data collected; (b) results derived from the performance of the Project in all forms and formats, and (c) any discovery or invention that may arise in the course of the Project by Site or the Personnel. Notwithstanding this, Site may use the data and results of the Study for its/his/her internal non-commercial research and educational purposes provided that until the Project results are public, as provided in **ARTICLE 7 (Publication)**, Site shall not make the results of the Study available to third parties without the prior written consent of PHRI. Subject medical charts shall remain the property of Site.

6.2 Site disclaims all rights, title and interest to the data and results, to any and all intellectual property arising out of or in connection with the Project, and to information and documents received by Site as a result of or in the course of performing the Study, except to the extent that such rights are expressly granted hereunder. Any discovery or invention shall be promptly communicated to PHRI. PHRI shall file and prosecute any patent applications, at its expense and in its sole discretion. Site and the Personnel agree to provide reasonable assistance with any patent applications. Any compensation payable for the assignment of the inventor rights is included in the consideration payable hereunder, whether or not itemized as such. Institution shall be responsible for payments to Investigator or Personnel according to Applicable Law or Institution policies for the assignment of inventor rights to PHRI.

ARTICLE 7. PUBLICATION

7.1 **Multi-Site Publication By Project Lead:** Site acknowledges that consolidated data from all sites will be analyzed collectively by a Project committee ("**Project Results**"). The Project committee will, regardless of the outcome, submit an initial publication to a peer reviewed, biomedical journal or otherwise make the Project Results public no later than twelve (12) months after the completion of the Project.

7.2 **Single Site Study Publication:** After the Project Results are public, or eighteen (18) months after the conclusion of the Project, Site shall have the right to publish the Study results from the data collected at its location in accordance with the terms of this **ARTICLE 7 (Publication)**. At least sixty (60) days prior to the date for submission of a publication, abstract, and/or presentation ("**Publication**"), Site shall provide copies of any proposed Publication to PHRI/NLO for review and comment by the Project committee. Site agrees to consider the comments, if any, of the Project committee.

7.3 If, in the course of review of the proposed Publication, PHRI/NLO and/or the Project committee identifies any Confidential Information that it or they may wish to protect, PHRI shall have the right to request amendments to the proposed Publication on reasonable grounds including without limitation to: (a) ensure that the proprietary information is not inadvertently divulged, (b) enable intellectual property rights to be secured, and/or (c) enable relevant supplementary information to be provided. Site shall comply with any reasonable request to amend or delete information in a proposed Publication, provided such request does not necessitate removal of Study data and/or results. In addition, on written notice, PHRI may require Site to postpone the Publication to enable PHRI to protect its intellectual property rights. Upon receipt of such written notice, Site shall delay the Publication for the period of time specified in the notice, provided that such period shall not exceed sixty (60) days.

7.4 Other than as agreed herein, no Party shall use the name(s) of another Party or its/his/her Personnel without the prior written consent of such Party. Site may acknowledge in general terms the existence of this Agreement and its receipt of financial support from PHRI in order to comply with Applicable Laws and for Publication of the Study Results, and with the prior written approval of PHRI/NLO in connection with advertising or promotional materials for the Project. PHRI may disclose the name(s) of Site in any Publication of the Project Results, and may use the

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Secretary

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SGPGIMS,Lucknow

names and the amount of funding provided to Site for registration of the Project on www.clinicaltrials.gov, www.ctri.in and to comply with Applicable Laws and general industry standards.

ARTICLE 8. DISCLAIMER

8.1 PHRI makes no warranties of any kind whatsoever concerning the efficacy or safety of the Project, the procedures, treatments and medical practices described in the Protocol, the Product, or the Protocol itself. Except as expressly provided herein, PHRI hereby specifically disclaims any and all warranties or conditions, which may be implied by law.

8.2 Site makes no warranties of any kind whatsoever concerning the success of the Study.

ARTICLE 9. INDEMNIFICATION AND INSURANCE

9.1 **PHRI:** PHRI/NLO agrees to defend, indemnify and hold harmless Site and its trustees, directors, officers and Personnel from and against any and all costs, losses, liabilities, damages, actions, proceedings, demands, claims and reasonable expenses including legal fees ("**Claims**") made by a third party to the extent directly resulting from PHRI's/NLO negligence, wrongful acts and omissions in connection with its performance or non-performance of its obligations under this Agreement.

9.2 **Site:** Site agrees to defend, indemnify and hold harmless PHRI/NLO, and its trustees, directors, officers, medical and professional staff, students, appointees, contractors, agents and sponsors (if any) from and against any and all Claims made by a third party to the extent directly resulting from Site's and the Personnel's negligence, wrongful acts and omissions in connection with its performance or non-performance of their obligations under this Agreement.

9.3 **Notification:** In connection with any Claim, each Party shall notify the other Parties promptly of any Claim and cooperate fully in the investigation and defense of any such Claims.

9.4 **Limitation of Liability:** Notwithstanding any other provision of this Agreement, under no circumstances will a Party be liable to another Party for any indirect, consequential or incidental damages that such other Party may have suffered, including without limitation damages for loss of profit or revenue and regardless of whether such other Party has been advised of the possibility of such damages arising, or for non-compensatory damages of any kind, including without limitation aggravated or punitive damages.

9.5 **Insurance:** During the Term and for the duration of their obligations surviving expiration or termination of this Agreement, PHRI and Institution will each obtain and maintain a policy or program of self-insurance at levels sufficient to support their obligations herein and in amounts appropriate to the conduct of their respective businesses, which at minimum, shall include comprehensive general liability coverage with limits of not less than the equivalent of two million dollars Canadian ($2,000,000) aggregate or amounts required by Applicable Laws.

9.6 **Investigator's License:** Investigator agrees to hold membership in the medical professional association in his/her jurisdiction for the duration of the Project and to provide evidence of such membership on PHRI's request.

9.7 NLO shall maintain in force a **clinical trial indemnity insurance** coverage for all Project Subjects recruited in India as required by Applicable Law. A copy of this will be provided to the Institution for reference and production to regulatory / Ethics office. NLO will provide payment to the Institution for reasonable unreimbursed medical expenses, including hospitalization, which the Institution may incur as a direct result of the treatment of a Subject's injuries that directly results from the Product or its administration during the Study, as determined by PHRI and the Investigator.

9.8 **Research Related Injury:** NLO shall be responsible for payment of the reasonable medical expenses incurred in diagnosing and treating any injury, illness, or adverse reaction of a Study

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Secretary

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SGPGIMS,Lucknow

Subject that results from the administration of the Product in accordance with the Protocol or the proper performance of any Protocol procedure.

9.9 A Party shall upon request provide the requesting Party with a copy of the relevant certificate of insurance coverage. As per Indian regulations, the expenses on medical management in case of any injury and financial compensation in case of clinical trial injury or death of the Project Subject shall be borne through the insurance cover undertaken by the NLO. Institution will consider building a contingency fund within the institution to meet the costs immediately and later get them reimbursed from NLO.

ARTICLE 10. TERMINATION

10.1 **For Default:** In the event either PHRI/NLO, on the one hand, or Site, on the other hand, fails to perform or performs improperly any of its material obligations under this Agreement, the non-defaulting Party shall provide the other Party or Parties with thirty (30) days' notice in writing to cure the default. In the event the default is not cured to the reasonable satisfaction of the non-defaulting Party, such Party may terminate this Agreement on notice to the other Parties. Either parties have equal rights to terminate this Agreement.

10.2 **For Safety or Other Reasons:** PHRI/NLO may terminate this Agreement at any time, on written notice to Site if: (a) the regulatory authorization or approval to perform the Project is withdrawn; (b) a decision is made to terminate the Project early due to safety or other reasons; (c) Site has not recruited a Subject into the Study within three (3) months of receipt of notice from PHRI to commence recruitment; or (d) Site is debarred or disqualified. Upon written notice to PHRI/NLO, Site may jointly terminate this Agreement if, in the reasonable judgement of Site, serious or life-threatening events raise issues of subject safety.

10.3 **For No Cause:** PHRI may also terminate this Agreement on thirty (30) days' prior written notice to Site for any reason.

10.4 **On-going Obligations:** Termination shall be subject to the on-going obligations of each of the Parties pursuant to **Section 10.5**. Immediately upon receipt of a notice of termination, Site shall cease recruitment of Subjects into the Study and cease conducting procedures as directed by PHRI and to the extent medically permissible.

10.5 **Closing Activities:** Regardless of the cause of termination, the Parties shall in all instances cooperate in closing-out of the Study and, if applicable, comply with all recommendations of the Project steering committee.

10.6 **Payment:** In the event of early termination of this Agreement, other than for a material breach by Site, PHRI shall pay all fees actually earned to the effective date of termination notice and for closing-out activities as determined by the Project steering committee. PHRI will consider payment of other reasonable non-cancellable expenses incurred by Site, but shall not be liable for such costs or expenses unless they have been pre-approved or subsequently agreed between the Parties.

10.7 **Survival:** The rights and obligations of Parties that by intent or meaning have validity beyond expiration or termination (including, without limitation, rights with respect to intellectual property, Publication, Confidential Information, privacy, and indemnification) shall survive the termination or expiration of this Agreement.

ARTICLE 11. NOTICE

11.1 Any notice required by this Agreement shall be in writing and delivered to the addresses or facsimile numbers specified below or to such other address as each party may from time to time designate to the other in writing. Delivery shall be deemed received as follows - if prior to 4:00 pm on a business day in the jurisdiction of the recipient and otherwise on the next business day by: (a) personal delivery, when delivered personally; (b) courier, upon courier's verification of

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delivery; (c) facsimile, successfully received transmission at recipient's location; or (d) electronic mail transmission successfully received by the recipient.

If to PHRI:
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Attention: POISE-3 Project Manager
Tel: 905-521-2100 x 40526
Fax: 905-297-3779
Email: shirley.pettit@phri.ca

If to NLO:
The Dean, St. John's Research Institute
a unit of CBCI Society for Medical Education
St. John's National Academy of Health Sciences
Johnnagar, Bangalore
560 034, India
Tel: +91 80 49467001
Fax: +91 80 25501088
Email: deansoffice@sjri.res.in

If to Site (Institution):
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow
Department of Anaesthesiology
Raebareli Road
Lucknow, Uttar Pradesh, 226014
India
Tel: 91-522-2495048
Fax: 05222668017
Email: sdhiraaj@gmail.com

If to Site (Investigator):
Dr. Sanjay Dhiraaj
Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow
Department of Anaesthesiology
Raebareli Road
Lucknow, Uttar Pradesh, 226014
India
Tel: 91-522-2495048
Fax: 05222668129
Email: sdhiraaj@gmail.com

With copy marked to:
Dr. Denis Xavier
Head - Division of Clinical Research & Training
St. John's Research Institute
St. John's National Academy of Health Sciences
Johnnagar, Bangalore-560 034, India
Tel: +91 80 49466140, +91 80 4946010, +91 80 49467080
Fax: +91 80 49467090
Email: denis@sjri.res.in

11.2 Where any notice is given to PHRI under this Agreement in relation to any alleged breach or default of this Agreement by PHRI or any Claim against PHRI, Site shall also provide the notice to:

Research Counsel
Population Health Research Institute
237 Barton Street East
Hamilton, ON L8L 2X2
Canada
Fax: 905-296-2369
Email: phri.contracts@phri.ca

ARTICLE 12. CONCLUDING PROVISIONS

12.1 **Entire Agreement, Amendment and Assignment:** The Exhibits and the Protocol are incorporated herein by reference and form part of this Agreement. This Agreement sets forth the entire agreement and understanding of the Parties as to the subject matter herein. Any amendments or modifications to this Agreement shall be in writing and signed by authorized representatives of each Party. Institution and/or Investigator may not assign this Agreement or any obligation hereunder without the prior written consent of PHRI/NLO.

12.2 **Recitals:** The Parties acknowledge the foregoing recitals to be true and correct.

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12.3 **Conflict:** In the event of any conflict between this Agreement and the Protocol, this Agreement will govern for any non-clinical matters and the Protocol will govern for any scientific and clinical matters.

12.4 **Independent Contractors:** As between PHRI/NLO on the one hand, and Site and the Personnel on the other hand, the work performed pursuant to this Agreement shall be as independent contractors and not as partners, joint venturers, employees, subcontractors or agents. No Party has the power or authority to bind another Party.

12.5 **Force Majeure:** In the event that performance of a Party's obligations are prevented by events beyond its reasonable control, including but not limited to, acts of God, regulations or acts of any governmental authority, war, civil commotion, strikes, other labor disturbances, epidemics, fire, earthquakes, storms or other catastrophes of a similar nature, the affected Party will notify the other Parties as soon as reasonably possible and the affected Party shall be relieved of its obligations for the duration and to the extent the performance of an obligation is prevented thereby. During the existence of any such condition, the affected Party shall use diligent efforts to remove the cause and resume performance of its obligations.

12.6 **Governing Law & Jurisdiction:** The interpretation and construction of this Agreement shall be governed by the laws of India excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this agreement to the substantive law of another jurisdiction. The Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts where the cause of action arises for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts.

12.7 **Invalidity:** The invalidity or unenforceability of any provision of this Agreement shall not affect the validity of any other provision hereof. The Parties shall make commercially reasonable efforts to replace any invalid or unenforceable provision with one that is valid and enforceable, and reflects the originally intended commercial objectives of the Parties.

12.8 **Signing:** This Agreement may be signed in any number of counterparts, each of which so executed is deemed to be an original and when joined together constitute one and the same original agreement. The Parties agree that fax or electronic copies have the same effect as original hardcopies.

- signature page to follow -

St. John's Research Institute Bangalore

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

Hamilton Health Sciences Corporation

Signature _____ Date: 2019-MAR-01 (YYYY-MMM-DD)
Name: Tanya Chow
Position: Director of Contracts, Population Health Research Institute

INVESTIGATOR

Signature _____ Date: 2019-01-29 (YYYY-MMM-DD)
Name: Dr. Sanjay Dhiraaj

INSTITUTION: Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow

Signature _____ Date: _____ (YYYY-MMM-DD)
Name: _____
DIRECTOR
Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA
Title: _____

On Behalf of ~~CBCI~~ St. John's Research Institute

Signature _____ Date: 2019 MAR 26 (YYYY-MMM-DD)
Name: Dr. TONY D.S. RAJ
DEAN
St. John's Research Institute
St. John's National Academy of Health Sciences
Koramangala, Bangalore – 560 034, INDIA
Title: _____

On behalf of ~~St. John's Research Institute~~ CBCI

Signature _____ Date: 2019 MAR 28 (YYYY-MMM-DD)
SECRETARY
C.B.C.I. SOCIETY FOR MEDICAL EDUCATION
ST. JOHN'S NATIONAL ACADEMY OF HEALTH SCIENCES
SARJAPUR ROAD, BANGALORE - 560 034
Name: Rev. Dr. Paul Parathazham
Title: Secretary

On behalf of NLO

Signature _____ Date: 2019 mar 16 (YYYY-MMM-DD)
Name: Dr. DENIS XAVIER, MD, M.SC.
Vice Dean (PG)
Professor of Pharmacology
St. John's Medical College
Bengaluru - 560 034, India.
Title: _____

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EXHIBIT 1 – PAYMENT SCHEDULE

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments will be processed on a quarterly basis with payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued within 25 days from the processing/run date (i.e., payment for run date March 31st is mailed on or prior to April 25th). Payments will be made for all CRFs received and validated to be clean prior to the run date, according to the payment schedule.

The fee per subject is inclusive of all costs (i.e. staff time, study lab investigations, event reporting costs, archiving costs, institutional overheads, cost to purchase TXA and any dispensation fees, participant expenses such as travel and parking, all applicable taxes including VAT or its equivalent).

Enrolment and Follow-up:

Visit Type	**Amount in CAD per Study Subject, per visit and receipt of all required CRFs for the visit**
Randomization Visit	75
Baseline	40
Hospital Discharge	50
1 Month	25
1 Year	40
Holdback fee *	20
Total Per Patient Fee (CAD) **	**250**

* Holdback fee will be paid after database lock if all required data for the participant has been collected and provided to PHRI prior to database lock.

** The actual fees paid will be based on completion of visits and collection of all required data.

Additional Payments for Product management at site:

Product management support fees will be provided in installments based on successful randomization of the first Study Subject and subsequent recruitment rate at Site towards various Study activities that will be required to be completed by the Site.

Subjects recruited	**Amount in CAD**
1st Subject recruited	200
20th Subject recruited	200
40th Subject recruited	200
50th Subject recruited	200

St. John's Research Institute Bangalore

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Executive Registrar
SGPGIMS,Lucknow

EXHIBIT 2 – PAYMENT RULE FORM

COUNTRY:	**INDIA**
CENTRE #:	**464**
INSTITUTION:	**Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow**
INVESTIGATOR:	**Dr. Sanjay Dhiraaj**

Payment will be in **CAD and will be converted to rupees using the exchange rate as of the date of processing**. Payments will be processed on a quarterly basis with the payment run cut-offs on March 31st, June 30th, September 30th and December 31st of each year. Payments will be issued and sent out within 25 days from the processing/run date (i.e., payment for run date March 31st will be sent on or prior to April 25th) provided that a minimum of **500 CAD** has been earned within such payment period. Payments will be made for all CRFs received and validated to be clean prior to this date, according to the attached payment schedule.

Payments will be made to only one party. **(ALL INFORMATION BELOW MUST BE PRINTED)**

The following information is required in order to generate payment by wire transfer. Incomplete information could result in delay in payment.	
Bank Name:	STATE BANK OF INDIA
Bank Address:	STATE BANK OF INDIA, SANJAY GANDHI PGIMS, RAEBARELI ROAD, LUCKNOW, U.P.-226014
Bank SWIFT code:	SBININBB500
Beneficiary Name:	DIRECTOR SGPGIMS, RESEARCH ACCOUNT
Beneficiary Address:	DIRECTOR SGPGIMS, RESEARCH ACCOUNT, SANJAY GANDHI PGIMS, RAEBARELI ROAD, LUCKNOW, U.P.-226014
Beneficiary IBAN or Account number:	10095237491
IFSC Code (if applicable):	SBIN0007789
Reference (if applicable):	
Contact name and email of person generating the invoice (if applicable):	DR SANJAY DHIRAAJ

Institution Signature:	Date:
Name of the signatory:	
Investigator Signature:	Date
Name of the signatory: SANJAY DHIRAAJ	

The information below is required before PHRI can initiate any payment.

Are you an entity that has to submit value added tax? ___Yes ___ No Tax rate: ___%
If payment to the Investigator please provide following:
Social Security (US)/Social Insurance Number (Canada) or other applicable personal income tax identifier #:
Investigator First Name, Middle Initial and Last Name:
If payment to a business entity such as the Investigator's professional corporation or the Institution please provide the following:
Tax ID #/GST Registration:
PAN card no: #:
For HHSC use only – Vendor ID #:

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Executive Registrar
SGPGIMS,Lucknow

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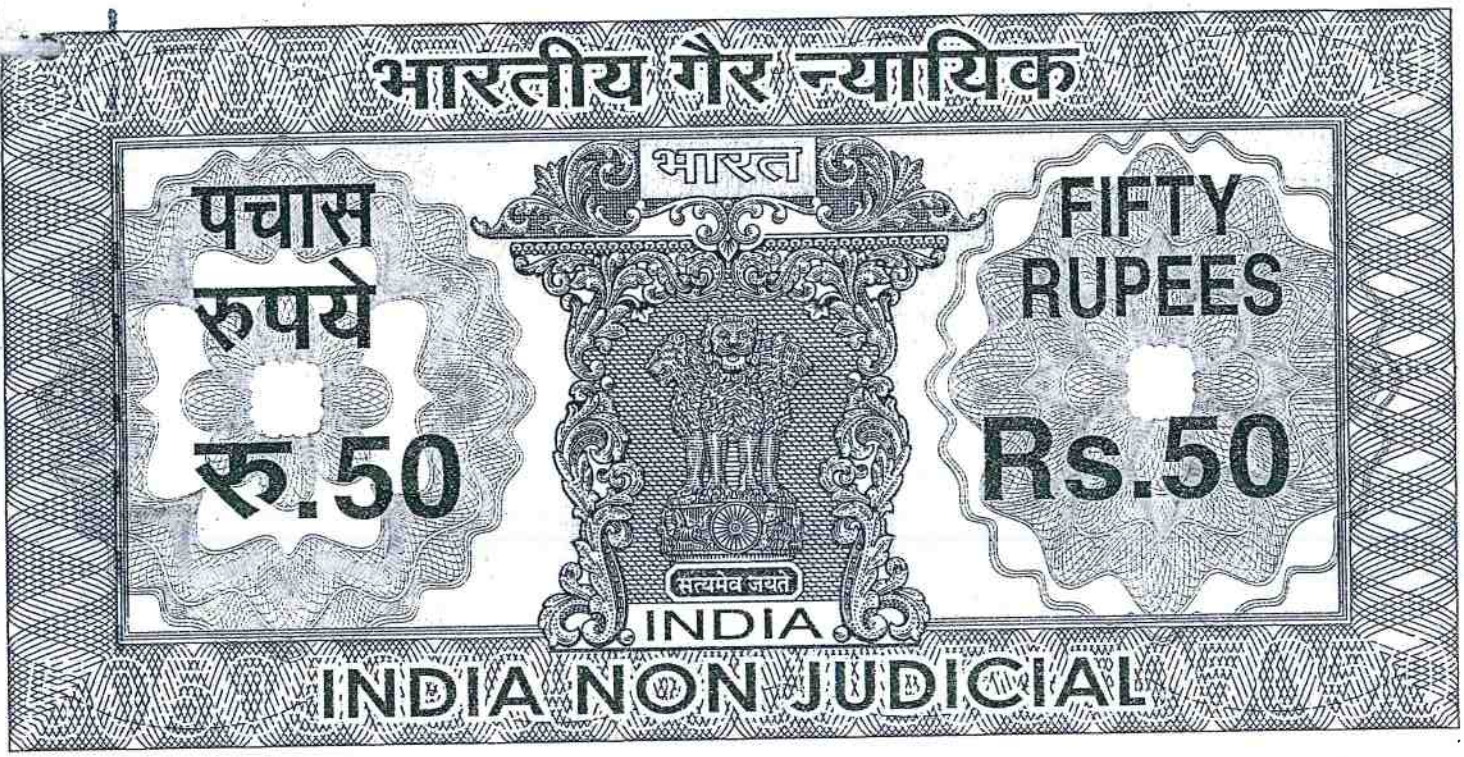

उत्तर प्रदेश UTTAR PRADESH

BU 274405

MEMORANDUM OF AGREEMENT

This MEMORANDUM OF AGREEMENT is made on this ....., **Two thousand and Nineteen** BY AND BETWEEN President of India, acting through **Secretary,** Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi, hereinafter referred to as the 'DBT' (which expression unless excluded by or repugnant to the subject shall mean and include its successor-in-office and assigns) of the ONE PART;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences an autonomous institution created by act of state legislature of UP (Act no 30 of 1983) having its registered office at Raebareli Road, Lucknow, 226014 hereinafter referred to as **SGPGI**. (which expression shall where the context so admits include its successors and permitted assigns) of the OTHER PART;

WHEREAS DBT being desirous **of Medical Biotechnology** decided to support a project submitted by Amita Aggarwal for the attainment of the objectives, hereinafter described in the Annexure I annexed hereto;

Amita Aggarwal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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उत्तर प्रदेश UTTAR PRADESH BU 274406

This Memorandum of Agreement (MoA) defines the role and responsibilities of the participating agencies, monitoring and other matters related to the **Multi-institutional Network Program on Systemic lupus Ervthematosus Understanding the diversity of SLE**

NOW THE PARTIES HERETO AGREE AS FOLLOWS:-

1.0 . ROLE OF DEPARTMENT OF BIOTECHNOLOGY, NEW DELHI

To provide funds to the extent of **Rs 33738828** over a period of **5** years from the date of sanction of the project, to **August 30, 2018** for undertaking activities as detailed in Annexure 1. Details of the funds to be provided are given in Annexure II.

2.0. ROLE OF SGPGI

2.1. To provide their contribution of none for 5 years from date of sanction of the project as detailed in Annexure – II. *(if a jointly supported project)*

2.2. To provide existing facilities as mentioned in the project document.

2.3. To be responsible for accomplishing objectives identified and activities listed.

Lt Col Varun Bajpai VSM
Executive Registrar
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2.4. To allow the Scientists authorized by DBT to work with the Research & Development team of the center in all stages of process development and production.

2.5. To recruit all scientific and non-scientific staff as sanctioned by DBT.

2.6. To prepare and submit all periodical reports and other documents that would be required by DBT.

2.7. To maintain a separate audit head of account for the grants received from DBT for the project.

2.8. To submit an annual audited statement of expenditure incurred under the project.

2.9. To ensure effective utilization of the grant given by DBT for the purpose for which it was granted and to ensure timely progress of project work.

2.10. The manpower, both scientific and non-scientific, recruited shall be purely on contractual terms & conditions such that the contract for engagement of the manpower shall run concurrently with the said project period only.

3.0 DURATION OF PROJECT

3.1 Duration of project shall be 5 years from the date the Project has been sanctioned by DBT.

4.0 RIGHTS OF OWNERSHIP/TECHNOLOGY TRANSFER AND UTILIZATION

4.1 The know-how generated from the project by Dr Amita Aggarwal will be the joint property of SGPGI- and DBT, Government of India. It shall be the responsibility of SGPGI to take necessary action for protection of the intellectual property arising out of the PROJECT through proper instruments, such as, patents, copy rights, etc.

4.2 The know-how developed may be transferred to other entrepreneurs on a non-exclusive basis on such terms and conditions as may be determined by DBT.

Amita Aggarwal

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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IN WITNESS WHEREOF the parties hereto have signed, sealed and delivered this Agreement on the day, month and year first above written in presence of:

Witnesses:

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

1.

(Designation)

2.

For and on behalf of The President of India

Witnesses:

1. Dr. Sudhir Sinha
2. Mr. Arvind Srivastava

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

(Designation)

For and on behalf of SGPGI, Lucknow

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

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

TERMS & CONDITIONS OF THE GRANT

(To be signed and enclosed with concern filled proforma)

1. Approval of the Research proposal and the grant released would be for the specific project mentioned in paras I to V of this proposal and grant should be exclusively spent on the project for which it has been sanctioned within the stipulated time. The Institute is not permitted to seek or utilise funds from any other organisation (Government, Semi Government, Autonomous or Private) for this research project. Any unspent part of amount would be surrendered to the Govt. of India through an account payee demand draft drawn in favour of the "Drawing and Disbursing Officer, Department of Biotechnology, New Delhi", and carry forward of funds of the next financial year for utilization for the same project may be considered only with the specific approval of the Department of Biotechnology (DBT).

2. For permanent/semi-permanent assets acquired solely or mainly out of the grant, an audited record in the form of a register in the prescribed proforma (enclosed at **Appendix-'A'**) shall be maintained by the Institute. The term **"assets"** means (I) immovable property and (II) movable property of a capital nature, where the value exceeds Rs. 1000/- The grant will not be utilised for construction of any immovable property, Full facilities by way of accommodation, etc. for the project will be given by the Institute.

3. All the assets acquired from the grant will be the property of Govt. of India and should not without the prior sanction of the Deptt. of Biotechnology, be disposed of, or encumbered or utilised for purpose other than those for which the grant has been sanctioned.

4. At the conclusion of the project, the Govt. of India will be free to sell or otherwise dispose of assets which are the property of the Government. The Institute shall render to Govt. necessary facilities for arranging the sale / disposal of these assets. **The Government may, however, consider the request of host institutions to retain the assets created under a project for carrying out similar work for the promotion of science.**

5. The implementing Institute/PI will furnish progress report of work on the project every six months. The progress of the project will also be reviewed/monitored at least once a year by the concerned Task Force/Project Monitoring Committee, etc. In addition the DBT shall designate Scientists/Specialists to visit the Institute periodically for reviewing the progress of work and for suggesting such measures as to ensure early realisation of the objectives of the project. On completion of the project five copies of a consolidated report of the work done on the subject would be submitted to the Department of Biotechnology.

6. The Institute is required to send to DBT a list of assets referred to at Sl. No. 2 above at the end of each financial year as well as at the time of seeking further installments of the grant.

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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7. The Institute would furnish to the Deptt. of Biotechnology a Utilization Certificate (Copy enclosed at **Appendix - 'B'**) and an audited statement of expenditure **(Copy enclosed at Appendix - 'C'**) duly signed by the P.I., the Head of the Institute and the Head of the Finance wing, pertaining to the grant at the end of each financial year as well as a consolidated statement of expenditure at the end of the completion of the project.

8. A stamped receipt be sent to the Deptt. of Biotechnology on receipt of the Cheque/ Demand draft towards each release.

9. The Comptroller and Auditor-General of India at his discretion shall have the right of access to the books and accounts of the Institute for the grant received from the Government.

10. The Institute would maintain separate audited accounts for the project. If it is found expedient to keep a part or whole of the grant in a bank account earning interest, the interest thus earned should be reported to the Deptt. of Biotechnology.

11. Sale proceeds, if any, as a result of the development of the project arising directly from funds granted by the Deptt. of Biotechnology shall be reported to the Govt. of India. The Govt. of India may at its discretion allow a portion of such receipt to be retained by the Institute for its utilisation for the project activities.

12. Investigators/Institutes wishing to publish papers based on the research work done under Deptt. of Biotechnology projects should acknowledge the financial support received from the Deptt. of Biotechnology.

13. Investigators/Institutes may utilize various resources such as the Bioinformatics resources, experimental materials, reagents, cell lines, animals, etc. from the National facilities/Institutes/Centres established by this Department as per the terms of transactions followed by them. More information may be obtained about such facility from DBT websites: http://www.dbtindia.org// www.dbtindia.nic.in, www.btisnet.ac.in.

14. Investigators / Institutes shall follow the detailed instructions on technology transfer and Intellectual Property Rights (IPR) as given at Annexure - V. The same has the approval of the Ministry of Finance, Govt. of India vide Deptt. of Expenditure, Plan Finance II – Division Letter No. 33 (5) /PF.II/99 dated 22nd February, 2000. Any deviation from these instructions may be brought to the notice of this Department.

15. Investigators / Institutes may file patents with the help of the Biotechnology Patents Facilitating Cell (BPFC) established at DBT on priority bases. The format for filing the patents may be seen at Annexure –VI.

16. The Govt. of India (Deptt. of Biotechnology) will have the right to call for drawings, specifications and other data necessary to enable the transfer of know-how to other parties and the Institute shall supply all the needed

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information at the request of the Department of Biotechnology which will ensure confidentiality. The information required for commercializing Biotechnologies may be furnished to this Deptt. as per the format enclosed at Annexure – VII. More information on commercialization can be found at the website www.ebc.nic.in.

17. The Institute may not entrust the implementation of the work for which the grant is being sanctioned to another institution and to divert the grant receipts as assistance to the latter institution. However, in such situations the express permission of DBT may be obtained. In case the grantee is not in a position to execute or complete the project, it may be required to refund forthwith to the Govt. of India (Department of Biotechnology) the entire amount of grant received by it.

18. The human resources that may be engaged for the project by the Institute are not to be treated as employees of the Govt. of India and the deployment of such human resource at the time of completion or termination of project, will not be the concern/responsibility of the Govt. of India. The Organisation may make reservations for Scheduled Castes, Schedule Tribes etc. in the human resource to be engaged for the project in accordance with the instruction issued by the Govt. of India from time to time.

19. The Deptt. of Biotechnology reserves the right to terminate the grant at any stage and also to recover the amounts already paid if it is convinced that the grant has not been properly utilized or the work on the project has been suspended for any unduly long period or appropriate progress is not being made.

20. The project will become operative with effect from the date of release of the first installment for the project.

21. If the Investigator to whom a grant for a project has been sanctioned leaves the institution where the project is being implemented, he shall submit five copies of complete and detailed report of the work done by him on the project and the money spent till the date of his/her release and shall also arrange to refund the unspent balance , if any.

22. The organisation should maintain subsidiary accounts of the Govt. of India grant and furnish it to the Audit Officer as and when the recurring and non-recurring expenditure exceeds the limits of Rs. 5.00 lakhs.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Signature of Project Coordinator
(applicable only for multi-institutional projects)

Date :

Signature of Executive Authority of Institute/ University With seal

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

Date : 31.10.2019

Signature and stamped of Principal Investigator :

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Date :

Signature and stamped of Co-Investigator **Signature and stamped of Co-Investigator**

Date :

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SGPGIMS,Lucknow

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No. BT/PR23111/MED/30/1852/2017
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, 6-8th Floors
CGO Complex, Lodhi Road,
New Delhi- 110 003
Dated: 31/08/18

ORDER

Sanction of the President is hereby accorded, under Rule 18 of the Delegation of Financial Powers Rules ,1978 , for the implementation of the project entitled: **"Multi-institutional Network Program on Systemic lupus Erythematosus Understanding the diversity** of SLE" for a period of 5 Year 0 Month at a total cost of Rs. **125958656** (Rupees Twelve Crores Fifty Nine Lakhs Fifty Eight Thousand Six Hundred and Fifty Six Only) on the terms and conditions detailed here under:-

2 The Project :

2.1 Title : **"Multi-institutional Network Program on Systemic lupus Erythematosus Understanding the diversity of SLE"**

2.2 **Details of the Investigatiors:**

Project Cordinator

Prof. Amita Aggarwal
Professor
Department of Clinical Immunology
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Department of Immunology
Rae Barielly Road PIN:226014, Rae Bareli, Uttar Pradesh, 226014

Prof. Amita Aggarwal
Professor
Department of Clinical Immunology
Sanjay Gandhi Post Graduate
Institute of Medical Sciences
Department of Immunology
Rae Barielly Road PIN:226014, Rae
Bareli,Uttar Pradesh, 226014

Dr. Ashish Jacob Mathew
Assistant Professor
Clinical Immunology and
Rheumatology
Christian Medical College, Vellore
Clinical Immunology and
Rheumatology
Christian Medical College, Vellore,
Vellore,Tamilnadu, 632004

nerated through eProMIS

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

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Dr. B Ravindran
PI
Professor Emeritus
INSTITUTE OF LIFE SCIENCES, Bhubaneswar
Institute of Life Sciences, Nalco Square, Bhubaneshwar, Khorda,Orissa, 751023

Dr. Manish Rathi
Additional Professor
Nephrology
Postgraduate Instutite of Medical Education and Research
Department of Nephrology, PGIMER, Chandigarh, Chandigarh,Chandigarh, 160012

Dr. Ranjan Gupta
Assistant Professor
Rheumatology
All India Institute of Medical sciences,New Delhi
Flat No. B-1/101, Varun Apartments, Sector No. 9, Plot No. 12, Rohini, New Delhi., Sri Ganganagar,Rajasthan, 110085

Prof. Bidyut Das
Professor
Medicine
S.C.B.Medical College, Cuttack
Department of Medicine, SCB Cuttack, Orissa, Cuttack,Orissa, 753002

Prof. Liza Rajasekhar
Professor
Rheumatology
Nizam's Institute of Medical Sciences
Department of Rheumatology, Hyderabad,Telangana, 5000082

Prof. Parasar Ghosh
Professor
Clinical Immunology and Rheumatology
INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH
Department, Kolkata,West Bengal, 700020

Prof. Vineeta Sobha
Professor
Clinical Immunology AND Rheumatology
St John's Medical College, St John's National Academy of Health Sciences
St John's hospital Bangalore, Bangalore, Karnataka, 560034

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
...S, Lucknow-226 014 (U.P.)

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Executive Registrar
SGPGIMS,Lucknow

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Prof. Vir singh Negi
Professor
Clinical Immunology
Jawaharlal Institute of P.G. Medical Education & Research
Department of Clinical Immunology JIPMER,
,Pondicherry, 605006

CO-PI:

Prof. Ramnath Misra
Professor
Clinical Immunology
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Department of Clinical Immunology, SGPGI,
Lucknow, Lucknow - 226014, Uttar Pradesh

2.3 Objectives:

Overall Objectives:

1. Development of an inception cohort from different parts of India for the assessment of clinical features, socio-demographic features, auto-antibodies, disease progression and outcome and evaluation of regional differences
2. Generation of a bio-repository to store samples that may be used in future for genetic studies and biomarker discovery
3. Assessment of soluble and cell-linked biomarkers in SLE patients with fever to determine if they can help differentiate infection from disease activity
4. To study the role of high dose vitamin D supplementation as an add on treatment in SLE patients

2.4 Time Schedule:

The duration of the project is 5 Year 0 Month from the date of this sanction order.

2.5 Project Cost:

The total cost of the project is Rs. **125958656/-**(Rupees Twelve Crores Fifty Nine Lakhs Fifty Eight Thousand Six Hundred and Fifty Six. Only) as per details given below :

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

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Institute	Year I	Year II	Year III	Year IV	Year V	Total Cost(Rs.)
1. All India Institute of Medical sciences,New Delhi	2477000	1952000	1952000	1802000	1802000	9985000
2. Christian Medical College, Vellore	5130448	3703276	3703276	1702000	1702000	15941000
3. INSTITUTE OF LIFE SCIENCES, Bhubaneswar	2488000	1919200	1953520	1791272	1833008	9985000
4. INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH	2477000	1952000	1952000	1802000	1802000	9985000
5. Jawaharlal Institute of P.G. Medical Education & Research	4688276	4163276	4163276	1802000	1802000	16618828
6. Nizam's Institute of Medical Sciences	2477000	1952000	1952000	1802000	1802000	9985000
7. Postgraduate Institute of Medical Education and Research	2477000	1952000	1952000	1802000	1802000	9985000
8. Sanjay Gandhi Post Graduate Institute of Medical Sciences	13720276	6485276	6285276	3624000	3624000	33738828
9. St John's Medical College, St John's National Academy of Health Sciences	2427000	1902000	1902000	1752000	1752000	9735000
Total (Rs.)	38362000	25981028	25815348	18299272	17921008	125958656

Institute wise details are:

Budget Head	Year I	Year II	Year III	Year IV	Year V	Total(Rs.)
1. Sanjay Gandhi Post Graduate Institute of Medical Sciences						

Prof. Amita Aggarwal
Head
Rheumatology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

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SGPGIMS 1st Year IInd IIIrd IV V

Equipment	6135000.00					6135000.00
Manpower	3435276.00	3435276.00	3435276.00	2274000.00	2274000.00	14853828.00
Consumables	3660000.00	2560000.00	2360000.00	950000.00	950000.00	10480000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	150000.00	150000.00	150000.00	100000.00	100000.00	650000.00
Contingency	240000.00	240000.00	240000.00	200000.00	200000.00	1120000.00
Total (Rs.)	13720276.00	6485276.00	6285276.00	3624000.00	3624000.00	33738828.00

2. Jawaharlal Institute of P.G. Medical Education & Research

Equipment	675000.00					675000.00
Manpower	2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9993828.00
Contingency	140000.00	140000.00	140000.00	100000.00	100000.00	620000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	150000.00	150000.00	150000.00	50000.00	50000.00	550000.00
Consumables	1160000.00	1310000.00	1310000.00	250000.00	250000.00	4280000.00
Total (Rs.)	4688276.00	4163276.00	4163276.00	1802000.00	1802000.00	16618828.00

3. Christian Medical College, Vellore

Equipment	1475000.00					1475000.00
Manpower	2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9993828.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Contingency	140000.00	140000.00	140000.00	100000.00	100000.00	620000.00
Consumables	952172.00	1000000.00	1000000.00	200000.00	200000.00	3352172.00
Total (Rs.)	5130448.00	3703276.00	3703276.00	1702000.00	1702000.00	15941000.00

4. All India Institute of Medical sciences,New Delhi

Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00

5. INSTITUTE OF LIFE SCIENCES, Bhubaneswar

Equipment	800000.00					800000.00
Manpower	720000.00	751200.00	785520.00	823272.00	864720.00	3944712.00
Contingency	200000.00	200000.00	200000.00	200000.00	200000.00	1000000.00
Travel	200000.00	200000.00	200000.00	200000.00	200000.00	1000000.00
Consumables	568000.00	768000.00	768000.00	568000.00	568288.00	3240288.00
Total (Rs.)	2488000.00	1919200.00	1953520.00	1791272.00	1833008.00	9985000.00

6. INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH

Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00

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7. Nizam's Institute of Medical Sciences						
Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00
8. Postgraduate Instutite of Medical Education and Research						
Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Overhead	50000.00	50000.00	50000.00	50000.00	50000.00	250000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Total (Rs.)	2477000.00	1952000.00	1952000.00	1802000.00	1802000.00	9985000.00
9. St John's Medical College, St John's National Academy of Health Sciences						
Equipment	675000.00					675000.00
Manpower	1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
Contingency	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Travel	100000.00	100000.00	100000.00	100000.00	100000.00	500000.00
Consumables	250000.00	400000.00	400000.00	250000.00	250000.00	1550000.00
Total (Rs.)	2427000.00	1902000.00	1902000.00	1752000.00	1752000.00	9735000.00

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 (U.P.)

2.6 Equipment:

The details of the equipment sanctioned for the implementation of the project at **Annexure-I**

2.7 Manpower:

The details of the manpower sanctioned for the implementation of the project at **Annexure-II**

3. Head of Account:

The **Non-Recurring** expenditure involved is debitable to:

Demand No. 85	**Department of Biotechnology**
3425	Other Scientific Research 2018-2019
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development.
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.35	Grants for creation of capital assets

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Executive Registrar
SGPGIMS,Lucknow

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e Recurring expenditure involved is debitable to:

Demand No. 85	Department of Biotechnology
3425	Other Scientific Research 2018-2019
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.31	Grants-in-Aid General

4. **Terms & Conditions:**

In case the whole or a part of the amount of the grant-in-aid is being refunded. an interest rate at the rate of ten percent thereon shall be recovered.

The equipment sanctioned under the project should be purchased with in 18 months from the date of the release of the grant.

.1 The other terms and conditions governing this sanction are attached at Annexure- III.

.2 A Memorandum of Agreement (MoA) will be signed between the Department of Biotechnology and the grantee institution on Non-Judicial stamp paper Rs. 100/- in the enclosed format and the second release/installment will be made only after signing of MoA by the grantee institutions and its acceptance by DBT. In case of NGO or Private Institution, MOA signed is mandatory for re-release. A format of the MoA is enclosed in Annexure-IV

1.3 The Institute/Agency will keep the whole of the grant in a Bank Account earning interest. and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the institute/Agency and shall be adjusted towards further installment of the grant and or at the time of Final Settlement of Accounts.

5. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.

6. The Director, INSTITUTE OF LIFE SCIENCES, Bhubaneswar, Bhubaneswar, Orissa and The Director, INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH, Kolkata, West Bengal and The Director, Jawaharlal Institute of P.G. Medical Education & Research, Pondicherry, Pondicherry and The Director, Nizam's Institute of Medical Sciences, Hyderabad, Telangana and The Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow, Uttar Pradesh and The Dr. Paul Parathazham, St John's Medical College, St John's National Academy of Health Sciences, Bangalore, Karnataka and The Dr. Subhash Varma; Postgraduate Institutite of Medical Education and Research, Chandigarh, Chandigarh and The Principal, Christian Medical College, Vellore, Vellore, Tamilnadu and The Principal, S.C.B.Medical College, Cuttack, Cuttack, Orissa and The Prof. M.C. Misra, All India Institute of Medical sciences,New Delhi, New Delhi, Delhi would be responsible for submission of Statements of Expenditure (SoE), utilization certificates (UC), Assets Certificates, Manpower staffing & expenditure details in prescribed DBT formats to DBT in respect of grants released in this project from time to time.

7. PI's of DBT sponsored projects can consider appointment of JRF from Category-II merit list of DBT-BET exam so that candidates can be paid fellowships at par with NET/GATE/BET qualified candidates as per DST OM No. A.SR/S9/Z-09/2012 dated on 21 Oct 2014. However, there is no compulsion on PI's to select candidates for JRF in their projects from Category-II of DBT-BET.

8. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organisations shall be

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General India under the provision of CAG(DPC) Act 1971 and internal audit by the Principal Accounts Office the Ministry or Department, whenever the Institution or Organisation is called upon to do so.

If the Research Project involves biological resource, the obligations under the Biological Diversity Act 2002 as applicable shall be complied with by the Project Investigator, the details of such obligations can be accessed at www.nbaindia.org

10.This issues under the power delegated to this Department and with the concurrence of IFD vide their SAN No.**102/IFD/SAN/1165/2018-2019** dated **July, 18 2018.**

11.This sanction order has been noted at serial no. 59 in the Register of Grants.

(Dr. Sandhya R Shenoy)
Scientist 'E'

To,
The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi - 110 002.
2 Amita Aggarwal(Project Co-ordinator), Department of Clinical Immunology, SGPGI Lucknow 226014
3 The Director, INSTITUTE OF LIFE SCIENCES, Bhubaneswar, Nalco Square, Chandrasekharpur, Bhubaneswar - 751023, Orissa
4 The Director, INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH, 244 A J C Bose Road, Kolkata - 700020, West Bengal
5 The Director, Jawaharlal Institute of P.G. Medical Education & Research, Dhanvantri Nagar, Pondicherry - 605006, Pondicherry
6 The Director, Nizam's Institute of Medical Sciences, Punjagutta, Hyderabad - 500082, Telangana
7 The Director, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raibareli Road, Lucknow - 226014, Uttar Pradesh
8 The Dr. Paul Parathazham, St John's Medical College, St John's National Academy of Health Sciences, St. John's Medical College, Sarjapur Road, Bangalore - 560 034, Bangalore - 560034, Karnataka
9 The Dr. Subhash Varma, Postgraduate Instutite of Medical Education and Research PGIMER,Sector-12, Chandigarh,Pin- 160-012, India, Chandigarh - 160012, Chandigarh
10 The Principal, Christian Medical College, Vellore, Christian Medical College, Thorapadi P.O., Vellore , Vellore - 632004, Tamilnadu
11 The Principal, S.C.B.Medical College, Cuttack, CUTTACK,ORISSA, Cuttack - 753007, Orissa
12 The Prof. M.C. Misra, All India Institute of Medical sciences,New Delhi, Ansari Nagar East, New Delhi, New Delhi - 110029, Delhi
13 Dr. Ashish Jacob Mathew, Assistant Professor, Clinical Immunology and Rheumatology, Christian Medical College, Vellore- 632004, Tamilnadu
14 Dr. B Ravindran, PI, Professor Emeritus, INSTITUTE OF LIFE SCIENCES, Bhubaneswar, Institute of Life Sciences, Nalco Square, Bhubaneshwar, Khorda - 751023, Orissa
15 Dr. Manish Rathi, Additional Professor, Nephrology, Postgraduate Instutite of Medical

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

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SGPGIMS,Lucknow

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Education and Research, Department of Nephrology, PGIMER, Chandigarh, Chandigarh - 160012, Chandigarh

16 Dr. Ranjan Gupta, Assistant Professor, Rheumatology, All India Institute of Medical sciences,New Delhi, Flat No. B-1/101, Varun Apartments, Sector No. 9, Plot No. 12, Rohini, New Delhi., Sri Ganganagar - 110085, Rajasthan

17 Prof. Amita Aggarwal, Professor, Department of Clinical Immunology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Immunology, Rae Barielly Road PIN:226014, Rae Bareli - 226014, Uttar Pradesh

18 Prof. Bidyut Das, Professor, Medicine, S.C.B.Medical College, Cuttack, Department of Medicine, SCB Cuttack, Orissa, Cuttack - 753002, Orissa

19 Prof. Liza Rajasekhar, Professor, Rheumatology, Nizam's Institute of Medical Sciences, Department of Rheumatology, Hyderabad - 5000082, Telangana

20 Prof. Parasar Ghosh, Professor, Clinical Immunology and Rheumatology, INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH, Department, Kolkata - 700020, West Bengal

21 Prof. Ramnath Misra, Professor, Clinical Immunology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Clinical Immunology, SGPGI, Lucknow, Lucknow - 226014, Uttar Pradesh

22 Prof. Vineeta Sobha, Professor, Clinical Immunology AND Rheumatology, St John's Medical College, St John's National Academy of Health Sciences, Department of Clinical Immunology and Rheumatology, St John's hospital Bangalore, Bangalore - 560034, Karnataka

23 Prof. Vir singh Negi, Professor, Clinical Immunology, Jawaharlal Institute of P.G. Medical Education & Research, Department of Clinical Immunology JIPMER, - 605006, Pondicherry

24 Cash Section, DBT (2 copies).

25 Sanction Folder.

26 File Copy.

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

Sowmya R. Shenoy
(Dr. Sowmya R. Shenoy)
Scientist 'E'

Annexure -I

Details of the Equipment sanctioned for the implemention of the project titled "Multi-institutional Network Program on Systemic lupus Erythematosus Understanding the diversity of SLE":

Sanjay Gandhi Post Graduate Institute of Medical Sciences			
SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freezer	1	100000.00
2.	Centrifuge	1	45000.00
3.	Laptop/Computer	1	50000.00
4.	Server at Coordinating Centre	1	150000.00
5.	Pipettes	1	55000.00
6.	-80 degree freezer	3	3000000.00

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Executive Registrar
SGPGIMS,Lucknow

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	Nanodrop	1	1400000.00
8.	Computer with Printer	1	50000.00
9.	Software for Biorepository	1	800000.00
10.	Barcode Reader & Printer	1	25000.00
11.	pippetes	1	50000.00
		Total	6135000.00

Jawaharlal Institute of P.G. Medical Education & Research

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 freezer	1	100000.00
2.	Centrifuge	1	450000.00
3.	Sample Label printer and reader	1	20000.00
4.	Pipettes	2	50000.00
5.	Laptop for data entry in OPD	1	50000.00
		Total	675000.00

Prof. Amita Aggarwal
Head
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SGPGIMS, Lucknow-226 014 (U.P.)

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SGPGIMS,Lucknow

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ristian Medical College, Vellore

No.	Name of Equipment	No.	Cost(Rs.)
1.	- 20 degree freezer	1	100000.00
2.	Pippete set	1	55000.00
3.	computer	1	50000.00
4.	sample label printer	1	20000.00
5.	centrifuge	1	450000.00
6.	-80 degree freezer	1	800000.00
		Total	1475000.00

Postgraduate Instutite of Medical Education and Research

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 freezer	1	100000.00
2.	Centrifuge	1	450000.00
3.	Sample Label printer and reader	1	20000.00
4.	Pipettes	1	55000.00
5.	Laptop for data entry in OPD	1	50000.00
		Total	675000.00

INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freer	1	100000.00
2.	centrifuge	1	450000.00
3.	sample label printer and reader	1	20000.00
4.	pipetteset	1	55000.00
5	Laptop for data entry in OPD	1	50000.00
		Total	675000.00

Nizam's Institute of Medical Sciences

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freezer	1	100000.00
2.	centrifuge	1	450000.00

Prof. Amita Aggarwal
Head
Clinical Immunology
SGPGIMS, Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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	sample label printer and reader	1	20000.00
	Pipette set	1	55000.00
	laptop	1	50000.00
		Total	675000.00

All India Institute of Medical sciences,New Delhi

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 degree freezer	1	100000.00
2.	centrifuge	1	450000.00
3.	sample label printer	1	20000.00
4.	pipette set	1	55000.00
5.	computer	1	50000.00
		Total	675000.00

INSTITUTE OF LIFE SCIENCES, Bhubaneswar

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-80 degree freezer	1	800000.00
		Total	800000.00

St John's Medical College, St John's National Academy of Health Sciences

SNo.	Name of Equipment	No.	Cost(Rs.)
1.	-20 freezer	1	100000.00
2.	centrifuge	1	450000.00
3.	Sample Label printer and reader	1	20000.00
4.	Pipettes	1	55000.00
5.	Laptop for data entry in OPD	1	50000.00
		Total	675000.00

Sandhya R. Shenoy
(Dr. Sandhya R. Shenoy)
Scientist 'D'

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Annexure -II

...ails of the manpower sanctioned for the implemention of the project titled "Multi-institutional ...etwork Program on Systemic lupus Erythematosus ...nderstanding the diversity of SLE":

Head	No. of Position	Year I	Year II	Year III	Year IV	Year V	Total (Rs.)
1. All India Institute of Medical sciences,New Delhi							
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00
2. Christian Medical College, Vellore							
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Lab Technician Lab Technician	2	432000.00	432000.00	432000.00			1296000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other1-SRO	1	729276.00	729276.00	729276.00			2187828.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9993828.00
3. INSTITUTE OF LIFE SCIENCES, Bhubaneswar							
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1	312000.00					312000.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1		343200.00				343200.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1			377520.00			377520.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1				415272.00		415272.00
Data Entry Operator Data Entry Operator @ 26000/- + 10% increment per year	1					456720.00	456720.00
Lab Assistant Lab Assistant	2	408000.00	408000.00	408000.00	408000.00	408000.00	2040000.00
Total(Rs.)		720000.00	751200.00	785520.00	823272.00	864720.00	3944712.00

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Executive Registrar
SGPGIMS,Lucknow

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4. INSTITUTE OF POST GRADUATE MEDICAL EDUCATION AND RESEARCH

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

5. Jawaharlal Institute of P.G. Medical Education & Research

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Lab Technician Lab Technician	2	432000.00	432000.00	432000.00			1296000.00
Other1 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Other1 SRO	1	729276.00	729276.00	729276.00			2187828.00
Other2 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Total(Rs.)		2463276.00	2463276.00	2463276.00	1302000.00	1302000.00	9993828.00

6. Nizam's Institute of Medical Sciences

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

7. Postgraduate Instutite of Medical Education and Research

Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

9. Sanjay Gandhi Post Graduate Institute of Medical Sciences

Data Manager DATA MANAGER	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Lab Technician Lab Technician	1	216000.00	216000.00	216000.00	216000.00	216000.00	1080000.00
Lab Technician Lab Technician (3 years Sub project)	2	432000.00	432000.00	432000.00			1296000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other1 Senior Technical Assistant	1	384000.00	384000.00	384000.00	384000.00	384000.00	1920000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00

Prof. Amita Aggarwal
Dermatology
SGPGIMS

Lt Col Varun Bajpai VSM
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SGPGIMS,Lucknow

Other2 SRO	1	729276.00	729276.00	729276.00			2187828.00
Total(Rs.)		3435276.00	3435276.00	3435276.00	2274000.00	2274000.00	14853828.00
10. St John's Medical College, St John's National Academy of Health Sciences							
Lab Assistant Lab Assistant	1	210000.00	210000.00	210000.00	210000.00	210000.00	1050000.00
Other1 Junior Medical Officer	1	720000.00	720000.00	720000.00	720000.00	720000.00	3600000.00
Other2 Nurse	1	372000.00	372000.00	372000.00	372000.00	372000.00	1860000.00
Total(Rs.)		1302000.00	1302000.00	1302000.00	1302000.00	1302000.00	6510000.00

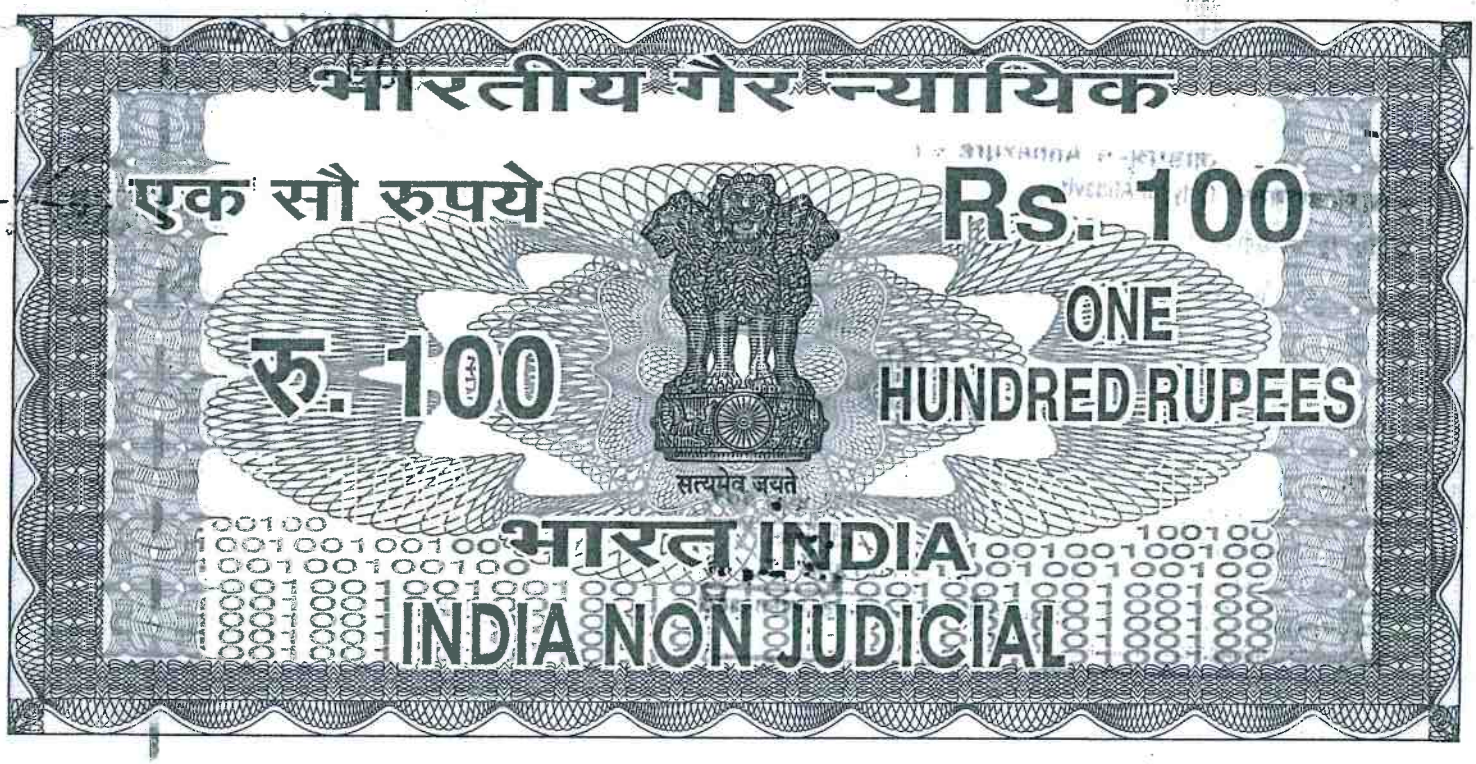
Emoluments detail of research personal(s) mentioned in table(s) of Annexure-II shall be applicable only if candidate(s) met educational qualification and eligibility criteria as per DST OM No.SR/S9/Z-09/2012 dated 21.10.2014.

Prof. Amita Aggarwal
Head
Clinical Immunology & Rheumatology
SGPGIMS, Lucknow-226 014 (U.P.)

(Dr. Sandhya R. Shenoy)
Scientist 'E'

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow



महाराष्ट्र MAHARASHTRA ◑ 2018 ◑ TE 426392

प्रधान मुद्रांक कार्यालय, मुंबई
प.मू.वि.क्र. ८०००००३
- 3 APR 2018
सक्षम अधिकारी

श्री. प्र. ना. चिंचघरे

AGREEMENT
between

WBIO
Wockhardt BioAG
Grafenauweg 6, Ch-6300 Zug, Switzerland

And

WL
Wockhardt Limited
Registered office at D-4, MIDC, Chikalthana, Aurangabad-431006
and
Global headquarters at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051

And

INVESTIGATOR
Dr. Brijesh Singh
Dept of General Surgery, Sanjay Gandhi Post Graduate Institute of Medical **Sciences**,Lucknow 226014
Uttarpradesh

And

INSTITUTION
Sanjay Gandhi Post Graduate Institute of Medical **Sciences**,Lucknow 226014
Uttarpradesh

(WBIO, WL, the INSTITUTION, the INVESTIGATOR jointly referred to as "the Parties")

The Parties are pleased that the discussions between representatives of the WBIO on one hand and the INVESTIGATOR on the other hand, have resulted in the INVESTIGATOR's agreement to participate in the collaborative clinical research study: W-771/2349-301

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

Preamble:

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

This Clinical Trial Agreement (hereinafter referred to as "Agreement") is entered into on this day **28 Jan 2018 AMONG**

Wockhardt Limited, a company originally incorporated in India having its registered office at D-4, MIDC, Chikalthana, Aurangabad- 431006, and Global headquarters at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051, (herein after referred to as ("WL")

AND

WOCKHARDT BIO AG, whose registered address is Grafenauweg 6, 6300 Zug, Switzerland hereinafter referred to as WBIO

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institute established under Sanjay Gandhi Post Graduate Institute of Medical Sciences Act, **at Raebareli Road, Lucknow-226014, Uttar Pradesh,** India, through its **"Director/Director's Nominee** Prof RAKESH KAPOOR .[herein referred to as "Institute"] of the Third part.

AND

Dr.BRIJESH SINGH a **GENERAL AND LAPARASCOPIC SURGEON , Department of GENERAL SURGERY , Sanjay Gandhi Post Graduate institute of Medical Sciences** [hereinafter referred to as **"Principal Investigator"**] of the Fourth Part.

WHEREAS The Sponsor, Institute and, Principal Investigator are willing to jointly carry out the Study Number: _____

Entitled……"……
……" **[Hereafter referred to as "Study"]** described in StudyProtocol;

AND WHEREAS WBIO is desirous of engaging the said Principal Investigator and Institute for carrying out the Study through **Site Management Organization (SMO) [if needed]**

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

1.0 Statement of work

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

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

1.3 Study Timelines: Study Timelines for the purpose of this Agreement will be as provided in the Protocol.

2.0 Obligations and Responsibilities of the Principal Investigator

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

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

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

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

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

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

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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

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

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

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

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

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

2.14 The Principal Investigator will be responsible for obtaining IEC and WBIO permission for storage of blood or tissue samples for future use.

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

3.0 Obligation and Responsibilities of the Institute:

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

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

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

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

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

3.6 Necessary infrastructure support to PI.

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Executive Registrar
SGPGIMS,Lucknow

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

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

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

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

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

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

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

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

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

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

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

3.18 Review of final report.

3.19 Approval of storage of blood or tissues for use in future studies.

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

3.21 Institutional clearance for sample to be sent abroad for non-pharmacokinetic studies.

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

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

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

3.25 Audited statement of utilization of Funds.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.0 Obligation and Responsibilities of the Sponsor

4.1 To provide investigator's brochure, Protocol, Case Report Form (CRF) draft Clinical Trial Agreement (CTA), Insurance policy from an Indian Insurance company and regulatory approvals.

4.2 To provide adequate supplies of trial drug, comparator and /or placebo prepared under proper quality control.

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

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4.5 Not to send samples for Pharmacogenetic study abroad.

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

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

4.9 To define and follow procedure for premature termination.

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

5.0

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

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

(b) Violation of the approved Protocol;

(c) Scientific misconduct or negligence by the Sponsor or his representative or

Contract research organization (CRO) or Principal Investigator, Co-investigator or any member of his/her team

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

(e) Use of placebo in a placebo-controlled Clinical Trial;

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Executive Registrar
SGPGIMS,Lucknow

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

(g) For injury to a child in utero because of the participation of parent in Clinical Trial;

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

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

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

6.0 Undertaking and Representation of Principal Investigator

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

7.0 Undertaking and Representation of Institute

Institute hereby represents that:-

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

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

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

8.0 Undertaking and Representation of Sponsor

Sponsor hereby understands and represents that:-

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

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Executive Registrar
SGPGIMS,Lucknow

9.0 Administration

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

9.2 The following Study plan will apply to the Study:

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

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

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

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

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

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

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

10.0 Trial Drug; Materials Transfer; Records Retention; Inspection

10.1 Trial drug:

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

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

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

(iv) Institute and Principal Investigator will ensure that empty and partially used Trial Drug container and any Trial Drug remaining at the Trial close-out visit at the Trial Site or upon early termination of this Agreement are disposed of or returned to Sponsor in accordance with the Protocol.

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

(vi) Unless required by the Protocol, Institute will not modify the Trial Drug or its container. If the Institute policy requires any modification to the Trial Drug container, such modification must be approved in advance in writing by Sponsor. Principal Investigator solely for purposes of the Trial and only as specified in the Protocol and this Agreement. They may, however, be retained in the Institute for use in a future study to be approved by Institutional Ethics Committee (IEC).

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

11.0 Representation and Warranties

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

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

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12.0 Confidentiality

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

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

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

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

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

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

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

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

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

13.0 Return of Confidential Information

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

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

14.0 Trial Results and Inventions

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

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

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

Goods and Service Tax (GST)

The Institution, Investigator and SMO will issue GST invoice as per time specified under Section 31 (5) of the CGST Act, 2017, clearly mentioning its GSTIN and containing other details required under GST laws to WL for the services rendered. Further, WL will make the payment after deducting applicable taxes and records of such taxes deducted at sources will be made available to them by WL.

i) Obligation of Institution, Investigator and SMO

The Institution, Investigator and SMO shall comply with all applicable laws including GST and other indirect taxes, safety and health laws

ii) Compliance

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The Institution, Investigator and SMO confirm that they are duly registered under GST laws, labor laws and Professional Tax Act. Further, the provisions of all applicable laws captioned above are also applicable to employees employed by them.

iii) Anti Profiteering/ Passing Benefits

The Institution, Investigator and SMO shall pass on to WL all the benefits of either reduction in tax rates, exemptions, concessions, rebate, set off, credits, etc. or introduction of new tax rates exemptions, concessions, rebate, set off, credits etc. pertaining to all taxes, duties, imposts, fees and levies in respect of the supplies of goods or performance of obligations including reduction in procurement price, under the Agreement. This would specifically include reduction of tax rates as a result of statutory changes or judicial rulings and reduction in price where the Institution, Investigator and SMO are benefited due to reduction in taxes.

iv) Indemnity

The Institution, Investigator and SMO hereby represent that they are registered under GST and shall be compliant of GST provisions including issuance of proper tax invoice to enable WL avail entire input tax credit on timely basis. The Institution, Investigator and SMO further represent that they shall timely deposit GST amount due to the Government and file periodic statements / returns as per the provisions of GST Law and comply with all the requirements under GST law, to ensure timely receipt of input tax credit benefit of the taxes charged by them on their outward supplies to WL. In case of non-compliance of the GST provisions by the Institution, Investigator and SMO resulting in blockage or denial of any input tax credit benefit to WL, the Institution, Investigator and SMO shall hereby indemnify WL for input tax credits so denied along with interest, penalty and other costs.

v) Transition Clause

The Institution, Investigator and SMO should support WL on various aspects to comply with the transition provisions under GST. The Institution, Investigator and SMO should also take best of efforts to assist WL in identifying the tax benefits or refunds as the case may be, that may accrue on stocks, credits, taxes, etc on the GST Implementation appointed date and pass-on the same to WL.

vi) Change in law

Any statutory variation in duties, levies or taxes if applicable and specified in this Agreement, or the introduction of new duties, levies or taxes from the date of submission of bid/ quotation till the scheduled date for completion of work contemplated under the Agreement which include defect liability period if any, shall be communicated to WL prior to its levy. Institution, Investigator and SMO will not levy any such additional duties, levies or taxes without prior approval of WL. Further, any statutory variation in taxes will be levied after mutual agreement of all the parties.

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16.0 Use of other parties' names

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

17.0 No joint venture etc.

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

18.0 Insurance and Indemnification

Insurance:

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

Indemnification:

Sponsor shall, at all times to come, indemnify the Principal Investigator and Institute for any direct damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institute arising directly or indirectly out of the performance of the Study pursuant to the Protocol and SOP only to the extent such claims are solely attributable to Sponsor.

Principal Investigator and Institute shall be responsible for all direct damages, losses and liabilities including reasonable attorney fees arising out of the negligence or intentional misconduct of its affiliates, employees, agents and contract personnel while providing services under this Agreement or claims arising from breach of any applicable laws or breach of any representations and warranties as mentioned herein the Agreement.

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19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

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

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

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

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

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

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

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

20.1 Unless earlier terminated in accordance with the provisions of this Agreement, the term of this Agreement shall commence on the Effective Date and shall terminate 36 months after the Effective Date. The Date of execution of this Agreement shall be the effective Date. The term of this Agreement may be extended by consent of all parties to this Agreement.

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

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

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

21.0 Effect of termination

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

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

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

22.0 Recordkeeping

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

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

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

23.0 Publication

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

24.0 Miscellaneous

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

For providing insurance to Clinical Trial Subjects in case of injuries or death, The parties to this Agreement have tied up with insurance company (The.....Raheja QBE General Insurance Co. Ltd..) which covers per patient amount (..2,00,000 INR....per patient limit). This insurance is valid from the period from .....6/1/18.....) to (.....5/1/19.....). This insurance shall be extended from time to time till the expiry of Agreement.

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

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

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

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

25.0 Governing Law

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

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26.0 Jurisdiction

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

27.0 Arbitration

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

28.0 Amendment

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

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Exhibit A
Payment Schedule for W-771/2349-301

(A)Per patient PI fee

Milestones	PI Fee in INR
Screening (Visit 1)	5,600
Randomization and Hospitalization (visit 2)	5,500
Early on Therapy (Visit 3)	5,000
Visit 4 (Late on Therapy)	5,000
PK Sampling (Levonadifloxacin IV and Oral arm)	3,000
Visit 5 (End of Study)	5,500
Visit 6 (Test of Cure)	5,500
All-cause mortality (Telephonic)	900
Per Patient Cost	36,000.00
25% Institutional Overhead Cost	9,000.00
Total Per Patient Cost	**45,000.00**

(B) Patient related cost: Patient travel reimbursement*
***INR 500 X 5 visits = 2,500/- per patient**

Total Site budget (A+B)

Description	Amount (INR)	No. of subjects	Total cost (INR)
Total Per patient cost	45,000.00	15.00	6,75,000.00
CRC Payments	10,000.00	12 months	1,20,000.00
Patient travel*	2,500.00	15.00	37,500.00
Start-Up Cost	15,000.00	-	15,000.00
Grand total			**847,500.00**

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- *The amount of INR 500 has been considered for calculation purpose. The travel reimbursements up to INR 1000 will be made as per actuals.
- #Budget is based on number of patients enrolled and visits completed. Budget can increase or decrease based on total number of subjects enrolled in the study.
- **Start-Up cost will be a one-time payment made to the Site.
- Archival cost for the Site will be not be applicable as documents will be archived by the WBIO.
- Exhibit A will be applicable for Site payments only after Site Initiation Visit.
- All payments will be done only after the completion of data entry for the specific visit for each subject.
- Screen failure cost will be INR 1500 provided screening procedures are conducted. Sites will be paid in the ratio of 1:4 (screen failure: randomized) for screen failure subjects.
- TDS will be deducted as per government of India regulations.
- Budget shared in Exhibit A is exclusive of Service taxes that may be applicable for services provided.
- Local laboratory charges and hospitalization charges would be paid as per actual invoices submitted in original which could vary from case to case basis.
- Payment for any additional visits conducted would be based on original invoices submitted by the Principal Investigator.
- The last payment to the Site would be released only after the data for this study has been locked.
- Sponsor will provide camera and laptop to the Investigator for use during the trial duration. If the Investigator randomizes 20 subjects with Gram-positive infection (as confirmed by the culture report from the Central Laboratory) in the stipulated trial duration as specified by the Sponsor, the camera and laptop will not be returned to the sponsor and will remain with the Investigator.
- In case the Investigator fails to enrol 20 subjects as specified above, the laptop and camera will be returned to the sponsor on completion of the trial without any further delay.
- .In addition to above, Ethics committee fees on actual basis would be borne by Wockhardt.
- Payment will be processed within 45 days from receipt of original invoice at Wockhard

- PI fee to be drawn in favour of:

Payee name	Director, SGPGIMS RESEARCH SCHEME ACCOUNT , LUCKNOW
PAN	AAAJS3913N
GSTN	09AAAJS3913N2ZN
Name of the Bank & Branch	State Bank of India, SGPGIMS Branch Lucknow
Bank account number	10095237491
IFSC Code	SBIN007789

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IN WITNESS WHEREOF THE PARTIES HERETO HAVE EXECUTED THE AGREEMENT AS OF THE DAY AND YEAR FIRST ABOVE WRITTEN.

For WBIO: Wockhardt BioAG Grafenauweg 6, Ch-6300 Zug, Switzerland **Signature:** _____ **Name:** Mr. Ajay Sahni **Role:** Director **Date:**	**For WL:** Wockhardt Limited Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai – 400 051 **Signature:** Ashima Bhatia **Name:** Dr Ashima Bhatia **Role:** Sr. V. P., Global Clinical Development **Date:**
INVESTIGATOR Department of GENERAL SURGERY , Sanjay Gandhi Post Graduate institute of Medical Sciences, Lucknow, Uttar Pradesh 226014 **Signature:** _____ **Name:** Dr.Brijesh Singh **Role:** Investigator **Date:** 02 May 2018	**For the INSTITUTION:** Sanjay Gandhi Post Graduate institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh 226014 DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA **Signature:** _____ **Name:** Prof Rakesh Kapoor **Role:** DIRECTOR, SGPGIMS, LKO **Date:**

Dr. BRIJESH SINGH
M.B.B.S.,M.S. (Surgery)
Gen. & Laparoscopic Surgeon
S.G.P.G.I.M.S., Lucknow
Regn. No. - 42177

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SGPGIMS,Lucknow

महाराष्ट्र MAHARASHTRA ◐ 2017 ◐ SR 500670

प्रधान मुद्रांक कार्यालय, मुंबई
प.मू.वि.क्र. ८०००००८
22 NOV 2017
सक्षम अधिकारी
श्री. दि क. गवई

REGISTRY AGREEMENT

This **REGISTRY AGREEMENT** is made and entered into as of the 12th Day of December 2017 ("the Effective Date") by and between

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED, having its registered office at Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072, represented by Dr. Chirag Trivedi duly authorized for the purposes hereof ("the Sponsor")

AND

DR. RAJ KUMAR SHARMA having his address at Sanjay Gandhi Postgraduate Institute of medical Sciences, Raebareli Road, Lucknow-226014, UP State, India ("the Investigator"),

AND

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS) having its Raebareli Road, Lucknow-226014, UP State, India, represented by **PROF. RAKESH KAPOOR,** Director, duly authorised for the purposes hereof, ("the Institution"),

The Sponsor, Investigator and the Institution hereinafter referred to individually as the "Party" and collectively as the "Parties".

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PREAMBLE

WHEREAS, Sponsor wishes to perform A Registry to describe clinical experience with Thymoglobuline® used as induction immunosuppression in patients undergoing renal transplantation ("the Study") in accordance with Amended Protocol 01 bearing Study name: RISE Study, as amended from time to time during the term of this Agreement ("Term"), which is attached hereto as Appendix 1 ("the Protocol");

AND WHEREAS, the Investigator has reviewed the Protocol, desires to participate in the Study and assures that he has the necessary personnel, infrastructure and technical means to perform the Study;

AND WHEREAS, SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES (SGPGIMS) is a Government Hospital providing highest caliber faculty, high class education, research and patient care;

WHEREAS, the INVESTIGATOR is an acknowledged Nephrologist and is presently working in SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES College and Hospital; and

AND WHEREAS, SGPGIMS Research Scheme Account belong to the INSTITUTION for providing the services of managing the funds of the INSTITUTION;

AND WHEREAS, Institution is equipped to undertake the Study and Institution and Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

NOW, THEREFORE, the Parties agree to set out in this Agreement the terms and conditions governing their collaboration with respect to the performance of the Study.

1. OBLIGATIONS OF INVESTIGATOR

1.1 Conduct of the Study: The Study shall be performed in compliance with (i) this Agreement (ii) the Protocol, (iii) all applicable laws, regulations and directives, (iv) generally accepted practices relating to non-interventional studies and to investigators conducting such studies, and (v) guidelines, procedures and any reasonable instructions provided by Sponsor. Investigator shall comply with all the provisions of the Protocol, as may be amended from time to time during the Term. Investigator shall comply with the timelines in ***Appendix 2***.

1.2 Investigator and Study Site: The Study will be carried out by the Investigator at Sanjay Gandhi Postgraduate Institute of Medical Sciences (SGPGIMS), Raebareli Road, Lucknow-226014, UP State, India (the "Study Site"). The Investigator shall obtain and maintain, during the Term, all necessary authorizations for the performance of the Study at the Study Site, under due observance and compliance with all applicable laws.

1.3 Recruitment of Patients: The Investigator shall be responsible for the recruitment of Patients for the Study (the "Patients"). The number of Patients to be recruited is estimated to be 20. The Investigator shall inform Patients in a language that could be understood by the Patients (i) the purpose of the Study; (ii) Patients' personal data will be used for the Study; and (iii) any other relevant aspect of the Study. The Investigator shall obtain consent from each Patient, or their respective legal representative, before the Patient's participation in the Study, using the informed consent form provided by Sponsor. Investigator shall ensure Patients' consent is given without any undue influence or coercion from any person involved in the Study.

1.4 Data collection: The Investigator shall use the Case Report Forms provided by Sponsor (the "CRF") for the data collection and will ensure that the contents of the CRF are accurate and precise, with reference to source document. If Sponsor requests Investigator to submit electronic CRF, Sponsor will provide Investigator with a computer and internet connection to be used solely for the completion and submission of the electronic CRF, and the necessary training. The Investigator shall take all reasonable precautions to avoid any damage or loss of Sponsor's computer, which will be returned to Sponsor promptly upon completion of the Study. The Investigator shall (i) report on the progress of the Study on such regular basis as requested by Sponsor; (ii) promptly submit the completed CRF to the Sponsor; and (iii) respond promptly to any query from the Sponsor on any CRF.

1.5 Sub-Investigator: The Investigator shall not delegate the performance of the Study (in whole or in part) to any third party except with the prior written consent of Sponsor. Any approved sub-

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investigator ("Sub-investigator") shall, at all time, work under the supervision and responsibility of the Investigator. Notwithstanding Sponsor's consent, the Investigator shall continue to be responsible for the proper performance of any activities delegated to Sub-Investigator and for the performance of his/her obligations under this Agreement.

1.6 Pharmacovigilance: The Investigator shall comply with all pharmacovigilance reporting requirements applicable to the Study in accordance with all applicable laws and regulations and Sponsor' procedures on pharmacovigilance reporting communicated by Sponsor to Investigator before or after the Effective Date, as may be amended from time to time during the Term.

1.7 Declaration to relevant authorities: The Investigator shall be responsible for the declaration(s) to all relevant authorities (including without limitation any medical association or health authority) required under applicable laws and regulations in relation to the payments received by the Investigator under this Agreement.

"Affiliates" shall mean, any corporation, partnership or other entity controlled by, controlling or under common control with sanofi-aventis (Trade Register : 395 030 844 RCS PARIS) and with the Sponsor, with "control" meaning the direct or indirect ownership of more than 50% of the capital stock or the voting rights in such corporation, partnership or other entity or the power to direct or cause the direction of the management or policies of such corporation, partnership or other entity through the ownership of securities or interests, by contract or otherwise.

1.8 Legal standing: The Investigator represents and warrants that (i) he/she has the legal right, authority and power to enter into and discharge his/her obligations under this Agreement and that (ii) he/she is not (and will ensure that any Sub-Investigator is not), disqualified or debarred from participating in the Study by any regulatory authority or under investigation that will lead to such consequence, and or otherwise prohibited or restricted in any way under any contractual obligation, and is fully and will remain fully authorized, qualified and free to perform the Study during the Term.

2. OBLIGATIONS OF SPONSOR

2.1 Items supplied: Sponsor shall provide the Investigator with all necessary information, documents and materials as it deems necessary for the performance of the Study.

2.2 Financial compensation: In consideration for the due and proper performance of the Study in accordance with the terms of this Agreement, Sponsor shall pay the Investigator the financial compensation set forth in the Financial Terms and Conditions attached in ***Appendix 2***.

3. OWNERSHIP AND USE OF DATA, RESULTS AND DOCUMENTS

3.1 All intellectual property rights owned by Sponsor and/or its Affiliates (as defined hereinafter) related to the Product and/or to any information provided by Sponsor and/or its Affiliates to Investigator for the purpose of this Agreement is the exclusive property of Sponsor and/or its Affiliates.

3.2 Nothing in this Agreement shall be construed as granting to the Investigator and/or any Sub-Investigator, any right, interest or licence to use any of such intellectual property rights, including with respect to any developments, improvements or variations thereof.

3.3 All the results, data, materials, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate, full and exclusive property of the Sponsor and or its Affiliates. For this purpose, Investigator presently assigns, and undertakes to procure the assignment by any Sub-Investigator to the Sponsor and or its Affiliates (or its designee) any and all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all materials created in relation to the Study. Investigator acknowledges that the compensation for any such assignment is included in the Financial Compensation paid by Sponsor under this Agreement.

4. CONFIDENTIALITY, RESTRICTED USE AND PUBLICATION

4.1 Confidentiality and Restricted Use: The Investigator agrees that during the Term and for a further period of five (5) years thereafter, he/she shall, and shall procure that any Sub-Investigator shall, hold

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SGPGIMS,Lucknow

and maintain in strict confidence all proprietary and confidential information of Sponsor, including without limitation financial, scientific, corporate, industrial, product and business information disclosed by Sponsor and or its Affiliates and any and all results, information, data and documents generated, produced or obtained in relation to this Agreement) (the "Confidential Information") and not use the Confidential Information for any purpose other than the performance of this Agreement. However, no provision of this Agreement shall be construed so as to preclude use or disclosure of information:

a) which was already known to the Investigator before Sponsor's disclosure, as evidenced by his/her written records;
b) which is disclosed in good faith to the Investigator after the Effective Date by a third party lawfully in possession of such information and not under an obligation of nondisclosure or restricted use towards the Sponsor;
c) which is or becomes public knowledge through no fault of the Investigator;
d) which is disclosed by the Investigator as a result of applicable laws and regulations provided Sponsor is notified before such disclosure to enable Sponsor to seek protective measures, if it deems appropriate, unless otherwise prohibited by law, in which case Sponsor will be notified as soon as reasonably practicable; or
e) which is developed by Investigator independently from the Confidential Information.

4.2 Publication: Investigator shall not make any publication or communication relating to the Study and or the results of the Study, without the prior written approval of Sponsor.

5. PERSONAL DATA PROTECTION

5.1 The Patient data and specific data regarding the Investigator and Collaborators which may be collected by the Sponsor and included in the Sponsor's databases, shall be treated by both Parties in compliance with all applicable laws and regulations. These data may be transferred by the Sponsor or its representative to Health Authorities or to a Sponsor's representative located in a country where there is no personal data protection law, or where the level of protection imposed by local law is less stringent than requirements of the European Union under which Sanofi is governed.

5.2 As data controller, when processing or archiving data pertaining to the Investigator, the Collaborators and/or the Patients, the Sponsor shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

5.3 The Investigator, the Collaborators and/or the Patients have the right to access and, where appropriate, to request the rectification and/or deletion of their personal data by sending a written notice to the address of the Sponsor, to the attention of the Data Privacy/Compliance officer Dr. Chirag Trivedi (e-mail: chirag.trivedi@sanofi.com). Deletion of data is possible only for justifiable reason and if it is not required by law to keep it.

6. AUDIT AND INSPECTIONS

The Investigator shall keep accurate, complete and up-to-date records of all activities under this Agreement (the "Record"). During the term of this Agreement and for a period of five (5) years thereafter, Investigator shall permit the Sponsor' auditors, and/or any regulatory authority to audit and inspect the Record and shall comply with the provisions on audit set forth in the Protocol.

7. DEBARMENT AND SENTENCING FOR MALPRACTICE

7.1 The Investigator represents and warrants that neither he/she nor any Collaborators involved in conducting the Study, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct including without limitation United States 21 U.S.C. §335a and 21 CFR §312.70.

7.2 The INVESTIGATOR shall immediately notify the Sponsor should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the twelve (12) months following the expiration or termination of the Contract.

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8. ANTI-BRIBERY

8.1 The Investigator represents and warrants that he/she nor any of his/her personnel are officials, agents, representatives or employees of any government or political party or any international public organization where they may be in a position of official government authority able to use that position to help the Sponsor obtain or maintain business or obtain a business advantage.

8.2 The Investigator further represents and warrants that he/she has not made and agrees that he/she shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by "Anti-Bribery Provisions").

9. TERM AND TERMINATION

9.1 Term: This Agreement shall be effective on the Effective Date which shall be 12th December 2017 and shall remain in force until acceptance by Sponsor of all data generated from the Study and resolution of all queries arising there under unless earlier terminated under *Section 9.2.*

9.2 Early termination: Notwithstanding any other provisions of this Agreement, the Sponsor may, by notice to Investigator, terminate this Agreement at any time without any liability or compensation to the Investigator, which termination will take effect on the date specified in the notice. Either Party may terminate this Agreement, if the other Party breaches any terms of this Agreement and fail to rectify the breach within ten (10) days from the date of the notice from the non-defaulting Party.

9.3 Consequences of termination: Termination of this Agreement shall not affect any right which has accrued before the termination. Upon receipt of Sponsor's notice of termination, Investigator shall procure the Investigator and Sub-Investigator to cease all activities related to the Study and shall promptly return to Sponsor all data, results, reports or other materials disclosed by Sponsor and or its Affiliates for the performance of the Study and all data, results, reports or other materials arising out of, or conceived during the Study. Sponsor shall settle any amount due to the Institution within forty-five (45) days from the effective date of termination. The provisions of Articles 3, 4, and 6, and Sections 1.4, 1.6, 1.7, 9.3 and 10.6 shall survive termination or expiration of this Agreement.

10. GENERAL

10.1 Entire agreement : This Agreement and its appendices constitute the entire agreement between the Parties with regard to Patient matter and supersedes all previous agreement and or arrangement, oral or in writing. In case of any conflict between any provision of this Agreement and the Protocol, the terms and conditions of (a) the Protocol shall prevail with respect to scientific and medical matters; and (b) this Agreement shall prevail with respect to all other matters; to the extent of such inconsistency.

10.2 Independent Contractor: The relationship of the Parties under this Agreement is that of an independent contractor and no Party shall be considered an agent, employee or joint venture partner of the other party and shall have no right to bind the other party in any manner whatsoever.

10.3 Severability: If any provision of this Agreement shall be held to be invalid, illegal or unenforceable, such provision shall be deemed severed from this Agreement without affecting the validity, legality or enforceability of the remaining provisions.

10.4 Notice: Any notice to be given under this Agreement shall be in writing in English and shall be sent personally to the address provided in this Agreement or as may be notified in writing by one party to the other from time to time.

10.5 Assignment: Investigator shall not assign any of his/her rights and or obligations under this Agreement except with the prior written consent of Sponsor. Sponsor may assign this Agreement to any entity.

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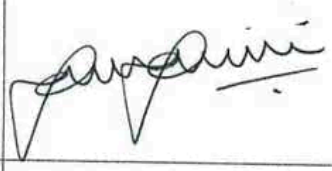
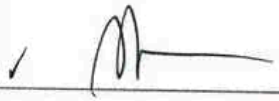
Executive Registrar
SGPGIMS,Lucknow

10.6 Governing law / Dispute resolution: The validity, construction and performance of this Agreement will be governed by and construed for all purposes in accordance with the laws of India. Any disputes arising out of this Agreement shall firstly be resolved by the Parties amicably, failing agreement the Parties shall refer the dispute to the competent courts of Mumbai.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by them and/or on their behalf by their duly authorised representatives.

SANOFI-SYNTHELABO (INDIA) PRIVATE LIMITED		**SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES**	
[Signature]		[Signature]	
[Name]	DR. CHIRAG TRIVEDI	[Name]	PROF. RAKESH KAPOOR
[Title]	Clinical Study Unit-Director	[Title]	Director

The INVESTIGATOR	
[Signature]	
[Name]	DR. RAJ KUMAR SHARMA
[Title]	Investigator

Prof. R. K. Sharma
Senior Professor & Head
Deptt. of Nephorology &
Former Director & Dean
S.G.P.G.I.M.S., Lucknow

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Executive Registrar
SGPGIMS,Lucknow

APPENDIX 2

1. FINANCIAL TERMS AND CONDITIONS

- For:
  i. Investigator fees/ Co-investigator fees for all study related activities
  ii. Site coordinator fees for all study related activities

- Financial Compensation to the Investigator, per patient per completed CRF: Rs.25,000/- (Rupees Twenty Five Thousand only).

  Such amount is divided as follows:

Milestone	Investigator Payment per Patient (In INR)	Site Coordinator's Fees Per patient (In INR)	Total Amt (In INR)
Visit 1	4800	1200	6000
Visit 2	2600	650	3250
Visit 3	3000	750	3750
Visit 4	4000	1000	5000
Visit 5	2600	650	3250
Visit 6	3000	750	3750
TOTAL	**20000**	**5000**	**25000**

- The last payment will be done once all the Data is cleaned for database Lock.
- A DCF shall be considered "completed" when the DCF is fully completed and delivered to the Sponsor and any queries raised there-under by Sponsor are resolved.
- Total maximum Financial Compensation: **Rs.25,000/-** (Rupees Twenty Five Thousand only) for per patients recruited.
- 25% Institutional Overhead will be paid additionally.
- Note that, if coordinator is to be provided by Sanofi, the Study Coordinator Fees will not be applicable for the site.
- All payments made as per this Agreement are subject to tax deduction at source.
- No other charge or cost shall be borne by the Sponsor for performance the Study by Investigator unless otherwise provided herein.
- All payments under this Agreement will be made within forty-five (45) from the date of receipt by Sponsor of the relevant invoice(s) made out in the name of Sanofi Synthelabo (India) Private Limited and shall be sent to:

  Sanofi House, CTS No. 117-B,
  L&T Business Park, Saki Vihar Road,
  Powai, Mumbai – 400072
  Attention: Accounts Department

- Any out of pocket expenses approved in advance by Sponsor before incurring shall be reimbursed to Investigator subject to the receipt by Sponsor of an itemized invoice and relevant supporting documents, upon request.

- The Investigator will be responsible for any taxes and or other contributions applicable to Financial Compensation.

2. TIMELINES APPLICABLE TO THE STUDY

- Study start date:31-Jul-2017
- Cut off date, i.e. latest date before which Investigator shall have delivered the completed DCFs and responded to all queries: Jul-2019 (as applicable)
- All payments shall be made in favour of **"Director, SGPGIMS Research Scheme Account"**
- PAN No : **- AAAJS3913N**

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SGPGIMS,Lucknow

ગુજરાત गुजरात GUJARAT BE 84835

અનુ.નં. ૨૪૩૨૬ તા. ૧૨/૦૩/૨૦૧૮ રૂ. ૧૦૦/-
અંકે રૂપિયા એકસો પુરાનો સ્ટેમ્પ જે સાંધણ સાથે
રૂ. --- તે આજરોજ
શ્રી મેરીલ લાઈફ સાયન્સ પ્રા. લી.
રે. ચલા તા. વાપી ને વેચાણ આપ્યો

લેનારની સહી

સ્ટેમ્પ વેન્ડરનું નામ અને સહી લા.નં. ૧/૨૦૦૨
હીરેન જે. પટેલ, રતનવાડી, પારડી.

CLINICAL TRIAL AGREEMENT

This Agreement (Hereinafter **"Agreement"**) is made and entered into on this 23rd day of Mar 2018 by and among:

Meril Life Sciences Pvt. Ltd.,with its principal office located at **Bilakhia House, Survey No.135/139, Muktanand Marg, Chala, Vapi-396191, Gujarat, India**represented by **Dr.Ashok Thakkar, Head-Clinical Research.** [hereinafter "the **SPONSOR" or "Meril**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns)] of the First Part.

And

Sanjay Gandhi Postgraduate Institute of Medical Sciences with his principal office located at **Rae Bareli Road, Lucknow-226014, Uttar Pradesh, India** (Hereinafter "**Institution** or **Centre** or **Study Site**") represented by **Prof. Rakesh Kapoor** having registered office at **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India** [Hereinafter referred to as the "**Institution**" (which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns) of the Second Part.

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Executive Registrar
SGPGIMS,Lucknow

MERIL LIFE SCIENCES PVT.

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અનુ.નં. ૨૪૩૩૦ તા. ૨૨/૦૬/૨૦૧૮ રૂ. ૧૦૦/-
અંકે રૂપિયા એકસો પુરાનો સ્ટેમ્પ જે સાંધણ સાથે
રૂ. --- તે આજરોજ
શ્રી મેરીલ લાઈફ સાયન્સ પ્રા. લી.
રે. ચલા તા. વાપી ને વેચાણ આપ્યો

લેનારની સહી

સ્ટેમ્પ વેન્ડરનું નામ અને સહી લા.નં. ૧/૨૦૦૨
હીરેન જે. પટેલ, રતનવાડી, પારડી.

And

Dr. Nirmal Gupta with his principal office located at **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India** (hereinafter "**Investigator**") of the Third Part.

(Hereinafter individually "**Party**" or collectively "**Parties**")

WHEREAS the Sponsor is a Medical Devices company involved in research, development, manufacture and sale of medical devices for use in humans;

WHEREAS the Institute is recognized for its expertise and interest in multispecialty and have the facilities, infrastructure and expertise to conduct the clinical study entitled:

Dafodil™ 1 - A prospective, multi-center, single-arm clinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.

(Hereinafter referred to as the "**Clinical Trial**" or "**Study**")

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SGPGIMS,Lucknow

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WHEREAS the Sponsor is desirous of conducting the Clinical Trial; and

NOW, THEREFORE, the Parties mutually agree as follows:

1 Definitions

1.1 "**Affiliate**" means a business entity which controls, is controlled by, or is under the common control with the Sponsor or the Institute. For the purpose of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

1.2 **"Agent(s)"** shall include, but shall not be limited to, any person (including the Investigator, any nurse or other health professional), any such person's principal employer in the event it is not the Centre and where such person is providing services to the Centre under a contract for services or otherwise, and/or any contracted third party providing services to the Centre under a contract for services or otherwise for the Study.

1.3 "**Agreement**" means this agreement, any signed amendment to it, as well as any documents which are signed consequently in relation to the study including Protocol, exhibits, schedules, or other addendums attached and/or referred to in this Agreement. In case of discrepancy between the numbered Clauses of this Agreement and any addition to this Agreement such as exhibit, Protocol, etc., the numbered Clausesof this Agreement shall prevail.

1.4 **"Confidential Information"** includes, but is not limited to,any knowledge and information pertaining to a Party's products and processes, ingredients, recipes, know-how, product plans , business plans, management reports, financial statements, internal memorandum, reports, patient information, inventions, designs, drawings, methods, processes, systems, technology, technical information relating to the disclosing Party's research, improvements, materials, data, trade secrets, marketing and regulatory strategy, customer lists, supplier lists, database and any other information pertaining to the business of a Party, which is not readily available to the public and does not constitute Results.

1.5 **"Effective Date"** means the date of the latest to occur of the following two conditions:
(i) Signature of this Agreement by the last Party to sign and
(ii) Approval of the Study by the competent ethics committee, institutional review board or equivalent body.

1.6 **"Fee"** shall mean the fee payable by the Sponsor for performing the Study.

1.7 **"ICH GCP"** shall meanE6(R1) guideline for Good Clinical Practise (GCP) issued by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use(ICH) in 1996 with applicable updates and amendments thereof.

1.8 **"Intellectual Property"** means any registered and unregistered intellectual property rights, such as, but not limited to, patents, designs, trademarks, trade names as well as copyrights, know-how, trade secrets and Confidential Information.

1.9 **"Lead Investigator"** means a physician chosen by Meril to provide scientific and medical supervision of the entire multi-centre Study.

1.10 **"Investigator"** means the person designated by the Centre and agreed upon by Meril who will take primary responsibility for the conduct of the Clinical Trial at the Centre, or any other person as may be agreed from time to time among the Parties as a replacement.

1.11 **"Protocol"** means the Study protocol no.MLS/MYV-1and all its amendments duly signed by the Investigator and the Sponsor.

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1.12 **"Research Subject"** means any person recruited to participate in the Study as a patient.

1.13 **"Results"** means the contents and results of all work and activities realized by the Centre including the Agents pursuant to this Agreement, limited to results, clinical data and medical conclusions related to the treatment of the Research Subjects with the Study Device in accordance with the Protocol.

1.14 **"Study Device"** means **Dafodil Pericardial Bioprosthesis** as defined in the Protocol.

1.15 **"Study"** means the **Dafodil™ 1 - A prospective, multi-center, single-armclinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.**

1.16 **"Study Deliverables"** shall mean the completed case report forms, any electronic databases required to be created under the Protocol, and any Study reports prepared by the Institute for the Sponsor (including, with respect to the data contained in such case report forms, electronic databases, and reports, only the compilation of data or any substantially similar compilation).

1.17 **"Trial Monitor"** mean one or more persons appointed by the Sponsor to monitor compliance of the Clinical Trial with ICH GCP and to conduct source data verification.

2 Scope of the Agreement

2.1 Meril is sponsoring the Study entitled: **Dafodil™ 1 - A prospective, multi-center, single-arm clinical study to evaluate safety and performance of the Dafodil Pericardial Bioprosthesis in patients who require replacement of their natural or prosthetic aortic or mitral valve.**

2.2 Name of the study: **Dafodil™ – 1**

2.3 Meril shall act as the Sponsor of the Study, and the Centre shall act as one of the clinical sites at which the Study will be conducted. The Investigator has agreed to serve at the Centre as Principal Investigator in connection with the conduct of the Study. The Institute shall notify the Sponsor in advance if the Investigator is unable or unwilling to continue the Study or if the Investigator's affiliation with the Institute ceases, whereupon the Centre shall identify a successor whose appointment shall be subject to Meril's written approval.

2.4 The Investigator shall perform the Study in conformance with; (i) ICH-GCP guidelines, (ii) ISO 14155,(iii) Medical Device Directives of Global Harmonization Task Force and European Union,(iv) the Protocol, (v) all reasonable written instructions of the Sponsor and (v) all applicable laws, rules and regulations (including, but not limited to the Indian Drug and Cosmetic Act 1940, the Indian Drug and Cosmetic Rules, 1945, any other guidance and notification issued by Central Drug Standard Control Organization (as may be amended from time to time).

2.5 The Institute/the Investigator shall seek approvals which may be required to carry out the Study, including approval from Ethics Committee (EC) or Institutional Review Board (IRB) or equivalent body as required by the applicable laws and applicable standards before commencing the Study.

2.6 The Institute shall comply with applicable laws in the collection, storage, and transfer of any clinical samples or other human materials taken from Study Subjects, and shall obtain any consents required from Study Subjects for the use of such materials in accordance with the Protocol. The Institute shall ensure that any use of such materials, whether in the Study or otherwise, shall be consistent with such consents and applicable laws.

2.7 The Institute shall ensure that the clinical samples or other human materials taken from Study Subjects are tested in accordance with the Protocol and at a laboratory designated by the Sponsor.

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2.8 The Sponsor shall comply with applicable laws in the performance of its activities relating to the Study, and shall obtain all approvals and consents required in connection with such activities. The Sponsor shall conduct such Study-related activities in a manner consistent with the Informed Consents and all other applicable consents.

2.9 The Investigator shall ensure the study participation is voluntary and the participants have the right to withdraw at any time during the conduct of the study.

2.10 The Sponsor may amend the Protocol at any time. Any such amendment shall be in writing and sent to the Institute, and will not take effect until approved by the appropriate approving bodies such approval shall not be unreasonably withheld, conditioned or delayed.

2.11 The Centre shall enrol approximately 10-15 eligible Research Subjects for participation in the Study.

2.12 The Centre shall collect Research Subject specific data as per the prescribed study schedule in the Protocol on Case Report Form (paper or electronic) (hereinafter CRF) for the entire duration of the study. The Centre shall provide appropriate resources and facilities to enable the Investigator to conduct the Study in a timely and professional manner and according to the terms of this Agreement. The Centre shall ensure that only individuals who are appropriately trained and qualified will assist the conduct of the Study. The Centre is responsible for ensuring that all personnel of the Centre and Agents participating in the Study comply with the terms and conditions of this Agreement.

2.13 The Centre and the Investigator shall use their best endeavours to ensure that the recruitment of the Research Subjects is achieved in accordance with the timelines as specified. The Study being a multi-centre clinical trial, the Sponsor may amend the number of Research Subjects to be recruited at the Centre. If in the reasonable opinion of the Sponsor, recruitment at the Centre is proceeding at a rate below that required meeting the timeline, the Sponsor may, by a notice to the Centre, cease further recruitment. On the other hand, if the recruitment at the Centre is proceeding at a rate above that required meeting the timeline, the Sponsor may, with agreement of the Centre increase the number of the Research Subjects to be recruited.

2.14 Subject to the Centre's and the Investigator's overriding obligations in relation to the Research Subjects and individual patient care, neither the Centre nor the Investigator shall, during the term of this Agreement, conduct any other trial which might hinder the Centre's or Investigator's ability to recruit and study the required cohort of the Research Subjects.

2.15 Meril shall provide training to the personnel designated by the Centre for conducting the Study related activities. In addition, Meril shall conduct follow-up monitoring as it deems appropriate.

2.16 The details of activities of the Study (notably detailing scientific goals, methodology, and time schedule) are provided in the Protocol. The Centre and the Investigator shall not deviate from the Protocol except to the extent necessary for safety of the Research Subject/s and shall promptly notify the Sponsor and the EC/IRB in writing of any deviation from the Protocol with reasons.

2.17 The Institute shall refrain from, and shall cause the Investigator and the Agents to refrain from using the Study Device in any manner that is contrary to the provisions of, or outside the scope of, the Protocol or that is contrary to the written instructions of the Sponsor.

2.18 The decision to include any Research Subject in the Study shall occur only after the decision to use the Study Device on said Research Subject has been made exclusively on medical grounds by the Investigator. On enrolling the subjects in the study, the Centre shall complete the Electronic Case Report Forms (hereinafter "**eCRF**") for the Research Subject specific data as per the prescribed study schedule in the Protocol for the entire length of the Study. The Centre shall provide all necessary and sufficient facilities, equipment, resources and personnel to perform the services required hereunder.

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2.19 The Institute and the Investigator shall supervise Agents employed by the Institute for conduct of the Study (the Study Staff), and shall ensure (directly in the case of employees, and by contract in the case of contractors) that all Study Staff are appropriately trained, qualified, and certified, and are informed of and abide by the applicable terms of this Agreement.

2.20 The Institute shall keep and maintain, diligently and in sufficient detail to satisfy all applicable legal requirements, such Study data and records as are required by the Protocol and applicable laws, including any source data, clinical data of Research Subjects and Study Deliverables (the "Study Documents").At the Sponsor's request, the Institute shall retain the Study Documents beyond the period required by the applicable laws Study Documents in accordance with applicable laws. After the required retention period (including any additional period requested by the Sponsor) has expired, the Institute shall provide the Sponsor sixty (60) days' written notice before destroying any Study Documents.

2.21 In order for Meril to monitor the progress of the Study, a regular exchange of letters, emails and phone calls between Meril and the Investigator shall occur during the performance of the Study. Face-to-face meetings may also be held between Meril and the Investigator as often as reasonably necessary. The Institute and the Investigator will allow, with reasonable prior notice, Meril and /or the regulatory authorities to perform facility and site audit.

2.22 The Institute shall permit the Trial Monitor to access the Study Documents during regular business hours, upon reasonable advance notice to the Institute by the Sponsor. The Sponsor shall comply with applicable laws regarding the confidentiality of Study Subjects' medical records and other health information, shall hold the Study Subjects' personal identifying information in confidence, and shall act in accordance with the Informed Consents and the HIPAA Authorizations. Subject to the foregoing, the Trial Monitor may copy Institute records containing such information. The Institute may redact personal identifying information of Study Subjects before giving them to the Study Monitor for copying these records. The Sponsor shall not attempt to contact any Study Subject except to the extent expressly permitted by the IRB or as required to comply with applicable laws.

2.23 During monitoring as per Clause 2.19, the Trial Monitor has the right to inspect any facility being used for the Study and to examine any procedures or records relating to the Study. The Trial Monitor/Sponsor will alert the Centre and the Investigator to significant issues (in the opinion of the Trial Monitor/Sponsor) relating to the conduct of the Study.

2.24 The sponsor's monitor to send the post-monitoring visit report promptly to the site.

2.25 In the event that the Sponsor reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Centre and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor. The Sponsor shall, subject to any obligations of confidentiality, communicate the results of such investigation to the Centre. In the event that the Centre reasonably believes there has been any research misconduct in relation to the Clinical Trial, the Sponsor shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Centre, the results of which shall, subject to any obligations of confidentiality, be communicated to the Sponsor.

2.26 The Institute shall make available to the Sponsor or its designated agent the Study site, the Study Staff, and, subject to applicable laws relating to patient confidentiality, all Study Documents for purposes of review and audit upon reasonable advance notice during regular business hours. If the Investigator fails to correct any violations of the Protocol, this Agreement, or applicable laws found in such audit after receiving written notice thereof, the Sponsor may provide notice to the Institute of such violations, whereupon the Institute shall promptly take action to correct them.

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2.27 The Institute shall provide the Sponsor prompt, advance notification of any audit by a regulatory authority, which audit is directly related to the Study (or, when advance notification is impracticable, prompt notification of any completed audit). To the extent possible, the Institute shall permit the Sponsor to review and comment in advance on any written communication from the Institute to the regulatory authority in connection with such an audit; provided, however, that such review does not adversely impact the timeliness of the Institute's response to the regulatory authority. The Institute shall promptly provide the Sponsor with copies of all communications between the Institute and the regulatory authority related to such audit unless prohibited from so doing by the regulatory authority, and shall promptly take action to correct any deficiencies found by the regulatory authority during the audit. With respect to a pending audit directly related to the Study by any regulatory authority, the Institute shall permit the Sponsor's representatives to be present at such audit unless prohibited from so doing by regulatory authority. With respect to any audit by any regulatory authority, which audit is not directly related to the Study, the Institute shall promptly notify the Sponsor of any findings of such an audit that would be likely to have an adverse effect on the Institute's ability to conduct the Study.

2.28 The sponsor to send the DSMB report if applicable and its timely submission to Ethics Committee.

2.29 The Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a Study Subject that is directly related to the conduct of the Study in accordance with the Protocol and the Sponsor's written instructions to the Institute (or to the extent that the Sponsor's written instructions conflict with the Protocol, the Sponsor's written instructions to the Institute only). The Sponsor is not required under this Section 2.26 to provide compensation for (a) other injury- or illness-related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the Institute nor the Study Subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the Protocol or other misconduct or negligence, in each case by any Agent of the Institute (including the Study Staff and the Investigator), or (d) medical expenses for injury or illness unrelated to the Study Device and unrelated to the proper performance of any other procedure required by the Protocol or Sponsor's written instructions to the Institute. The Sponsor confirms that it has taken appropriate insurance policy for the conduct of the Study as per the applicable laws.

3 Confidentiality

3.1 The Centre and the Investigator agree that any Confidential Information (or any evaluation thereof including but not limited to analysis, deconstruction, disassembling or reverse engineering) received from Meril shall be held in strict confidence and centre shall not disclose or use (other than in connection with or expressly permitted by this Agreement). All Confidential Information shall remain the property of Meril. Such information shall be used by the Centre and its Agents including the Investigator only in the performance of their duties hereunder, and shall not be used or disclosed, directly or indirectly to any third party, except as necessary to accomplish the purposes of this Agreement and then only if such Agents, and third party/parties are bound by an obligation of confidentiality consistent with the terms of this Agreement or as required by the law. The Centre hereby assures that their Agents including, but not limited to, the Investigator shall comply the provisions of this Clause. Upon the request of Meril, the Centre shall promptly return to Meril all Confidential Information of Meril in the possession of the Centre, the Investigator or other personnel and Agents, together with any documents or notes containing such Confidential Information, except for one archival copy which may be retained by the Centre if required in order to monitor compliance with the terms of this Agreement and the applicable laws.

3.2 The Centre, the Investigator, or any other personnel of the Centre, or Agents shall not publicly or privately disclose or divulge any term or provision of this Agreement or the transactions contemplated hereby without the prior written consent of Meril, except as may be required by applicable law, rule, regulation or order and the internal reporting requirements of the Centre, and

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except for communications to employees or Agents in order to perform the work required under this Agreement.

3.3 In the event the Centre, the Investigator or any of their personnel including Agents are required to disclose Confidential Information of Meril under any applicable law, regulation, legal process, judicial order or by any applicable order or requirement of any governmental or regulatory authority, it may do so only to the extent required; provided, however, that the Centre and the Investigator shall:

(a) give prompt notice to Meril of the required disclosure of Confidential Information sufficiently in advance of making the required disclosure to allow Meril a reasonable opportunity to take steps to object to, prevent, and/or limit its disclosure or obtain a protective or other similar order with respect to the required disclosure; and

(b) Restrict the disclosure to only that portion of the Confidential Information which is required to be disclosed.

3.4 Subject to Clause 6 below, the Centre and the Investigator undertake to keep the Results confidential and not to disclose to any third party.

3.5 Meril agrees to keep confidential, the Confidential Information received from the Institute or Investigator related to the Study. Meril agrees that all such information will not be disclosed to any of its agents or affiliates, including the Contract Research Organization, which will be involved in execution of one or more processes of the Study, for any purpose other than execution and conduct of the Study.

4 Privacy and Data Protection:

The Parties agree that each will comply with their respective obligations as required under applicable privacy and data protection laws. The Institute and the Investigator will obtain the consent of each Research Subject for the use, processing, holding and transfer of their data to other countries that may not have same level of data protection as in India.

5 Publication of Results

5.1 Meril reserves all the rights of publication and presentations of all the aspects of the Study including the outcomes of the study; interim and final.

5.2 Meril shall follow publication guidelines related to such publications and presentations.

5.3 The Chief Investigator shall be first author of the main scientific publication (multi-Centre Results), while other investigators shall appear in accordance with generally accepted standards for authorship, followed by Sponsor's Study Head – Clinical Research, the Medical Writer and the statistician, and the relevant persons from the CRO. Study publication will be registered in a manner that meets the criteria of the International Committee of Medical Journal Editors. The publication of the Results from the Centre shall not be allowed until principal scientific publication of the main Study is published. The Centre shall be allowed to publish sub-studies of the whole Study only after written approval by the Sponsor. All publications will follow the uniform requirements for manuscripts submitted to biomedical journals by the International Committee of Medical Journal Editors.

5.4 Subject to and without prejudice to above, the Centre may publish or present the Results collected or produced as a result of its participation in the Study in appropriate scientific journals, meetings or other professional publications, only under the following conditions:

(a) The proposed publication or presentation is consistent with the rules and conventions governing similar studies in all relevant jurisdictions.

(b) A draft of the proposed publication or presentation has been provided to Meril at least thirty (30) working days prior to the first intended submission for publication or presentation. Meril

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will review and respond with its comments, if any, within (30) working days of receipt of such copy. If Meril believes that any proposed publication or presentation contains any Confidential Information of Meril, then Meril shall so notify the Centre and the Centre and Investigator shall delete such Confidential Information of Meril from the proposed publication or presentation. If Meril believes that any proposed publication or presentation contains any patentable Results, the disclosure of such proposed publication or presentation to any third party shall be delayed for an additional ninety (90) working days to permit the filing of a patent application by Meril. Should Meril request such a delay, Meril shall use its best efforts consistent with reasonable business and scientific practice to do all things which it believes would expedite the filing of such patent application.

(c) Meril retains the right of final review prior to publication.

(d) The Centre shall give credit to Sponsor for its sponsorship of the Study in all publications or presentations related to the Study.

6 Results and Intellectual Property

6.1 The Centre and its Agents (including employees, the Investigator, contractors, consultants and other personnel) shall promptly disclose in writing to Meril, all the Results and Intellectual Property pertaining to the Results. Meril shall own and retain all right, title and interest in and to any Results and Intellectual Property resulting from all work performed in connection with the Study. To the extent that such Intellectual Property pertaining to Results does not vest automatically in Meril, the Centre hereby irrevocably agrees to assign and does hereby assign to Meril all rights, title and interest in and to any Intellectual Property that may inure to its benefit in connection with work performed pursuant to this Agreement and will execute and will cause its Agents including the Investigator to execute all documents which may be necessary to give effect to the provision contained herein. The Centre shall not assign, transfer or waive any rights it may have as an employer to any Results or any Intellectual Property pertaining to Results that is conceived or developed by personnel at the Centre (including the Investigator) in the performance of this Agreement to any entity other than the Sponsor.

6.2 Meril shall own complete data sets and Results produced under this Agreement and shall own all right, title and interest in and to any and all copyrights or copyrightable material, including software programs, produced, composed, or fixed in any tangible medium of expression in the performance of work under this Agreement. Meril shall have sole right to determine the disposition of all or any part thereof.

6.3 Neither the Centre nor the Investigator shall use any name, trademark, logo, symbol, or other image of Sponsor in advertising, publicity or otherwise, without the prior written consent of Meril. Neither the Centre nor the Agents including the Investigator, and representatives, shall issue or disseminate any press release or statement, or initiate any communication of information regarding the Study, written or oral, to the communications media or to any third party without the prior written approval of Meril.

6.4 The Parties acknowledge and agree that certain pre-existing Intellectual Property owned by Meril, Institute and Investigator shall not be affected by this Agreement. Except as otherwise expressly provided herein, no right or interest in or to any patents, trade secrets or other Intellectual Property owned or otherwise held by Meril or the Institute or the Investigator is granted or implied hereunder.

7 Financial terms and conditions – Fee and taxation

7.1 Meril shall pay Fee as per the attached Exhibit-A.

7.2 In case of death of the Research Subject, all the balance remuneration till the last completed follow-up will be paid after submission of death form duly monitored for completeness, and report of the Ethics Committee to the Sponsor. In case of Research Subject lost to follow-up,

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terminated by the Investigator or Research Subject withdrawing consent, payment up to the last completed visit will be made.

7.3 If as a part of the Study and as directed by Meril, the Clinical examinations/investigations are conducted as per the Protocol; the payment for such Clinical examinations/investigations will be made as per Exhibit-A. Meril shall not be liable to pay any such charges if the Clinical examinations/investigations are not conducted in compliance with the Protocol.

7.4 The Fee will be paid by Meril every three months during the study duration. The final payment will be settled at the time of site close-out visit.

7.5 The payee will generate an invoice addressed to the Study Director/Head – Clinical Research of Meril. The invoice should include all details relevant to the milestone payment (as in Exhibit-A) during the period of the invoice with clear statement of amount of the Fee to be paid. The payment will be released by Meril within 30 working days of receipt of such invoice.

7.6 Meril will deduct tax on all payments as per the applicable law for which tax deduction certificates will be provided.

7.7 Invoicing address: Dr Ashok Thakkar, Head-Clinical Research,Meril Life Sciences Pvt. LtdBilakhia House, Muktanand Marg, Chala, Vapi 396191 Gujarat, India
Email: ashok.thakkar@merillife.com

Shipping address:

Dr. Ashok Thakkar
Head-Clinical Research
Meril Life Sciences Pvt. Ltd.
Survey No.135/139, Bilakhia House,
Muktanand Marg,
Chala, Vapi – 396 191
Gujarat, India.

The Invoices shall include details of enrolled, followed up and completed subjects during the period of the invoice with clear statement of amount of Fee to be paid. The due date of the invoices shall be 60 days from the date of receipt of invoices by Meril.

Bank details for payment:

Payee Name (Account Name): Director, SGPGIMS, Research a/c.

Account Number: 10095237491

Bank Name: State Bank of India

Branch Name: SGPGI Bank, Lucknow

Swift/IFSC Code: SBIN0007789

PAN Number: AAAJS3913N

Send to: Dr. Nirmal Gupta
Prof. & Head of Department of Cardiovascular and Thoracic Surgeon,
Sanjay Gandhi Postgraduate Institute of Medical Sciences,
Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India

All bank charges in India shall be borne by Meril. All bank charges outside India shall be borne by payee.

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8 Ownership:

All documents, protocols, data, know-how, methods, operations, formulas, Confidential Information and materials provided to the Centreby the Sponsor pursuant to this Agreement are and shall remain Sponsor's Property. The completed CRFs, the final reports and other Results of the study shall also be owned by the Sponsor. Sponsor shall not own patients' medical records.

9 Quality of performance - representation and warranties

9.1 The Centre and Investigator shall perform their obligations with care, skill and diligence, in accordance with the highest applicable professional standards recognized in the profession, and shall be responsible for the quality, accuracy and completeness of all medical treatments and procedures, and shall ensure the accuracy of the data obtained from the research and procedures conducted at the Centre. The Centre shall comply with all applicable legal and regulatory requirements. The Centre shall comply with Good Clinical Practice (GCP) guidelines during the course of the Study. The Centre and the Investigator shall comply with all provisions of this Agreement and the Centre shall be liable for any breach of the same by the Investigator.

9.2 The Centre and the Investigator hereby undertake:

(i) To comply with the Protocol and with the recommendations, suggestions and relevant literature provided by Meril;

(ii) To maintain proper written records concerning all matters in connection with the Study;

(iii) To submit to Meril any written report(s) as provided in the Protocol;

(iv) To report adverse and serious adverse events to Meril in writing within 24 hours after the occurrence thereof; and

(v) To obtain informed consent from the Research Subjects in the format and manner provided in the Protocol.

9.3 The Centre shall, in all respects and at all times, protect the personal rights of the Research Subjects, in particular regarding informed consent procedures and personal data. All information and data relating to the Research Subjects collected during the course of the procedures and research performed in connection with the Study by the Centre and its Agents including the Investigator will be treated as confidential and maintained in a safe and secured manner consistent with the Protocol. The Centre shall take all actions necessary to ensure compliance with this section by its Agents including, without limitation, the Investigator, the treating physicians, other participating investigators and all hospital personnel. All information and data delivered to Meril shall be stripped of all information that identifies the Research Subject as required by the applicable laws and regulations. For this reason, a Research Subject identification code shall be used for the transmission of data and other information of the Study.

9.4 Unless otherwise instructed by Meril, the Centre shall be permitted to distribute the data and other information to any data management company/CRO designated in writing by Meril.

9.5 The Centre and the Agents including the Investigator shall not make any representations, warranties or guarantees with respect to the specifications, features or capabilities of the Study Device that are not consistent with Meril's documentation accompanying the Study Device or Meril's literature describing the Study Device, including the limited warranty and disclaimers. Neither the Centre, nor the Agents including the Investigator shall change, extend, or alter any warranty, representation or obligation which is binding upon Meril or its Affiliates.

9.6 The Centre and the Investigator shall cooperate with Meril's designated representatives and regulatory authorities regarding all matters related to the Study, including, but not limited to, auditing, monitoring and enabling full access to all documents, records, reports or other information related to the Study. Meril shall notify the Investigator in advance if and on what dates it intends to visit the Centre to inspect, monitor and/or audit the conduct of the activities related to the Study. The Centre and the Investigator will render whatever assistance is reasonably requested by Meril to enable it to conduct such activities, including, without

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limitation, providing access to requested information and documentation and correcting any matters that have been identified as items requiring attention or correction. All monitoring by Meril shall be conducted in accordance with applicable GCP Guidelines.

9.7 The Centre hereby represents and warrants that it has the physical facilities, equipment and personnel adequate to perform the Study in a proper manner in accordance with its obligations.

9.8 The Centre and the Investigator represent and warrant that the execution, delivery and performance of this Agreement will not, directly or indirectly, result in any violation or breach of any material contract, license, or permit to which they are a party or by which they are bound, or result in a violation of any law, rule, regulation, order, judgment or decree (including any rule or regulation of a medical professional society or similar group) to which the Centre or its personnel including the Investigator are subject. The Centre and the Investigator further represent and warrant that the execution, delivery and performance of this Agreement does not and shall not require any consent, approval, authorization or permit of, or filing or notification to, any governmental or professional entity which the Centre or the Investigator has not timely obtained.

10 Liability

10.1 Meril undertakes to indemnify, defend or cover costs for defence and release from liability ("Indemnify") the Investigator associated with the Study, Institute, their management staff, representatives (collectively referred to as the "Indemnified Parties") in relation to any claim of a third party regarding compensation for damages, costs, liabilities, expenses, including costs for legal representation of the Indemnified Parties, incurred as a result of a damage to the health of Research Subjects due to the failure of the Study Device provided, however, that to the extent that the claim is a direct result of (a) the failure of the Institute or one of its Agents (including the Investigator) to follow the Protocol or the Sponsor's written instructions (each when applicable), accepted medical practice, or applicable laws, or (b) any other negligence or wilful misconduct of the Institute or one of its Agents (including the Investigator), the Sponsor shall have no such obligation, and the Institute shall indemnify, defend, and hold harmless the Sponsor (and its officers, directors, employees, and agents, as applicable) from any loss, liability, damage or expense, but only to the extent arising from any such claim.

10.2 **Indemnification Procedure.** The Party seeking indemnification (the "Indemnitee") shall promptly notify the other Party (the "Indemnitor") of any claim, loss, or expense likely to lead to a claim for indemnification, along with all material related information. If such notice is not prompt, the Indemnitor's obligation under this Clause11 will be reduced to the extent that such delay prejudices the Indemnitor's defense of the claim. The Indemnitor shall have the right to manage the defense and settlement of any claim, except that the Indemnitor may not enter into any settlement admitting fault on behalf of the Indemnitee without the Indemnitee's prior written approval. The Indemnitee may not enter into any settlement of any such claim without the written permission of Indemnitor. The Indemnitee shall reasonably cooperate with the Indemnitor in the defense of the claim. The Indemnitee may hire its own counsel, at its own expense, to monitor the defense. In addition, the Indemnitee may elect to assume control of the defense of such claim, in which case the Indemnitor shall have no obligation to indemnify or further defend the Indemnitee with respect to such claim.

10.3 **Insurance.** During the term of this Agreement and for so long thereafter as may be necessary, the Institute and the Sponsor each shall carry liability insurance in the type and amount appropriate and customary for the conduct and sponsorship of the Clinical Trial, respectively as per applicable regulations to cover any claims that may arise in connection with its responsibilities under this Agreement. Upon request, each Party shall provide to the other Party a certificate of such insurance or evidence of such a self-insurance plan.

10.4 The Investigator will cooperate with Meril in collection of all requisite documents and completion of required process for insurance procedure for compensation claims towards Clinical Trial Liability Policy taken by Meril.

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10.5 For clarity, the general product liability of Meril for the Study Device remains unaffected by the Clause 11.3.

10.6 In no circumstances shall any Party be liable to another Party in contract, tort (including negligence or breach of statutory duty) or otherwise howsoever arising or whatever the cause thereof, for any loss of profit, business, reputation, contracts, revenues or anticipated savings for any special, indirect or consequential damage of any nature, which arises directly or indirectly from any default on the part of any other Party.

11 Term and termination

11.1 **Term.** This Agreement shall come into effect upon the Effective Date and shall remain in force till the Study is completed and the Parties have discharged their obligations pursuant to this Agreement. The Parties expect this Agreement to expire after the day of "Site Close-out Visit"at the Institute by the Sponsor that is indicative of completion of participation of the Investigator and the Centre in the Study as well as finalization of the Study data base whichever is later; unless terminated earlier pursuant to this Clause 11.

11.2 **Sponsor Termination.** The Sponsor may terminate this Agreement (a) upon thirty (30) days' written notice to the Institute, in its sole discretion; (b) upon thirty (30) days' written notice to the Institute, for failure of the Sponsor and the Institute to agree upon a new Investigator pursuant to Clause2.3; (c) upon written notice to the Institute, if progress of enrolment at the Centre justifies such termination, in the sole discretion of the Sponsor; (d) upon written notice to the Institute, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Clause 2.9; (e) upon oral notice (promptly followed by written notice) to the Institute, if approval for the Study is not granted or is revoked by the relevant IRB; (f) upon oral notice (promptly followed by written notice) to the Institute, if any person performing activities under this Agreement is debarred, excluded or disqualified from participation in any federal health care program; or (g) upon oral notice (promptly followed by written notice) to the Institute, if the Sponsor determines that termination of the Study is necessary for the safety of the Study Subjects.

11.3 **Termination by Institute.** The Institute may terminate this Agreement (a) upon thirty (30) days' written notice to the Sponsor, for failure of the Sponsor and the Institute to agree upon a new Investigator pursuant to Section 2.3; (b) upon written notice to the Sponsor, if the Parties are unable to agree on amendments to this Agreement related to amendments to the Protocol pursuant to Section 2.9; or (c) upon oral notice (promptly followed by written notice) to the Sponsor if the Institute determines that termination of the Study is necessary for the safety of the Study Subjects.

11.4 **Termination for Material Breach.** Either Party may terminate this Agreement upon written notice to the other Party if the other Party materially breaches this Agreement and the breaching Party fails to cure the breach within thirty (30) days after receipt of written notice of the breach from the other Party.

11.5 **Procedures upon Early Termination.** If this Agreement is terminated before completion of the Study, the Institute shall cease enrolling Study Subjects immediately (or, in the case of termination by the Sponsor, as soon as the Institute has been notified of such termination), and shall cease conducting the procedures set out in the Protocol to the extent that doing so is medically permissible and appropriate. The Sponsor and the Institute shall negotiate in good faith on the subsequent treatment or transfer of the Study Subjects. In case of termination of the Study before completion, the Sponsor shall reimburse the Institute for (i) obligations incurred in accordance with the Study budget that cannot be cancelled or mitigated by the Institute using reasonable efforts, (ii) reasonable costs incurred in connection with the safe withdrawal of the Study Subjects from the Study, and (iii) mutually agreed post-termination expenses.

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11.6 **Return of Property.** Upon termination or expiration of this Agreement, the Institute shall, and shall cause the Investigator and Agents to, return to the Sponsor within thirty (30) days any unused Study Devices (is supplied by the Sponsor) except as required by law, any equipment on loan or lease from the Sponsor, and any copies of Confidential Information provided by the Sponsor that are in the possession or under the control of the Institute or the Investigator; provided, however, that the Institute may retain any copies of such Confidential Information to the extent required by applicable law. At the Sponsor's request and expense, the Institute shall dispose of the unused Study Devices and Control Devices (if supplied by the Sponsor) in accordance with Sponsor's instructions, subject to applicable law.

11.7 **Final Accounting.** The Institute shall deliver to the Sponsor, within ninety (90) days after expiration or early termination of this Agreement, a final accounting of amounts due (and reasonable supporting documentation, which requirement shall be satisfied by properly completed CRFs as to completed visits by Study Subjects), taking into account payments made and not yet made under the payment schedule, and expenses reimbursable pursuant to Clause8, from one Party to the other Party. Undisputed amounts due shall be paid within sixty (60) days thereafter.

11.8 Upon expiration or termination of this Agreement, all rights and obligations shall expire forthwith, except those rights and obligations which by their nature are intended to survive the expiration or termination of the Agreement, including Clause 3 (Confidentiality), Clause 4 (Privacy and Data protection), Clause 5 (Publication of Results), Clause 6 (Results and Intellectual Property), Clause 8 (Ownership), Clause 9 (Quality of performance - representation and warranties), Clause 10 (Liability) and Clause 12.8 (Governing Law/Jurisdiction), and each of their subparts.

12 Miscellaneous provisions

12.1 **Regulatory Approvals.** Each Party represents that it has and will maintain during the term of this Agreement all regulatory approvals required for the conduct of its respective activities in connection with the Study, and that all the Agents who perform activities under this Agreement on its behalf (including, in the case of the Institute, the Study Staff) have and will have the necessary expertise, training, qualifications, and certifications.

12.2 **Debarment.** The Institute certifies that it will not engage, directly or indirectly, any person (including the Investigator) to perform services under this Agreement if (a) that person is debarred by the applicable law or to the Institute's knowledge is threatened with debarment by a pending proceeding, action, or investigation, (b) that person is excluded from participation in any federal health care program or is the subject of an exclusion proceeding, or (c) that person is otherwise disqualified under federal or state law, or to the Institute's knowledge is threatened with such disqualification by a pending proceeding, action, or investigation, from participating in the Study. The Institute certifies that it will immediately notify the Sponsor in writing if any such debarment, exclusion, or disqualification occurs, or if any such debarment, exclusion, or disqualification proceeding, action, or investigation is commenced or, to the Institute's knowledge, is threatened, with respect to any such person.

12.3 **No Conflicting Obligations.** The Institute represents and covenants that none of the Institute or any member of the Study Staff or none of the Agents is or will become subject to any conflicting obligations that would materially interfere with the performance of the Study or any of the Institute's other obligations under this Agreement. The Parties agree that the conduct of other clinical trials targeting the same disease or patient population as the Study does not necessarily constitute such a conflicting obligation. The Institute represents that it has a system in place to manage, eliminate, or otherwise resolve conflicts of interest. The Sponsor shall not, and shall cause its agents and contractors to refrain from, making any payments directly to Study Staff for performing the activities set out in the Protocol.

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12.4 **Independent Contractors.** Nothing contained herein shall be construed as evidence of an employment relationship between Meril and the Centre (or any personnel of the Centre including the Investigator and Agents). In performing the services hereunder, the Centre shall be deemed as an independent contractor to Meril for all purposes. Neither the Centre nor the Investigator shall have any authority to incur any liability on Meril's behalf, or to bind Meril to any obligation without the express written authorization of Meril.

12.5 **Assignment.** Neither Party may assign this Agreement without the prior written consent of the other Party, except that (a) either Party may assign this Agreement to an Affiliate, or to a third party in connection with a merger or sale of all or substantially all of its assets relating to the Study or the Study Device; and (b) the Sponsor may delegate its obligations or assign its rights under this Agreement to a contractor, provided that the Sponsor remains liable for the performance of all delegated obligations. Any Party making an assignment pursuant to this Clause 13 (other than an assignment to an Affiliate) shall provide prompt written notification to the other Party. In the case of any assignment (but not a delegation), the assignee shall assume all of the obligations of the assignor under this Agreement.

12.6 **Integration and Modification/Waiver.** This Agreement together with any exhibits hereto, constitute the entire agreement between the Parties with respect to the subject matter hereof and supersedes all prior agreements, discussions and understandings between the Parties. No amendment, modification or waiver of any term or provision of this Agreement shall be effective except by written instrument duly executed by each Party. No waiver of any breach of this Agreement shall be held to be a waiver of any other or subsequent breach.

12.7 **Force Majeure.** Noncompliance by a Party with this Agreement due to any cause beyond the reasonable control of the Party, such as war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, failure of public utilities or common carriers (each, an event of "Force Majeure"), shall not constitute a breach of this Agreement. That Party shall be excused from performance under this Agreement to the extent and for the duration of such event of Force Majeure; provided, however, that it first notifies the other Party in writing thereof and that it uses reasonable efforts to cause such event of Force Majeure to abate.

12.8 **Governing Law/Jurisdiction.** This Agreement shall be construed and interpreted in accordance with the laws of India, without regard to its conflict of law's provisions. Any action brought to enforce or interpret this Agreement shall be brought in the courts of Mumbai, subject to appeal in the higher courts in India, and each Party hereby consents to the jurisdiction thereof.

12.9 **Severability.** If any term or provision of this Agreement is held to be invalid, unenforceable, or void by a court of competent jurisdiction, the remaining terms and provisions shall nevertheless be enforceable according to their terms.

12.10 **Counterparts.** This Agreement may be executed in one or more counterparts, which taken together, shall constitute one and the same instrument.

12.11 **Interpretation.** Unless the context of this Agreement requires otherwise, words of one gender include the other gender; words using the singular or plural number also include the plural or singular number, respectively; the terms "Clause" and "Section" refer to the specified Clause and Section of this Agreement; and the term "including" means "including, without limitation."

12.12 **Notices.** The Parties shall send notices in writing, referencing this Agreement. Notice shall be deemed given: (a) when delivered personally; (b) one (1) day after having been sent by facsimile, with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid; (c) by e-mail with a copy sent promptly by registered or certified mail, return receipt requested, postage prepaid;five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid; or (d) two (2) days after deposit with a

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nationally recognized overnight carrier, with written verification of receipt. Notice shall be given to the addressee below:

To the Institute:	**Sanjay Gandhi Postgraduate Institute of Medical Sciences** Attention: **Prof. Rakesh Kapoor** E-mail: director@sgpgi.ac.in
With a copy to:	**The Principal Investigator** Attention: **Dr. Nirmal Gupta** E-mail: drnirmalgupta@gmail.com
To the Sponsor:	**Meril Life Sciences Pvt. Ltd.** Attention: **Dr. Ashok Thakkar** E-mail: ashok.thakkar@merillife.com

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IN WITNESS WHEREOF, The Parties have duly executed this Agreement as of the date first written above.

Sponsor: Meril Life Sciences Pvt. Ltd.

Signature:

Date: 26/MAR/2018

Name: **Dr. Ashok Thakkar**

Title: **Head of Clinical Research**

Address for Notices: **Meril Life Sciences Pvt. Ltd., Bilakhia House, Muktanand Marg, Chala, Vapi-396191 Gujarat, India.**

Institute: Sanjay Gandhi Postgraduate Institute of Medical Sciences

Signature:

Date:

Name: **Prof. Rakesh Kapoor**

Director
Sanjay Gandhi Postgraduate
Institute of Medical Sciences
Lucknow-226014 (U.P) INDIA

Title: **Director SGPGI**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

Investigator: Dr. Nirmal Gupta

Signature:

Date: 27/03/18

Name: **Dr. Nirmal Gupta**

Title: **Principal Investigator**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

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EXHIBIT-A

Fee Schedule

Meril shall pay to the Payee (as per Clause 7 of the Agreement) following Fee subject to and in compliance with the terms and conditions of this Agreement.

Total 30,000.00 INR (Thirty Thousand Indian National Rupees) for each enrolled Research Subject will be paid to **Director, SGPGIMS, Research a/c** based on submission of the data in compliance with the terms and conditions of this Agreement. The schedule of payment will be as given in the following table.

Visit type	Amount/per Research Subject in ₹
1. Screening, Enrolment and Follow Ups	
(A) On Research Subject Screening	5,000.00
(B) Submission of completed electronic Case Report Forms ("eCRFs") (Baseline, Post Implant-Discharge,30-days follow-up)	12,000.00
(C) Submission of completed e-CRFs till and including 180-day follow up	2,000.00
(D) Submission of completed e-CRFs till and including 1-year follow up	2,000.00
(E) Submission of completed e-CRFs till and including 2-year follow up	2,000.00
(F) Submission of completed e-CRFs till and including 3-year follow up	2,000.00
(G) Submission of completed e-CRFs till and including 4-yer follow up	2,000.00
(H) Submission of completed e-CRFs till and including 5-year follow up	2,000.00
(I) Site Close Out (After Final Data Base Lock)	1,000.00
Grand Total (A-I)	**30,000.00**

- All protocol specific Lab Investigations and diagnostic procedures cost will paid as pass-through cost post generating Invoice based on original supporting bills with applicable taxes.
- Patient travel reimbursement will be paid as per actual to subject, maximum up to INR 1500/- on return clinic follow up as per the protocol specific visits for each visit depending on your distance from the Hospital/Centre.
- All payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable.
- Reimbursement of any additional pass through cost including optional cost shall be subject to sponsor's prior approval and at actual.

Invoicing Instructions

Invoices in the name of "Meril Life Sciences Pvt. Ltd." shall be sent to:
Dr. Ashok Thakkar
Meril Life Sciences Pvt. Ltd.
Survey No.135/139, Bilakhia House,
Muktanand Marg ,
Chala ,Vapi – 396 191
Gujarat, India.

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IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the date first written above.

Sponsor: Meril Life Sciences Pvt. Ltd.

Signature:

Date: 26/MAR/2018

Name: **Dr. Ashok Thakkar**

Title: **Head of Clinical Research**

Address for Notices: **Meril Life Sciences Pvt. Ltd., Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala, Vapi-396191 Gujarat, India.**

Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences

Signature:

Date:

Name: **Prof. Rakesh Kapoor**

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

Title: **Director SGPGI**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

Investigator: Dr. Nirmal Gupta

Signature:

Date: 27/03/18

Name: **Dr. Nirmal Gupta**

Title: **Principal Investigator**

Address for Notices: **Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow - 226014, Uttar Pradesh, India**

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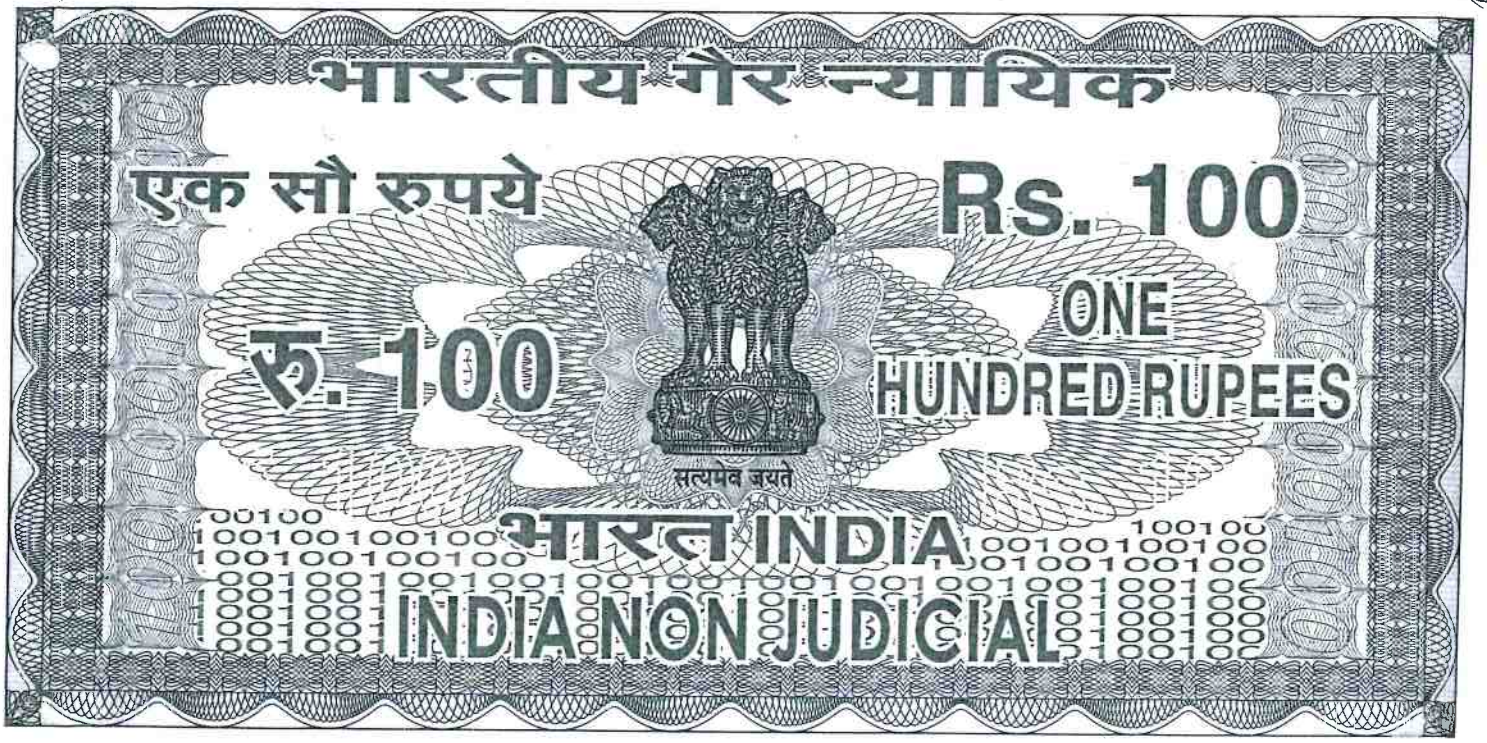

पश्चिमबङ्ग पश्चिम बंगाल WEST BENGAL Z 793626

CLINICAL STUDY AGREEMENT

This Clinical Study Agreement ("Agreement") is made as of 11-Sep-2018 (the "Effective Date") by and among

1 Dr. Piyali Bhattacharya, Consultant Paediatrician, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India ("Principal Investigator")

And

2 Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India (Institute)

And

3. Medclin Research Pvt Ltd, having its Registered Office at Acropolis , Unit No 10/5 , 10th floor, 1858/1, Rajdanga Main Road,Kolkata-107 ("CRO")

And

4. Wockhardt Ltd. having its Registered office address at D-4, M.I.D.C, Chikhalthana, Aurangabad – 431006 and its Global Headquarter at Wockhardt Towers Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400051 ("Sponsor")

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WHEREAS,

a. The research contemplated by this Agreement is of mutual interest and benefit to the Sponsor, and will further the Sponsor's instructional and research objectives;

b. Sponsor based on the representation and warranties given by the CRO, desires to engage CRO on non-exclusive basis to initiate study of A Phase II / III, prospective, randomized, active-controlled, open label, Parallel group, 2-arm, Multi-centric trial for evaluation of Efficacy, Safety, and Tolerability of DTaP+Hib (Diphtheria, acellular Pertussis, Tetanus and Hemophilus influenza b) combination vaccine in Indian pediatric population in comparison with Pentaxim® (Diphtheria, acellular Pertussis, Tetanus, Hemophilus influenza b and IPV) combination vaccine of Sanofi Pasteur (WOC/DTH/CT-56/15) ."

c. The CRO has approached the Institution and Principal Investigators to perform the study in accordance with the Declaration of Helsinki (1996), the ICH Guidelines on Good Clinical Practice and Local Regulations and have accordingly finalized the Clinical Trial Protocol.

d. the Study contemplated by this Agreement will further the Sponsor's interest in advancing medicine and patient care and the said study contemplated by this Agreement;

e. the Institution is equipped to undertake the Study and the Institution, CRO and Principal Investigator have agreed to perform the Study for Sponsor according to the terms and conditions hereinafter set forth;

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants expressed herein, the parties agree as follows:

1. **REPRESENTATIONS AND WARRANTEES:**

a. Each party represents and warrants to and covenants with the other that:

i. It has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this agreement; , wherever applicable,

ii. It has the corporate power and authority to enter into and perform its obligations under this Agreement, whenever applicable,

iii. This Agreement has been duly authorized, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

iv. Neither the execution and delivery of this Agreement by either party, nor the performance by such party of its obligations hereunder nor compliance by such party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any indenture, mortgage, lease, agreement, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such party;

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b. **CRO represents and warrants that**

i. it has the facilities, professional, technical and clerical staff, experience, and expertise sufficient in quality and quantity to perform the Services and the Clinical Study pursuant to the Protocol within the time frame set forth herein and all appropriate permits and authorisations necessary to provide and perform, to the highest of professional standards, the services for the conduct of the clinical study in accordance with this agreement, the Protocol, ICH, GCP and all applicable standard operating procedures and has capability to perform or arrange for the performance of all services required by SPONOSR.

c. **Institution represent that**

i. The Institution represents that it is entitled to procure and the Institution will procure the services of Principal investigator and shall ensure the performance of the obligations of the Principal Investigator set out in this agreement.

ii. The Institution shall notify the Sponsor if the Principal Investigator ceases to be employed by or associated with the Institution and shall use its best endeavors to find a replacement acceptable to both the SPONSOR and CRO. In order to ensure high standard of clinical trials, if no mutually acceptable replacement can be found the SPONSOR may terminate this agreement pursuant to clause 24(d). However in such an event CRO shall be eligible to receive money for the work successfully completed as certified by SPONSOR including the non-cancellable cost, if any, till the date of termination of this Agreement, within 60 days from the date on which both the parties mutually agreed.

d. **Principal Investigator represent that:**

i. The Principal Investigator hereby confirms that he is a competent person to sign this agreement on behalf of his sub-investigators and research staff. The terms "Investigator" or "Investigators" as used in this Agreement refers, as applicable, to the Principal Investigator and his sub investigators and research staff and the Institution.

ii. he (the term "he" shall include "she") is free to participate in Clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his (the term "him" shall include "her") performance of the obligations detailed in this Agreement.

iii. he is not involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration (FDA), the Medicines and Healthcare Products Regulatory Agency (MHRA), the European Medicines Evaluation Agency (EMEA), The Drug Controller general of India (DCGI) or other

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regulatory authorities. No data produced by him in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

iv. he has considered, and is satisfied that, facilities appropriate to the Clinical Trial are available to him at the Trial Site and that he is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the CRO to perform the Clinical Trial efficiently and in accordance with the provisions of this Agreement.

2. Obligations/Responsibilities:

a. Principal Investigator

i. Principal Investigator will ensure that only individuals, who are appropriately trained and qualified, assist in the conduct of the Study as sub investigators or research staff.

ii. Principal Investigator will ensure that all personnel, who assist in the conduct of the Study, are informed of and agree to abide by all terms of this Agreement applicable to the activities they perform. Principal Investigator is accountable to THE SPONSOR OR its representative for the compliance of Investigators to the terms of this Agreement.

iii. Principal Investigator shall not reassign the conduct of the Study to a different Principal Investigator without prior written authorization from THE SPONSOR or its representative.

iv. Principal Investigator may delegate duties and responsibilities to sub investigators or research staff only to the extent permitted by the relevant laws and regulations governing the conduct of clinical investigations in India.

v. Principal Investigator will comply with the policies and procedures of the organization / institute with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Sponsor or its representative promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

vi. The Principal Investigator shall be responsible for obtaining and maintaining all approvals from the relevant local research ethics committee for the conduct of the Clinical Trial and the principal investigator shall keep the SPONSOR fully apprised of the progress of ethics committee submissions and shall upon request provide the SPONSOR with all correspondence relating to such submissions. The Principal investigator shall not consent to any change in the Protocol

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requested by the relevant ethics committee without the proper written consent of the SPONSOR.

vii. The Study will be conducted by the Principal Investigator at the Institution with the prior approval and ongoing review of all appropriate and necessary review authorities and in accordance with all requirements of the Sponsor and all applicable laws and regulations

viii. The Principal Investigator shall provide Sponsor with written evidence of review and approval of this Study by the institutional review board or such other committee that is responsible for reviewing and approving research (the "EC") prior to the initiation of the Study and with evidence of the EC's ongoing review and approval of the Study.

ix. The Principal Investigator agrees to perform the Study according to the Protocol, and in accordance with all applicable rules and regulations, including the ethical principles for medical research involving human subjects, World Medical Association, declaration of Helsinki, good clinical practices for clinical research in India, ethical guidelines for biomedical research on human participants by ICMR, Schedule Y and good clinical practice: ICH topic e6.

x. The Principal Investigator agrees not to implement any deviation from or changes to the Protocol without Sponsor's written consent and prior EC approval, except as necessary to protect the safety, rights or welfare of a patient enrolled in the Study.

xi. The Principal Investigator further agrees to use best efforts to provide Sponsor's with the data called for in the Protocol, including copies of each research subject's signed informed consent form, a signed authorization as required under any applicable India regulations/policies and properly completed case report forms, in a timely manner. The informed consent form shall comply with the requirements of GCP guidelines. The Institution will provide for (i) access to the research subject's medical records by Sponsor's and by the DCGI and other appropriate regulatory agencies and (ii) the use of Study data by Sponsor for any purpose that it deems appropriate provided that the research subject's personal identifying information has been removed. In the event of a conflict between terms of the Protocol and this Agreement, the terms of this Agreement shall govern.

xii. The Principal Investigator shall promptly report to Sponsor any significant developments that may occur during the Study, including but not limited to adverse clinical events as described in the Protocol.

xiii. The Principal Investigator and Institution agree to permit representatives of Sponsor and other regulatory authorities having jurisdiction over the Study to examine at any reasonable time during normal business hours (i) the facilities where the Study is being conducted, (ii) raw study data and (iii) any other relevant information necessary for Sponsor, the DCGI or other regulatory

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authority to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable laws and regulations. The Principal Investigator shall notify Sponsor immediately if another regulatory authority schedules or, without scheduling, begins such an inspection.

xiv. The Principal Investigator agrees to maintain records and data related to the Study in compliance with all applicable requirements, and in any event, for at least a period of at least 3 years after the completion/termination of the study or submission of the data to the regulatory authority(ies) whichever is later. The Principal Investigator will insure that all Study data are promptly and accurately recorded on Sponsor's recording forms, whether electronic or paper.

xv. In the event that during the term of this Agreement, either the Institution or Principal Investigator becomes debarred or receives notice of an action or threat of an action with respect to its debarment, the Institution or Principal Investigator, as the case may be, shall notify Sponsor immediately. Institution hereby certifies that it has not and will not use in any capacity the services of any individual, corporation, partnership or association that has been debarred. In the event that Institution becomes aware of the debarment or threatened debarment of any person or entity providing services to Institution which directly or indirectly relate to services provided under this Agreement, Institution shall notify Sponsor immediately and shall take appropriate measures to ensure that there is no delay in the Studies.

b. Institution:

i. The Institution shall ensure that all employees and agents of Institution who are assigned to perform services under the Agreement are made aware of the obligations contained in the Agreement and the Protocol and are bound by such obligations.

ii. The Institution and Principal Investigator shall all the time comply with all types of License, permission or certificates as required under laws, rules and regulations.

iii. The Institution shall bear all costs related to the performance of the Study except as expressly set forth in section 23.1 and attached budget.

iv. Institution shall apply its best efforts to retain the services of the Principal Investigator.

v. In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform the Sponsor/CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, who shall have a similar background and also knowledge of the Clinical Trial.

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vi. Any successor to the Principal Investigator must be approved, in writing, by the Sponsor/CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this agreement and to sign each such document as evidence of such agreement (although failure to sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

vii. The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India.

viii. The Institution agrees to immediately inform the Sponsor/CRO in writing if any person, including but not limited to the Principal Investigator, who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or to the best of the Institution's knowledge, is threatened, relating to the debarment of the Institution or any person performing services hereunder.

ix. The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with:

1. The Protocol and all other terms of this Agreement;

2. All laws and regulations pertaining to the transportation, storage, use, administration and disposal of drugs, vaccines/biologicals, and the conduct of clinical investigations among which the Helsinki Declaration but not limited to Schedule Y, Drug and Cosmetic Act of India, with the Good Clinical Practice approved by the Indian Regulatory Authorities.

3. Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs;

4. Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP;

5. All applicable laws and regulations.

x. The Institution agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

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xi. Such informed consent shall be obtained by the Principal Investigator using the informed consent form template developed for the Trial Site. The Privacy Rules shall be followed in order to obtain consent from Subjects as required throughout the Clinical Trial.

c. Sponsor / CRO

i. Sponsor / CRO agrees to provide to the Principal Investigator as designated by CRO all information concerning the Study Material that is necessary for safe and proper handling and storage of the Study Material and for performance of the Study.

ii. Sponsor / CRO agrees to provide the Study Material for use in the Study in accordance with the Protocol.

iii. The CRO shall be responsible for GCP, Protocol compliance, and Regulatory compliance.

3. **Sponsor Right**:

a. The Sponsor reserves the right to make any changes, amendments, addendum or supplements to the Protocol from time to time, as it may think fit and shall inform CRO and the Principal Investigator by giving a written notice to abide by the same.

b. Sponsor shall have the right to designate a different investigator or other supporting personnel so long as the choice is reasonably acceptable to CRO.

c. SPONSOR has a right but shall not be under any obligation to review all the investigators, supporting personnel and subcontracted vendors recommended by the CRO for performance of this agreement.

d. SPONSOR's representatives may visit CRO's premises / Site with a prior written notice at reasonable times and with reasonable frequency during normal business hours to obtain information regarding the progress of Study. CRO will assist SPONSOR in scheduling such visits. The costs of such visit shall be entirely borne by the SPONSOR. During such visits, SPONSOR'S representatives may examine the controls and procedures used by CRO in the performance of quality assurance inspections. SPONSOR shall also examine the completeness of the Services that CRO is providing to SPONSOR.

4. PAYMENT OF FEES:

a. As compensation for Institution / Investigator performance of the Services described in Protocol, SPONSOR / CRO shall pay Institution / Investigator fees for the services in the amounts and upon the terms specified in the Study Budget "Budget") attached to and made a part of this agreement.

b. Institution / Investigator shall not revise its prices for any reason unless mutually agreed in writing by all parties during the term of this Agreement. In any case,

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Institution / Investigator shall endure that the overall budget shall not exceed the total study budget as specified which shall form the part of this Agreement unless agreed by SPONSOR / CRO.

c. Institution / Investigator will not charge any amount to SPONSOR / CRO for their services which were not provided by the SPONSOR / CRO or agreed upon by and between the parties.

d. SPONSOR / CRO will reimburse Institution / Investigator for travel and other reasonable out-of pocket expenses incurred by Institution / Investigator personnel at the request of the SPONSOR / CRO. All pass through costs invoiced to SPONSOR / CRO will be at actual cost with no mark-up for administration or overhead. Travel and reasonable out-of-pocket expenses shall include the following:

i. Travel via commercial airlines, economy class; train or rental car;
ii. Local travel to places other than CRO's office by personal car at a rate to be agreed between the parties for each country
iii. Actual and reasonable lodging and meal expenses
iv. Actual and reasonable telephone expenses, mailing expense, express courier performance of services and photocopying expense incurred in the performance of the services under this agreements and
v. Other reasonable and necessary expenses as approved by SPONSOR.

e. Institution / Investigator shall submit a reasonable detailed invoice of services performed and completed, travel and out-of-pocket expenses to SPONSOR / CRO on a quarterly basis. A study startup fees of Rs. 40,000 will be given at site initiation visit.

f. The payments is excluding GST or similar taxes levied by state/central government on SPONSOR / CRO's fees. Any income tax, withholding tax or similar taxes deductible from the payment will be deducted by SPONSOR / CRO.

5. **Protocol.** Investigator will conduct the Study in accordance with the Protocol, ICMR GCP guidelines and applicable rules and regulations in India.

6. **Amendments.** The Protocol may be modified only by a written Amendment, signed by both THE SPONSOR and THE PRINCIPAL INVESTIGATOR.

7 **Emergency Amendments**. If it is necessary to change the Protocol on an emergency basis for the safety of the subjects, Investigator will notify THE SPONSOR and the responsible Independent Ethics Committee or Institutional Review Board (as applicable) as soon as practicable but, in any event, not later than five working days after the change is implemented. Any emergency change to the Protocol must be followed by a written Amendment.

8 No Additional Research. The Institution & Principal Investigator ensures that no additional research may be conducted on Study subjects during the conduct of the Study unless it is approved and documented as a sub-study protocol or an Amendment to the original Protocol. Such prohibited

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research activities include, but are not limited to, analyses of biological samples from Study subjects for any non-therapeutic purpose.

9. **Subject Enrolment.** Investigator has agreed to enrol in Study a maximum of 20 subjects for phase II within one month and 50 subjects for phase III within three months unless THE SPONSOR extends this enrolment no. and period by written notification. A qualified subject is one who meets all Protocol criteria such as inclusion & exclusion criteria and agrees to participate in the study through informed consent in writing.

9.1 **Failure to Enroll.** If Investigator fails to enroll subjects at a rate adequate to meet the enrolment requirement, THE SPONSOR shall be free to terminate the Study early (see Section 24(d) Termination).

9.2 **Study Conduct.** Investigator will conduct Study in accordance with the Protocol, THE Sponsor's written instructions, ICMR, Good Clinical Practice (GCP) guidelines and all applicable governmental laws, rules, and regulations.

10 **Ethics Committee ("EC").** Before the Study is initiated, Investigator will ensure that both the Studies and the informed consent forms are approved by an Ethics Committee that complies with all applicable laws and regulations. Investigator will further ensure that the Study is subject to continuing oversight by the EC throughout its conduct.

11 **Study Disapproval.** If, through no fault of Investigator, the Study is disapproved by EC, this Agreement will immediately terminate with no penalty to the Investigator, as provided in Section 24(a), Disapproval by EC, below.

12 **Data Protection:** Data collected in Study may include personal data and sensitive information which is subject to specific legislation relating to the processing, storage, transfer and use of such data or information. The Investigator will comply with all relevant laws relating to the protection and use of personal data and data privacy in its conduct and reporting of the Study. The Investigator shall take all technical and organizational measures to prevent unauthorized or unlawful processing or accidental loss or destruction of, or damage to, or disclosure of such data. THE SPONSOR / CRO will take appropriate measures to protect the confidentiality and security of all personal data that it receives from Investigator in connection with the Study. Personal data relating to the Investigator shall be processed and used for the purposes of administration of this agreement and in connection with the Study and will be held on one or more databases for the purposes of determining the Investigator's involvement in future research and in order to comply with any regulatory requirements. Such data may be disclosed or transferred to other members of Wockhardt Limited, to representatives and contractors working on behalf of THE SPONSOR group and to regulatory authorities across the world. The Investigator shall ensure that all necessary consents are in place to comply with the provisions of this clause (13).

13 Informed Consent and Authorization to Use and Disclose Health Information

13.1 **Informed Consent:** Investigator will provide THE SPONSOR / CRO an opportunity to review and approve the content of the informed consent form (including any revisions made during the course of the Study) before it is used. Investigator will obtain an audio-video and written informed consent from each study subject and will maintain a signed

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original of that consent in the subject's record. Investigator will allow THE SPONSOR / CRO to inspect signed informed consent forms or photocopies there during monitoring visits or audits (see Monitoring and Audits, Section 16).

13.2 **Adverse event:** Investigator will report adverse events experienced by Study subjects in accordance with instructions in the Protocol and applicable regulations. This includes, where required, prompt reporting by telephone or facsimile. THE SPONSOR shall, so far as is lawful, have full responsibility for the reporting of all adverse events to local and international regulatory and/or health authorities.

14. **Confidential Information.** During the course of the Study, Investigator may receive or generate information that is confidential to THE SPONSOR. Any information marked by the sponsor as confidential and provided to the investigator 3 month before the execution of this agreement will also be treated as confidential information.

14.1 **Definition**. Except as specified in Section 14.2, Exclusions, below, "Confidential Information" includes

a. the Protocol,
b. the Investigator Brochure,
c. The informed consent of participants.
d. Study Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), subject to Investigator's right to publish the results of the Study (as described in Section 18, Publications, below),
e. Biological Sample Analysis Data (as defined in Section 15, Study Data, Biological Samples, and Study Records, below), and
f. any other information related to the Study, THE SPONSOR'S DRUG, or THE SPONSOR technology, research, or business plans that THE SPONSOR provides to Investigator in writing or other tangible form and marks as CONFIDENTIAL or initially discloses orally and then summarizes and confirms in writing as CONFIDENTIAL within 90 days after the date of oral disclosure.

14.2 **Exclusions.** Confidential Information does not include information that

a. is known or open to the public or otherwise in the public domain at the time of disclosure,
b. becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Investigator,
c. is already known to Investigator at the time of disclosure and is free of any obligations of confidentiality, or
d. is obtained by Investigator, free of any obligations of confidentiality, from a third party that has a lawful right to disclose it.

14.3 **Obligations of Confidentiality**. Unless THE SPONSOR provides prior written consent, Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by law.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

a. Required disclosure of Confidential Information to the EC or to regulatory representatives is specifically authorized.

b. Publication of the results of the Study based on Study Data collected or generated by Investigator is specifically authorized, subject to the provisions of Section 18, Publications, of this Agreement.

14.4 **Disclosure Required by Law.** If disclosure of Confidential Information to any party other than the EC relevant regulatory authority is required by law, that disclosure does not constitute a breach of this Agreement so long as Investigator

a. notifies THE SPONSOR in writing in 15 working days advance of the disclosure so as to allow THE SPONSOR to take legal action to protect its Confidential Information,

b. discloses only that Confidential Information required to comply with the legal requirement, and

c. continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

14.5 **Individually Identifiable Health Information**. If, in connection with this Study or performance of this Agreement, THE SPONSOR comes into contact with individuality identifiable health information relating to subjects who are not Study subjects, THE SPONSOR agrees to maintain the confidentiality of such information and not to use it for any purpose.

14.6 **Survival of Obligations.** These obligations of confidentiality survive termination of this Agreement and continue for a period of five years after completion of the studies.

14.7 **Return of Confidential Information**. If requested by THE SPONSOR in writing, Investigator will return all Confidential Information except that required to be retained at the Study site by law. However, Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

15. Study Data. Biological Samples and Study Records.

15.1 **Study Data.** During the course of the Study, Investigator will collect and submit certain data to THE SPONSOR or its agent, as specified in the Protocol. This may include case report forms or their equivalent ("Case Report Forms"), or other types of medical reports, subject diary, or any combination of these (collectively, "Study Data"). Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Investigator will deliver Study Data to THE SPONSOR or its agent within the time periods specified below.

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a. **Ownership of Study Data**. Subject to Investigator's right to publish the results of the Study (see Section 18, Publications), THE SPONSOR is the exclusive owner of all Study Data.

b. **Non-exclusive License.** THE SPONSOR grants Investigator no right to use study data for any purpose including research and/or education purpose.

c. **Data Management and statistical Analysis**: THE SPONSOR or its representative shall carry out the data management and statistical analysis. THE SPONSOR may consult and / or provide THE PRINCIPAL INVESTIGATOR for interpretation during report writing.

d. **THE SPONSOR** is the exclusive owner of study data.

15.2 **Biological Samples**. If so specified in the Protocol, Investigator may collect and provide to THE SPONSOR or its designee biological samples (e.g., blood,) obtained from Study subjects for testing that is directly related to subject care or safety monitoring.

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

b. **Analysis samples.** THE SPONSOR or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, THE SPONSOR will provide the results of these tests ("Biological Sample Analysis Data") to the Investigator or Study subject.

c. **Ownership**. THE SPONSOR is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

15.3 **Study Records.** Investigator will ensure that subject's Study records, which include the Investigator's copies of all Study Data as well as relevant source documents (collectively, "Study Records"), are kept up to date and maintained in accordance with applicable regulations and institutional guidelines.

a. Retention. Investigator will retain Study Records, under storage conditions conducive to their stability and protection, for a period of at least 3 years after the completion/termination of the study or submission of the data to the regulatory authority (ies) whichever is later unless THE SPONSOR authorizes, in writing, earlier destruction. Investigator agrees to notify THE SPONSOR before destroying any Study Records after the required retention period. Investigator further agrees to permit THE SPONSOR to ensure that the records are retained for a longer period if necessary, at THE SPONSOR expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

16 Monitoring. Inspections and Audits.

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SGPGIMS,Lucknow

16.1 **Monitoring.** THE SPONSOR / CRO or its representative shall be entitled at its absolute discretion (and in such form as THE SPONSOR / CRO sees fit) to monitor and audit the conduct of the Study. Upon reasonable notice, Investigator will permit THE Sponsor's / CRO's representatives access to the premises, facilities, procedures and records relating to the Study, investigators, and research staff as required to accomplish this. The Investigator agrees to co-operate and provide all reasonable assistance with any monitoring and/or auditing activity. No such monitoring and/or auditing by THE SPONSOR / CRO will relieve the Investigator of any of its obligations hereunder.

16.2 **Inspections and Audits.** The Study is subject to inspection by regulatory agencies worldwide. Regulatory inspections may occur after completion of the Study and may include auditing of Study Records. Auditing involves comparison of Case Report Forms or Data Records with the source documentation on which they are based. THE SPONSOR / CRO or its representative may also choose to audit Study Records as part of its monitoring of Study conduct.

a. **Notification.** Investigator will notify THE SPONSOR / CRO or its representative as soon as reasonably possible if the site is inspected or scheduled to be inspected by a regulatory agency.

b. **Cooperation.** Investigator will cooperate with regulatory agency or THE SPONSOR / CRO or its representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

c. **Resolution of Discrepancies.** Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records.

d. **Inspection Findings and Responses.** Investigator will promptly forward to THE SPONSOR / CRO or its representative copies of any inspection findings that Investigator receives from a regulatory, agency. Whenever feasible, Investigator will also provide THE SPONSOR / CRO or its representative with an opportunity to prospectively review and comment on any Investigator responses to regulatory agency inspections.

e. **Data Clarification Form**: THE SPONSOR / CRO or its representative may raise data clarification forms (queries) during or after the monitoring and/or auditing and/or statistical review of the study, which THE PRINCIPAL INVESTIGATOR or his/her nominee shall clarify within 7 working days.

f. **Study Conduct Evaluations.** THE SPONSOR / CRO or its external service providers may document and evaluate the performance of Investigator in the conduct of the Study. THE SPONSOR / CRO or its representative will use these evaluations solely for internal purposes.

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17. **Inventions.**

18.1 **Notification**. If the conduct of Study results in any invention or discovery whether patentable or not ("Invention"), Investigator will promptly inform THE SPONSOR or its representative.

18.2 **Assignment**. Investigator will assign all interest in any such Invention to THE SPONSOR, or its representative free of any obligation or consideration beyond that provided for in this Agreement.

18.3 **Assistance**. Investigator will provide reasonable assistance to THE SPONSOR or its representative in filing and prosecuting any patent applications relating to Invention, at THE Sponsor's expense.

18. **Publications.**

The findings of this study may be published in a scientific journal or presented at a scientific meeting with prior permission from SPONSOR The sponsor reserves the right to review all manuscripts prior to submission for publication or any paper before it is presented. In accordance with standard editorial and ethical practice, the sponsor will generally support publication of multicentric trials only in their entirety and not as individual center data. Authorship will be determined by mutual agreement between the sponsor in conjunction with the CRO and the Principal investigator(s).

19. **Debarment and Exclusion**. Principal Investigator and Investigator each certify that it/s/he is not debarred and that it/s/he is not and will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Investigator and Principal Investigator will notify THE SPONSOR promptly if either of these certifications needs to be amended in light of new information.

20. **Use of Name.** Neither party will use the name of the other party or any of its employees for promotional or advertising purposes without written permission from the other party. However, THE SPONSOR reserves the right to identify THE PRINCIPAL INVESTIGATOR and Investigator in association with a listing of the

Protocol in publicly available listings of ongoing clinical trials, or other subject recruitment services or mechanisms.

21. **Assignment and Delegation.**

21.1The Principal Investigator may not assign its rights or delegate or subcontract any duties under this Agreement without written permission from THE SPONSOR / CRO any attempt to so assign, delegate, or subcontract is invalid. THE SPONSOR / CRO authorizes delegation or subcontracting any duties.

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21.2 **Affiliates**. As used in this Agreement, the term "affiliate" means any entity that directly or indirectly controls, is controlled by, or is under common control with THE SPONSOR / CRO.

21.3 **Successors and Assigns**. This Agreement will bind and inure to the benefit of the successors arid permitted assigns of each party.

22. **Conflict with Attachments**. If there is any conflict between this Agreement and any Attachments to it, or between this Agreement and the Protocol, the terms of this Agreement control.

23. **Liability, Indemnification and insurance**

23.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject, he or she shall be given free medical management as long as required or until it is proved that the injury is not related to the IP (whichever is earlier)

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of study related injury or death of the subject shall be borne by the sponsor;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death:

(a) Adverse effect of the Investigational Medicinal Product;

(b) Violation of the Protocol, scientific misconduct or negligence by the Sponsor's Representative, CRO or the Investigator, Provided that if such violation of the Protocol, scientific misconduct or negligence is by the Investigator, then the Investigator will be liable to reimburse to the Sponsor representative the expenses on such medical management and financial compensation that the sponsor's representative shall have paid to the subject or his/her nominee(s), as the case may be;

(c) Failure of the Investigational Medicinal Product to provide intended therapeutic effect where the standard care though available was not provided to the subject as pee trial protocol;

(d) Use of placebo in a placebo-controlled trial where the standard care though available was not provided to the subject as pee trial protocol;

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

(f) For injury to a child in-utero because of the participation of parent in the Study;

(g) Any clinical trial procedures involved in the Study."

(9) The Sponsor's representative shall indemnify, defend and hold harmless the Indemnitee, from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from the use of the Product in connection with the Clinical Trial.

23.2 In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the Sponsor's / CRO's representative and shall assist the Sponsor's representative and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses. The Principal Investigator and the Institution agree to cooperate with and to authorize the Sponsor's representative to carry out the sole management and defense of such claim or action. Neither the Principal Investigator nor the Institution, its trustees, officers or Related Persons shall compromise or settle any claim or action without the prior written approval of the Sponsor.

23.3 Notwithstanding the foregoing, the Sponsor's representative shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless the Sponsor, officers, directors, agents and employees for loss or damage resulting from:

(i) failure of the Institution or the Principal Investigator or the Additional Personnel to adhere to the terms and provisions of the Protocol or any amendments thereto (including but not limited to the Principal Investigator's and the Institution's obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol (and any appendix or attachment to the Protocol), or the Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Clinical Trial, including but not limited to the Product, any comparative drug and any placebo;

(ii) Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable Health Authorities' requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

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

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

23.4 The Institution shall secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:

(i) Medical professional and/or medical malpractice liability (including coverage for the Principal Investigator);
(ii) General liability (including coverage for the Clinical Trial site); and
(iii) Worker's compensation coverage,

in amounts required by applicable federal, provincial or state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Clinical Trial.

Upon request of the Sponsor, copies of certificates evidencing such insurance coverage will be made available to the Sponsor's representative and the Institution shall provide thirty (30) days' prior written notice to the Sponsor's representative in the event of cancellation or any material change in such insurance.

Term:

The term of this Agreement shall commence on the Effective Date and terminate upon the completion of the Study and the submission of all information and reports as described in the Protocol unless sooner terminated as provided herein.

24. **Termination.**

24.1 **Termination Conditions**. This Agreement terminates upon the earlier of any of, the following events:

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

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

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

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

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

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

24.2 **Payment upon Termination**. If the Study is terminated early in accordance with Section 24 Termination Conditions, above, THE SPONSOR / CRO will provide a termination payment equal to the amount owed for work already performed, in accordance with Attachment A, less' payments already made. If the Study was never initiated because of disapproval by the EC (see Section 23.1.a, Disapproval by EC , above), THE SPONSOR / CRO will reimburse Investigator for EC fees and for any other expenses that were prospectively approved, in writing, by THE SPONSOR or its representative.

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

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

15. Force majeure: Neither party shall be liable to the other party or shall be in default of its obligations hereunder if such default is the result of war, hostilities, revolution, civil commotion, strike, epidemic, accident, fire, wind, flood or because of any act of God or other cause beyond the reasonable control of the Party affected. The Party affected by such circumstance shall promptly notify the other party in writing when such circumstance cause a delay or failure in performance ('a Delay') and when they cease to do so. Any such non-performance shall be excused for the period of such delay, provided Investigator

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/ Institution / CRO has used best efforts to mitigate the disruption in services and the resulting costs of such delays to SPONSOR / CRO. SPONSOR / CRO shall have the right to terminate a agreement affected by the Delay if Delay affect the performance and such delay lasts for more than ninety (90) days.

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

If to Sponsor:	Attn: Dr. Agam Shah Phone: 022- 26596762
If to Institution:	Attn: Prof Rakesh Kapoor Phone: 0522-2494001
If to CRO:	Attn: Dr. Monjori Mitra Phone: 9831075734
If to Principal Investigator:	Attn: Dr. Piyali Bhattacharya Phone: 9415104073

24 **Modification**. Any alteration, modification or amendment to this Agreement must be in writing and signed by each of the parties.

25. **Entire Agreement.** This Agreement and any Exhibits and Attachments represent the entire understanding between the parties relating to the conduct of this Study. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive termination.

26. To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial will be retained for a period of at least 3 years after the completion/termination of the study or submission of the data to the regulatory authority (ies) whichever is later. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform the Sponsor, the Parties shall discuss in good faith in order to find an alternative solution for the proper archiving of these elements in accordance with the applicable regulations. Subjects' files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of the Sponsor

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21. Governing Law: This agreement shall be interpreted and enforced under the laws of India and the Courts of Lucknow shall have exclusive jurisdiction to resolve any dispute under this Agreement.

Any dispute or difference which may at any time arise between the parties hereto as to the construction, meaning or effect hereof or as to any clause, matter or thing herein contained or as to the rights or liabilities of the parties hereunder then the Parties shall attempt to settle such dispute amicably between them. In the event that such dispute has not been amicably settled within 90 days, then such a question or dispute shall be referred to the arbitration of a sole arbitrator to be mutually appointed by both the parties, under and in accordance with the provisions of the Arbitration and Conciliation Act, 1996 and the rules thereunder, as amended from time to time. The venue of such Arbitration shall be in Lucknow and the arbitration proceedings shall be conducted in English. The decision of such arbitrator shall be final, binding and conclusive on the Parties. The parties hereto agree that the Courts in Lucknow, India alone shall have exclusive jurisdiction in respect of any matters pertaining to, arising out of or in connection with Agreement.

Executed by the parties

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

SPONSOR

Wockhardt Ltd.
Mumbai.

11-9-18

Name: Dr Rishi Jain, VP – Medical Affairs, Wockhardt Ltd.
Date: _____

CLINICAL RESEARCH ORGANIZATION

Medclin Research
Kolkata.

Name: DR. MONJORI MITRA, RESEARCH DIRECTOR
Date: 03/09/2018

THE PRINCIPAL INVESTIGATOR

PI Name: DR. PIYALI BHATTACHARYA
Date- 19/11/2018.

INSTITUTION

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

Name:
Date- 04.12.2018

I have read and understand this Agreement and accept the terms as they relate to my activities as Principal Investigator. I further agree to ensure that all sub-investigators and research staff are informed of their obligations under this Agreement.

Principal Investigator

Date- 19/11/2018.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

EXHIBIT A

Site Budget (Per Subject)					
Sl.No	**Budgetary Provision per completed subject**	**Rs.**	**No.**	**Units**	**Amount in Rs per subject**
1	Investigator fees	5800	1	Subject	5800
2	Phlebotomist	200	1	Subject	200
3	Total fees				6000
4	Reimbursements (travel)	300	4	visit	1200
					7200
Sl.No	**Budgetary Provision per incomplete subject**				**Amount in Rs per subject**
1	Investigator fees	2900	1	Subject	2900
2	Phlebotomist	100	1	Subject	100
3	Total fees				3000
5	Reimbursements (travel)	300	2	visit	600
					3600
Sl.No	**Other Expenses to be borne directly**				**Amount in Rs per subject**
1	EC fees				Actuals
2	CRC	15000	10	Months	150000
3	Institutional Overheads	25% of PI fees			Acttuals

a. The Principal Investigator hereby confirms that she has read and understood the clinical trial protocol entitled "A Phase II / III, prospective, randomized, active-controlled, open label, Parallel group, 2-arm, Multi-centric trial for evaluation of Efficacy, Safety, and Tolerability of DTaP+Hib (Diphtheria, acellular Pertussis, Tetanus and Hemophilus influenza b) combination vaccine in Indian pediatric population in comparison with Pentaxim® (Diphtheria, acellular Pertussis, Tetanus, Hemophilus influenza b and IPV) combination vaccine of Sanofi Pasteur". (WOC/DTH/CT-56/15, Version 02 / 20 May 2016, Amendment No. 03/ 03 Oct 2017).

b. All amendments and appendices have also been read and understood. The investigator agrees to the protocol of this trial and will perform the study in accordance with ICMR Good Clinical Practice, and applicable laws, rules and regulations.

c. The Sponsor had declared that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely Drugs & Cosmetics Act, 1940 and

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Drug & Cosmetic Rules 1945 and their subsequent amendments (including Schedule Y) are obtained by them for use of the same on children.

EXHIBIT B

Serial No.	Milestone
1.	Study Startup fee – Rs. 40,000
2.	Completion of 20 subjects (Phase II)
3.	Initiation of Phase III – Rs. 40,000
4.	Completion of 50% subjects
5.	Completion of Phase III (Excluding 10 % of the total budget of Phase III)
6.	Signing of clinical study reports (10% of total Budget)

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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL07431673165790Q
Certificate Issued Date	:	30-Mar-2018 12:28 PM
Account Reference	:	IMPACC (IV)/ dl732103/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL73210318441565745325Q
Purchased by	:	JSS Medical Research India Private Limited
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	JSS Medical Research India Private Limited
Second Party	:	Not Applicable
Stamp Duty Paid By	:	JSS Medical Research India Private Limited
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

DATED 29 May 2018
JSS MEDICAL RESEARCH INDIA PRIVATE LIMITED
Vatika Mindscapes (Tower B), Plot 12/2, Sector 27D,
Faridabad- 121003 (Haryana) India
(AS THE CRO)
Dr. Sudeep Kumar
Professor
Department of Cardiology
Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
(AS THE PRINCIPAL INVESTIGATOR)
AND
Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
(AS THE SITE/INSTITUTION)

CLINICAL TRIAL AGREEMENT

JSS Signatory

PI Signatory

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Statutory Alert:

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

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JSS Signatory

PI Signatory

Institution head signatory

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This Clinical Trial Agreement (the "**Agreement**") is dated: 29 May 2018.

BETWEEN:

1. **JSS Medical Research India Private Limited.,** a company registered under the provisions of Indian Companies Act, 1956, having its office at 12/2, 6th Floor, Tower-B, Vatika Mindscapes, Sector 27-D, Faridabad-121003, Haryana, India acting through Kishor Kumar, Financial Controller, India being authorized to sign this Clinical Trial Agreement on behalf of Sponsor, Abbott Healthcare Pvt. Ltd. (hereinafter referred to as "**JSS India**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

2. **Dr Sudeep Kumar**, working as [Professor, Department of Cardiology at [Sanjay Gandhi, PGIMS Hospital] having his residence at SGPGI Campus Raebareli Road Lucknow (hereinafter referred to as the "**PI**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

   And

3. **Sanjay Gandhi, PGIMS Hospital**, a *hospital/health care centre/company/nature of entity* registered under the provisions of Indian Companies Act, 1956 OR any other relevant law, having its registered office at Rae bareli road, Lucknow-226014 acting through its Dr Rakesh Kapoor, Director being authorized to sign this Agreement (hereinafter referred to as the "**Site**" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

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

Whereas:

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

B. The Site is engaged in Clinical Trials and the PI is a *consultant* at the Site.

C. Abbott Healthcare Pvt. Ltd (hereinafter referred to as "**sponsor**") is Sponsor, desires to conduct a clinical trial in respect of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction and JSS India, the PI and the Site have represented willingness to participate in the Clinical Trial.

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

JSS Signatory

PI Signatory

Institution head signatory

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1. **Definitions and Interpretations**

1.1 In this Agreement:

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

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

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

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

"**Clinical Trial**" shall mean a clinical trial "A Prospective, Randomized, Double-blind, Double dummy, Multi Centre, Comparative Phase III Clinical Trial to Evaluate the Efficacy and Safety of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction". Conducted as per the Protocol.

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

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

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

"**Drug**" or "**Clinical Trial Drug**" shall mean the chemical compound invented by Sponsor, excluding a placebo, in respect of which the Clinical Trial is being conducted.

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

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

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

"**Feasibility Study**" shall mean shall mean a feasibility study conducted by JSS India to assess the feasibility of conducting clinical study(ies) in respect of a Project prior to commencement of a Project.

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

"ICH GCP Guidelines" shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June 1964 with applicable updates and amendments thereof.

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

"Indian GCP" shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research. **"Information Brochure"** shall mean the information brochure of Sponsor.

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

"Investigational Products" shall mean the chemical compound invented by Sponsor, including a placebo, in respect of which the Clinical Trial is conducted or any medical device, etc. developed by Sponsor.

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

"Subject" shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

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

"Protocol" shall mean Protocol Version 1.1 dated 30 June 2017, Protocol No. IVAP3001 as provided by Sponsor.

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

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

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

"Services" shall mean the services detailed in Schedule 'A'.

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

"Sponsor Property" shall mean all data and information generated or derived by JSS India arising out of any Services performed by JSS India.

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

1.2 In this Agreement:

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

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

references to this Agreement include the Recitals and the Schedules;

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

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

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

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

2. Scope of the Agreement

The PI agrees to perform the Clinical Trial for and on behalf of the JSS India/sponsor in accordance with the Protocol and/or any other document specifically provided in this respect by JSS India.

3. Term

3.1 This Agreement shall commence on the Effective Date and shall continue till the Clinical Trial is completed as per the Protocol or till the date it is terminated earlier in accordance with this Agreement (the "**Term**").

4. Clinical Trial

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

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

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

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5. Responsibilities and Obligations of the Parties

5.1 JSS India shall be responsible for the following:

i. Clinical Trial Documents, Investigational Products: Providing all the Clinical Trial Documents and the Investigational Products in advance or on time to the PI and/or the Site on behalf of sponsor.

ii. Other Duties: Site Monitoring, Medical Monitoring, Clinical Data Management, including electronic data capture Statistical Programming, Clinical Study Report preparation & IMP logistic management

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

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

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

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

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

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

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

6 Representations, Warranties and Covenants.

6.1 JSS India represents, warrants and covenants to Sponsor as follows:

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

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

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

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

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

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

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

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

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

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

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

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

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

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

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

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

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

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

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

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

ii. Upon JSS India request from time to time, PI will certify in writing, the PI compliance with the foregoing provisions of this paragraph.

7 Use of Name

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

8 Ownership of Property and Data

Sponsor shall have sole ownership and rights to any inventions or discoveries relating to the Drug or study, whether patentable or not, made in the performance of this Agreement.

9 Record Retention and Site Audits

a. The Site shall retain all records and documents pertaining to a Clinical Trial for a period of at least fifteen (15) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the

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

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

10 Publications

JSS India and Sponsor shall retain ownership of all original Case Report Forms, data, analyses and reports that result from the Clinical Trial. Notwithstanding the foregoing, the PI and the Site understand and agree that participation in the Clinical Trial may involve a commitment to publish the data from the Clinical Trial in a cooperative publication with other investigators prior to publication or presentation of individual investigator results. The PI and the Site may only publish the results of the Clinical Trial in accordance with Applicable Laws and with prior written information & approval from the Sponsor . The PI and the Site agrees to delete any information that may be confidential or proprietary.

11 Fees

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

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

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

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

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

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

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(b) the JSS India, if so authorized, shall pay the invoiced amount within sixty (60) business days of the date of the invoice. The payment shall be made through crossed cheque/DD, as applicable:

PAYEE INFORMATION:

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

Payee details:

PAYEE NAME	Director SGPGI Research Account
PERMANENT ACCOUNT NUMBER (PAN) OF PAYEE	AAAJS3913N

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

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

12 Insurance

a. JSS India shall maintain all adequate insurance coverage, including a (i) professional liability insurance, (ii) indemnity insurance covering JSS India, the PI and the Site, (iii) human clinical trial insurance covering JSS India, the PI and the Site during the Term.

b. The JSS shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4 to the Site and the PI.

13 Indemnification

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

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

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

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

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

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

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

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

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

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

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

13.3 The Site, the PI, the Site Indemnitees, the Clinical Trial and JSS India or the associated staff (each Party referred to as "**Indemnified Party**") seeking indemnification under Clause 3 above, directly or due to a third-party claim shall give written notice to the JSS India, against whom such indemnification rights are claimed. Pursuant to Clause 3 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify the JSS India/Sponsor shall not relieve the JSS India/Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced the JSS India/Sponsor or its defences. With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 3 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense of Sponsor, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own if Sponsor fails to initiate the same within fifteen (15) business days of receipt of the notice in writing of such legal claim or proceeding from Sponsor; provided, however, that: (i) the Indemnified Party shall obtain the prior written consent of the JSS India/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if (A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against Sponsor, (B) such settlement does not expressly unconditionally release the JSS India/Sponsor from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or (C) involves criminal or quasi-criminal allegations against the JSS India/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim; (ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified

Party or payable by Sponsor in connection with such claim or legal proceeding; (iii) the JSS India/Sponsor shall be entitled to participate in the defence of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and (iv) if the Indemnified Party abandons or fails to reasonably assume the defence of any such claim or legal proceeding, JSS India/Sponsor may assume control of the defence of such claim or legal proceeding at its own expense; provided, however, that if the JSS India/Sponsor shall control the defence of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, the JSS India/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim, if (A) pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnified Party, (B) such settlement does not expressly unconditionally release the Indemnified Party from all liabilities and obligations with respect to such claim and all other claims arising out of the same or similar facts and circumstances, with prejudice, or (C) involves criminal or quasi-criminal allegations.

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

13.5 Entire Obligation

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

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

14 **Confidentiality**

a. All of the information disclosed by JSS India or developed hereunder by the PI, the Site or associated staff shall be subject to the following provisions: (a) neither the PI, the Site, nor associated staff or any other person engaged in the Clinical Trial shall disclose the information to any third party (other than JSS India or its representatives) without the prior written permission of by JSS India and (b) neither the PI, the Site nor associated staff or any other person engaged in the Clinical Trial shall use the information for any purpose other than the conduct of the Clinical Trial. However, nothing herein shall be construed as preventing the PI or the Site from publishing the data generated from the study, as provided in Clause 7 above.

b. In handling a Subject's medical records, the PI, the Site and associated staff shall hold in strict confidence the identity of the Subject, and shall comply fully with any and all Applicable Laws regarding the confidentiality of such records.

15 Termination

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

15.2 The CRO may terminate for any of following reasons:

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

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

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

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

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

f. Unauthorized replacement of PI

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

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

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

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

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

16 Miscellaneous

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

If to JSS India:

JSS Medical Research India Private Limited
Vatika Mindscapes (Tower B), 6th Floor,
Plot 12/2, Sector 27D, Faridabad-121003,
Haryana, India
Attention: Dr. Renu Razdan
Designation: Vice President, India Operations
Telephone: +91 129 6613 500
E-mail: renu.razdan@jssresearch.com

If to the PI:

Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
Attention: Dr. Sudeep Kumar
Designation: Associate Professor
Telephone: 9919002761
Email:sudeepkumar@yahoo.com

If to the Site:

Sanjay Gandhi PGIMS,
Rae Bareli Road, Lucknow
Uttar Pradesh-226014
Attention: Dr. Rakesh kapoor
Designation: Director
Telephone: 9415410130
Email: rkapoor@sgpsi.ac.in

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

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

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

16.5 Force Majeure: In the event either Party shall be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of a Disability, then performance of such act (except for the payment of money owed) shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of the commencement and termination of the Disability. In case a Disability continues for more

than three (3) months, the Party(ies) unaffected by the Disability may terminate this Agreement upon prior written notice to the affected Party. Should the Disability affect the performance of both parties, then such termination shall only be by mutual written agreement.

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

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

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

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

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

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

JSS Signatory

PI Signatory

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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

JSS India

By:
Print Name: Kishor Kumar

Title: Financial Controller
JSS Medical Research India Private Limited

Date: 28 MAY 2018

The Principal Investigator

By:
Print Name: Dr Sudeep Kumar
Title: Professor
SGPGIMS, Lucknow

Date: 01 June 2018

The Site

By:
Print Name: Dr Rakesh Kapoor
Title: Director
SGPGIMS, Lucknow

Date: 18 JUNE 2018

JSS Signatory

PI Signatory

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Schedule A

[List of services to be provided by the PI and/or the Site]

Protocol Title: A Prospective, Randomized, Double-blind, Double dummy, Multi Centre, Comparative Phase III Clinical Trial to Evaluate the Efficacy and Safety of Ivabradine Prolonged Release Tablets in Patients with Stable Chronic Heart Failure with Systolic Dysfunction

Protocol ID: IVAP3001

List of services to be provided by the PI and/or the Site, but not limited to:

1. *Identification of protocol eligible patients for the study*
2. *Administration of informed consent process and AV recording*
3. *Recruiting patients as per protocol inclusion & exclusion criteria*
4. *Administration of patient diaries as per protocol*
5. Treat study participants as per randomization & adequate treatment follow-up
6. *Taking complete medical history of the patients*
7. *Responsibility for adverse events reporting*
8. *Writing the patient study summary-completion of source documentation*
9. Compliance to study subject visits as per Protocol
10. Transcription of data in to electronic case report form & resolution of data queries
11. Allow oversee of the study by CRO or their designee through regular monitoring visits
12. Site readiness for regulatory inspection & external/internal audits
13. IP management as per protocol and Archival of study documents & material
14. Regulatory document submission & management as applicable
15. Coordination with Ethics committee
16. Maintain Study site files

JSS Signatory

PI Signatory

Schedule B

Budget and Payment Schedules

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Payment shall be made against invoices sent every month according to table mentioned below.

The Parties understand and agree that the currency of the Agreement is and shall remain India Rupee (INR) and shall not be modified notwithstanding any exchange fluctuations that may occur.

All invoices shall be sent to the following address:

JSS Medical Research India Private Limited.
Plot No. 12/2, 6th Floor, Vatika Mindscapes Tower-B,
Near Sarai Khwaja Metro Station,
Sector-27D, Faridabad – 121003 (INDIA)

Each invoice must be an original copy (PDF or fax copies are not acceptable) and contain, as a minimum, the following information:

a) The Research Institution's Name and Address as it is written at the front of this Agreement
b) A description of the deliverable along with supporting attached (e.g. final written report) associated with the invoice
c) The total invoice amount in the currency specified in this Agreement, Payee Name, PAN
d) Signed & date by authorized signatory

Payment Schedule/Milestones per patient:

Visit Type	Amount INR	Approx. Percentage
V1(Including 2D Echo)	7750	25.8%
V2	3250	10.8%
V3	6250	20.8%
V4	3500	11.6%
V5	3500	11.6%
V6	5750	19.1%
Sub Total per subject	30000	NA
IOH @ 25%	7500	25%
Total for per protocol completed patient	37500	NA
Start up Amount	25000	NA

The cost for the trial will be as mentioned below:

a) The cost per protocol-correct and completed subject will be INR 30,000 (excluding Institutional overhead)
Note: Completed patient means once the subject has completed the final follow up and complete data entered and verified in the eCRF by the monitor.

This will include the following fees, as applicable, but not limiting to:

- The PI fees, study team fees, costs for unscheduled visits, site infrastructure maintenance for this study, stationery, courier and other study-related bills.

JSS Signatory

PI Signatory

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

b) If required/requested by site, A nonrefundable advance amount of INR 25000 would be issued to the site upon receipt of completely executed agreement and unconditional EC approval.

c) The following costs incurred by site, where applicable, would be reimbursed to site upon receipt by CRO of original receipts/ bills:

i. Fees related to local Ethics Committee reviews
ii. SAE management costs: The SAE management costs are applicable to all SAEs only related to the Clinical Trial/ protocol/ Investigational Product. The costs would be reimbursed to the site once the original bills/receipts are made available to CRO i.e. bills pertaining to hospitalization, investigations & procedures, medications for the SAE.
iii. This Clinical Trial will not involve any monetary expenses. Subjects will be reimbursed for all their expenses in connection with this Clinical Trial on actual basis (e.g. travel costs) by CRO. Subject travel re-imbursement will be paid on actuals upto Rs. 500 per visit upon producing the vouchers/ bills for the same to CRO.

d) The fees for a screen failure patient will be INR 5000. This screen failure payment includes all charges. The screen failure cost shall be applicable for every 3rd Screen failure.

e) Institutional overhead 25% of the total budget (if applicable)

JSS Signatory

PI Signatory

Institution head signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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SCHEDULE C

JSS India on behalf of Abbott Healthcare Pvt.Ltd will make the payments as follows:

(i) Payments will be made once the CRFs for the patient visits have been verified by the CRO/ designee & query has been resolved. Invoices will be raised on monthly basis and sent to CRO for payment. Invoices will be raised on the basis work completed during previous month In the event that a subject withdraws or is withdrawn from the Trial for reasons beyond the Investigator's control (but after commencing the dosing regimen in accordance with the Protocol), payment shall be made pro rata (based on the number of visits completed) in respect of that subject provided all data in respect of that subject up to the time of that subject's withdrawal from the Trial have been completed and sent to and accepted by CRO.

(ii) Invoices will be paid within 60 days of receipts to the payee. Service tax as applicable will be levied on each invoice according to the guidelines of service tax rules of India.

(iii) From each invoice CRO will keep 15% retention money and the same will be paid once all queries are resolved and Clinical trial/Site is closed out in all respects.

(iv) There is no other amount payable to Institute/Investigator for the Clinical Trial (except) mentioned in this agreement.

(v) Above budget does not include any Related Adverse Event or Serious Adverse Event expenses. Any related Adverse Event or Serious Adverse Event expenses will be reimbursed on actual. Reimbursement of Adverse Event or Serious Adverse Event management will include but not limited to Investigations, Hospitalisation, Treatment costs. Site agrees to take approval for any special investigations in case of Adverse Events. Site agrees to give timely update on the plan of management in terms of cost, on the cost incurred in management of the above events.

vi) In case of early termination of Clinical Trial, final payment calculation will be based on actual work completed. In case extra payment has been made, payee will refund the extra money. In case there is any amount payable to payee the same will be paid by CRO.

vii) All payments are subject to TDS (other taxes as applicable) and all payments will be made once payment is received by CRO from Sponsor.

Summary of the items included in payment & items not to be reimbursed:

Items included in payment:

Items included in Professional fees of per patient cost:
• PI fees
• Clinical Trial team fees
• Administrative cost
• Payments for unscheduled visits
• Site infrastructure (including Telephone/ fax/ internet), IMP storage.
• Stationary and Couriers
Pass through costs to be paid on Actuals:
• Ethics Committee fees
• SAE management costs, if any
• Subject Compensation if any
• Travel reimbursements of patients

JSS Signatory

Institution head signatory

PI Signatory

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Authorised Signatory

MUMBAI - 400 027

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FIRST ADDENDUM TO CLINICAL TRIAL AGREEMENT

This First Addendum is made at Mumbai and entered into on 9th day of March, 2021 by and between;

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

AND

Dr. Sanjoy Kumar Sureka consulting at **Department of Urology and Renal Transplant, Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh- 226014, India** (hereinafter referred to as "**the Investigator**", which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executors, administrators and successors) and the Second Part;

AND

Sanjay Gandhi Postgraduate Institute of Medical Sciences, Rae Bareli Road, Lucknow, Uttar Pradesh- 226014, India represented by Prof. R. K. Dhiman whose designation is **Director**; hereinafter referred to as "**the Institution**", (which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the Third Part;

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

WHEREAS

A. By a Affiliation Agreement for Researchers dated 23rd Feb 2018 entered into between the Parties hereto ("**Agreement**"), the Investigator and the institution have agreed to provide certain services to Novartis on the terms and conditions contained in the Agreement.

B. Now by this first Addendum, the Parties are desirous of amending the following clause 7 on the terms and conditions herein after appearing.

This Agreement shall be effective from 02-Jul-2020 and shall remain in force until 30-June-2021 (both days inclusive) unless earlier terminated in accordance with this Section.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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

1. This Addendum shall be effective from 02-Jul-2020 and shall be coterminous with the Agreement read with the Prior Addendums for all intents and purposes.

2. Save and except to the extent aforesaid, all other terms and conditions of the Agreement shall continue to remain unaltered, valid and binding upon the Parties.

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

Novartis Healthcare Private Limited

By: _____

Name: Murugananthan K.

Title: Country Monitoring Head

Date: 17 Feb 2021

Sanjay Gandhi Postgraduate Institute of Medical Sciences

By: _____

Name: **Dr. Sanjoy Kumar Sureka**

Title: Investigator

Date:

By: _____

Name: **Prof. R. K. Dhiman**

Title: Institute

Date:

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

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules. You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.
2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.
The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.
In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.
You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent
I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.
I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

- ☐ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..
- ☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.
- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date: _____

Name: **Dr. Sanjoy Kumar Sureka**
Principal Investigator

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 3
Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:
- (i) securing any improper advantage; or
- (ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –
- (i) transactions are executed in accordance with management's general or specific authorization;
- (ii) transactions are recorded as necessary
  - (I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and
  - (II) to maintain accountability for assets;
- (iii) access to assets is permitted only in accordance with management's general or specific authorization; and
- (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ANNEX 4: NOVARTIS PROFESSIONAL PRACTICES POLICY

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INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL92242882852943Q
Certificate Issued Date	:	23-Feb-2018 10:53 AM
Account Reference	:	IMPACC (IV)/ dl982203/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL98220387808030675496Q
Purchased by	:	PHARMAZZ INDIA PRIVATE LIMITED
Description of Document	:	Article 5 General Agreement
Property Description	:	CLINICAL TRIAL AGREEMENT FOR ALZHEIMER PHASE II STUDY
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PHARMAZZ INDIA PRIVATE LIMITED
Second Party	:	SGPGI LUCKNOW AND PROF JAYANTEE KALITA
Stamp Duty Paid By	:	PHARMAZZ INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL TRIAL AGREEMENT BETWEEN

Pharmazz India Private Limited (Sponsor)

And

Sanjay Gandhi Post Graduate Institute of Medical Sciences (Institution)

And

Prof. Jayantee Kalita (Principal Investigator)

PHARMAZZ INDIA PVT. LTD. Saving Lives Through Innovation

Prof. J. KALITA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(27)

FOR THE STUDY

Title of Study: A Prospective, Multicentric, Randomized, Double Blind, Placebo Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of mild to moderate Alzheimer's disease.

Protocol Number: PMZ-1620/CLINICAL-2.2/2017

Version Number: 01

Date of Protocol: 14 June 2017

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter referred to as the "**Agreement**") is made on 28 Mar 2018 ("**Effective Date**") at New Delhi **BY AND BETWEEN**:

PHARMAZZ INDIA PVT LTD, a Company incorporated and existing in accordance under Indian Companies Act, 1956, with its Office at B-4 Sarita Vihar New Delhi 110076 hereinafter referred to "**Pharmazz**", which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE FIRST PART**;

AND

Sanjay Gandhi Post Graduate Institute of Medical Sciences, an Institution having its office Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014, (hereinafter referred to as **"Sanjay Gandhi Post Graduate Institute of Medical Sciences"**, which expression shall, unless repugnant to the context or meaning thereof, be deemed to include its successors and permitted assigns) **OF THE SECOND PART**;

AND

Prof. Jayantee Kalita a registered medical practitioner holding MCI registration number-9795 , is the Professor, , Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014(hereinafter referred to as "**Principal Investigator**"), which expression shall, unless repugnant to the context be deemed not to include its successors and permitted assigns **OF THE THIRD PART**;

PHARMAZZ INDIA PVT. LTD.

J. KALITA

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(24)

Pharmazz , **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator shall hereinafter be collectively referred to as the "**Parties**". Each of the Parties shall hereinafter individually be referred to as a "**Party**".

RECITALS

1. WHERE **(Sanjay Gandhi Post Graduate Institute of Medical Sciences)** is a pioneering institution of world-class investigator sites in India. It is a chain of investigator sites having an exclusive set up for conducting Phase II to Phase IV clinical trials and has assured the sponsor of its capability and infrastructure and logistics to conduct the desirous clinical trial

2. Pharmazz has rights to Intellectual Property related to PMZ-1620 is a lyophilized IRL-1620 Injection, proposed to act as as a Treatment agent in Alzheimer's disease.

3. Principal Investigator **Prof. Jayantee Kalita, DM (Neurology)** is a registered medical practitioner and has been actively involved in many clinical trials both as sub-investigator and as principal investigator.

4. **AND WHEREAS** Pharmazz is desirous of entering into an agreement with **Prof. Jayantee Kalita** for conducting Clinical Trial Phase II study titled "A Prospective, Multicentric, Randomized, Double Blind, Placebo Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of mild to moderate Alzheimer's disease" **Sanjay Gandhi Post Graduate Institute of Medical Sciences** Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014

5. The Principal Investigator has, after careful review of the Protocol provided by Pharmazz and other materials relating to the Clinical Trial conveyed his willingness to **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the proposed Study. Principal Investigator understands that he is bound under his duty to complete this said trial unless repudiated by law or government order.

NOW THEREFORE, THE PARTIES HEREBY AGREE BY AND BETWEEN AS FOLLOWS:

1. DEFINITIONS AND INTERPRETATION

1.1 **Definitions**

All capitalized terms whenever used in this Agreement, unless repugnant to the meaning or context thereof, the following words and terms shall have the meanings set forth below:

a) "**AGREEMENT**" shall mean this Clinical Trial Agreement;

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Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

b) **"CONFIDENTIAL INFORMATION"** means and includes any non-public information disclosed by either party to the other party either directly or indirectly, in writing, orally, by inspection/observation, in any floppy diskette, photocopy, scan, magnetic tape etc., information pertaining to and without limitation to know-how, technical data, trade secrets, research and product plans, services, prototypes, equipments, samples, services, customer lists, marketing strategies, developments, inventions, financial and other business information with regard to this project;

c) **"EFFECTIVE DATE"** shall mean the date of execution of this Agreement;

d) **"INTELLECTUAL PROPERTY"** shall mean and include patents, copyrights, trade names, trademarks, service marks, mask works, trade secrets, inventions, databases, names and logos, trade dress, technology, know-how, and other proprietary information and licenses from third persons granting the right to use any of the foregoing, including all registrations and applications for any of the foregoing that have been issued by or filed with the appropriate authorities, any common-law rights arising from the use of the foregoing, any rights commonly known as "industrial property rights" or the "moral rights" of authors relating to the foregoing, all rights of renewal, continuations, divisions, extensions and the like regarding the foregoing and all claims, causes of action, or other rights arising out of or relating to any actual or threatened infringement by any person relating to the foregoing; all computer applications, programs and other software, including without limitation operating software, network software, firmware, middleware, and design software, all design tools, systems documentation and instructions, databases, and related items; and all cost information, sales and pricing data, customer prospect lists, supplier records, customer and supplier lists, customer and vendor data, correspondence and lists, product literature, artwork, design, development and manufacturing files, vendor and customer drawings, formulations and specifications, quality records and reports and other books, records, studies, surveys, reports, plans and documents. The term shall include all present and future Intellectual Properties, particularly with respect to the present study;

e) **"INTELLECTUAL PROPERTY RIGHTS"** shall mean and include, but shall not be limited to, all foreign and domestic rights, contained in the Intellectual Property defined herein above;

f) **"STUDY" or "CLINICAL TRIAL"** shall mean study entitled "A Prospective, Multicentric, Randomized, Double Blind, Placebo Controlled Phase II Clinical Study to Compare the Safety and Efficacy of PMZ-1620 Therapy along with Standard Supportive Care in Subjects of mild to moderate Alzheimer's disease. As defined in the Protocol.

PHARMAZZ INDIA

KAUR

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

g) "**PROTOCOL**" shall mean: The description of the Study contained in the Study protocol number PMZ-1620/CLINICAL-2.2/2017 (a copy of which is attached as Exhibit A) and all amendments thereto as the Parties may from time to time agree in writing.

h) "**STUDY DRUG**" or "**Investigational Drug**" shall mean: IRL-1620 For Injection 30 µg/vial.

i) "**ETHICS COMMITTEE**" shall mean: An independent body, including but not limited to, independent ethics committee or institutional review board, constituted and registered with the licensing authority under the provisions of Drugs and Cosmetic Act, 1945 and rules amended thereof.

1.2 **Interpretation**

In construing this Agreement:

a) Unless the context otherwise requires, words importing the singular shall include the plural and vice versa;

b) References to a person includes an individual, body corporate, association or body of persons (whether or not incorporated), trust, firm or any other entity by whatever name called;

c) Clause headings are for reference only and shall not affect the construction or interpretation of this Agreement;

d) References to Recitals, Clauses, Exhibits and Schedules are references to Recitals, Clauses, Exhibits and Schedules of and to this Agreement;

e) All the Exhibits referred to in this Agreement shall be deemed to be a part and parcel of this Agreement.

f) wherever the context so demands the references to a Party to this Agreement includes references to its successors or assigns (immediate or otherwise) of that Party and reference to agreements shall include reference to all the amendments thereto made in writing;

g) unless otherwise specified, time periods within or following which any payment is to be made or act is to be done shall be calculated by excluding the day on which the period commences and including the day on which the period ends and by extending the period to the following Business Day if the last day of such period is not a Business Day;

h) unless otherwise specified, whenever any payment is to be made or action taken under this Agreement is required to be made or taken on a day other than a Business Day such payment shall be made or action taken on the next Business Day;

i) the terms "herein", "hereof", "hereto", "hereunder" and words of similar purport refer to this Agreement as a whole; and

PHARMAZZ INDIA PVT. LTD. Serving Through Innovation

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(23)

j) Unless otherwise specified, any reference to "consent" or "approval" of a Party under this Agreement shall mean the consent or approval of such Party at its sole discretion.

2. ROLE &RESPOSIBILITIES

The Scope of Services (hereinafter referred to as '**Services**'), under this Agreement includes **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator to complete the following -

Responsibility of the Sanjay Gandhi Post Graduate Institute of Medical Sciences & Principal Investigator

The **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees to provide full support to the Principal Investigator **at Sanjay Gandhi Post Graduate Institute of Medical Sciences** Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014, to conduct the Clinical Trial in **Sanjay Gandhi Post Graduate Institute of Medical Sciences** premises and to make all reasonable endeavors to retain the P.I. and utilize reasonably the facilities available in the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the said hospital for the Study and shall allot qualified co-investigators, sub investigators, if any, and other persons, with prior consent of concerned authorities for proper conduct of the Study in accordance with the terms of this Agreement and the Protocol.

2.1 The Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be jointly and severally responsible

a) to conduct and complete the Clinical Trial of the Pharmazz strictly in accordance with the applicable regulatory requirements and the Protocol as approved by the Ethics Committee; Guidelines/ Standard Operating Procedure/ Protocol will be provided by the sponsor to conduct clinical trial which has to be adhered to in consonance with Hospital's protocol and the same is annexed hereto as Exhibit A, which also forms part of this agreement.

b) to comply with all applicable rules, regulations and guidelines, both national and international, including but not limited to, ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95), Good Clinical Practice Guidelines issued by CDSCO, Directorate General of Health Services, Govt. of India; Drugs and Cosmetics Act 1945 and Rules, gazette, notifications made thereunder (as amended from time to time), ethical principles contained in the current revision of Declaration of Helsinki, Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research ("**Applicable Laws & Guidelines**");

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c) to fulfill all other terms and conditions stipulated herein and in the Exhibits hereto, during the period of, and also after the completion of, the Clinical Trial as agreed upon; and

d) to provide Pharmazz a copy of registration certificate issued by the licensing authority to Ethics Committee before initiation of the Clinical Trial.

2.2 The Principal Investigator shall personally review all case report forms including Electronic Case Report Forms to assure its completeness and accuracy. A case report form/eCRF is deemed complete when:

a) the case report form has been completed by the Principal Investigator in accordance with Study requirements;

b) it relates to a properly qualified subject who participated in and completed the Study in accordance with all Study requirements and directions from the Pharmazz; and

c) it can be used in all analyses of the Study results.

The Principal Investigator undertakes that all data shall be submitted in a timely manner to Pharmazz.

Principal Investigator shall at all-time exercise independent medical judgment as to the compatibility of each subject with the Study as per Sponsor's Protocol requirements. Principal Investigator shall notify the Pharmazz, Chairman of Ethics Committee and licensing authority i.e. DCGI within twenty four (24) hours in writing of any serious adverse events related to or unrelated to the Study Drugs and of overdoses and any other event as set forth in detail in the Protocol and as required by the Drugs & Cosmetic Act with latest amendments.

The Principal Investigator and Pharmazz shall provide report of serious adverse events of death after due analysis to the Head of Institution, Chairman of the Ethics Committee, IEC and Chairman of the expert committee constituted by licensing authority with a copy to the licensing authority of any deviations in the Protocol or serious adverse events within fourteen (14) calendar days from the date of occurrence of such deviation and/or serious adverse events of death, as the case may be.

The Principal Investigator and Pharmazz shall provide report of serious adverse events other than death after due analysis to the Head of Institution, Chairman of Ethics Committee, licensing authority within fourteen (14) calendar days of occurrence of such serious adverse events other than death.

In the event the Principal Investigator becomes unwilling or unable to perform the Study, at any latter stage, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall provide notice promptly to the Study subjects, Ethics Committee and Pharmazz before Principal Investigator intends to withdraw from Clinical Trial. The Principal Investigator and **Sanjay Gandhi Post Graduate**

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Institute of Medical Sciences shall endeavour to promptly recommend a replacement of Principal Investigator, from among the consultants of the **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz shall have the exclusive right to approve or reject any such replacement of Principal Investigator. The new principal investigator which is approved by the Pharmazz shall be required to agree to the terms and conditions of this Agreement.

2.3 If there is a change in the Principal Investigator, the Organizational Official selects and appoints a new Investigator for the study. The outgoing Investigator notifies the Sponsor and the EC that he or she has relinquished the responsibilities of the Principal Investigator to the person named. The newly appointed Principal Investigator notifies the EC that he or she has read the protocol and agrees to accept the responsibility of the Principal Investigator for that research study. This new Investigator starts research work only after completion of required applicable training.

2.4 Principal Investigator shall ensure that the informed consent form signed by or on behalf of the Study subjects have been reviewed and approved by Ethics Committee prior to initiation of the Study. Upon approval of the informed consent form by the Ethics Committee, a copy of the approval letter shall be provided to the Pharmazz by the Principal Investigator, who shall further obtain informed consent form duly signed by each of the subjects or on behalf of the Study subjects enrolled in the Study in accordance with Applicable Laws and Guidelines. The Principal Investigator shall ensure to maintain for record an audio – video recording of the informed consent process of individual subjects including procedure of providing information to the subjects and their understanding on such consent. However, the audio-video recording shall be shared with the Ethical committee or the regulatory agency if required. The Study of the Pharmazz is being entrusted to the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** as a technical assignment, based on the skill, knowledge and experience of the Principal Investigator in the specialty areas related to the Clinical Trial and **Sanjay Gandhi Post Graduate Institute of Medical Sciences's** experience in conducting Clinical Trial and requisite infrastructure and logistics. The Principal Investigator shall be personally obligated to conduct and complete the Clinical Trial in accordance with the Protocol as well as other terms and conditions specified by the Pharmazz herein. All items received from the Pharmazz, from time to time, (including, but not limited to, Study Drug, documents, Confidential Information, communications, instructions etc.), records and registers required to be maintained and all data generated hereunder by the Principal Investigator, shall be under the exclusive care, custody and responsibility of the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** throughout the period of the Clinical Trial and **with third party vendor or sponsor** for a period of fifteen (15) years after the Study completion or such longer period as required by Applicable Laws & Guidelines. At the end of such period mentioned above, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall obtain written approval from Pharmazz before destruction of such data.

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2.5 Principal Investigator agrees to follow Sponsor's requirement for the Study related duties and functions under this Agreement and the Protocol.

Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall ensure that all the individuals involved in the conduct of the Study shall strictly adhere to the terms and conditions of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and Principal Investigator represents and warrants that it shall not use in any capacity, in connection with the Study, any individual who is not duly qualified or has been debarred pursuant to any Applicable Laws & Guidelines or against whom any action, suit, claim, investigation or legal or administrative proceeding is pending.

2.6 Principal Investigator represents and warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and/or debarment of the persons engaged by Principal Investigator to assist for the Study.

2.7 Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** represents and warrants that all the necessary approvals, permissions and sanctions from Ethics Committee and all the government and regulatory authorities to conduct the Clinical Trial have been obtained **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Pharmazz will provide the Study Drug to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** free of cost/charge and in such quantities sufficient to complete the Study, together with guidelines and descriptions for the safe and proper use, administration, storage and disposal of the Study Drug. Principal Investigator shall use Study Drug and other items provided by the Pharmazz only to conduct the Study in accordance with the Protocol and Applicable Laws & Guidelines and instructions of the Pharmazz and shall not chemically, physically or otherwise modify the Study Drug, unless specifically required to do so by the Pharmazz in writing to the Principal Investigator. Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** jointly and severally agrees that they shall administer, handle, use, store, and or dispose the Study Drug and other items provided by the Pharmazz in compliance with Pharmazz's instructions and all Applicable Laws & Guidelines.

The Parties hereby clearly understand that the subject matter of the Agreement is to clinically evaluate the Safety and Efficacy of PMZ-1620 therapy along with standard supportive care in subjects of Alzheimer's Disease.

3 VISIT AND INSEPECTION

3.1 The Pharmazz or its authorized representatives, and regulatory authorities to the extent permitted by law, shall have the absolute right to:

a. examine and inspect the **Sanjay Gandhi Post Graduate Institute of**

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Medical Sciences's facilities whenever Principal Investigator is conducting Study;

b. Inspect and copy all data and work products relating to the Study, and audit all reports and data from Principal Investigator to ensure compliance with the terms of this Agreement and Protocol.

c. Sponsor will provide the Investigator with the monitoring reports timely for review and consideration.

4 RECORDS AND REPORTING

The sponsor agrees to promptly report any new findings to the Institution/Investigator that could affect the safety of participants or influence the conduct of the study. The sponsor agrees to promptly report Data and safety monitoring reports to the Institution/Investigator.

The sponsor agrees to communicate findings from a completed study to the Investigator and Institution when those findings directly affect participant safety. These findings would be communicated within (03 months) after completion of the study.

5 PAYMENT, PRICING TERMS

5.1 Pharmazz agrees that in consideration of the Principal Investigator's and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** carrying out the Clinical Trial in accordance with the terms of this Agreement, the Pharmazz shall make the payment of the amount as set forth in Exhibit B, to the **Director SGPGI, Research Account** in accordance with the payment schedule set forth therein which shall include the remuneration and all other related cost.

5.2 The Parties agree that the payment of the amount set forth in **Exhibit B** will be paid by the Pharmazz to the **Director SGPGI, Research Account** to compensate all the expenses incurred by them in execution and conducting the Clinical Trial so that, neither the Study subject, nor the insurance program nor the public assistance agency nor the Sponsor shall be liable for the same. The payment of the amount set forth in Exhibit B is also meant to compensate Principal Investigator for the professional and clerical allowances for all the activities as per the Protocol including but not limited to, preparation of the subject records, medication accountability records and other trial related documentation.

5.3 The Parties agree that the amount of payment as mentioned in Exhibit B to be paid to **Director SGPGI, Research Account** shall be paid by Pharmazz.

5.4 Pharmazz shall be entitled to deduct tax at source i.e TDS (if applicable) while making payment to **Director SGPGI, Research Account** under this Agreement. The Budget as reflected in **Exhibit B** is exclusive of taxes.

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5.5 Site will raise GST visit wise as mentioned in Exhibit B. All payments under this Agreement will be made within 15 days from the date of receipt of Invoice.

6 REPRESENTATION AND WARRANTIES

6.1 Each Party represents that it is authorized to enter into this Agreement and that the terms of this Agreement are not inconsistent with or a violation of any contracted or other legal obligation to which it is subject.

6.2 Each Party represents that in performing under this Agreement it shall (a) conduct business in conformance with sound ethical standards of integrity and honesty; b) conduct business in such a way as to not give the appearance of impropriety, even when the behavior or activity is in compliance with the law; and (c) not achieve business results by illegal act or unethical conduct, corrupt and fraudulent practice.

6.3 Sponsor represent that it has all necessary or appropriate qualifications, authorizations, licenses or permits as the sponsor to conduct the study.

6.4 The Parties understand and agree that neither Principal Investigator / Institution's provision of the Services nor its receipt of consideration under this Agreement, shall require, induce, or in any way influence the Principal Investigator / Institution or any of its Affiliates to promote, recommend, require the use of, or list on any formulary, any pharmaceutical product reviewed or involved in the provision of the Services, or any pharmaceutical product manufactured, produced or distributed by Sponsor, or to not list any other pharmaceutical product on any formulary.

7. COMPLIANCE OF LAW

In performing its obligations and exercising its rights under the agreement, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI shall fully comply with all applicable law of India (including without limitation all statutes, Labour Law legislation, decrees, all relevant testifying certificates, ordinances, administrative orders, rules, regulations, and other mandatory directives, policies, and instructions with binding legal effect)

The Second Party i.e. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be solely liable to pay all costs of such compliance. In addition, the Second Party shall be solely responsible to obtain in a timely and effective manner all licenses, permits, and other approvals, if any, necessary for Second Party's successful implementation of its objective under the agreement.

Sanjay Gandhi Post Graduate Institute of Medical Sciences and PI are jointly and severally responsible for all costs, risks, damages, and other liability incurred by it as a result of its failure to comply with the applicable law.

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The Second Party and PI will provide the Sponsor with all necessary documentation to support Sponsor's regulatory filings, as and when required.

8. TERMS AND TERMINATION

8.1. This Agreement shall come into effect on the Effective Date and shall remain in effect for a period of two year from the Effective date of this Agreement.

8.2 Both Parties have the right to terminate this Agreement with or without cause by giving the other Party 90 day written notice.

8.3 On termination or expiry of this Agreement in accordance with the terms hereof, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and the Principal Investigator shall be discharged from all its obligations and duties under this Agreement.

9 VALIDITY & TERMINATION

9.1 Pharmazz may unilaterally terminate this agreement at any time, in whole or in part, for any of the following reasons by giving thirty (30) days written notice: -

a) Material breach of trust by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and PI

b) **Sanjay Gandhi Post Graduate Institute of Medical Sciences** financial insolvency, bankruptcy, assignment in favor of creditors or similar or comparable status

c) Determination by the Pharmazz that the Principal Investigator is not performing the Study as required in the Protocol and/or is not meeting the agreed parameters upon enrollment and as per his undertaking and site feasibility report provided **(Exhibit D);**

d) Failure of the Principal Investigator's or its associated staff or any other person engaged in the Study (excluding subjects) to be available, upon reasonable prior notice by the Pharmazz, to meet at mutually convenient time with the Pharmazz enabling it to monitor the course of the Study as necessary and to discuss information relevant to the Study;

e) Determination by the Pharmazz that business or safety reasons relating to the use of the Study Drug or scientific considerations require termination;

f) At the request of either DCGI or Ethics Committee;

g) Notification to the Pharmazz from central or state regulatory authorities to terminate the Study;

h) Failure of the Principal Investigator **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to provide access by the Pharmazz's representatives all

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original medical records necessary to verify entries on the Study case report forms/ electronic case report forms;

10 SUSPENSION

The agreement may be suspended in whole or in part, at any time or from time to time: (1) by mutual agreement; (2) for Second Party's and PI's default or substantial non-compliance with the requirements of the agreement. In each case, written notice will be issued stating the effective date of the action.

The cure period shall be effected by written notice to the Second Party and PI, which notice shall identify the basis for suspension and/or possible termination, the reason(s), therefore, the effective date of the action, a statement identifying which part (or all) of the remainder of the agreement Term or the program activities are subject to possible termination, and procedures and standards, as appropriate, for phase down costs and submission of final invoices. The notice shall be effective on the date stated in the notice, or the date the notice is delivered to Second Party and PI, whichever is later. The Second Party and PI shall be given reasonable opportunity to present to the Pharmazz a plan of corrective action and shall have (thirty) 30 days to cure all issues as identified in the notice. If Pharmazz and Second Party mutually agree on the plan in writing, Second Party and PI will be provided an additional period of time, specified and agreed to in writing by the parties, to remedy the delay in meeting its obligations. If Pharmazz is dissatisfied with the corrective action plan or failure of Second Party and PI to meet the deadline of (30) days for corrective measures then Pharmazz may terminate the agreement in whole or part effective on such date.

11 EFFECT OF TERMINATION

11.1 Upon receipt of notice of termination, the Principal Investigator shall immediately stop enrolling subjects into the Study and to the extent medically permissible, cease administering the Study Drug and conducting Clinical Trial on subjects already entered into the Study. In case of early termination of this Agreement, due to any reason the Principal Investigator shall request all Study subjects within one month from the date of termination notice to attend a follow up visit for proper safety assessment of the subjects enrolled. The Principal Investigator shall use all reasonable efforts to check for completion of reports as per protocol and Investigator brochure for all subjects that have been entered into the Study prior to the date of termination of this Agreement.

11.2 Upon termination or completion of the Study, the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return or certify in writing to the Pharmazz all unused Study drugs, case report forms, whether completed or not and other related materials including but not limited to materials that were

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furnished to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** by or on behalf of the Pharmazz. In case, the Pharmazz desires destruction of aforementioned material, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall return such material to Pharmazz.

12 INDEMNIFICATION; LIMITATION ON LIABILITY; INSURANCE

12.1 The Pharmazz irrevocably agrees that it shall indemnify, defend and hold harmless the Principal Investigator, **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and all its directors, staff and agents from and against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees related to the clinical trial or arising as a result of (i) either breach of any representation/warranty made by the Pharmazz herein and or (ii) of personal injury to (including death of) Study subject, except to the extent such claims are attributable to:

a) the failure of the Principal Investigator, any co-investigator or any other personnel involved in the performance of the Study to adhere to the terms of the Study Protocol or any written instruction relative to the administration, use, handling, storage of any drugs used in the performance of the Study, or comply with any Applicable Laws & Guidelines; or

b) any negligent or wrongful act or omission, or willful malfeasance/misconduct of the Principal Investigator/co-investigator/any other personnel (including employees, agents or independent contractors) involved in the performance of the Study.

The indemnity granted in this Article shall apply separately to each Indemnity in such manner and to the same extent as though a separate indemnity had been given to each. Said indemnity shall survive the completion or early termination of this Agreement.

12.2 It is a condition precedent to the Pharmazz's indemnification obligations under above mentioned clause 12.1 that:

a) Whenever Principal Investigator has information from which it may reasonably conclude an incident of bodily injury or death has occurred, Principal Investigator shall immediately give notice to Pharmazz of all pertinent data surrounding such incident. In addition, Principal Investigator shall comply with all of their obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol; and

b) the Principal Investigator under clause 12.1 above must (i) promptly notify the Pharmazz of the assertion of any such claims (ii) authorize and permit Pharmazz to conduct and exercise sole control of the defense and deposition (including all decisions relative to litigation, appeal or settlement) of such claims and (iii) fully cooperate with Pharmazz regarding any such claims (including access to pertinent records and documents and provision of relevant testimony) and in determining the scope of Pharmazz's obligations hereunder. Subject to the foregoing, Principal

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Investigator may also participate with prior consent of the Pharmazz in any such claims at his own cost and expense. Principal Investigator agrees to cooperate with and to authorize Pharmazz to carry out sole management and defense of such claim or action. Principal Investigator shall not compromise or settle any claim or action without the prior written approval of Pharmazz.

The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** hereby irrevocably agree that they shall indemnify and hold harmless the Pharmazz, its present and future directors, officers and or employees against any and all, damages, suits, actions, claims, costs and expenses including reasonable attorney's fees and any cost of medical treatment of any illness or injury sustained by a Study subject, (collectively the "**Claims**") arising out of or in relation to (i) any breach of any of the representations and/or warranties made/held out by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** in this Agreement; or (ii) breach of any of the terms of this Agreement by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iii) intentional deviation or omission or negligence in conducting the Study by the Principal Investigator, the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or any individual engaged by Principal Investigator to support him in the conduct of the Study; or (iv) failure to follow the instructions of Pharmazz by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences**; or (v) failure of the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** to conduct the Study in accordance with the Protocol, Applicable Laws & Guidelines. The Institution and the Principal Investigator however shall in no event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof if the same is due to negligence and / or misconduct on the part of Pharmazz.

Sponsor warrant that they shall provide a diligent defense against and/or settlement of, any claims brought or actions filed for the loss which is the subject of the indemnity, whether such claims or actions are rightfully or wrongfully brought or filed. Sponsor shall have the right to settle claims at its sole expense.

12.3 Sponsor shall provide the cost of medical management and compensation as per Rule 122-DAB-Compensation in case of injury or death due to study drug during the conduct of clinical trial.

a) In case of an injury occurring to the clinical trial subjects, he or she shall be given free medical management as long as required or till such time it is established that the injury is not related to the clinical trial, whichever is earlier.

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b) In case the injury occurring to the trial subject is related to the clinical trial, such subject shall also be entitled for financial compensation as per order of the Licensing Authority defined under clause (b) of rule 21, and the financial compensation will be over and above any expense incurred on the medical management of such subject.

c) The expense on medical management and financial compensation in the case of clinical trial injury or death of the trial subject shall be borne by the sponsor of the clinical trial.

12.4 **Insurance**

The Pharmazz undertakes that it will secure and maintain in full force and effect throughout the performance of the Study (and following termination or early termination of the Study and to cover any claims arising from the Study) a clinical trial liability insurance policy from an Indian insurance company for an amount appropriate to, and in accordance with, the DCGI rules. This Insurance covers the Clinical Trial to be conducted for the Study at **Sanjay Gandhi Post Graduate Institute of Medical Sciences.** The Insurance policy is attached at Exhibit E.

13. PUBLICATION OF RESULTS

It is the general policy of the Pharmazz to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice no interim data should be published by the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the Pharmazz for its perusal, comments and approval. The Pharmazz may at its discretion may either refuse the publication or forward it to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** along with its comments or modifications which shall be final and binding on the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences.**

14. PUBLICITY AND PRODUCT PROMOTING ACTIVITY

It is agreed that no Party shall issue any press release or other third party communication relative to this Agreement without the prior written consent of the other Party except to the extent that the Pharmazz shall have absolute right to issue any press release relating to the Study related data. Principal Investigator shall not use the name of the Pharmazz and/or its employees in any advertising or sales promotional material or in any other way not required by law or regulation without the prior written consent of the Pharmazz.

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15. INTELLECTUAL PROPERTY RIGHTS

Sanjay Gandhi Post Graduate Institute of Medical Sciences agrees that all the Intellectual Property Rights with regard to **PMZ-1620** are and shall remain Pharmazz's exclusive property, and understands that **Sanjay Gandhi Post Graduate Institute of Medical Sciences** acquires no right, title, or interest in the Intellectual Property and the know-how used/created for the purpose of this Agreement. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agrees that all rights that may be created by the use of the Intellectual Property under this Agreement by **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall inure to the sole benefit of Pharmazz and shall be the exclusive property of Pharmazz. **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not at any time do or suffer to be done any act which would impair materially Pharmazz's proprietary rights in or to, or infringe, any Intellectual Property Rights of Pharmazz.

Pharmazz will be exclusively responsible if any dispute or claim arises regarding the ownership of the patent rights, copy rights & trade mark rights used by Pharmazz.

16. CONFIDENTIALITY

a) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences, New Delhi** agree to keep confidential and secret all materials, documents and confidential information that the Pharmazz discloses to the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences, New Delhi** pursuant to this Agreement and also all materials, documents and information's gathered, generated or developed by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** under the Study including but without limitation to results and discoveries emanated from the Study, regardless of whether such information is marked as "Confidential," "Proprietary" or the like, which is furnished to the Principal Investigator by or on behalf of the Pharmazz whether in written, electronic, oral, visual or other form (**"Confidential Information"**).

b) The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree, represent and warrant that any Confidential Information that they receive shall be protected at least, with the same degree of care and protection in the strictest confidence as of its own and shall take all reasonable measures to protect it. The Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall use such Confidential Information only for the purpose of fulfilling their obligations mentioned herein and shall not disclose such Confidential Information without the prior written consent of the Pharmazz to any third party except as required by law provided that the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall:

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First give prompt notice of such disclosure requirement to the Pharmazz so as to seek any limitations on or exemptions from such disclosure requirement; and

Reasonably co-operate with the Pharmazz in any such efforts of defense in the confidential and proprietary information to be made before appropriate authority.

c) Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** may disclose Confidential Information to their co-investigator, hospital authorities, Ethics Committee members and others who are required to be involved in the Study on a need-to-know basis provided that: (i) such receiving party shall always remain liable to maintain the confidentiality in terms hereof and (ii) all such receiving party shall be bound by obligations of confidentiality with respect to such Confidential Information at least as stringent as those provided herein. Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall be liable for any breach of this Agreement by its representatives. The obligations of confidentiality hereunder shall continue for a period of fifteen (15) years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that Principal Investigator and/or the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** can prove and produces credible written evidence to establish that such information or material:

i. at the time of disclosure or after disclosure to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** becomes part of the public domain by publication or otherwise, except by breach of this Agreement by the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or their successors or assigns;

ii. by written records were in the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences**'s possession at the time of disclosure by the Pharmazz were not acquired directly or indirectly from the Pharmazz;

iii. subsequent to disclosure hereunder, the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** receives from a third party legally in a position to provide with information to the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences,** provided, however, that such was not obtained by said third party directly or indirectly from the Pharmazz under an obligation of confidentiality.

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d) All clinical data, including case report forms and other information and discoveries resulting from the Study ("**Inventions**") shall be the sole property of the Pharmazz and will be treated as "Confidential Information" by the Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** and may be used by the Pharmazz in any manner. Further, Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall assign to the Pharmazz all of their rights, title, and interest in such Inventions.

e) All Confidential Information disclosed pursuant to this Agreement, together with all copies thereof, summaries and all information, know-how, data and materials generated by the use of the Confidential Information, shall be returned to the Pharmazz by Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** forthwith upon written request or upon termination of this Agreement, whichever is earlier.

f) Principal Investigator and the **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Confidential Information is of a special and unique kind, the protection of which is essential to the operation of the Pharmazz, and that if there is a breach (either actual or threatened) by the Principal Investigator/ **Sanjay Gandhi Post Graduate Institute of Medical Sciences** or co-investigator or a party in receipt of Confidential Information under this Agreement, the Pharmazz would have complete remedy at law. Therefore, in addition to any other remedies that may be available at law or equity, Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** agree that the Pharmazz shall be entitled to seek from any court of competent jurisdiction, injunctive relief, specific performance or other equitable relief, for any actual or threatened violation of this Agreement (without the necessity of posting any bond or other security proving special damages) and that the Principal Investigator and **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall not oppose the granting of such relief. In the event of any litigation relating to this Agreement, if a court of competent jurisdiction determines that this Agreement has been breached by one Party, then that Party shall reimburse the non-breaching Party for all its costs and expenses (including, without limitation, attorney fees and other legal expenses) incurred in connection with all such litigation.

g) Institution Information. During performance of this Agreement, Sponsor representatives may gain access through site visits or otherwise to information relating to Institution's business or research operations, policies, or procedures that Institution identifies to Sponsor as proprietary and confidential or that is reasonably apparent to Sponsor to be so. Unless Institution provides written consent, Sponsor will not copy or remove such information, use such information for any purpose other than performance of this Agreement, or disclose such information to any third party except as required by law.

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Executive Registrar
SGPGIMS,Lucknow

17. SEVERABILITY & WAIVER AND ASSIGNMENT

a) The invalidity or unenforceability of any term or provision of this Agreement, the remaining provisions shall stand to the fullest extent permitted by law. The failure of any Party at any time or times to require performance of any provision hereof shall in no manner affect the right of such Party at a later time to enforce such provision or any other provision of this Agreement. The parties agree that they negotiate in good faith or will permit a court/ Arbitration to replace any provision hereof so held invalid with a valid provision.

b) Waiver by either Party or the failure by either Party to claim a breach of any provision of this Agreement shall not be deemed to constitute a waiver or estoppels with respect to any subsequent breach of any provision hereof but only by an instrument in writing..

c) This Agreement shall not be assigned as a whole or in part by any party without the prior written consent of the other parties except for the following types of general support services: communication, translation, photocopy of documents or similar services, failing which all actions taken will be null and void.

18. MISCELLANEOUS

a) It is agreed by the Parties that the Principal Investigator and Sanjay Gandhi Post Graduate Institute of Medical Sciences shall act in the capacity of independent contractor hereunder and not as employees, agents or joint ventures of or with any Parties including Pharmazz. Neither Principal Investigator nor **Sanjay Gandhi Post Graduate Institute of Medical Sciences** shall have any authority to represent, or bind the Pharmazz.

b) Principal Investigator shall comply with all the terms of the undertaking annexed hereto as **Exhibit C** and be read as part of this agreement, he has provided to the Pharmazz under this Agreement.

c) This Agreement contains the entire understanding of the Parties hereto and supersedes all prior oral and written agreements and understandings of the Parties except confidentiality agreement, if any, pertaining to the subject matter hereof.

d) If the terms contained in any of the Exhibit attached hereto conflict with any provisions contained in this Agreement, the terms contained in this Agreement shall prevail. Unless otherwise provided herein, this Agreement may not be amended, supplemented or otherwise modified except by an instrument in writing signed by the Parties hereto.

e). The governing (applicable) language of this agreement shall be English, and all notices and other communications relating or pursuant to the provisions of

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the agreement (including, without limitation, those in connection with issues, disagreements and disputes) shall be in such language. This agreement, its formation and the facts and circumstances surrounding its making and performance, shall be interpreted in accordance with the following, and listed in order of precedence: (1) the express terms and conditions of the agreement; (2) the local laws of India

19. NOTICES

19.1. Unless otherwise provided herein, any communication, notice or notice of conditions interfering the performance of the agreement, report, payment or document to be given by one party to the other shall be in writing and shall be deemed given when received and acknowledged in case of electronic mode: Notifications shall be made to the following addresses:-

Pharmazz	**Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Mr. Sunil Gulati Chief Operating Officer	Dr. Rakesh Kapoor Director SGPGI	Prof. Jayantee Kalita Principal Investigator
Pharmazz India Pvt. Ltd. B-4 Sarita Vihar New Delhi 110076, **Email**: sunil.gulati@pharmazz.com	Sanjay Gandhi Post Graduate Institute of Medical Sciences Raebareli Road, Lucknow,-226014,. **Email:** director@sgpgi.ac.in	Sanjay Gandhi Post Graduate Institute of Medical Sciences, Department of Neurology, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow,-226014 **Email:** jayanteek@yahoo.com

19.2.1. Any dispute or difference whatsoever arising between the Parties out of or relating to the construction, meaning, scope, operation or effect of this Agreement or the validity or the breach thereof shall be exclusively settled by arbitration., which shall be governed by the Arbitration and Conciliation Act, 1996 as amended from time to time. The arbitral tribunal shall comprise of sole arbitrator to be appointed as per provisions of Arbitration and Conciliation Act, 1996 as amended from time to time. The language to be used in the arbitral proceedings shall be English. The award rendered by the arbitrator shall be final and binding upon the Parties hereto. Place of Arbitration shall be Delhi and both the parties shall bear the cost of arbitration in equal excluding counsel cost Parties agree that for claiming injunctive relief and for the enforcement of arbitral award only Delhi courts shall have exclusive jurisdiction in all matters arising out of or with this Agreement. This Agreement shall be governed by Laws of India.

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20. RENEWAL CLAUSE

The agreement can be renewed by way of mutual consent of the parties in the event of requirement of further study of the protocol to complete the obligations enumerated herein above.

21. FORCE MAJEURE

Any delay or failure by the either party of required obligations shall be excused if and to the extent caused by acts of God, fire, storm, lockout, strike, terrorist act, flood, sabotage, Government Notification/ order, embargo, war (whether declared or not), riot, or other causes beyond the reasonable control of the said Party. If and when either party asserts Force Majeure as an excuse for failure to perform their obligations, then the said Party must notify the other Party in writing and upon the review of the said party's notice, the other Party shall determine whether the term of the agreement shall be extended for a reasonable time period to complete activities interrupted by the delays.

22. FURTHER ASSURANCES

Each party agrees that subsequent to the execution and delivery of this Agreement it will execute and deliver any further legal instruments and perform any acts which are or may become reasonably necessary to effectuate the purposes of this Agreement.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed as of the date first set forth above in triplicate each being legally authentic and binding.

For **Pharmazz India Pvt. Ltd.**	For **Sanjay Gandhi Post Graduate Institute of Medical Sciences**	**Principal Investigator**
Signature: ..... Name: Mr. Sunil Gulati Title: Chief Operating Officer	Signature: ..... Name: Dr. Rakesh Kapoor Title: Director SGPGI	Signature: ..... Name: Prof. Jayantee Kalita Title: Principal Investigator

DIRECTOR
Sanjay Gandhi Post Graduate
Institute of Medical Sciences

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Executive Registrar
SGPGIMS,Lucknow

(4)

Exhibit-A

Clinical Trial Protocol

REFERENCE ENCLOSED

Dr. KALITA
Professor
Deptt. of Neurology
SGPGIMS, Lucknow
Reg.No:- 9705 (A&C)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(5)

Exhibit B

(Budget and Payment Schedule)

Total duration of Study			12 months
Subject enrollment duration			6 months
Total number of subjects			15
Payment heads	**Total per subject**	**No. of Subjects**	**Amount per Head**
Investigator's Fees (In Rupees)	24000	15	360000
Study Coordinator Fees (In Rupees)	16000		240000
Protocol Procedures (Lab expenses) (In Rupees)	2940		44100
CT/ MRI cost (In Rupees)	9600		144000
Subject Travel (In Rupees)	4000		60000
Institutional Overhead on Investigator's & Coordinator's fees (In Rupees)	10000		150000
Total Study Budget (In Rupees)			998100

- Protocol Procedures includes Lab expenses that is composed of cost of all the tests mentioned in protocol. INR 55 shall be added to the Protocol procedures on Visit 1,3, 4,5,6,7 for UPT if the subject is female.
- Recruitment of estimated number of trial subjects should be completed within 6 months
- Archival fee will be paid on close out visit and it will be as per the institutional EC SOP
- In addition to the above fee, Pharmazz shall pay for unscheduled visit (only if required) activities listed in Protocol.

Payee Details

Payee Name	Director SGPGI, Research Account
Name of the Bank & Branch	State Bank Of India
A/C No:	10095237492
IFSC	SBIN0007789
MICR	226002034
PAN No./TAN No.	AAAJS3913N
GST No. (if applicable)	Not applicable

PHARMAZZ INDIA PVT. LTD.

D.J. KALITA
Professor
Deptt. of Neurology
SGPGIMS, Lucknow
Reg.No.- 97

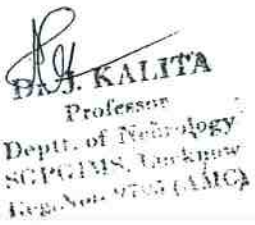
Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(4)

Exhibit-C

Principal Investigator's Documents

REFERENCE ENCLOSED



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SGPGIMS,Lucknow

(3)

Exhibit-D

Site Feasibility Questionnaire

REFERENCE ENCLOSED

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Dr. J. KALITA
Professor
Deptt. of Nephrology
SGPGIMS, Lucknow
Reg.No:- 0795 (SMC)

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Executive Registrar
SGPGIMS,Lucknow

(2)

Exhibit-E

Insurance Policy for study

REFERENCE ENCLOSED

PHARMAZZ INDIA PVT. LTD. Science & Innovation

Dr. J. KALITA
Professor
Deptt. of Neurology
SGPGIMS, Lucknow
Reg. No:- 9705 (AMC)

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Exhibit-F

Phase II Clinical Trial NOC

REFERENCE ENCLOSED

Dr. J. KALITA
Professor
Deptt. of Nephrology
SGPGIMS, Lucknow
Reg.No:- 9795 (MC)

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Executive Registrar
SGPGIMS,Lucknow

पश्चिमबङ्गा पश्चिम बंगाल WEST BENGAL Z 792508

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO BY AND BETWEEN:

Medclin Research Pvt. Ltd., a Company incorporated in accordance with the laws of India, under the Companies Act, 1956, having its office at Acropolis , unit 10/5 , 10th floor 1858/1,Rajdanga Main Road, Kolkata- 700107, hereafter referred to as **Clinical Research Organization(CRO)**

On the first part,

AND:

Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India

(Hereafter referred to as the "**Institution**")

AND:

Dr. Piyali Bhattacharya, Consultant Paediatrician, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road, Lucknow 226014, Uttar Pradesh, India

(Hereafter referred to as the "**Principal Investigator)**

On the second part,

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Executive Registrar
SGPGIMS,Lucknow

With each of the parties collectively or individually referred to as "Party" or "Parties"

THIS AGREEMENT RELATES TO THE FOLLOWING CLINICAL TRIAL:

A Multicentric, Randomized, Double Blind, Placebo Controlled Trial to assess the Efficacy and Safety of *Saccharomyces Boulardii CNCM-I 3799 and Bacillus Subtilis* CU – 1 *combination* For treatment of Acute Diarrhoea in Indian Children

PREAMBLE

WHEREAS, ALKEM Laboratories Ltd.is the Sponsor, as defined in the ICH GCP guidelines, of the above mentioned Clinical Trial and therefore wishes to perform this Clinical Trial;

WHEREAS, Medclin Research Pvt. Ltd. Is the CRO with Institution and the Principal Investigator are willing to organize, conduct and perform this Clinical Trial on behalf of the Sponsor;

WHEREAS, the Institution and the Principal Investigator have capable personnel and the necessary expertise to organize and perform clinical trials.

WHEREAS, the Principal Investigator is responsible for the scientific supervision and direction of the Clinical Trial and will conduct the Clinical Trial in the facilities of the Institution;

NOW THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), the Parties hereby agree as follows:

ARTICLE I – DEFINITIONS

For the purposes of this Agreement the following words and phrases shall have the following meanings:

- "**Additional Personnel**" means any co-investigator and/or any of Institution's contractors, employees, post-doctoral fellows, residents, demonstrators, students and/or technical staff, who may be involved in the Clinical Trial (as hereinafter defined), other than the Principal Investigator.

- **"CRO"** means Contract Research Organization; a person or an organization (commercial, academic, or other) contracted by the Sponsor, to perform one or more of a sponsor's trial-related duties and functions.

- **"Agreement"** means this Clinical Trial Agreement, all amendments and supplements to this Agreement and all schedules to this Agreement.

- "**Case Report Form**" means the form to be completed and returned to the Sponsor/CRO for each Subject participating in the Clinical Trial.

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- **"Clinical Trial"** means the clinical trial above-mentioned in the Preamble of the Agreement.

- **"Confidential Information"** means any and all information relating to the Sponsor, CRO which is of a confidential and proprietary nature, including but not limited to preclinical, clinical or formulation data, investigator's brochures, case reports, source documentation, study protocols and SOPs (as defined hereafter) as amended from time to time.

- **"Control"** means, whether used as a noun or verb, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

- **"Control Product"** means placebo to be used in the Clinical Trial in accordance with the Protocol.

- **"Enrollment Cap"** means that the Sponsor/CRO reserves the right to limit enrollment by giving written notice, or by giving notice by telephone followed by written notice, to the Institution and the Principal Investigator to cease further enrollment of Subjects in the Clinical Trial.

- **"GCP"** means:
  (i) The set of regulations established by Health Authority(ies) for conducting clinical studies including, without limitation, the set of regulations established by the CDSCO.
  (ii) The current international ethical and scientific quality standards for designing, conducting, recording and reporting clinical studies known as ICH Guidelines for Good Clinical Practice.

- **"Health Authorities"** means applicable health authorities, either governmental, regulatory or otherwise, including but not limited to the Drug Controller General of India (DCGI),

- **"ICH"** means the International Conference of Harmonization.

- **"IEC"** means the Institutional Ethics Committee responsible for review and approval of the Protocol.

- **"IND"** means an investigational new drug.

- **"Indemnitee"** means collectively the Institution, its Trustees, Officers, Directors, Agents, Additional Personnel and the Principal Investigator.

- **"Inventions"** means any inventions, discoveries, or innovations, products, processes, data, reports, results, formulations, technologies and compounds, whether patentable or not, arising directly or indirectly, in the performance of the Clinical Trial under this Agreement or using Clinical Trial funds or otherwise arising out of use of the Product.

- **"Investigational Product"** GUTGAIN ™ to be used in the Clinical Trial in accordance with the Protocol.

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- **"Person"** means an individual, partnership, joint venture, trustee, trust, corporation, unincorporated organization or other entity or a government, state or agency, or political subdivision thereof.

- **"Personal Data"** means any and all data concerning an individual participating in the Clinical Trial whether as a Subject or as an Investigator.

- **"Principal Investigator"** means the person who is named on the head of the Agreement and corresponds to the person who is named *"Investigator"* or *"Principal Investigator"* for either the entire study or a study site.

- **"Privacy Rules"** means any national and international standards of practice, establishing a category of information regarding the patients or Subjects, which may be used or disclosed to others in certain circumstances or under certain conditions.

- **"Processing"** means, in accordance with applicable rules and regulations, any operation or set of operations which is performed upon the Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

- **"Protocol"** means the last approved version of the protocol including any and all amendments, which will be considered as attached hereto upon completion, and is incorporated herein by reference.

  It is agreed that this Agreement shall be governed by the most recent version of the Protocol, and should this Agreement be executed prior to complete finalization of the Protocol, the last-dated version thereof will be considered to be incorporated by reference in place of any prior versions. In the event that there is a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement will govern with respect to contract terms and conditions but the Protocol will govern with respect to the conduct of the Clinical Trial and with respect to serving the best interests of patient welfare.

- **"Public Presentation"** means, collectively or individually, drafts of abstracts and/or manuscripts for publication (including slides and texts of oral or other public presentations).

- **"Recipient"** means, collectively and individually, the Institution and/or the Principal Investigator.

- **"Related Person(s)"** means any Person(s) having a relationship with a Party whether as an employee, Additional Personnel, agent or representative.

- **"Subject"** means an individual who is selected in accordance with the terms of the Protocol to participate in the Clinical Trial.

- **"SOPs"** means the Standard Operating Procedures as amended from time to time to be used for the purpose of the Clinical Trial

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- **"Trial Product"** means collectively the Investigational Product and the Control Product.

- **"Trial Site"** means the location(s) where the Clinical Trial activities are conducted by the Institution and/or the Principal Investigator.

ARTICLE 2 – SCOPE OF WORK

The Institution and the Principal Investigator shall conduct the Clinical Trial relating to the Product in accordance with the Protocol. Creation and modification of the Protocol shall be the sole responsibility of the Sponsor.

ARTICLE 3 - CLINICAL TRIAL APPROVALS

3.1 The Principal Investigator is responsible for ensuring that the Ethics Committee is registered before starting the Clinical Trial. The Investigator is responsible to follow up and ensure updating of serious adverse events causality opinion by the Ethics Committee to Appropriate Authority, Sponsor and CRO.

3.2 The Principal Investigator shall be responsible for having the Clinical Trial documents (such as Protocol, informed consent form and / or site inform consent form, any advertisement(s) pertaining to the recruitment of Subjects in the Clinical Trial) approved by the IEC prior to the beginning of the Clinical Trial.

3.2 In the event the IEC requests that changes be made to the Protocol such as the informed consent form template, the Institution shall immediately inform Sponsor/CRO of the IEC request in detail. Any modifications to the Protocol including the informed consent form template must be approved by the Sponsor's representative, CRO and/or appropriate regulatory authority, if applicable, before being implemented by Institution.

3.3 The Institution and the Principal Investigator shall not modify the Protocol without the prior written approval of the Sponsor.

3.4 The Sponsor's representative, shall be responsible for the submission of any IND application, if applicable resulting from the Clinical Trial, and the Parties agree to fully cooperate as necessary with the Sponsor's representative, and at Sponsor's expense, in the completion and filing of the IND.

ARTICLE 4 – ORGANIZATION OF THE CLINICAL TRIAL

4.1 The **estimated** time schedule of the Clinical Trial described in detail in the Protocol may be summarized as follows:

- Planned starting of the Subjects' recruiting process: May 2018
- Planned final report: 3 months post LSLV from all sites.

It is understood that the effective beginning of the Clinical Trial is dependent upon timely approval of key Clinical Trial documents and/or performance of preparatory

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activities by Sponsor's representative, CRO and/or third parties (e.g. IEC/IRB or Health Authority) and/or availability of the Trial Product. Thus, any delay in this approval and/or the performance of those preparatory activities and/or availability of the Trial Product may have a cascade effect on the Clinical Trial initiation. The Principal Investigator and the Institution agree that any such delay shall not entitle them to any compensation or remedy.

4.2 It is estimated that the Principal Investigator participating in this Clinical Trial will enroll a target number of Subjects of 45 Subjects in total, in approximately 50 to 180 days.

If not achieved, the Sponsor's representative/CRO might decide to reallocate the Subjects enrollment to another site and in this case, the rules set forth in section 4.2.1 of the Agreement will be applied.

For a multi-center Clinical Trial, the Sponsor's representative/CRO may amend the number of Subjects to be recruited by the Principal Investigator and in this case the rules set forth in sections 4.2.1 and/or 4.2.2 of the Agreement will be applied.

4.2.1 If in the reasonable opinion of the Sponsor/CRO, recruitment of Subjects is proceeding at the Trial Site at a rate below that required to enable the relevant timeline to be met, the Sponsor's representative/CRO may by notice to the Institution require recruitment at the Trial Site to cease and the terms of the Agreement shall relate thereafter to the number of Subjects who have been accepted for treatment in the Clinical Trial at the date of such notice; or

4.2.2 If recruitment of Subjects is proceeding at the Trial Site a rate above that required to meet the relevant timeline the Sponsor/CRO may with the agreement of the Institution increase the number of Subjects to be recruited by the Principal Investigator.

For a multi-center Clinical Trial having a competitive enrollment, the Sponsor/CRO reserves the right to request the Principal Investigator to limit recruitment of further Subjects or cease the recruitment, notably if the recruitment target for the Clinical Trial has been reached. In such event, the Sponsor's representative/CRO will inform the Principal Investigator on interrupting the recruitment of any Subject who has not yet signed the informed consent form.

The Principal Investigator shall upon receipt of a notice for stopping recruitment, stop immediately further recruitment of Subjects. Payment shall only be made according to the number of Subjects recruited up to the date of receipt of the said notice of stopping. The Sponsor's representative/CRO will neither take any responsibility, nor make any payment for the Subjects recruited after this date.

4.3 It is agreed among the Parties that the Principal Investigator and the Additional Personnel shall attend the mandatory training session(s) organized in relation with the Clinical Trial.

The Parties agree to inform each other of the Clinical Trial performance and therefore agree to organize and to participate in meetings related thereto.

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SGPGIMS,Lucknow

The Principal Investigator agrees to take the necessary time to meet with any person duly appointed by the Sponsor/CRO for monitoring the Clinical Trial.

4.4 If, at any time, Institution or Principal Investigator have reason to believe that the Clinical Trial will not be initiated or completed as per the schedule initially anticipated and agreed upon by the Parties, Sponsor's representative/CRO will be advised immediately, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by Sponsor's representative/CRO as provided in Article 14 hereafter.

ARTICLE 5 - OBLIGATIONS OF THE INSTITUTION AND/OR THE PRINCIPAL INVESTIGATOR

5.1 The Institution shall apply its best efforts to retain the services of the Principal Investigator.

In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform the Sponsor/CRO by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, which replacement shall have a similar background and also knowledge of the Clinical Trial.

Any successor to the Principal Investigator must be approved, in writing, by the Sponsor/CRO and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

The Institution represents and warrants that it will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to the notification by Medical Council of India.

The Institution agrees to immediately inform the Sponsor/CRO in writing if any person, including but not limited to the Principal Investigator, who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or to the best of the Institution's knowledge, is threatened, relating to the debarment of the Institution or any person performing services hereunder.

5.2 The Institution shall ensure that the Principal Investigator and any Additional Personnel conduct the Clinical Trial in accordance with:

(a) The Protocol and all other terms of this Agreement;

(b) All laws and regulations pertaining to the transportation, storage, use, administration and disposal of drugs, vaccines/biologicals, and the conduct of clinical investigations among which the Helsinki Declaration as amended in Edinburgh, Scotland (October 2000), including, but not limited to the Public

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Executive Registrar
SGPGIMS,Lucknow

Health Service Act, the Food, Drug and Cosmetic Act of India, with the Good Clinical Practice approved by the Indian Regulatory Authorities.

(c) Any and all Sponsor's/CRO's requirements, directions or instructions, including but not limited to the SOPs;

(d) Those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP;

(e) All applicable laws and regulations.

5.3 The Institution agrees that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents/ Legally Acceptable Representatives having authority over them, have given written consent to their inclusion in the Clinical Trial.

Such informed consent shall be obtained by the Principal Investigator using the informed consent form template developed for the Trial Site. The Privacy Rules shall be followed in order to obtain consent from Subjects as required throughout the Clinical Trial.

5.4 The Institution and the Principal Investigator shall have the following record keeping and reporting obligations:

(i) To prepare and maintain complete and accurate written records, accounts, notes, reports and data relating to the Clinical Trial under this Agreement.

(ii) To prepare and submit to the Sponsor's representative, CRO (in a periodic and timely manner during the term of this Agreement) all raw data and other material called for in the Protocol, in the form of properly completed Case Report Forms supplied by the Sponsor, for each Subject. All Case Report Forms and the information and data stored in any electronic database shall be the exclusive property of the Sponsor.

(iii) To retain in a secure facility the essential (including but not limited to the original informed consent form signed by each Subject) and the supporting documents relating to the Clinical Trial during five (5) years. Following this retention period or at any time during this period, if the Institution or the Principal Investigator can no longer retain these elements, the Institution shall inform the Sponsor, the Parties shall discuss in good faith in order to find an alternative solution for the proper archiving of these elements in accordance with the applicable regulations. Subjects' files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations. No document shall be destroyed without the prior written permission of the Sponsor.

5.5 The Principal Investigator shall report any adverse experiences and adverse events observed in the Clinical Trial to the Sponsor/CRO. All adverse experience/event reports

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Executive Registrar
SGPGIMS,Lucknow

shall be prepared and collected by the Principal Investigator according to the procedures outlined in the Protocol.

5.6 The Institution and the Principal Investigator shall use their best efforts to complete expeditiously the Clinical Trial in accordance with the time-schedule provided for in the Protocol.

5.7 The Institution shall, on or before the signing date of this Agreement, supply the Sponsor/CRO with a complete list of its Additional Personnel who it anticipates will be involved in carrying out Institution's obligations under this Agreement, specifying the role each individual will play in carrying out these obligations. The Institution agrees to inform the Sponsor/CRO of any changes to such list and train new Additional Personnel to the specificities of the Clinical Trial.

5.8 The Institution and the Principal Investigator agree to inform the Sponsor's representative/CRO of any cooperation or collaboration they would like to undertake regarding a therapeutic/ prophylactic concept similar to the one studied according to the Protocol if such a project would compete with the Clinical Trial. The Sponsor's representative/CRO will be entitled to terminate this Agreement if such a cooperation or collaboration is deemed by the Sponsor's representative/CRO to be incompatible with its interests.

5.9 The Sponsor's representative/CRO registers all its clinical trial protocols on the web site http://ctri.nic.in. If local regulations require the Clinical Trial to be registered locally, the Institution and the Principal Investigator are in charge of doing it and informing the Sponsor. The Sponsor's representative/CRO shall support them by providing the required information.

ARTICLE 6 – TRIAL PRODUCT, EQUIPMENT AND DOCUMENT

6.1 The Trial Product, as well as the documents and the material necessary to conduct the Clinical Trial, as described in the Protocol, shall be supplied free of charge to the Institution by the Sponsor. In certain circumstances, the Sponsor's representative/CRO might instruct the Institution to purchase the Control Product and/or equipment. In such a case, the Sponsor's representative, will reimburse these expenses to the Institution at invoice value (all invoices are requested by the Sponsor's representative, CRO prior to reimbursement).

The Institution shall inform the Sponsor's representative/CRO on or before the signing date of this Agreement of the name and complete address to which the Product shall be shipped by the Sponsor.

6.2 All the Trial Product, the document, the equipment and the material supplied pursuant to this Agreement shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to the Agreement. It is understood that the Trial Product is provided by the Sponsor's for the sole purpose of conducting the Clinical Trial.

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THE SPONSOR'S REPRESENTATIVE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE TRIAL PRODUCT OR ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OTHER THAN FOR ITS USE IN THIS CLINICAL TRIAL.

All unused doses of Trial Product shall be promptly returned to the Sponsor's representative/CRO upon the completion of the Clinical Trial as directed by the Sponsor, or upon earlier termination of this Agreement, unless written authorization to destroy the Trial Product is given by Sponsor. If authorization to destroy unused Trial Product is previously given in writing, the Institution shall provide the Sponsor's representative/CRO with documentation as to the method of destruction. The Institution shall conform with all laws and regulations pertaining to the disposal of drugs, vaccines/biologicals during any destruction of unused quantities of the Product. Upon delivery, the Institution and the Principal Investigator shall be responsible for any improper administration, storage or handling of the Trial Product and for its use beyond its applicable expiration date.

6.3 If some products among the Investigational Product and/or Control Product were to be recalled, the Principal Investigator and the Institution commit to implement the Sponsor's instructions immediately and to quarantine the product(s) at stake.

ARTICLE 7 - AUDITS

7.1 During the Clinical Trial and for such additional period of time that the records are required to be retained by law or otherwise, it is agreed that representatives of the Sponsor/CRO may arrange with the Principal Investigator or her designee, after having duly informed the Institution respecting at least seven (7) days prior notice:

(i) To examine and audit, at regular business hours, the locations where the Clinical Trial is performed;

(ii) Subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Clinical Trial conducted under this Agreement and to inspect and make copies of all data necessary for the Sponsor's representative/CRO to confirm that the Clinical Trial is being conducted in conformance with the Protocol and in compliance with all applicable legal and/or regulatory requirements of any and all Health Authorities; and

(iii) To meet with any person involved in the Clinical Trial's performance.

7.2 The Institution agrees to assist the Sponsor/CRO, to the extent deemed reasonable by the Sponsor/CRO, in facilitating the Sponsor's representatives' examination, inspection, auditing and copying of materials relating to the Clinical Trial and in order to enforce the rights granted to the Sponsor's representative/CRO in this Article 7.

The Principal Investigator and the Institution agree to take any action, as reasonably requested by the Sponsor/CRO to properly correct or address any deficiencies noted

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during any audit and agree to cooperate with the Sponsor's representative/CRO with respect to any action taken to address any such deficiencies.

7.3 If the need arises (or if the need be), the Institution agrees to notify Sponsor/CRO within twenty-four (24) hours in the event that a Health Authority notifies the Institution of a pending inspection/audit. In addition, the Institution will forward to Sponsor/CRO any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to accept Sponsor's/CRO's assistance in responding to any citations. Such responses shall be made within ten (10) business days of issuance of any citations or within any earlier deadline set by the issuing Health Authority. The Institution shall also provide the Sponsor's representative/CRO with copies of any documents provided to any inspector or auditor. In the event any applicable Health Authority requests or requires any action to be taken to address any citations, the Principal Investigator and the Institution agree, after consultation with the Sponsor/CRO, to take such action as necessary to address such citations, and agree to cooperate with the Sponsor/CRO with respect to any such citation and/or action taken with respect thereto.

ARTICLE 8 - FINANCIAL PROVISIONS

The financial provisions applicable to the Agreement in consideration of the performance of the Clinical Trial are provided for in Schedule A attached hereto.

ARTICLE 9 - CONFIDENTIALITY

9.1 Before and during the course of the Clinical Trial, the Recipient may obtain, or have access to Confidential Information.

Except as expressly set forth in this Article, the Recipient shall each cause its Related Person(s) to keep the Confidential Information confidential, and the Recipient shall not disclose directly or indirectly, and shall cause its Related Persons not to disclose directly or indirectly, any Confidential Information to anyone, except that the foregoing restriction shall not apply to any information disclosed hereunder if such Confidential Information, as reasonably demonstrated by the Recipient:

(i) is generally available to the trade or public or becomes after the time of receipt by the Recipient part of the public domain, other than by reason of any breach or default by the Recipient or any of its Related Persons of a confidentiality obligation under this Agreement;

(ii) was already known to the Recipient at the time of disclosure by the Sponsor/CRO;

(iii) is disclosed to the Recipient or any of its Related Persons by a Third Party who has the right to disclose such information; or

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(iv) based on such person's good faith judgment with the advice of counsel, is otherwise required to be disclosed in compliance with applicable legal requirements to a Health Authority.

Whenever the Recipient becomes aware of any state of facts which would or might result in disclosure of Confidential Information pursuant to subparagraph (iv) above, it shall, if possible, promptly notify the Sponsor's representative/CRO prior to any such disclosure so that the Sponsor's representative/CRO may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement.

In any event, if the Recipient is unable to promptly notify the Sponsor's representative/ CRO or if such protective order or other remedy is not obtained, or if the Sponsor's representative/CRO waives compliance with the provisions of this Agreement, the Recipient will furnish only that portion of the information which its counsel directs is legally required and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded the Confidential Information.

The Sponsor's representative/CRO shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security except as required by the relevant laws, enjoining or restraining the Recipient and any of its Related Persons from any violation or threatened violation of this Article.

9.2 The Recipient agrees that no Confidential Information shall:

(i) Be used in its own business except as necessary to the fulfillment of the rights and obligations of the Recipient under this Agreement;

(ii) Be disclosed, assigned, licensed, sublicensed, marketed, transferred or loaned, directly or indirectly to any third party other than to an Affiliate or a representative of the Recipient in accordance with the provisions of this Agreement, except as necessary to the fulfillment of the rights and obligations of the Parties under this Agreement;

(iii) Be used or exploited by the Recipient or any of its Related Persons for its or their respective benefit or the benefit of any other relationships with customers of such Party and its Related Persons.

(iv) Be used by the Recipient for obtaining intellectual property rights.

Without limiting the generality of the foregoing, the Recipient agrees that, it shall not (and shall not permit any of its Related Persons) at any time to use any Confidential Information in the conduct of its business without the prior written consent of the Sponsor/CRO.

The obligations set forth in this Article shall extend to copies, if any, of Confidential Information made by the Recipient and/or its Related Persons and to documents prepared by such persons which embody or contain Confidential Information.

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9.3 The Recipient shall deal with Confidential Information so as to protect it from disclosure with a degree of care not less than that used by it in dealing with its own information intended to remain exclusively within its knowledge and shall take reasonable steps to minimize the risk of disclosure of Confidential Information which shall include, without limitation, ensuring that only their respective Related Persons who have a *bona fide* "need to know" such Confidential Information for purposes permitted or contemplated by this Agreement shall have access thereto.

The Recipient shall notify all of its Related Persons who have access to Confidential Information of its confidentiality and the care therefore required, and shall obtain from any such Related Person an agreement of confidentiality incorporating the restrictions set forth herein.

9.4 The obligations set forth in the present article shall survive the termination of this Agreement for a period of Five (5) years.

9.5 Except as otherwise agreed to by the Parties in writing, the Recipient shall (and shall cause its Related Persons to), within thirty (30) days after the termination of this Agreement, return to the Sponsor's representative/CRO or destroy all documents and tangible items then in its possession which it has received from the Sponsor's representative/CRO or its Related Persons pertaining, referring or relating to the Sponsor's Confidential Information, as well as all copies, summaries, records, descriptions, modifications, and duplications that it, or any of its Related Persons has made from the documents or tangible items received from the Sponsor's representative/CRO or Related Person; provided, however, that the Recipient may retain one copy of each document in its legal files solely to permit the Recipient to continue to comply with its obligations hereunder and, in addition, may upon notice to the Sponsor, retain in its legal files or in the office of outside legal counsel one copy of any document solely for use in any pending legal proceeding to which such document relates.

ARTICLE 10 – INVENTIONS AND PATENTS

The sole and exclusive right to any Inventions shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor's representative/CRO in writing of any such Inventions, and at Sponsor's request, and expense, Institution and Principal Investigator will cause to be assigned to Sponsor's representative/CRO all right, title, and interest in and to any such Inventions and provide reasonable assistance to obtain patents including causing the execution of any invention assignment or other documents.

ARTICLE 11 – DATA, PUBLICATIONS, OTHER RIGHTS

In recognition of the importance of disseminating information relating to any novel or important observations or results that may arise from the Clinical Trial, and understanding that such need must be balanced with the Sponsor's obligations to maintain control over Confidential Information as well as to comply with all appropriate Health Authorities' rules and regulations, the Parties hereby agree to the following:

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11.1 The Institution and the Principal Investigator agree that all research data and results generated during the course of or as a result of the Clinical Trial shall be the property of the Sponsor. The Principal Investigator and the Institution further agree to execute any documents or undertake any further actions requested by the Sponsor's representative/ CRO to evidence transfer of title to such data.

11.2 Subject to the terms and conditions of this Agreement, the Institution and the Principal Investigator have the right to publish or publicly present their results of the Clinical Trial. The Principal Investigator and the Institution agree not to publish or publicly present any interim results of the Clinical Trial without prior review by the Sponsor, as provided below. The Principal Investigator and the Institution further agree to provide ninety (90) days written notice to the Sponsor, including a complete copy of the intended Public Presentation, prior to submission for publication or presentation to permit the Sponsor to review a Public Presentation which reports any results arising out of the Clinical Trial. The Sponsor shall have editorial rights with respect to a Public Presentation and the right to review and comment on the data analysis and presentation to ensure that:

(i) Confidential Information is protected by the provisions contained in Article 11.4 below;
(ii) The information contained in the Public Presentation are accurate; and
(iii) The Public Presentation is fairly balanced and in compliance with applicable Health Authorities' regulations.

If the Parties disagree concerning the accuracy and appropriateness of the data analysis and presentation, and/or confidentiality of Sponsor's Confidential Information, the Institution agrees to meet with Sponsor, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

In the event that the Parties cannot resolve their dispute within a period of ninety (90) days, they may refer the matter to an independent adjudicator having expertise in the field of the Clinical Trial selected jointly by them who shall decide the matter. The Parties agree to abide by the adjudicator's decision. The Principal Investigator and Institution agree not to release a Public Presentation until such time as a resolution has been reached, whether by the Parties on their own, or by the adjudicator.

11.3 To the extent that the Institution's participation in the Protocol is a part of a multi-center clinical trial, the Institution and the Principal Investigator agree that an initial Public Presentation of their results shall occur only together with the other sites unless specific written permission is obtained in advance from the Sponsor for Public Presentation of separate results. The Sponsor shall advise as to the implications of timing of any Public Presentation in the event the Clinical Trial is still in progress at sites other than the Principal Investigator's one and any institution or investigator participating in a multi-center clinical trial shall follow the Public Presentation review procedures set forth in Article 11.2 above.

11.4 No Public Presentation shall contain any Confidential Information. Public Presentation shall be confined to new discoveries and interpretations of scientific fact. At the

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Sponsor's request, the Sponsor shall be acknowledged as one of many or as the sole financial Sponsor, as the case may be, of the Clinical Trial reported in the Public Presentation.

11.5 The Institution and the Principal Investigator shall be aware that a publication or presentation of patentable subject matter prior to filing respective patent application will jeopardize such patent rights. Therefore, if the Sponsor believes there is a patentable subject matter contained in any Public Presentation submitted for review, the Sponsor shall promptly identify such subject matter to the Institution. If the Sponsor requests and at the Sponsor's expense, the Institution and the Principal Investigator shall use their best efforts to assist the Sponsor in filing a patent application covering such subject matter prior to any publication.

Furthermore, in the event that the review of the proposed publications or other public disclosure results in a determination that potentially patentable subject matter would be disclosed, and that such disclosure would be prejudicial to perfecting Sponsor's intellectual property rights, the Principal Investigator or Institution shall delay the publication or public disclosure for an additional ninety (90) days, at Sponsor's request, to allow for filing the necessary patent applications.

ARTICLE 12 – LIABILITY, INDEMNIFICATION AND INSURANCE

12.1 In accordance with Rule 122-DAB of the Drugs & Cosmetics Rules, 1945 in the event of injury to or death of a Subject during the Study, the following shall apply:

(1) In the case of an injury occurring to the Subject, he or she shall be given free medical management as long as required or until it is proved that the injury is not related to the IP (whichever is earlier)

(2) In case the injury occurring to the Subject is related to the Study, such Subject shall also be entitled for financial compensation as determined by the Licensing Authority under the said Rules over and above the expenses incurred on the medical management of the Subject;

(3) In the case of Study related death of the Subject, his/her nominee(s) would be entitled for financial compensation as per the order of the Licensing Authority and the financial compensation will be over and above any expenses incurred on the medical management of the Subject;

(4) The expenses on medical management and financial compensation in the case of Study related injury or death of the Subject shall be borne by the Sponsor;

(5) Any injury or death of the Subject occurring in the Study due to the following reasons shall be considered as Study related injury or death and the Subject or his/her nominee(s), as the case may be will be entitled for financial compensation for such injury or death:

(a) Adverse effect of the Investigational Medicinal Product;

(b) Violation of the Protocol, scientific misconduct or negligence by the Sponsor's Representative, CRO or the Investigator, Provided that if such violation of the

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Protocol, scientific misconduct or negligence is by the Investigator, then the Investigator will be liable to reimburse to the Sponsor Representative the expenses on such medical management and financial compensation that the Sponsor's Representative shall have paid to the Subject or his/her nominee(s), as the case may be;

(c) Failure of the Investigational Medicinal Product to provide intended therapeutic effect;

(d) Use of placebo in a placebo-controlled trial;

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

(f) For injury to a child in-utero because of the participation of parent in the Study;

(g) Any clinical trial procedures involved in the Study."

(6) The Sponsor's representative/CRO shall give an undertaking along with the application for clinical trial permission to the Licensing Authority defined in clause (b) of Rule 21, to provide compensation in the case of clinical trial related injury or death for which subjects are entitled for compensation/

(7) The Sponsor's representative, CRO in case of injury or death occurring to the clinical trial subject, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII.

(8) However, the Sponsor's representative, CRO is liable to pay the medical management fee or compensation, only for those clinical trial related injury or death which happened by or before 28 day from the day of administering the product to the subject.

(9) The Sponsor's representative, CRO shall indemnify, defend and hold harmless the Indemnitee, from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from the use of the Product in connection with the Clinical Trial.

Therefore, the Sponsor's representative, CRO shall maintain, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this section 12 and shall also provide product liability and clinical trials liability coverage. The minimum amounts of insurance coverage required shall not be construed to create a limit of the Sponsor's liability with respect to its indemnification under this section 12. The Sponsor's representative/CRO shall maintain the aforementioned insurance during the Clinical Trial. This obligation to maintain insurance shall survive the termination of this Agreement. The Sponsor's representative/CRO shall provide the Institution with written evidence of such insurance upon the written request of the Indemnitee.

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12.2 In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the Sponsor's representative/CRO and shall assist the Sponsor's representative/CRO and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses. The Principal Investigator and the Institution agree to cooperate with and to authorize the Sponsor's representative/CRO to carry out the sole management and defense of such claim or action. Neither the Principal Investigator nor the Institution, its trustees, officers or Related Persons shall compromise or settle any claim or action without the prior written approval of the Sponsor.

12.3 Notwithstanding the foregoing, the Sponsor's representative/CRO shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless the Sponsor, CRO, officers, directors, agents and employees for loss or damage resulting from:

(i) failure of the Institution or the Principal Investigator or the Additional Personnel to adhere to the terms and provisions of the Protocol or any amendments thereto (including but not limited to the Principal Investigator's and the Institution's obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol (and any appendix or attachment to the Protocol), or the Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Clinical Trial, including but not limited to the Product, any comparative drug and any placebo;

(ii) Failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable Health Authorities' requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

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

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

12.4 The Institution shall secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:

(i) Medical professional and/or medical malpractice liability (including coverage for the Principal Investigator);
(ii) General liability (including coverage for the Clinical Trial site); and
(iii) Worker's compensation coverage,

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in amounts required by applicable federal, provincial or state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Clinical Trial.

Upon request of the Sponsor, copies of certificates evidencing such insurance coverage will be made available to the Sponsor's representative/CRO and the Institution shall provide thirty (30) days' prior written notice to the Sponsor's representative/CRO in the event of cancellation or any material change in such insurance.

ARTICLE 13 - TERM

This Agreement shall become effective from the day of last signature and shall remain in full force and effect until completion of the final report of the Clinical Trial.

ARTICLE 14 – TERMINATION AND ENROLLMENT CAP

14.1 The Sponsor's representative/CRO may terminate this Agreement at any time by giving thirty (30) days written notice to the Institution. In the event thirty (30) days is determined by the Institution to be insufficient notice based upon evaluation of risks to enrolled Subject(s) then receiving the Product, the Parties will cooperate to safely withdraw Subjects from the Clinical Trial over a mutually agreeable period of time but in no event shall the Sponsor's obligation to supply the Product hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event the Sponsor's representative/CRO believes that immediate termination is necessary due to its evaluation of risks to enrolled Subject(s), the Sponsor's representative/CRO may terminate this Agreement immediately.

The Sponsor's representative/CRO reserves the right not to perform the Clinical Trial. In such a case, the Agreement shall be considered as automatically terminated upon the Sponsor's/CRO's formal notice to both the Institution and the Principal Investigator.

14.2 Notwithstanding any other provision hereof, the Sponsor's representative/CRO shall be entitled to terminate this Agreement for any Material Breach, which shall be defined as:

(i) The Institution and/or the Principal Investigator's failure to comply with their obligations, responsibilities and the terms and conditions of this Agreement including the Protocol;

(ii) The Institution and/or the Principal Investigator's failure to comply with: (a) their obligations for keeping the Sponsor's representative/CRO informed of all necessary and relevant information in connection with the Protocol; (b) any applicable law, rule or regulation relevant to the Clinical Trial; or (c) the work to be performed under this Agreement; or

(iii) A breach by the Institution, the Principal Investigator, or their Related Persons of the confidentiality provisions of this Agreement.

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14.3 Upon termination, for any reason:

(i) The Institution shall return to the Sponsor's representative/CRO all unused materials, including but not limited to, the Product and any clinical supplies (unless written authorization to destroy them is given by the Sponsor/CRO, in which case the Institution shall comply with the applicable provisions of Article 6 hereof);

(ii) Except in the event of termination because of a Material Breach by the Institution, and unless otherwise specified in writing between the Parties, the total sums payable by the Sponsor's representative/CRO pursuant to this Agreement shall be equitably pro-rated for actual work performed in accordance with the Protocol to date of notice of termination with any unexpended portion of funds previously paid by the Sponsor's representative/CRO to the Institution being refunded to the Sponsor/CRO;

(iii) In the event of termination as a result of a Material Breach, the Parties agree to make a good faith effort to reach agreement to compensate the Institution for actual work performed in accordance with the Protocol to date of notice of termination; and

(iv) The Principal Investigator shall return to Sponsor's representative/CRO all Confidential Information (as defined in Article 9 hereof) owned or controlled by the Sponsor's representative/CRO and in the possession of the Institution or its Related Persons;

(v) The Principal Investigator must submit to the Sponsor's representative/CRO the Case Report Forms for all the work in progress as of the effective date of termination.

14.4 The termination of this Agreement shall not relieve either Party of its obligations set out in Sections 5.3, 5.4, 5.5 and Articles 6, 7, 9, 10, 11 and 12 of this Agreement

14.5 Upon receipt of notice of Enrollment Cap, the Institution and the Principal Investigator agree to enroll no further Subjects in the Clinical Trial, and the funds payable pursuant to this Agreement shall be adjusted to reflect only the number of Subjects actually enrolled and the number of visits and technical procedures actually performed prior to receipt of such notice. The Institution and the Principal Investigator, as the case may be, shall refund to Sponsor's representative/CRO any funds received in advance from Sponsor's representative/CRO that are in excess of the adjusted funding.

ARTICLE 15 – DATA PROTECTION

15.1 It is understood among the Parties that Personal Data will be collected during the course of the Clinical Trial.

The Institution, the Principal Investigator and the Sponsor's representative/CRO agree to comply with all applicable Privacy Rules relating to such Personal Data including, if

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necessary, notification of their Processing activities under this Agreement to the supervisory authority.

The Principal Investigator and the Institution shall take any other steps requested by the Sponsor's representative/CRO in order to enable the Sponsor's representative/CRO to comply with any notification or other obligations applicable to it or its Affiliates under such laws.

Sponsor's representative/CRO represents and affirms to the Institution and the Principal Investigator that it has complied with, and will continue to comply with its obligations under the Privacy Rules applicable to the Clinical Trial.

15.2 The Principal Investigator and the Institution shall:

(a) Ensure that Personal Data collected for the purpose of the Clinical Trial will be processed only in accordance with this Agreement or as otherwise instructed in writing from time to time by the Sponsor.

(b) Ensure that Personal Data are not disclosed or transferred to any Third Party without the prior written consent of the Sponsor, except:

(i) As specifically stated in this Agreement, or

(ii) Where such disclosure or transfer is required by any applicable law, regulation or supervisory authority, in which case the Institution and Principal Investigator shall, wherever possible, notify promptly in writing (and in any event within five days of receipt) the Sponsor's representative/CRO prior to complying with any such request for disclosure or transfer and shall comply with all reasonable directions of the Sponsor's representative/CRO with respect to such disclosure or transfer.

(c) Ensure that Personal Data are accurate and, where necessary, kept updated and use best efforts to ensure that any Personal Data which are inaccurate or incomplete are erased or rectified where appropriate.

(d) Ensure that all appropriate technical and organizational measures are taken to protect Personal Data against accidental or unlawful destruction or accidental loss or alteration, or unauthorized disclosure or access and against all other unlawful forms of Processing.

(e) Notify the Sponsor's representative/CRO in a timely manner of any accidental, unlawful or unauthorized uses or disclosures of Personal Data; ensure that it refers any communication received from a Subject relating to the Subject's rights to access, modify or correct its Personal Data to the Sponsor's representative/CRO and to comply with all instructions of the Sponsor's representative/CRO before responding to such communications; comply with the provisions of this Agreement and the reasonable instructions of the Sponsor's representative/CRO to return, store or destroy the Personal Data.

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15.3 According to Privacy Rules, the Principal Investigator may request access to [his/her] Personal Data or to have [his/her] Personal Data rectified, blocked, erased or destroyed. In such case, the Principal Investigator shall send a written notice to:

Medclin Research Pvt. Ltd.
Acropolis , unit 10/5 , 10th floor
1858/1,Rajdanga Main Road,kol-107

ARTICLE 16 – NOTICES

All notices required or permitted to be given under this Agreement shall be in writing and may be effectively given if delivered personally or if sent by prepaid registered mail, or by facsimile addressed in the case of the Sponsor's representative/CRO to:

Dr. Monjori Mitra
Research Director
Medclin Research Pvt. Ltd.
Acropolis , unit 10/5 , 10th floor
1858/1,Rajdanga Main Road,kol-107

or in the case of the Institution to:

Prof. Rakesh Kapoor
Director
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road, Lucknow 226014, Uttar Pradesh, India

For the Principal Investigator

Dr. Piyali Bhattacharya
Consultant Paediatrician
Sanjay Gandhi Post Graduate Institute of Medical Sciences
Raebareli Road, Lucknow 226014, Uttar Pradesh, India

Any such notice shall be deemed to have been given and received when actually received. Either Party may change its address for service from time to time by notice given in accordance with the foregoing.

ARTICLE 17 - REPRESENTATION

17.1 Representations and Warranties by the Sponsor's representative/CRO: The Sponsor's representative/CRO represents and warrants to the Institution and the Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Institution and the Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) The Sponsor and CRO are Institutions duly organized and validly existing under the laws of India; and

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(b) The Sponsor and CRO has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of their obligations under this Agreement;

(c) The Sponsor and CRO has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Sponsor/CRO;

(d) This Agreement has been duly authorized, executed and delivered by the Sponsor's representative/CRO and constitutes a legal, valid and binding obligation of the Sponsor's representative/CRO enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) The Sponsor's representative/CRO shall hold harmless the Principal Investigator, the Institution, its employees and representatives against any and all liability arising out of any misrepresentation from its part.

17.2 Representations and Warranties by the Institution: The Institution represents and warrants to the Sponsor's representative/CRO and Principal Investigator, as of the signing date of the Agreement, and acknowledges that the Sponsor's representative/CRO and Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) The Institution is a corporation duly incorporated and validly existing under the laws of Lucknow

(b) The Institution has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of its obligations under this Agreement;

(c) The Institution has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Institution;

(d) This Agreement has been duly authorized, executed and delivered by the Institution and constitutes a legal, valid and binding obligation of the Institution enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) The Principal Investigator is an employee of the Institution.

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17.3 Representations by the Principal Investigator: The Principal Investigator represents to the Sponsor's representative/CRO and the Institution, as of the signing date of the Agreement, and acknowledges that the Sponsor's representative/CRO and the Institution are relying on such representations in entering into this Agreement, that Principal Investigator has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of her obligations under this Agreement.

ARTICLE 18 – ETHICAL CONDUCT

The Parties will conduct themselves and undertake the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and all applicable anti-bribery legislation (national and foreign), including but not limited to the OECD Convention dated 17th December 1997 on combating bribery of public officials in international business.

In particular, the Parties will not offer, promise or give any improper pecuniary or other advantage, whether directly or through intermediaries to a public official, for the benefit of that official or of a third party, for the purpose of influencing decision or actions with respect to the subject matter of this Agreement.

Failure to comply with the provisions of this Article 18 will be deemed a material breach of a material provision of this Agreement.

ARTICLE 19 - BENEFIT, ASSIGNMENT & TRANSFER

This Agreement shall benefit and be binding upon all of the Parties hereto, and their respective successors and assigns. This Agreement is concluded by the Sponsor's representative/CRO intuitu personae. Hence the Agreement may not be assigned or transferred, whether directly or indirectly, by any Party without the prior written consent of the other Party, which consent may be reasonably withheld. However, the Sponsor's representative/CRO shall be entitled to assign and transfer to one or more of its Affiliates this Agreement, without the prior written consent of the other Party, with notice thereafter to the other Party.

The Institution and the Principal Investigator shall not be allowed to subcontract totally or partially the obligations the Sponsor's representative/CRO charged them with, without the prior written consent of the Sponsor. In this latter case, the Principal Investigator and the Institution shall be fully responsible for the part of the obligations so subcontracted and warrants to the Sponsor's representative/CRO that such part of the obligations shall be rendered under conditions consistent in all respect with the terms and conditions set forth herein. For sake of clarity, such consent from the Sponsor's representative/CRO will not relieve the Institution and the Principal Investigator from any liability or obligation under this Agreement and Institution and Principal Investigator will remain liable *vis-à-vis* the Sponsor's representative/CRO for the acts, omissions, defaults or negligence of its sub-contractors.

Initial here

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

ARTICLE 20 - LAW

This Agreement shall be governed by and construed in accordance with the laws of the Republic of India, exclusive of its conflicts of laws principles. All and any dispute arising in connection with the interpretation or execution of this Agreement shall be settled by the competent courts of Lucknow
- India.

ARTICLE 21 - PUBLICITY

No Party shall use the name of any other Party (or the name of any of the Sponsor's divisions or Affiliates) for promotional purposes without the prior written consent of the Party whose name is proposed to be used. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Clinical Trial, shall be made by the Institution or the Principal Investigator without the prior written approval of the Sponsor.

ARTICLE 22 - INDEPENDENT CONTRACTOR

Each Party acknowledges that it is an independent contractor. For greater certainty, the relationship between Sponsor, on the one hand, and Institution and Principal Investigator, on the other hand, shall not constitute a partnership, joint venture or agency. No Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior consent of the other Party to do so.

ARTICLE 23 – COUNTERPARTS

This Agreement may be executed in one or more counterparts, which, together, shall constitute one and the same Agreement.

ARTICLE 24 - AGREEMENT MODIFICATIONS

The provisions of this Agreement, may not be altered, amended or modified except by written agreement signed by both Parties.
The Parties acknowledge and agree that the schedule of the present clinical trial agreement may be subject to amendments and/or update and in such a case, the last-dated version approved in written by a representative of all Parties will be considered to be incorporated therein by reference in place of any prior versions.

Initial here

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

PGI/cardio/624/18

ram : AYURVIGYAN
E-mail : pkgoel@sgpgi.ac.in
: golf_pgi@yahoo.co.in

Phone (O): + 91-(522) 2494227, 2494277, 2494231
(R): + 91-(522) 2494228, 2668071 (Direct)
Fax : + 91-(522)-2668078, 2668017

18

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
DEPARTMENT OF CARDIOLOGY

Dr. Pravin K. Goel
M.D. (Med), D.M. (Cardiology), FACC, FSCAI, FICC
Formerly Fellow Cardiac Radiology,
Greenlane Hospital, Auckland.
Professor & Head

RAEBARELI ROAD
LUCKNOW – 226 014 (INDIA)

To,

Date: 08/10/2018

Faculty Incharge,

Research, SGPGIMS,

Lucknow.

Sub:-Submission of CTA for Director's signature

Dear Sir,

Please find herewith the CTA of the study titled 'A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50-yrs.) with ACS undergoing PCI by optical Coherance Tomography (OCT) Imaging' for the final approval and signature. I have attached three sets of CTA, Ethics committee approval of the study. The referenced study is an academic study so insurance is not applicable, however sponsor would be covering the entire expenses if the participant has any adverse events or injury related to study as already been undertaken by me in the ethics submission.

Thanking you,

Dr PK Goel
Prof and Head,
Deptt of Cardiology,
SGPGIMS, Lucknow.

Dr. P. K. Goel
Professor & Head
Cardiology
SGPGIMS, Lucknow

Returned on 12/10/18

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(17)

INDIA NON JUDICIAL

Government of National Capital Territory of Delhi

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-DL648607375799430
Certificate Issued Date	:	14-Aug-2018 11:52 AM
Account Reference	:	IMPACC (IV)/ dl713403/ DELHI/ DL-DLH
Unique Doc. Reference	:	SUBIN-DLDL71340333878650176618Q
Purchased by	:	ACADEMICS AND RESEARCH DEPARTMENT BATRA HOSPITAL
Description of Document	:	Article 5 General Agreement
Property Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	ACADEMICS AND RESEARCH DEPARTMENT BATRA HOSPITAL
Second Party	:	DR P K GOEL AND SANJAY GANDHI PGIMS LUCKNOW
Stamp Duty Paid By	:	ACADEMICS AND RESEARCH DEPARTMENT BATRA HOSPITAL
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

CLINICAL STUDY AGREEMENT

This Agreement ("the Agreement") is made on this 10/Aug/2018

By and between

Academics and Research Department, Batra Hospital & Medical Research Centre,1, Tughlakabad Institutional Area, Mehrauli Badarpur Road, New Delhi – 110062, India. (hereinafter referred to as **"Clinical Co-ordinating Center")** represented through its **Lead Investigator, Dr. Upendra Kaul.**

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(19)

AND

Sanjay Gandhi PGIMS, Lucknow India (hereinafter referred to as **"Site")**

AND

Dr. P K Goel with his office address **Sanjay Gandhi PGIMS, Lucknow** at, India. (hereinafter referred to as **Principal Investigator or "PI")**

The Clinical Co-ordinating Center, Principal Investigator and the Institution are henceforth referred to individually as **"Party"** and collectively as **"Parties".**

1. BACKGROUND

WHEREAS, Clinical Co-ordinating Center represented through its Lead Investigator has requested Institution and **Dr P K Goel** (Principal Investigator or "PI"), to conduct a clinical study: *"A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50 yrs.) with ACS undergoing PCI by optical Coherence Tomography (OCT) Imaging*

AND WHEREAS, Site is equipped to undertake the Study and Site has the experience and expertise to perform clinical studies of medical devices and Principal Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

Now, therefore, in consideration of the premises and the mutual promises and covenants expressed herein, Clinical Co-ordinating Center represented through its National Lead Investigator, Site and/or the PRINCIPAL INVESTIGATOR hereby agree to conduct the Study on the following terms and conditions and as described from time to time in the relevant statement of work (the "Statement of Work"):

2. RULES FOR INTERPRETING THIS AGREEMENT

Headings are for convenience only, and do not affect interpretation. The following rules also apply in interpreting this Agreement, except where the context makes it clear that a rule is not intended to apply.

(a) reference to any statute, regulation, proclamation, ordinance, by-law or guideline includes all statutes, regulations, proclamations, ordinances, by-laws or guidelines varying, consolidating or replacing them and a reference to a statute includes all regulations, proclamations, ordinances, by-laws or guidelines issued under that statute;

(b) Words importing the singular include the plural and vice versa and reference to one gender includes all genders;

(c) a reference to a document or agreement including this Agreement includes a reference to that document or agreement as amended, supplemented, varied or replaced from time to time;

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

4.3 Each Party warrants that the person executing this Agreement on its behalf is duly authorized to do so and that nothing contained herein conflicts with any of the provisions of the Memorandum and Articles of Association or similar or other documents relating to the incorporation or of the rules and regulations governing the party.

4.4 None of the services provided by Clinical Co-ordinating Center, under or in connection with this Agreement can or shall be construed as an undertaking that the Study under or pursuant to this Agreement will lead to any particular results or that Clinical Co-ordinating Center has any interest, right or liability in the results of the Study. Clinical Co-ordinating Center confirms that it provides only management services for the Study under agreement with Dr.P. K Goel (Principal Investigator) and all liabilities, responsibilities of the Study, and its results or impact, is solely of the Clinical Co-ordinating Center and Clinical Co-ordinating Center shall have no liability of any manner whatsoever in this regard. Clinical Co-ordinating Center has performed no independent research or analysis regarding the safety or efficacy of any Investigational Product, the Protocol, or any other Trial Materials or treatment procedures involved in this Study and therefore Clinical Co-ordinating Center does not make any warranties, express or implied concerning the same.

4.5 The Site/PI warrant that they have obtained all consents and approvals to carry out the Study as per the Protocol.

4.6 The Site/PI ensure that in the event of a temporary absence of the PI, a nominated and authorized substitute Sub-Investigator shall perform the functions of the PI, though the PI will remain responsible for all his/her obligations under this Agreement. Such nomination/authorization will be done with prior written approval of Clinical Co-ordinating Center. If, however a permanent substitution is required it will be notified to Clinical Co-ordinating Center who shall send a written approval only after consulting with the Clinical Co-ordinating Center, otherwise the Study will be suspended, till a resolution is found.

4.7 No Party hereto shall use the name of another Party hereto or the Clinical Co-ordinating Center either expressly or by implication in any news or publicity release, policy recommendation or commercial purpose without the express written approval of that Party or the Clinical Co-ordinating Center, as the case may be. Nothing herein shall be construed as prohibiting the Clinical Co-ordinating Center from reporting on this Study to other investigators conducting the Study, or of exercising its publication rights.

5. MONITORING AND REPORTING

5.1 As per the Protocol, Site/PI shall report any SAE suffered by a Patient during the Study, whether or not causally related to the study or Patient's participation in the Study, immediately (and in any event within 7 days) to Clinical Co-ordinating Center describing the circumstances under which the SAE occurred and the remedies applied. Site/PI shall follow-up such immediate report by sending a written report to Clinical Co-ordinating Center.

5.2 If in the medical judgment of the PI alternatives on or deviations from the Protocol are required due to a medical emergency, the alternatives and / or deviations and reasons for their use, will be documented and be forwarded to Clinical Co-ordinating Center at the earliest possible occasion following the occurrence of any such event, within Seven (07) days.

5.3 The Site/PI shall notify Clinical Co-ordinating Center promptly if any Regulatory Authority requests permission to inspect the Site/PI facilities, records regarding the Study and shall permit such Regulatory Authority to conduct such inspection. If the inspection occurs than the Site/PI shall provide Clinical Co-ordinating Center with all materials, correspondence, statements, forms and records received from or exchanged with the Regulatory Authorities.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

7.2 Any information, inventions or discoveries (whether patentable, copyrightable or not), innovations, communications and reports (collectively, "Inventions") conceived, reduced to practice, made or developed by Site/PI as a result of conducting the Study shall be promptly disclosed to Clinical Co-ordinating Center and shall be the sole property of Clinical Co-ordinating Center.

7.3 All data supplied by Clinical Co-ordinating Center to the Site and PI, and all data generated in the performance of the Study, (collectively, "Data") shall be and remain the absolute and exclusive property of Clinical Co-ordinating Center. All copy rights and other rights of intellectual and industrial property with regard to the Data shall be vested in Clinical Co-ordinating Center.

7.4 Site/PI hereby assign to Clinical Co-ordinating Center all of their rights, title and interest in and to the Inventions and Data and further agree, upon request by Clinical Co-ordinating Center and at Clinical Co-ordinating Center's expense, to execute such documents and to take such other actions as Clinical Co-ordinating Center deems necessary or appropriate to effect such assignment and to obtain patent or other proprietary protection in Clinical Co-ordinating Center's name covering any of the foregoing.

8. FEE AND COMPENSATION

8.1 In consideration for the Study, the PI will be paid fee/compensation in accordance with the approved payment rates detailed in the budget proposal attached hereto as **Exhibit B** and in accordance with the payment milestones mentioned therein (the "Payment Schedule"). The consideration mentioned under Exhibit B is the total consideration and includes the consideration for purchase of any equipment, infrastructure, admin overheads or hiring of any manpower required, if any, in connection with the Study. The Payment Schedule may be modified only upon the prior written consent of Clinical Co-ordinating Center. Non-emergency additional tests or services (tests or services not required by the Protocol or performed in excess of Protocol requirements) shall not be compensated hereunder unless the written consent of Clinical Co-ordinating Center has been obtained prior to the administration of such tests or services. the clinical coordinating center agrees to pay 18 % GST on top of the agreed budget as per the exhibit B of the clinical study agreement.

8.2 In the event of PI recruiting more or less than minimum number of eligible patients, the consideration for the services will be pro-rated according to the actual number of Eligible Patients enrolled as per the agreed per patient fee.

8.3 Upon completion or termination of the study, the Site/PI agrees to provide written acknowledgement to the Clinical Co-ordinating Center and Clinical Co-ordinating Center that all work requested under this Agreement has been completed and all monies due have been received. In any event, acceptance of payments as "final" constitutes such acknowledgement.

8.4 Clinical Co-ordinating Center further agrees to reimburse Investigator for the actual cost of diagnostic procedures and medical treatment necessary to treat a Patient injury related to the study. Patient injury means a study related physical injury or related psychiatric event caused by administration or use of the Clinical Co-ordinating Center devise required by the protocol that the trial patient would likely not have received if the patient had not participated in the trial. In Case of study related injury or death, Clinical Co-ordinating Center will provide complete medical care as well as compensation for the injury or death as per IRB/IEC recommendation.

9. TERM AND TERMINATION

9.1 The Study shall be completed within the time period of 4 years.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

liability, loss, or damage resulting from (1) a failure to adhere to the terms of the protocol, or this Agreement or Clinical Co-ordinating Center's written instructions (2) failure to obtain the Patients' informed consent (3) failure to comply with any applicable governmental requirements; or (4) negligence or willful malfeasance by the Site, its trustees, the Principal Investigator or associated staff is excluded from this agreement to indemnify and hold harmless.

The Site and the Principal Investigator agree to notify Clinical Co-ordinating Center as soon as they become aware of a claim or action as to which Clinical Co-ordinating Center has indemnification obligations under this agreement and to cooperate with and to authorize Clinical Co-ordinating Center to carry out the sole management and defense of such claim or action. Clinical Co-ordinating Center agrees, at its own expense, to provide attorneys to defend against any such claim or action, whether or not such claim or action is rightfully brought or filed. Neither the SITE, its trustees, Principal Investigator nor associated staff shall compromise or settle any claim or action without the prior written approval of Clinical Co-ordinating Center.

Neither Clinical Co-ordinating Center nor Clinical Co-ordinating Center shall assume any liability for any direct or indirect damage incurred by any of the patients in the course of normal patient care and/or treatment by the Site/PI.

11. CONFIDENTIALITY

11.1 In handling a Patient's medical records, the Site/PI and associated staff shall hold in strict confidence the identity of the patient and shall comply fully with any and all Regulations regarding the confidentiality of such records and data protection.

11.2 The Site/PI shall be responsible for effecting and maintaining all registrations for the processing of personal data that are required by Regulations, including under the Drugs and Cosmetics Rules 1945. PI hereby consents for Clinical Co-ordinating Center and Clinical Co-ordinating Center's affiliates to collect and/or otherwise process personal data provided by or relating to PI for purposes of sharing such personal data with Regulatory Authorities and for any use by Clinical Co-ordinating Center and its affiliates. PI agrees that Clinical Co-ordinating Center and Clinical Co-ordinating Center's affiliates may transfer such personal data to Clinical Co-ordinating Center's facilities, and to Regulatory Authorities.

11.3 The Site/PI acknowledge and agree that all information disclosed to them by or on behalf of Clinical Co-ordinating Center or developed by the Site or PI in connection with the Study is the proprietary information of Clinical Co-ordinating Center and shall be deemed to be Clinical Co-ordinating Center's Confidential Information and each undertakes to Clinical Co-ordinating Center, for its own benefit and for the benefit of Clinical Co-ordinating Center, that it will ensure that such information is kept confidential, without limitation forever even after expiry or termination of this Agreement and is nor disclosed to any third party without prior written consent of Clinical Co-ordinating Center. The Site/PI will hold in strictest confidence and will not directly or indirectly, disclose, reveal, report, use, lecture, broadcast, transfer, disseminate in any form, upon or publish any Confidential Information of Clinical Co-ordinating Center or Clinical Co-ordinating Center.

11.4 The Site/PI shall limit access to the Confidential Information of Clinical Co-ordinating Center to their officers, directors and employees (collectively "Representatives") who require access to such Confidential Information in order to effectuate the purposes of this Agreement. The Site/PI agrees and shall obligate their Representatives to agree, that they will use the same degree of care and discretion as they use to protect their own Confidential Information.

11.5 The Site/PI shall use the Confidential Information of Clinical Co-ordinating Center only for the purpose of fulfilling their obligations under this Agreement. The Site/PI shall not be entitled to use any of the results or data, or any other information, resulting from or related to the Study for own

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

13.4 **Entire Agreement**: This Agreement sets forth the entire Agreement and understanding of the Parties relating to the patient matter hereof, and supersedes all prior agreements, arrangements and understandings, written or oral, between the Parties.

13.5 **Severability**: If any provision of this Agreement shall be held invalid, illegal or unenforceable, such provision shall be enforced to the maximum extent permitted by law and in compliance with the Parties' intent, and the remaining provisions shall not be affected or impaired.

13.6 **Amendments, Waivers**: This Agreement may be amended, modified, superseded, cancelled, renewed or extended, and the terms or covenants hereof may be waived, only by a written instrument (which identifies this Agreement and states the plan or intent to modify) executed by all Parties hereto, or in the case of a waiver, by the Party waiving compliance.

13.7 **Assignment**: Site/PI may not assign this Agreement to any party and may not subcontract any of their obligations under this Agreement, unless Clinical Co-ordinating Center have given prior written consent for the same.

13.8 **Survival**: Notwithstanding the termination of this Agreement, obligations which have accrued or have application beyond the term including without limitation those relating to confidentiality, intellectual property, publications, indemnification and enforcement of Parties' rights, shall survive the expiration or earlier termination of this Agreement.

13.9 **Relationship of the Parties**: The Parties agree that Site/PI shall perform services hereunder as an independent contractor, and not as an agent, retaining control over and responsibility for its own operations and personnel. Site/PI shall not, and will ensure that its Representatives shall not, represent themselves to be the agents, employees, partners or joint-ventures of Clinical Co-ordinating Center and shall not otherwise cause Clinical Co-ordinating Center to be liable under any contract or otherwise.

13.10 **Attachments**: Exhibits A& B form an integral and substantial part of this Agreement.

13.11 **Force Majeure**: No Party hereto shall be liable in damages or have the right to cancel this Agreement for any delay or default in performing its obligations hereunder if such delay or default is caused by conditions beyond its control, including but not limited to natural disasters, acts of God, government restrictions/policy, laws, wars, terrorist acts, or insurrections. Whichever of Site/PI and Clinical Co-ordinating Center is affected by such circumstances (the "Affected Party") shall promptly notify the other (the "Non-Affected Party") in writing when such circumstances cause a delay or failure in performance ("a Delay"). In the event of a Delay lasting for four (4) weeks or more the Non-Affected Party shall have the right to terminate this Agreement immediately by notice in writing to the Affected Party.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(11)

EXHIBIT – A

LIST OF SERVICES

1. *IDENTIFICATION OF ELIGIBLE PATIENTS FOR THE STUDY*
2. *ADMINISTRATION OF INFORMED CONSENT PROCESS*
3. *ENROLLING PATIENTS AS PER PROTOCOL INCLUSION EXCLUSION CRITERIA*
4. *TREAT STUDY PARTICIPANTS AS PER PROTOCOL & ADEQUATE FOLLOWUP*
5. *TAKING COMPLETE MEDICAL HISTORY OF THE PATIENTS*
6. *PHYSICAL EXAMINATION – SIGNS AND SYMPTOMS OF ALL THE PATIENTS*
7. *RESPONSIBILITY FOR ADVERSE EVENTS REPORTING*
8. *WRITING THE PATIENT STUDY SUMMARY-COMPLETION OF SOURCE DOCUMENTATION*

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(10)

B. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

No payment will be made in the event of a failure to follow the study procedure as defined by the protocol, except where such failures are beyond the reasonable control of the Site. Reimbursement will not be provided for patients who enter the study but fail to meet all the inclusion and exclusion criteria. Reimbursement for discontinued or early termination patients will be prorated based on the number of confirmed completed visits.

C. PAYEE INFORMATION

The parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee (the "Payee").

Payments will be issued Quarterly by the Clinical Co-ordinating Center according to visits completed, as verified by the study monitor in the Electronic data captured tool –E-CRF records. Payments will be made by cheque in favor of this agreement payee details.

PAYEE NAME: Please note: This should be a business name and must match the business name used to file for your tax EIN or other tax ID number	Director SGPGIMS Research
PAYEE ADDRESS: Please Note: this should be street address, not a PO Box	Rae Bareli Road, Lucknow, 226014
PAYEE ACCOUNT NUMBER	10095237491
BRANCH ADDRESS	SBI (7789)
IFSC CODE	SBIN0007789
RTGS CODE	NA
SWIFT CODE	NA
MIRC NO	NA
TYPE OF ACCOUNT	Saving Account
PERMANENT ACCOUNT (PAN) OF PAYEE	AAAJS3913N
(GST NO)	09AAAJS3913N2ZN

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(9)

संजय गाँधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road Lucknow- 226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/** 346 **/2018**

Agenda Item No. 4 **Date:** 01-Aug-18

Title of project: "A prospective multi-centric study to investigate the plaque characteristics andnatural history of lesion in the non-culprit vessels in young Indian patients (<45 years) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging."

Principal Investigator: DrPK Goel **Department:** Cardiology

Name and Address of Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014

New/Re-review project: New

Date of IEC meeting: 18-Jul-18

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application to conduct the research study during the IEC meeting held on 18-Jul-18

List of documents reviewed:

1. Project Submission Form
2. Study Protocol
3. Case Report Form
4. Consent of Head of the PI's Department
5. Research Committee/Department committee /Doctoral Committee/Scientific Committee Approval
6. Undertaking by the PI
7. Conflict of Interest Statement by PI
8. CV of investigator outside SGPGI or of the student
9. Participant Information document (PID) consent forms CF) in English and Hindi

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(8)

संजय गाँधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ
SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road, Lucknow- 226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 PGI/BE/ 346/2018

Agenda Item No. 4 Date: 01-Aug-18

The following members of the Institutional Ethics committee (IEC) were present at the meeting held on 18-Jul-18

Dr. O. P. Asthana,Retd. Chief Scientist, Clinical and Exp. Med. Div.,CDRI, Lucknow- Chairman
Prof Rajan Saxena Dean SGPGI - Member
Prof Shally Awasthi Deptt of Pediatrics KGMU Lucknow - Member
Prof Vinita Das Deptt of Obst & Gynae KGMU Lucknow - Member
Justice Vishnu Sahai Former Judge Allahabad High Court - Member
Shri Vijai Varma, Chairman Upbhokta Forum Lucknow - Member
Dr Chandishwar Nath Retd Chief Scientist CSIR-CDRI Lucknow - Member
Shri Sharat Pradhan Senior Journalist Lucknow - Member
Shri. Yogesh Misra, Senior Journalist, Lucknow - Member
Dr. Mohan Gurjar, Deptt. Of CCM, SGPGI, Lucknow - Member
Dr. AK Srivastava, (Retd.) Dept. of Sociology, University of Lucknow (Spl. Invitee)- Member
Prof. Vinita Agrawal, Deptt. Of Pathology, SGPGI, Lucknow - Member Secretary

Scientific, ethical and legal issues and PID, CF were discussed.

The committee has given the following suggestions to the PI:

1. **The project has variation in age mentioned in the title submitted to IEC (mentions age <45 years) from that approved from Batra Hospital (mentions age ≤ 50years). Clarify.**
2. **Kindly clarify if FFR assessment is a non-invasive procedure or not.**
3. **Compensation clause needs clarification. Pg 42 mentions that 'any injury' will be taken care by 'clinical coordination center'. Clearly mention the name of the hospital and that the patient will not have to bear any cost of treatment for adverse event. Reimbursement of travel costs for follow up visits should be provided to the participants.**
4. **No insurance policy has been submitted. Insurance would be required to cover the cost of injury/adverse events.**
5. **CTA should be submitted to the Research Cell for approval and after approval, a copy should be submitted to the IEC for record.**

Decision - Minor Modification.

PI advised to submit within 4 weeks, failing which the project will not be considered in next IEC meeting for ethical approval.**Please reply by: 03-Sep-18**

Thanking you,

Your Sincerely,

Vinita Agrawal

(Dr. Vinita Agrawal)
Member Secretary
IEC, SGPGI, Lucknow.

Bajpai

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(7)

PGI/Cardio/530/18

Gram : AYURVIGYAN
E-mail : pkgoel@sgpgi.ac.in
: golf_pgi@yahoo.co.in

Phone (O): + 91-(522) 2494227, 2494277, 2494231
(R): + 91-(522) 2494228, 2668071 (Direct)
Fax : + 91-(522)-2668078, 2668017

SANJAY GANDHI POSTGRADUATE INSTITUTE OF MEDICAL SCIENCES
DEPARTMENT OF CARDIOLOGY

Dr. Pravin K. Goel
M.D. (Med), D.M. (Cardiology), FACC, FSCAI, FICC
Formerly Fellow Cardiac Radiology,
Greenlane Hospital, Auckland.
Professor & Head

RAEBARELI ROAD
LUCKNOW – 226 014 (INDIA)

Date:-20/08/2018

To,

Member Secretary,

IEC, SGPGI,

Lucknow.

Subject: Point wise clarification of the committee's comments on my submitted study.

IEC Code: 2018-103-EMP-104

Study title: A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50yrs.) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging

Dear Mam,

This is in response to your letter no PGI/BE/346/2018 dated 01/08/2018 please find the point wise clarification of the ethics committee's comments on my submitted study.

Thanking you,

Dr PK Goel,

Prof and Head,

Deptt. of Cardiology,

SGPGIMS, Lucknow.

OFFICE OF THE BIOETHICS CELL S.G.P.G.I. LKO. No. 24-8-18

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

(6)

To,

Date: 20.08.2018

Member Secretary,
IEC, SGPGIMS,
Lucknow.

Protocol Title: A prospective, multi-centric study to investigate the plaque characteristics and natural history of lesions in the non-culprit vessels in young Indian patients (≤50yrs.) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging

Dear Dr P.K Goel,

This is in response to your institutional ethics committee letter dated 1st Aug 2018 in which the ethics committee raised few queries for the above referenced study.

The responses for each of the queries are given below:

1. The project has variation in age mentioned in the title submitted to IEC (mentions age < 45 years) from that approved from Batra Hospital (mentioned age ≤ 50 years). Clarify.

Response: It is a typographical error please considered it as ≤ 50 years.

2. Kindly clarify if FFR assessment isa non-invasive procedure or not.

Response: FFR assessment is an invasive procedure but diagnostic only.

3. Compensation clause needs clarification.pg. 42 mention that 'any injury will be taken care by 'clinical coordination center'. Clearly' mention the name of the hospital and that the patient will not have to bear any cost of treatment for adverse event. Reimbursement of travel cost for follow up visit should be provided to the participants.

Response: Any injury related to participation in the entire study will be treated at SGPGI and it will be reimburse (treatment cost) for the adverse event by the sponsor (Clinical coordination Centre of Batra hospital and Medical Research Centre New Delhi). Sponsor will be giving INR 500 as a travel reimbursement only for 1-year OCT follow up visit (the same has incorporated in ICF) because the rest visits will be of telephonic.

4. No insurance policy has been submitted. Insurance would be required to cover the cost of injury/adverse events.

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(9)

Response: Since the referenced study is an academic study so "Insurance" is not applicable, however sponsor would be covering the entire expenses if the participant has any adverse events or injury related to study.

5. CTA should be submitted to the Research Cell for approval and after approval copy should be submitted the IEC for record.

Response: Once CTA is finalized, we will notify to the IEC for record.

20/8/18

Dr PK Goel,
Prof and Head,
Deptt. Of Cardiology,
SGPGIMS, Lucknow.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

Ethics Approval

(4)

संजय गांधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ
SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES,
Raebareli Road, Lucknow-226014 (India)

Dr. Vinita Agrawal
Professor (Pathology) and
Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/** 444/2018

Agenda Item No. 4 **Date:** 29-Sep-18

Title of project: "A prospective multi-centric study to investigate the plaque characteristics and natural history of lesion in the non-culprit vessels in young Indian patients (<45 years) with ACS undergoing PCI by Optical Coherence Tomography (OCT) imaging."

Principal Investigator: Dr PK Goel **Department:** Cardiology

Name and Address of Institution: Sanjay Gandhi Postgraduate Institute of Medical Sciences, Raebareli Road, Lucknow, 226014

New/Re-review project: New

Date, time and venue of meeting: 18-Jul-18 11.00 AM at Committee room of Guest house SGPGI

Dear Dr.

Institutional Ethics Committee reviewed and discussed your application to conduct the research study during the IEC meeting held on 18-Jul-18

List of documents reviewed:

1. Project Submission Form
2. Study Protocol
3. Case Report Form
4. Consent of Head of the PI's Department
5. Research Committee/Department committee /Doctoral Committee/Scientific Committee Approval
6. Undertaking by the PI
7. Conflict of Interest Statement by PI
8. CV of investigator outside SGPGI or of the student
9. Participant Information document (PID) consent forms CF) in English and Hindi

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SGPGIMS,Lucknow

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संजय गांधी स्नातकोत्तर आयुर्विज्ञान संस्थान, लखनऊ
SANJAY GANDHI POST GRADUATE INSTITUTE OF MEDICAL SCIENCES,
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Dr. Vinita Agrawal
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IEC code: 2018-103-EMP-104 **PGI/BE/** 444/2018

Agenda Item No. 4 **Date:** 29-Sep-18

The following members of the Institutional Ethics committee (IEC) were present at the meeting held on 18-Jul-18

Dr. O. P. Asthana,Retd. Chief Scientist, Clinical and Exp. Med. Div.,CDRI, Lucknow- Chairman
Prof Rajan Saxena Dean SGPGI - Member
Prof Shally Awasthi Deptt of Pediatrics KGMU Lucknow - Member
Prof Vinita Das Deptt of Obst & Gynae KGMU Lucknow - Member
Justice Vishnu Sahai Former Judge Allahabad High Court - Member
Shri Vijai Varma, Chairman Upbhokta Forum Lucknow - Member
Dr Chandishwar Nath Retd Chief Scientist CSIR-CDRI Lucknow - Member
Shri Sharat Pradhan Senior Journalist Lucknow - Member
Shri. Yogesh Misra, Senior Journalist, Lucknow - Member
Dr. Mohan Gurjar, Deptt. Of CCM, SGPGI, Lucknow - Member
Dr. AK Srivastava, (Retd.) Dept. of Sociology, University of Lucknow (Spl. Invitee)- Member
Prof. Vinita Agrawal, Deptt. Of Pathology, SGPGI, Lucknow - Member Secretary

IEC has taken following decisions for the study/trial;

Scientific, ethical and legal issues and PID, CF were discussed.
The committee has given the following suggestions to the PI:

1. The project has variation in age mentioned in the title submitted to IEC (mentions age <45 years) from that approved from Batra Hospital (mentions age ≤ 50years). Clarify.
2. Kindly clarify if FFR assessment is a non-invasive procedure or not.
3. Compensation clause needs clarification. Pg 42 mentions that 'any injury' will be taken care by 'clinical coordination center'. Clearly mention the name of the hospital and that the patient will not have to bear any cost of treatment for adverse event. Reimbursement of travel costs for follow up visits should be provided to the participants.
4. No insurance policy has been submitted. Insurance would be required to cover the cost of

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SGPGIMS,Lucknow

(2)

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Dr. Vinita Agrawal
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Member Secretary, Institutional Ethics Committee

Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/444/2018**

Agenda Item No. 4 **Date:** 29-Sep-18

injury/adverse events.

5. CTA should be submitted to the Research Cell for approval and after approval, a copy should be submitted to the IEC for record.

Decision Minor Modification.

As per above recommendations of IEC, the project/trial with documents has been reviewed by the Member Secretary and based on the documents submitted by PI following recommendation has been made.

Decision: Approved.'

With the following condition:-

Copy of approved CTA should be provided to IEC.

The approval is valid until one year or duration of project whichever is later from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of annual status report.

Following points must be noted:

1. IEC should be informed of the date of commencement of study (AN5-V2/SGSOP 06/V3) and annual progress.
2. PI and other investigators should co-operate with IEC, which may monitor the trial from time to time.
3. The decision was arrived at through consensus. Neither PI nor any of proposed studyteam members was present during the decision making of the IEC.
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD and getting IEC concurrence and submitting status report, including accounts details should be submitted to HOD, IEC and extramural sponsors.

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SGPGIMS,Lucknow

(1)

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Dr. Vinita Agrawal
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Communication of decisions of the 104 th Institutional Ethics Committee

IEC code: 2018-103-EMP-104 **PGI/BE/444/2018**

Agenda Item No. 4 **Date:** 29-Sep-18

5. New information or any SAE, which could affect any study, must be communicated to IEC and sponsors. The PI should report SAEs occurred for IEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the Bioethics cell should receive the SAE reporting form within 24 hours of the occurrence.

6. In the events of any protocol amendments, IEC must be informed and the amendments should be highlighted in clear terms

7. Any deviation/violation/waiver in the protocol must be informed to the IEC as detailed in AN1-V3/SGSOP 09/V3.

8. If project/drug/device trial initiation not done in next 6 months from date of approval from IEC, further extension will not be granted and it will require resubmission to IEC.

We hereby confirm that the Institutional Ethics Committee is organized and operates as per amended schedule Y (20th Jan 2005), ICH GCP guidelines and applicable regulations.

Thanking You,

Your Sincerely,

Vinita Agrawal

(Dr. Vinita Agrawal)

Member Secretary

IEC, SGPGI, Lucknow.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

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Kapra, Medchal-Malkajgiri Distri
Pin-500062. Cell No:

CLINICAL TRIAL AGREEMENT

PROTOCOL APL/CT/15/06

This Clinical Trial Agreement (the **"Agreement"**) is effective on 21 Feb 2018 fully executed by the parties (the **"Effective Date"**) and entered into by and between

CLINWAVE RESEARCH, a company incorporated under the Companies Act, 1956 having its Registered Office at A/221, 4-32-121, Phase-1, Allwyn colony, Kukatpally, Hyderabad-500072, India (hereinafter referred to as **"CRO"** which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

Dr. Vikas Kanaujia (Additional Professor), whose principal place of business is **Sanjay Gandhi Post Graduate Institute of Medical Sciences, Raebareli Road Lucknow, Uttar Pradesh, India-226014**

(hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

Sanjay Gandhi Post Graduate Institute of Medical Science, Raebareli Road Lucknow, Uttar Pradesh India-226014

(hereinafter referred to as the **"Institute"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest)

CRO, Principal Investigator and Institute is referred to herein individually as a "Party" and collectively as "Parties".

Whereas, Ajanta Pharma Limited, Plot number 43 AB, 44 BCD, Govt. Industrial Estate, Charkop, Kandivali (W), Mumbai-400067, India (Hereinafter referred to as the **"Sponsor"**) through its Agent CRO desires the Institution to study **"A Comparative, Randomized, Two Arm, Double Blind, Parallel group, Multicentric Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Ripasudil Hydrochloride Hydrate Eye Drops 0.4% w/v Vs Timolol Maleate Eye Drops 0.5% w/v in Subjects Suffering from Ocular Hypertension / Glaucoma.-** and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

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WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study (defined herein below);

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. **THE STUDY AND THE PROTOCOL**

The study of shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No. **APL/CT/15/06** and entitled **"A Comparative, Randomized, Two Arm, Double Blind, Parallel group, Multicentric Clinical Study to Evaluate the Efficacy, Safety and Tolerability of Ripasudil Hydrochloride Hydrate Eye Drops 0.4% w/v Vs Timolol Maleate Eye Drops 0.5% w/v in Subjects Suffering from Ocular Hypertension / Glaucoma"** a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored on behalf of the Sponsor by the CRO.

Institution's obligation to conduct the Study is expressly conditioned upon the approval of the Protocol by an IEC/IRB that complies with the requirements of Drug Controller General of India and Schedule Y and applicable regulatory requirements. Sponsor, Principal Investigator and Institution shall cooperate in preparing and filing the Protocol, Informed Consent Form and other information with the reviewing IEC (Institutional Ethics Committee) or IRB (Institutional Review Board).

2. **THE STUDY SCHEDULE**

A. **Study Initiation.** All contractual and regulatory documentation must be received by Sponsor and CRO before the initiation of the Study. The Principal Investigator shall initiate the Study at the earliest after receiving the applicable regulatory / IEC / IRB approvals.

B. **Enrollment.** Principal Investigator will enroll **minimum 30 Subjects** (as per the randomization schedule) and **not more than 50 Subjects** (as per the randomization schedule) (the "Site Maximum") for the duration of enrollment. The Principal Investigator shall commence enrollment of the Subjects once all the contractual and regulatory obligations have been met. Enrollment of, and payment for, each Subject over the Site Maximum shall require prior written consent of the Sponsor. Notwithstanding the foregoing, the Institution immediately shall cease enrolling the Subjects upon receipt of notice from the Sponsor, or the Sponsor's designee, that, in the sole determination of the Sponsor:

i. the Complete Study enrollment has been achieved; or

ii. the Sponsor has placed the Study on hold, for any reason; or

iii. the Study has been placed on hold by the DCGI or applicable regulatory agency for any reason.

C. **Study Documentation.** Case Report Forms ("CRFs") must be satisfactorily completed maximum within **three (3) days** of each Subject visit. If any tests are to be performed after the Subject visit, CRF shall be completed maximum within **three (3) days** of receipt of test results for each Subject, provided, however, that with respect to the last Subject enrolled at the Site, CRF for such Subject must be completed within **three (3) days** of such Subject's last visit to the Site. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. Safety data (Serious Adverse Event Report Forms) will be faxed / mailed to Sponsor and CRO within **twenty four (24) hours** of (i) the Subjects visit and (ii) receipt of the test results at, or from which, such event was reported, noted or recognized. Data Clarification Forms Queries ("DCFs") must be resolved within **two (2) days** of its receipt.

D. **Subject Samples.** All biological samples collected from the Subjects shall be prepared and shipped in accordance with appropriate reference of the Protocol / Study requirements / Study manuals.

E. **Study Completion.** The Institution shall complete the enrollment of all the Subjects within the specified timeline given or informed by the Sponsor/ CRO. The Institution shall input all final CRF data and complete the final CRFs not later than three days after the last Subject visit.

3. **PAYMENT**

A. **Budget and Payment Schedule:** CRO shall on behalf of the Sponsor reimburse the Institution all direct and indirect costs incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the **"Budget and Payment Schedule"**). Payment shall be made by

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Cheque/NEFT/RTGS payable to (**Institute**) PAN No. AAAJS3913N. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study.

B. **Payment of Costs outside Budget and Payment Schedule.** Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. **Payment Terms.** CRO shall have no obligation to make payments for any subject who is not qualified to participate in the protocol based on the inclusion and exclusion criteria described in the protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the sponsor's clinical and/or medical monitor identified in the protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. **Payment Recipient and Mailing Address.** All cheques shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

Address: **Dr. VIKAS KANAUJIA,**
Additional Professor, Department of Ophthalmology
Vth , Floor , New OPD Block , Department of Ophthalmology
Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raebareli Road Lucknow,Uttar Pradesh, India -226014

The further details for the payments should be provided as

1. **Cheque in the favor of:** DIRECTOR, SGPGIMS RESEARCH SCHEME ACCOUNT, LUCKNOW

2. **PAN No. - AAAJS3913N**

1.	**Name of Bank:**	State Bank Of India
2.	**Branch:**	SGPGIMS Campus, Raebareli Road, Lucknow **226014, UP**
3.	**Account No:**	10095237491
4.	**Branch Code:**	
5.	**IFS CODE :**	SBIN0007789

E. **Reimbursement.** Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. **Payments for Screen Failure:** Sponsor will not pay only for **Screen Failure subject**.

G. **Payment for Study Coordinator:** PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

4. **OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR**

A. **IEC/IRB Approval.** The Principal Investigator shall be responsible, with the cooperation of the Institution and Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the Sponsor or Sponsor's designee with written confirmation of the IEC / IRB's

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approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notify the Sponsor and/or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. **Performance of the Study.** The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted in accordance with (i) generally accepted standards of good clinical and research practice (including, without limitation, the guidelines set forth by the International Conference on Harmonization, if applicable); (ii) this Agreement; (iii) the Protocol; (iv) written instructions provided by the Sponsor or Sponsor's designee; and (v) all applicable local, state and federal laws, regulations, and policies governing the performance of clinical investigations, including, but not limited to local regulatory requirements. In the event of a conflict between any requirements in (i) through (v) above, the Principal Investigator shall comply with the most stringent requirement. The Principal Investigator shall make no changes to the Protocol, except as agreed to and approved in writing by the Sponsor and, where required, the IEC/IRB. Neither the Institution nor the Principal Investigator shall subcontract any of its obligations or any portion of this Agreement to any other individual or entity without the prior written consent of the Sponsor.

C. **Key Personnel.** The Parties acknowledge that the participation of the Principal Investigator is essential to the successful performance and completion of the Study. If, for any reason, the Principal Investigator withdraws from the Study, becomes unavailable, or is otherwise unable to complete his responsibilities under this Agreement, the Principal Investigator shall immediately notify the Sponsor or Sponsor's designee and the Sponsor or Sponsor's designee shall endeavor to agree upon a successor. Absent prompt agreement upon a successor, the Sponsor may terminate this Agreement as set forth in Clause 12(B) below.

D. **Sponsor Visits.** The Sponsor's representatives may conduct periodic visits, at mutually acceptable times during normal business hours, to: (i) inspect and examine the Institution's facilities at which the Study is being conducted or was conducted; (ii) review the progress of the Study (including without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

E. **Supplies.**

a. The Sponsor or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all

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SGPGIMS,Lucknow

rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug hereunder, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

F. **Study Records, Reports, and Data.**

i. *Study Records*. The Principal Investigator and the Institution shall, in a timely manner, prepare and maintain complete and accurate Study records as set forth in the Protocol and as may otherwise be required by applicable law, rule, regulation and good clinical practice (**"Study Records"**). The Principal Investigator shall make all Study Records, including, without limitation, source documents, signed Informed Consents, laboratory data, Drug inventory records, available to representatives of the Sponsor at the Sponsor's request. Except as otherwise expressly provided for in the Protocol or elsewhere herein, all Study Records shall be retained by the Principal Investigator for a period of **fifteen (15) years** after the approval of the Study Drug for marketing or the formal discontinuation of the clinical development of the Study Drug or as per instruction given by CRO/ sponsor for the same. Thereafter, prior to the disposal of the Study Records, Principal Investigator (as applicable) shall give the Sponsor not less than **sixty (60) days** prior express written notice thereof, and if the Sponsor requests in writing, the Principal Investigator shall transfer the Study Records to the Sponsor at Sponsor's expense. Study Records shall in no event be destroyed without Sponsor's prior written permission.

All the source documents pertaining to clinical conduct of the study shall be treated as confidential. All the Study Records shall be the sole and exclusive property of the Sponsor excluding the source data.

ii. *Case Report Forms*. The Principal Investigator shall complete full clinical evaluations and original CRFs on each Subject in accordance with the Protocol. The Principal Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to the Sponsor in the CRFs and in all required reports. In addition, the Principal Investigator shall deliver to the Sponsor or Sponsor's designee each completed CRF from monitoring visits as provided for in Clause 2(C) of this Agreement.

iii. *Annual Reports.* The Principal Investigator shall submit written summaries of the status of the Study to the IEC / IRB annually, or more frequently, if requested by the IEC/IRB.

iv. *Final Reports.* Upon completion of the Study, the Principal Investigator will provide a summary of the Study's outcome (**"Final Report"**) to the IEC/IRB. In addition, any Serious Adverse Events will be reported to the IEC/IRB.

v. In case the Principal Investigator is no longer associated with the Institute, Institute Head or authorized designee will be responsible for maintenance and retention of study records.

G. **Reporting of Serious Adverse Event.** The Institution and Principal Investigator shall notify CRO/Sponsor of any Serious Adverse Event encountered in the Study within **twenty four (24) hours** of awareness of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given by fax / mail, whether or not notification was initially given by telephone. The SAE reporting and follow up would be as per the current local applicable regulatory requirements.

5. **CONFIDENTIALITY**

A. **Confidential Information.** The term "Confidential Information" shall mean any and all information, data or know-how, trade secrets whether written or oral, technical or non-technical, as well as tangible materials including without limitation (i) financial, accounting, and business information, (ii) information relating to samples, compounds,

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SGPGIMS,Lucknow

procedures, Protocol, the Study Drug and all reports, documents, data and other information generated in connection with the Study or other information which the Institution or the Principal Investigator receives, directly or indirectly, from Sponsor and/or CRO and (iii) any other data or information that is generated by the Institution as required by the Protocol and/or this Agreement, including Case Report Forms, laboratory data and Study results, but not including the medical records of the Institution. Subject to the provisions of Clause 5(A)(*i*) through 5(A)(*iv*), the Parties shall not disclose Confidential Information without prior written authorization from the Disclosing Party for any purpose other than those specified in this Agreement. The obligations of non-disclosure shall not apply to the following:

i. Confidential Information that is already in the public domain at time of disclosure or becomes publicly available through no fault of the Receiving Party;

ii. Confidential Information that is already known to or independently developed by the Receiving Party as shown by its prior written records, provided that Receiving Party informs the Disclosing Party promptly upon the Receiving Party's discovery that the Confidential Information is already independently known to the Receiving Party;

iii. Confidential Information that lawfully and in good faith received from a third party who did not derive it, directly or indirectly, from the Disclosing Party; and

iv. Confidential Information required to be disclosed to a governmental or regulatory agency to the extent necessary for the required disclosure.

Disclosing Party: The term "Disclosing Party" shall mean the party disclosing Confidential Information to other party.

Receiving Party: The term "Receiving Party" shall mean the party receiving Confidential Information from the other Party.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. **Non-Disclosure and Non-Use.** Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of five (5) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. **Medical Confidentiality.** Notwithstanding any of the foregoing, Sponsor shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws.

6. **Protection.** Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care

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which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. **PUBLICATION**

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish his part, the prior written approval from Sponsor is required.

8. **OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES**

A. **Materials and Data.** The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the sole property of the Sponsor. Accordingly, the Sponsor shall have, in its sole discretion, the right to publish, disclose, disseminate, and use, in whole or in part, the same for any and all purposes, including, without limitation, in and for submissions to the FDA or other regulatory agencies.

B. **Patents and Inventions.** All right, title and interest in and to, whether domestic or foreign any inventions or discoveries (collectively, **"Inventions"**) first conceived of and reduced to practice prior to the Effective Date of this Agreement by the Principal Investigator, Institution or CRO as expressed in protocols, lab notebooks, or other written records, the know-how incidental thereto, and any patent applications and resulting patents derived there from shall be the exclusive property of that Party.

i. "New Invention or Discovery" shall mean any invention or discovery conceived and reduced to practice during and as a part of Study by the Principal Investigator or any faculty, staff, employees, students or agents of the Institution or the Principal Investigator, or jointly by such an individual or individuals with one or more employees or consultants of the Sponsor.

ii. New Inventions or Discoveries made jointly by the Institution, Principal Investigator, or any of their respective agents with one or more employees or consultants of the Sponsor that: (a) are improvements to, new uses of, or (where applicable) new dosages or dosage forms of the Study Drug or device that arise from the performance of the research; or (b) occur during the performance of the Study and are based upon or subject to the claims of Sponsor's patentable Inventions shall be the sole property of Sponsor.

iii. New Inventions or Discoveries arising out of the research performed under this Agreement solely by Institution, Principal Investigator, and/or any of their respective agents that is not covered by the provisions of Clause 7(B)(*iii*) (an **"Institution Invention"**) shall be the sole property of Institution (subject to any agreement between the Institution and Principal Investigator regarding the ownership of inventions).

iv. Institution and / or the Principal Investigator shall promptly notify the Sponsor a full written description of any New Inventions or Discoveries described in either Clause 7(B)(*iii*) or 7(B)(*iv*) of which they become aware. Sponsor shall have a time-limited, first option to negotiate an exclusive, worldwide, royalty-bearing license to any Institution Invention. Any such exclusive license shall include a reasonable royalty based on Sponsor's and Institution's respective contributions to Institution Invention and other terms that are typical in licenses of similar technology. Sponsor shall advise Institution in writing of its interest in obtaining an exclusive license to any Institution Invention within sixty (60) days of Sponsor's receipt of notice of Institution Invention. If Sponsor fails to notify the Institution within sixty (60) days or provides notice that it elects not to obtain an exclusive license, then Sponsor's option shall expire with respect to that particular Institution Invention and Institution shall be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the

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Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. **No Other Rights.** Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

9. **REPRESENTATIONS, WARRANTIES AND COVENANTS**

A. **Of the Principal Investigator.** The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the Sponsor (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable federal law relating to clinical studies that has not been disclosed to the Sponsor and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation (**"Notice of Intent to Disqualify"**). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the Sponsor with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will immediately terminate. If the Principal Investigator receives a notice or threat of action with respect to its debarment or a Notice of Intent to Disqualify, the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the Sponsor immediately and the Sponsor shall have the right to terminate this Agreement immediately without further cost or liability.

B. **Of the Sponsor.** The Sponsor represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the Sponsor's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

Sponsor represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) Sponsor has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular, Sponsor shall comply with all DCGI or FDA reporting rules that require it to inform Institution

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and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

C. **No Other Representations or Warranties.** Except for the limited representations and warranties given in this Clause 8, none of the Sponsor, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

D. **Of the Institution:** Institution will ensure that the Principal Investigator remits to the Sponsor all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

10. **GOVERNING LAW**

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Ahmedabad, India. It is expressly agreed that the arbitral award shall be final and binding upon both the Parties hereto. However, the final jurisdiction shall lie with the courts of Ahmedabad, India. Each of the Parties hereby expressly submits to the jurisdiction of the courts of Ahmedabad, India.

11. **INDEMNIFICATION**

A. **Sponsor Indemnification.** The Sponsor shall defend, indemnify, and hold harmless the Institution and its trustees, officers, the Principal Investigator, employees and agents (the "**Institution Indemnities**") from and against any liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Institution Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments but only to the extent such claims, suits, actions, demands or judgments arise from or are caused by the Study Drug and are not covered by insurance or self-insurance as set forth in Clause 11 and provided that the Study is conducted in accordance with (i) this Agreement and the Protocol; (ii) all written instructions provided by the Sponsor concerning the Study; (iii) all applicable federal, state, or local laws, rules, regulations, requirements, and policies; and (iv) the manner required of reasonable and prudent clinical investigators and physicians; and such loss does not arise out of the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institution Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees; and the Sponsor is notified within ten (10) working days of any complaint, claim, or injury relating to any loss for which indemnification and/or defense under this Agreement might be sought; and Principal Investigator and the Institution and its directors, officers, and employees fully cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement.

B. **Institution Indemnification.** The Institution shall defend, indemnify, and hold harmless the Sponsor and its affiliates and their respective directors, officers, employees, agents, successors, and assigns ("**Sponsor Indemnities**") from and against any and all third party liability, loss, damage, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Sponsor Indemnities or any one of them in connection with any third party claims, suits, actions, demands, or judgments to the extent such claims, suits, actions, demands, or judgments arise out of: (i) a failure to conduct the Study in accordance with this Agreement and the Protocol, all written instructions provided by the Sponsor concerning the Study, all applicable federal, state, or local laws, rules, regulations, requirements, and policies, and in the manner required of reasonable and prudent clinical investigators and physicians; and (ii) the negligent or reckless conduct or omission or intentional misconduct or malfeasance of any Institutional Indemnity, or any other person on the Institution's property or under its control, exclusive of the Sponsor's employees.

C. **Notification.** The Parties shall promptly notify each other of any such claims, suits, actions, demands, or judgments and the Parties shall reasonably cooperate with each other in the handling thereof.

D. **Claims.** The indemnifying Party, at its own expense, shall have the exclusive right to manage claims, control investigation and litigation, and select counsel, including the right to compromise or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromise or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

E. **Representation.** In the event a claim or action is or may be asserted, the non-indemnifying Party shall have the right to select and obtain representation by separate legal counsel. If the non-indemnifying Party exercises such right, all costs and expenses incurred by the non-indemnifying Party for such separate counsel shall be fully borne by the non-indemnifying Party; provided, that without the Indemnifying Party's prior written consent, the non-indemnifying Party shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the liabilities for which indemnification may be sought by an non-indemnifying Party Indemnity.

F. **Subject Injury.** Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the Sponsor in case of subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

12. **INSURANCE**

A. **Sponsor Insurance.** Sponsor shall maintain during the term of this Agreement and for a period of **One (1) year** thereafter, general liability insurance (with product liability endorsements) and professional clinical trial liability insurance coverage sufficient to meet its indemnification obligations. Sponsor will provide evidence of its insurance upon request and will provide to the Institution, **thirty (30) days** prior written notice of cancellation of its coverage. Sponsor further agrees to include Institution and Principal Investigator as additional insured on such policy.

B. **Institution Insurance.** Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 11 shall survive termination of this Agreement.

13. **TERM AND TERMINATION**

A. **Term.** This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F)(*iv*), above, unless earlier terminated in accordance with this Agreement.

B. **Termination.**

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i. Either Party may terminate this Agreement immediately upon written notice to the other if:

a. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;

b. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

c. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement..

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

iv. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, Sponsor will make payment to Institution for.

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. Reasonable non-cancelable obligations properly incurred for the Study by Institution prior to the effective date of termination.

v. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by Sponsor, to the extent medically permissible.

vi. **Immediate Termination by the Sponsor.** The Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.

vii. **Effect of Termination.** In the event this Agreement is terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the Sponsor to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the Sponsor's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the Study prior to termination. Within ninety (90) days from the effective date of any such termination, the Institution and the Principal Investigator shall provide to the Sponsor all data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes. The Sponsor shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement.

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viii. **Survival.** Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11,and 12 shall survive any termination of this Agreement for any reason.

14. **MISCELLANEOUS**

A. **Use of Names; Publicity.** Except as otherwise required by applicable law, regulation or court order, no Party to this Agreement will use the name or other identifying marks of any other Party or its affiliates or its employees in any advertisement, press release, or other public statement without prior written approval of the other Party; provided however that Sponsor may identify the Institution as a participating clinical site and the Principal Investigator as an investigator in a Study. The Institution and the Principal Investigator shall have the right to acknowledge the Sponsor's support of the research performed under this Agreement in scientific publications and other scientific communications (any such publications or communications shall be made in accordance with Article 6). Each of the Parties hereto shall not disclose to any third party the terms of this Agreement without the prior written consent of the other Party, except to advisors, investors, and others on a need-to-know basis under circumstances that reasonably ensure the confidentiality thereof, or to the extent required by law, regulation or court order.

B. **Independent Contractors.** The Parties acknowledge that the relationship between the Sponsor, CRO, Institution and Principal Investigator created by this Agreement is that of independent contractors and that neither the Principal Investigator nor Institution or CRO may create or assume any obligation on behalf of the Sponsor.

C. **Limitation of Liability.** In no event shall the Parties be liable to each other for any special, incidental, or consequential damages arising out of or relating to this Agreement, or the subject matter hereof, however caused and whether such claim is based in contract, tort (including negligence), or otherwise, even if an authorized representative of the Sponsor is advised of the possibility of such damages.

D. **Notices.** Any notices required or permitted to be given hereunder shall be in writing, shall be addressed to the Party to whom such notice is intended as follows, or such other address and/or number as such Party may substitute by written notice hereunder, and shall be effective on receipt.

E. **Assignment.** This Agreement shall be binding upon and inure to the benefit of the Parties hereto, their respective successors, assigns, legal representatives and heirs. The Sponsor may assign this Agreement to any successor to all or substantially all of the business of the Sponsor, or in connection with its merger, consolidation, change in control or similar transaction. Except as otherwise set forth above, this Agreement may not otherwise be assigned by a Party (whether voluntarily, by operation of law or otherwise) without the prior written consent of the other Parties. Any purported assignment of this Agreement in violation of this section shall be void.

F. **Modification; Waiver.** This Agreement may not be altered, amended or modified in any way except in writing signed by the Sponsor, the Institution and the Principal Investigator. The failure of a Party to enforce any provision of the Agreement shall not be construed to be a waiver of the right of such Party to thereafter enforce the provision or any other provision or right.

G. **Entire Agreement.** This Agreement and its Exhibits constitute the entire agreement between the Parties with respect to the subject matter hereof and supersede all prior discussions, negotiations, communications, understandings, agreements, representations and writings with respect to all matters covered by the Agreement. In any conflict between the terms of this Agreement and the documents incorporated herein, the terms of this Agreement shall take precedence except as otherwise specifically set forth in this Agreement.

H. **Severability.** In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

I. **Execution.** The Institution's IRB shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile signature.

J. **Changes to the Protocol.** If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement,

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however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

K. **Covenant Not to Hire**. Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

L. **Drug Safety and Reporting.** The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of SPONSOR and/or CRO's Medical Monitor concerning any AEs and also any follow-up queries from the regulatory authorities to the Sponsor. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.

Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR:

Name:	Dr. Rajasekhara Reddy
Cell number:	+91-7989233379
E-mail:	dr.sekhar@clinwave.in

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local ethics committee of SAEs reportable according to its national requirements and timelines, and of findings that could adversely affect the Subject's safety, could have an impact on the conduct of the Study, or could alter the ECs / IRB's approval to continue the Study.

CRO will be responsible to notify on time the health authorities in India.

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IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

INSTITUTE

By: _____ (Signature)

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

Prof. RAKESH KAPOOR
Director

_____

(Date)

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

PRINCIPAL INVESTIGATOR

By: _____

(Signature)

Dr. Vikas Kanaujia

_____

(Date)

CLINWAVE RESEARCH

By: _____

(Signature)

CLINWAVE RESEARCH HYDERABAD

Dr. Rajasekhar Reddy Tamma- Managing Director

21 Feb 2018

(Date)

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EXHIBIT A: PROTOCOL ALREADY SHARED WITH THE INVESTIGATOR

As Annexure 1

EXHIBIT B: BUDGET AND PAYMENT SCHEDULE

BUDGET:

Principal Investigator : Dr. VikasKanaujia, Additional Professor, Ophthalmology
Site Address :Sanjay Gandhi Post Graduate Institute of Medical Science,
Raebareli Road Lucknow, Uttar Pradesh India-226014, UP INDIA

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for patients is as follows:

Overall per Patient Budget

Investigator Grant for completed subjects	INR 4000/Patient
Subject Travel Reimbursement	200/ Visit = Total 14,00/ Patient
Institution Overhead	25 % on Site Study Budget
Total	INR 4,200/- (Four thousand two hundred rupees only)/ Completed Patient)

The Payee designated above will receive all compensation paid to the Institution in connection with the Investigator Agreement, if applicable. Payee will provide all applicable tax identification numbers and, upon reasonable request, will provide or assist CRO with forms related to applicable taxes.

Payment Adjustments

If Institution's/Principal Investigator's participation is terminated because no Study subjects have been enrolled, Institution/Principal Investigator will not be entitled to reimbursement or payment for any administrative costs that were incurred prior to such termination, except to the extent such costs are set forth expressly in this Investigator Agreement.

If, upon termination of this Investigator Agreement, CRO, on behalf of Sponsor, has prepaid funds that Institution/Principal Investigator has not earned in accordance with Exhibit A, Institution/Principal Investigator (or its designated payee) will return to CRO all such prepaid funds within **thirty (30) days** after the effective date of termination. Prepaid funds owed to CRO, if any, will be returned pursuant to instructions provided by the CRO accountant assigned to administer payments to the Payee.

In the event this Exhibit A sets forth a maximum number of subjects that may be enrolled by Institution in the Study or a maximum payment amount to Payee pursuant to the Study, Sponsor at its discretion may authorize increases in Study subjects and/or payments.

In the event the Protocol is amended, compensation paid to the Payee may be adjusted to give effect to the Protocol amendment.

During the course of the Study, Institution will have **forty five (45) days** after the receipt of final payment to dispute any reasonable payment discrepancies.

Invoices:

Send invoices to : Clinwave Research
Contact Person: Dr. KarthikaDadi
Address :A/221, 4-32-121, Phase-1, Allwyn colony, Kukatpally, Hyderabad-500072,

Failure to include Protocol number and Principal Investigator's name on all invoices may result in delayed payment.

Final Payment

The final payment will be made after the close-out visit by the CRO CRA, after all CRFs for all subjects have been received and accepted by a CRO project leader, and all data queries for Institution have been resolved satisfactorily.

Budget notes, payment schedule, conditions of payment and payment directions

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1. All amounts above are in Indian Rupee (INR).

2. Serious Adverse event related costs: Costs relating to SAE that arise due to study participation would be borne by the Sponsor on actual.

3. All payments are subject to withholding tax under all applicable laws including Income Tax Act, 1962.

4. Service Tax will be deducted and applicable as per current government rules and regulations (i.e. on date of invoice).

5. A service tax (as applicable) will be considered on total grant subject to availability of service tax registration number with service provider. Service tax will be paid and applicable to service provider, provided to reflect the service tax registration number on Invoice / Bills."

6. In case recruitment is not initiated within a reasonable time period, unutilized amount (In keeping with the payment head above) would have to be returned to Sponsor.

Lt Col Varun Bajpai VSM
Executive Registrar
SGPGIMS,Lucknow

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement is made by and between the following three parties:

1)ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com	Name: Dr Usha kant Misra Address:. Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel.: +91-8004904627 /+91-9450653685 Fax: +91-05222668811 Email ID: drukmisra@rediffmail.com **Hereinafter "PRINCIPAL INVESTIGATOR"**
	CO-INVESTIGATOR Name: Dr. Jayantee Kalita Address: Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel: +91-9450411673 / +91-8004904630 Email ID: jayanteek@yahoo.com **Hereinafter "CO- INVESTIGATOR"**
Hereinafter "ACCUTEST"	

3) INSTITUTE:

Name of the Authorized Signatory: Dr. Rakesh Kapoor
Designation: Director
Name of the Institute: Sanjay Gandhi Post Graduate Institute of Medical sciences
Address: Sanjay Gandhi Post Graduate Institute of Medical sciences
Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India.

Hereinafter "INSTITUTE."

Initial-1 (ACCUTEST): Initial-2 (PI): Initial-3 (INSTITUTE):

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This Clinical Trial Agreement is effective from the date of last signature("**Effective Date**")

Accutest is engaged in the business of clinical trials management as a contract research organization and intends to carry out a clinical study ("the Study") with "**A prospective, multicenter, post-marketing surveillance to assess safety & efficacy of perampanel in Indian patients as an adjunctive treatment in partial onset seizures with or without secondary generalized seizures in patients with epilepsy aged 12 years or older.**"("the **Protocol E2007-M091-508**") for the purpose of obtaining data for the application of the Study Drug.

The Study Protocol Number: E2007-M091-508

Subject to the condition of obtaining the pertinent ethics committee approval and the regulatory authorities' authorization, the parties intend to participate in the Study by rendering their services and agree to the following:

Section 1: Study Protocol

The nature and scope of the Study are ensured from the Protocol. The Protocol precisely and exhaustively describes the clinical research activities and responsibilities for careful execution by the Principal Investigator. Any changes to the Protocol are subject to Accutest's prior written consent which the Principal Investigator shall obtain, and the approval/notification of the competent ethics committee and the Drug Controller General of India ("**DCGI**"). The Protocol, including any amendments, constitutes an integral part of this Agreement ("The **Agreement**") and shall be valid upon signature of this Agreement. In the case of any inconsistency between this Agreement and the Protocol, this Agreement shall prevail. The Principal Investigator warrant that they have received the Protocol.

Section 2: Rules for the Conduct of the Study

2.1 Legal framework

The parties agree that the duties and obligations of the provisions of the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments as set out in the Protocol of the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice", the applicable national legislation on public health and pharmaceuticals including the Central Drugs Standard Control Organization's Good Clinical Practice Guidelines ("**GCP Guidelines**")valid at the time of the performance of this Agreement; and all other pertinent rules and regulations shall be applicable including but not limited to Schedule Y to the Drugs and Cosmetics Rules, 1945 ("**Schedule Y**"), and that the Agreement shall be construed accordingly.

2.2 General Duties and Obligations

The Principal Investigator shall carry out the Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement.

The Principal Investigator hereby warrants that they have sufficient resources with regard to time, adequate personnel and facilities for the performance of the Study. Unless expressly agreed otherwise, the responsibility for services of third parties (including, but not limited to sub-investigators and satellite sites) remains with the Principal Investigator. The Principal Investigator shall ensure that all personnel and third parties are bound by and comply with the terms of the Protocol and this Agreement.

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The Principal Investigator will inform Accutest, about all changes of personnel, facilities and clinical research methods at the Institute that may affect the Study.

In the event the Principal Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Principal Investigator will inform Accutest within 3 days of the Principal Investigator being unwilling or unable to perform the duties. The Principal Investigator shall continue to be bound by the provisions referred to in Section 5.2.

The Principal Investigator is an employee, of the Institute and Investigator guarantees the proper performance by him following all obligations hereunder.

2.3 Ethics Committee / Review Board / Regulatory Authority Approval / Notifications

Accutest shall undertake the necessary notifications to authorities in accordance with applicable laws. The Study shall not commence until the Principal Investigator is informed by Accutest that the authorities have given authorization.
Accutest will provide the Principal Investigator with all the documentation required for submission to the pertinent ethics committee. Institute/Principal Investigator will obtain the written approval of the appropriate ethics committee prior to the commencement of the Study and will furnish Accutest or its designate with the ethics committee's letter of approval and a list of all ethics committee meeting attendees.

The Study shall not commence until receipt of the ethics committee written approval and shall follow any conditions of approval imposed by the ethics committee, and the time interval has been observed and all regulatory documents that are necessary according to the ICH – GCP,Schedule Y, and other applicable pharmaceutical regulations are available.

Should the ethics committee express objections to the content or the performance of the Study, the parties will collectively develop modifications that accommodate the objections. Should the ethics committee approval be unobtainable nonetheless, the parties shall be entitled to mutually terminate this Agreement. Amendments to the Protocol must be submitted by the Principal Investigator to the pertinent ethics committee.

2.4 Subject Information and Informed Consent

The Principal Investigator shall ensure that during informed consent process, information to the subjects is provided individually and not in a group (in accordance with the provisions specified in Section 2.1 above) in a language that is best understood by the subject about the nature, significance and consequences of the Study, its expected duration, and the potential benefits and risks involved in Study participation.The explanation shall at least include all points listed in the ICH-GCP and Schedule Y.The Principal Investigator should obtain written Informed consent fromthepatient, record necessary source data (like IC-EC, ECG, Physical Examination, Vital,etc.) and submit verify the eligibility criteria prior to enrolling the patient in the study.The Principal Investigator shall conduct complete Informed Consent process as per current regulatory requirement and also document the written consent prior to the Study on a prepared Informed Consent Form (ICF) and shall hand out a copy of the ICF and subject information document to each subject. In accordance with the provisions specified in Section 2.1 above, Principal Investigator shall ensure that consent of the governing local health authorities and/or subject for the submission of ICF mentioned above anonymous data to and/or appropriate regulatory authorities, is obtained.

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All the study related documents should be preserved safely after the completion/termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently, if applicable.

Each subject will be informed accordingly, and his/her consent will be obtained

- that he/she is enrolled in the Study,
- that the subject's insurance has been effected and that each subject has obligations arising from the general insurance conditions; in particular these are:
- during the course of the Study the subject must immediately inform the Principal Investigator about any other medical treatment he/she undergoes;
- any health damage, which may be attributable to participation in the Study, must be immediately reported to the insurance company;
- that the necessary documentation of the subject's health and personal data and its distribution to Accutest, the competent health authorities, and other Institutes, as legally required, may take place.

In the event the patient or his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append his/her signatures to the Study informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the Study informed consent form

2.5 Enrolment Period

The recruitment phase may not commence until the written positive decision of the ethics committee has been obtained.

The Principal Investigator will recruit a maximum of **20 subjects** for the Study, as the enrollment is competitive amongst the investigative sites.

The Principal Investigator is aware that for this multicentre study, a competitive recruitment will apply. Should the total number of subjects enrolled in the study be met prior to the end of the anticipated enrollment period, Accutest shall have the right to end further enrolment of subjects; no payment will be made for any such additional subjects.

2.6 Study Documents and Drug Supplies

Accutest's designee shall ensure appropriate and timely supply of the documents and Study Drugs necessary for the performance of the Study. All supplies shall be returned to Accutest by the Principal Investigator/Institutein a timely manner throughout the performance of this Study, as outlined in the Protocol or when Accutest otherwise requests delivery of data, unused Drug, and clinical specimens.

The Principal Investigator hereby warrants that he/she shall:

a) account for all clinical supplies furnished by Accutest and keep a written inventory of any equipment supplied by Accutest according to guidelines provided by Accutest;

b) use the Study Drug solely for the Study, documenting each usage and to return all used and unused clinical or other supplies provided by Accutest upon conclusion of the Study;

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c) collect data properly and report to Accutest all relevant information and data obtained under the Protocol;

d) submit to Accutest signed CRFs/eCRFs resulting from the Study in a timely manner;

e) retain all necessary records and documents about the Study as required by applicable regulatory requirements, this Agreement, and/or the Protocol;

Moreover, the Principal Investigator shall update/maintain the investigator study file provided at the time of Site Initiation Visit (SIV) andas per ICH-GCP all relevant essential documents which are necessary for the conduct of the Study including but not limited to following:

a) Signed Protocol and amendments;

b) Investigator's Brochure and updates (If applicable);

c) Ethics Committee composition, approval(s)/opinion correspondence/reporting;

d) Notifications/Approval of regulatory authorities;

e) CVs and signature sheet for key study personnel (e.g. investigators);

f) Approved and signed informed consent forms;

g) CRFs/eCRFs (investigator's copy) (If applicable);

h) Serious adverse events documentation and related correspondence/reporting;

i) Instructions for handling of Study Drug;

j) Screening, enrollment, and monitoring logs and subject identification code list;

k) Study related correspondence with Accutest

2.7 Adverse Events

The Principal Investigator is obliged to document and manage all Adverse Events (AEs) in accordance with the Protocol and to notify Accutest of all Serious Adverse Events according to the study instructions ("Serious Adverse Event Reporting") within the timeline specified in the Protocolor as per current regulatory requirement

Section 3: Documentation and Monitoring

3.1 Documentation and CRF/eCRFs handling

The Principal Investigator shall keep all original medical files (paper and print-outs of electronic files) of every subject participating in the Study in addition to the Case Report Forms(CRFs)/electronic Case Report Forms (eCRFs). The medical file is the documentation containing all demographic and medical data of a subject. This medical file will clearly identify each Study subject and where the medical files are termed the source; entries on the CRFs/eCRFs must be traceable to entries in the medical file. In the course of the Study, the Principal Investigator undertakes to express medical data in writing using medical terminology where necessary, the status of the Study for the respective subject and be completed expeditiously following a subject visit. The Principal Investigator must sign all eCRFs/CRFs. The Principal Investigator should inform the general practitioner and, if applicable, any other physicians, treating the subject about his participation in this clinical Study. The Principal

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Investigator warrants that all eCRFs/CRFs submitted to Accutest are true, complete and correct and accurately reflect the results of the Study with respect to each person participating as a subject.

The Principal Investigator undertakes to cooperate with Accutest and acknowledges Accutest's right, upon a request, to be granted direct access to all requested trial-related records (including patient medical files).

3.2 Monitoring

The parties agree to frequent monitoring visits to the institute by Accutest. The monitor (CRA) will visit the Institute to discuss study progress with the Principal Investigator who will allow inspection of all study data including medical files requested by the monitor.

The CRAs will check the data entered in the eCRFs/CRFs. CRAs and possibly representatives of Accutest shall perform source data verification, comparing the CRFs/eCRFs with the medical records to validate the data. Despite the CRA's and other representatives' efforts, the Principal Investigator remain primarily responsible for the accurate and complete data entry in the CRFs/ eCRFs. All persons who obtain knowledge of medical records are subject to professional secrecy.

Such monitoring will be carried out during the study, but may also be demanded by the pertinent regulatory authorities after completion of the study. The Principal Investigator are obliged to inform Accutest immediately of any notification of an inspection by the pertinent regulatory authorities.

3.3 Audit and Regulatory Inspection

Audits or inspections may be carried out during the Study, but may also be demanded by the regulatory authorities after completion of the Study. In the event thatAccutest or authorities perform an audit, the Institute,Principal Investigator will allow access to the facilities, make documents available and if necessary provide information. Should a governmental or regulatory authority request or carry out an inspection of the Institute's or Principal Investigator's facilities, Principal Investigator has to immediately notify Accutestby telephone, mail or fax and allow Accutest to be present. The Principal Investigator shall provide to Accutest copies of all materials, correspondence, statements, forms and records that Principal Investigator receives, obtains, or generates pursuant to any such inspection.

Section 4: Confidentiality and Subject Data

4.1 Protection of Subject Data

On the CRFs/eCRFs, which will be used for evaluation of the Study, patient data will be documented in anonymous form only, i.e. without naming the subject, and passed on to Accutest and the DCGIand/or foreign regulatory authorities. The name of the subject, as well as other person-related data, will not be divulged by the Principal Investigator, or by Accutest. Accutest shall ensure that the protection of the data concerning subjects is safeguarded.

When, for reasons of the fulfilment of professional obligations or verification purposes, person-related data concerning the Principal Investigator or the subjectare stored or handled, reliable organizational measures must be employed to ensure that these data are not divulged to unauthorized third parties.

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Exception: When IEC or DCGI or any other regulatory authorities require the subject details then Principal investigator shall share photocopy and maintain the record in the file.

4.2 Confidentiality

Principal Investigator shall receive copies of the Study documents and the investigator site file. Principal Investigator/Institute is obliged to retain the documents facilitating identification of the Study patients, and all other Study Documentation disclosed by Accutest, for at least 15 years after the end or the premature termination of the Study or as communicated during site close-outvisit.Institute has no part to play in the closeout of the trial.Accutest is responsible for informing the Principal Investigator when it is no longer necessary to conserve all the Study documentation (ICH 4.9.5).

The Principal Investigator/Institute is obliged to maintain the secrecy of all information related to the Study and the Study Drug ("the **Information**"). The Principal Investigator shall procure that any co-workers assisting the Principal Investigator in the Study shall keep all such Information secure and strictly confidential as well. The Principal Investigator agrees not to use the Information for any purpose other than the performance of the Study.

The information shall not include:

- Information that enters the public domain and only then where this has occurred other than through unauthorized disclosure by the Principal Investigator or his co-workers.
- Information that is properly requested for by the ethics committee responsible for approving the Study may proceed or is requested by the pertinent regulatory authorities in accordance with prevailing legislation, provided that the Principal Investigator shall give prior written notice to Accutest of any such request for disclosure.

The above obligations of confidentiality shall remain in full force and effect.

4.3 Proprietary information

All documents, data, know-how, formulas and unused Study Drug provided to the Principal Investigator for purposes of the Study ("**Data**") are and will remain Accutest's property and will be returned to Accutestor their respective designates upon request. Notwithstanding the preceding, Accutest shall retain full ownership rights in and to all templates, programs and other materials developed or licensed by Accutest prior to or apart from the commencement of this Agreement, regardless of whether such materials are used in connection with this Agreement.The Principal Investigator hereby transfers and assigns to Accutest the Principal Investigator's worldwide right and title to all Data in perpetuity and agrees to undertake such actions reasonably requested by Accutest to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

4.4 Rights to results

Accutest shall have the right to use the results of the Study in any manner deemed appropriate to Accutest's business interests. All data attained during the performance of the Study are Accutest's property. The Principal Investigator assign worldwide rights and title to all data obtained in the Study in

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perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose. Principal Investigator shall notify Accutest of the results immediately, separately and in writing.

4.5 Intellectual Property

Neither the Principal Investigator nor his employees or agents shall acquire any rights of any kind whatsoever with respect to the Study Drug as a result of their performance under this Agreement. All inventions, discoveries, and technology relating to the Study Drug conceived by the Institute or its Principal Investigator, solely or jointly with others as a result of work done under this Agreement, shall be, and remain, at all times the sole and exclusive property of Accutest (subject to the right expressly reserved under Section 4.3).

The Principal Investigator hereby assign worldwide rights and title to the Intellectual Property in perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

The Principal Investigator warrant, by the execution of this Agreement, that they have not entered, and will not enter, into any contractual agreement or relationship which would in any way conflict with or compromise Accutest's rights to, any inventions, discoveries, or technology arising out of or related to their performance thereunder.

4.6 Publications

It is the general policy of the ARL & Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice, no interim data should be published by the Principal Investigator/ Institute unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institute request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the ARL & Sponsorfor its perusal, comments, and approval. The ARL or Sponsor may at its discretion either refuse the publication or forward it to the Principal Investigator/ Institute/ along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institute.

4.7 Publicity

No party to this Agreement shall use Accutest's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission of such party or Accutest, as appropriate.

Section 5: Term and Termination of the Agreement

5.1 This Agreement commences on the Effective Date provided that Accutest has received from the pertinent ethics committees and the DCGI, as required by law, approval to carry out the Study. This Agreement shall remain in force to the full conclusion of the Study according to the Study Protocol unless terminated prematurely. Accutest may terminate this Agreement immediately upon written notice to the Institute/Principal Investigator.

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5.2 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement.

Neither termination of this Agreement, however, effectuated, nor the end of the term shall cause the parties hereto to be released from their rights and obligations under Sections 3, 4, 6, 7 and 8, or under any other provisions of this Agreement that by their terms are understood to survive termination.

Upon completion of the Study, the Principal Investigator and the Institute shall return to Accutest, or its designee, all unused Study Drug, compounds, Comparator Drugs (when used), equipment as specified in Section 2.6 that were furnished to the Institute other than the investigator site file documents.

5.3 Should the Principal Investigator recognise within reasonable discretion that continuation of the Study is no longer possible, due to unexpected results medically not justifiable, due to severity of serious adverse events not justifiable or efficacy of the treatment with the Study Drug insufficient, he/she will immediately notify Accutest as well as the ethics committee. Should continuation not be justifiable, the Principal Investigator may arrange for immediate termination of the Study. In the event that the Study is terminated with the consent of Accutest,the Principal Investigator shall receive payment pro rata temporis basis for the efforts of the Study, in accordance with Appendix A.

5.4 Accutest may terminate its cooperation with the Principal Investigator prematurely, provided that:

a) one month after shipment of the Study material, no subjects have been enrolled or the Principal Investigator recruits no subjects or recruits such a low number of subjects that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase,

b) Accutest terminates the Study for the Study Drug or the indication is discontinued,

c) it is proved that the dosage used for the Study does not seem to be justified any more,
d) regulatory authorities or other pertinent institutions decide to terminate the Study in this center or as a whole,

e) the Principal Investigator fails to sufficiently adhere to the conditions of the Protocol and the need to exact and complete data documentation and the GCP Guidelines and Schedule Y.

5.5 Consequences of Termination: Upon the effective date of termination, the Principal Investigator shall:

a) terminate all services as efficiently and quickly as possible, except to the extent Institute/Principal Investigator is required to continue to follow the procedures and perform such services with respect to the ongoing Study, as may be necessary, until the appointment by Accutest of another Institute/Principal Investigator for the purpose of continuing the Study;

b) within 7 business days, provide copies of all information, data, documents (including but not limited to IPs, ICFs(blank copies), CRFs/eCRFs, Study related material & documents, and any clinical samples obtained with regard to the Study) prepared, conceived, generated or delivered by Principal Investigator as a result of or in connection with the conduct of the Study;

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c) Provide an accounting of all clinical supplies, which is subject to verification by Accutest. If Accutest objects to any charge, the parties shall use reasonable efforts to resolve expeditiously any disagreement.

Section 6: Payment Terms and Conditions

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

Payment of investigator grants on behalf of Accutest will be equatedwith respect to the number of subjects recruited and the services performed as set out in detail in the APPENDIX-I & II entitled "Investigator Grants."

In the case of any inconsistency between this Agreement and the APPENDIX, this Agreement shall prevail. For the avoidance of doubt, if any obligation is specified in one of these documents but not in the other, this shall not constitute an inconsistency.

In the event that Accutest or the Principal Investigator/Institute terminates the Agreement prematurely in accordance with Section 5.4, Accutest shall not pay grants for performance on subjects that do not conclude the Study provided that:

- where a subject has been recruited to the Study in violation of the Protocol, there shall be no obligation of payment;
- where failure by a subject to complete the Study is due to the omission of tests or assessments by the Principal Investigator, there shall be no obligation of payment;
- where failure by a subject to complete the Study is due to adverse effect, lack of effect, concomitant illness, non-compliance or non-attendance, provided that full data is available up to the time of the subject'sdropout and the event is satisfactorily recorded, payment shall be made in accordance with the above-referenced APPENDIX proportionately according to the amount of work carried out by the Principal Investigator pursuant to the Protocol;
- any sums advanced to the Principal Investigator prior to termination of this Agreement will be taken into account in calculating any sum due to the Institute or Principal Investigator and any balance outstanding and due to Accutest shall be paid to by the Principal Investigator;
- "Completed Patients" are subjectswho have completed the Study in accordance with the Protocol, and for whom full case report forms and any ancillary documentation required have been completed by the Principal Investigator to Accutest's satisfaction.

Section 7: Standard of Care, Insurance, Indemnity

7.1 Subject Insurance

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Thishas been obtained and will be provided to the site personnel before the initiation of the trial.

7.2 Product liability

Study Insurance will be provided to the site personnel before the initial of the trial.

7.3 Standard of care

In no event shall Accutest be held responsible for any controversy, demand or claim for the payment of damages deriving from Principal Investigator for-

(a) injuries or damages incurred if they are the result of or are alleged to be the result of negligence or willful misconduct on the part of the Instituteor agents or the Principal Investigator;

(b) activities contrary to the Protocol;

(c) unauthorized warranties made by the Principal Investigator concerning the product being tested;

(d) in any case, in which written, informed consent was not obtained for the subject involved in accordance with the Protocol.

The Principal Investigator hereby represent and warrant that they have obtained a professional liability insurance policy from a reputed and creditworthy insurance company, covering their liability for any damage, which may be caused as a result of fault or negligence, which they may commit in the performance of this Agreement. The Principal Investigator shall provide evidence of its insurance upon request by Accutest. The Principal Investigator shall be liable under this Agreement for direct damages resulting from negligence or wilful misconduct in the execution of the Study.

The Principal Investigator shall defend and hold harmless, and be responsible for losses suffered by Accutest and any agent and employees of Accutest from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the improper or negligent administration or use of the Study Drug during the course of the Study.

The Principal Investigator shall also indemnify, defend, and hold Accutest and its affiliates, directors, officers, employees and other representatives ("Accutest Indemnified Parties") harmless from and against any and all loss, costs, claims, actions, liability and/or suits, including without limitation, interest, penalties and reasonable attorneys' fees ("Accutest's Claims"), incurred by Accutest that arose from or was a result of following:

(a) any material breach by Principal Investigator under this Agreement;

(b) the failure, or act, error, deviation, omissions, negligence, gross negligence or intentional misconduct of the Principal Investigator in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(c) Principal Investigator's violation of any and all applicable laws rules and regulations of India;

(d) Principal Investigator's breach or default in performance of its obligations in connection with the Study;

(e) Principal Investigator's material deviation from the Protocol;

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(f) Principal Investigator's failure to complete the Study and any such delay attributable solely to Principal Investigator's willful misconduct, or failure to comply with its obligations under this Agreement.

Section 8: Parties

8.1 Conflict of Interests

The Principal Investigator warrant that they, as well as all their support personnel, are not presently under any agreement or obligation which conflicts with the duties and obligations owed to Accutest under this Agreement, and further agree not to undertake any such obligations or agreement during the course of the Study.

Where (if applicable) it is intended that the Study Drug will be the subject of a submission to the regulatory authorities for a New Drug Application, the Principal Investigator certifies that he/she shall, in any form or manner reasonably requested by Accutest, disclose, and shall use his/her reasonable best efforts to cause any sub-investigators for the Study to disclose, all of the following that they and their spouses, domestic partners and dependent children own or possess directly, indirectly, or equitably (all collectively "Financial Interests"):

(a) All compensation, payments (including other research grants, consulting or director's fees, honoraria, speaking and meeting travel fees and reimbursement) and items or services of value provided by or on behalf of Accutest (excluding compensation received under this Agreement);

(b) All licenses, assignments, or other conveyances of rights or interests in real, personal or intellectual property ofAccutest or relating to the Study Drug;

(c) All forms of interests in the equity (including stock, options, and warrants) or debt of Accutestor of other entities having a financial interest in the Study Drug; and

(d) All other financial interests, payments, and other compensation.

During the conduct of the Study and for one (1) year after its completion, the Principal Investigator agrees to execute and update such forms, disclosures, and certifications now or subsequently required by Accutest related to the Financial Interests. The Principal Investigator hereby warrants that he/she has implemented a "Conflicts of Interests" disclosure and management policy and program that complies with the requirements and regulations issued or administered by the pertinent regulatory authorities, and the Principal Investigator warrants that he/she has and will continue to comply with such policies and programs.

8.2 Independent Contractor, Employees

The Institute and the Principal Investigator shall perform services under this Agreement only as independent contractors for Accutest, and nothing contained herein shall be construed to be inconsistent with that relationship or status. The Principal Investigator and his respective employees shall not be considered employees or agents of Accutest. This Agreement shall not create a business organization of any kind.

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The parties agree that they shall not directly or indirectly solicit for employment, employ or otherwise retain staff of the other party during the term of this Agreement or within the period of three (3) years following termination of this Agreement.

The Study is performed independently from any business transactions and decision on supply purchases with Accutest. The Instituteandthe Principal Investigator will not receive any benefits from the conduct of the Study beyond the remuneration agreed herein.

8.3 Assignment

Principal Investigator shall not assign his rights or obligations out of this Agreement to any third parties without Accutest's prior written consent. The Institute and the Principal Investigator understand and agree that this Agreement is being entered into to perform services forAccutest and that accordingly, Accutest may freely assign its rights and obligations out of this Agreement.

The Institute/Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Accutest. Any such consent shall not relieve the Institute and/or the Principal Investigator of its obligations hereunder.

Section 9: Communications

The Parties undertake to notify each other of all cases that influence the performance of this Agreement. Correspondences shall be made to the following addresses:

1)ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: rajendra.talele@accutestgloabal.com	Name: Dr Usha kant Misra Address:. Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel.: +91-8004904627 /+91-9450653685 Fax: +91-05222668811 Email ID: drumisra@rediffmail.com
	CO-INVESTIGATOR Name: Dr. Jayantee Kalita Address: Sanjay Gandhi Post Graduate Institute of Medical sciences Raibareli road, Luknow, Uttar Pradesh, Uttar Pradesh, India. Tel: +91-9450411673 / +91-8004904630 Email ID: jayanteek@yahoo.com

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Executive Registrar
SGPGIMS,Lucknow

3) INSTITUTE:

Name: Dr. Rakesh kapoor
Address: Sanjay Gandhi Post Graduate Institute of Medical Sciences,
Raibareli road, Lucknow, Uttar Pradesh, Uttar Pradesh, India.
Tel.: +91-0522-2494001
Email ID: director@sgpgi.ac.in

Section 10: Contractual

10.1 Entire Agreement

This Agreement (including the Protocol and the APPENDIX) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by all parties and refers to this Agreement.

10.2 Applicable Law, Place of Venue

The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof.

The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Lucknow, india will have sole jurisdiction over the litigation.

10.3 Severability

Should any of the provisions of this Agreement be declared entirely or in part invalid or unenforceable by the pertinent authorities according to the applicable laws, the remaining terms of this Agreement shall not be affected by such declaration. Such invalid provision shall be replaced by a valid provision reflecting - to the extent possible - the intent of the original provision.

10.4 Waiver

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

Section 11: Miscellaneous

Principal Investigator/Institute hereby confirms,

A. that he/she has never been subject to debarment proceedings indicted, convicted, or otherwise engaged in conduct for which a person can be debarred by law,

B. To have received a copy of the Investigator's Brochure and to be informed of its contents.

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

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The Investigator consents that his/her contact data, as well as information about the conduct of the Study, may be stored and processed for evaluation purposes during and after the completion of the Study by Accutest.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 20-Apr-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date **Dr. Usha kant Misra** **Co- Investigator:** Signature and Date **Dr. Jayantee Kalita**
3) INSTITUTE: For Signature and Date DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA **Name & Designation: Dr. Rakesh Kapoor-Director**	

APPENDIX I

Financial Support for Investigator:

(a) **Total payment, compliance, completed patients, inclusion Criteria:**

Payment of remuneration will only be made under the condition that the Study is conducted in accordance with the Protocol, the Study documentation is complete and evaluable, can be verified from the subject medical files, and is submitted to Accutest at the stipulated points in time. Should these prerequisites not be fulfilled, the remunerations are forfeited, particularly for patients who are included in the Study despite non-compliance with the inclusion or exclusion criteria.

Unless expressly agreed otherwise in writing, total payment will not exceed the amount set out below.

For each evaluable patient who completes the study visits in accordance with the Protocol, GCP, and application regulatory requirement, Accutest will compensate the Investigator remuneration as specified in Appendix II.

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Payments for any costs not expressly specified herein, including but not limited to hospital overhead fees, staff costs, pharmacy fees, other tests,(if applicable) and travel costs, must come from the per patient enrolment fee.

(b) Payments will be made based upon the completed CRF/eCRFs collected by Accutest

(*Please refer Appendix II for payment detail).*

(c) Pro rata temporis payment

Should the Study be prematurely discontinued, the remuneration will be calculated on a pro rata temporis basis. For patients who do not complete the Study, remuneration may be paid on pro rata temporis basis. Payment will include only those patients participating in the Study whose date of joining the Study is not later than the date of the premature termination of the Study.

(d) Protocol violators, exclusion

For Protocol violators due to missed or delayed visits or in the event of a violation on the part of a patient of a Protocol resolution or the Regulations for Good Clinical Practice, no compensation will be paid for that patient /payment may be made at Accutest's sole discretion.

(e) Income tax

All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. Accutest will deduct the tax at the time of making payments unless a valid certificate (Form 15 AA – for no TDS) from tax authority is made available in advance.

(f) Payment details

Accutest, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payees through A/C Payee Cheque as agreed by all signatories. Full of the grant shall be paid to the PI/ institute according to the payment milestones provided in APPENDIX II.

PI/ Institute payment
Payee Name: Director Research Account, SGPGIMS, Lucknow
PAN number: AAAJS3913N
GST Number: NA

Note:

1. Provide legible scan/photocopy of the PAN cards at the time of the signing of this agreement.
2. All local investigations (local lab tests, CT scans,any diagnostic assessments etc.) would be done to the payee mentioned for "PI/ institute payment" without deducting TDS. (A separate bill for patient payment should submitted).

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

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PI Name: Dr. Usha Kant Misra Site Name: Sanjay Gandhi Post Graduate Institute of Medical Sciences

Protocol Number: E2007-M091-508

1) ACCUTEST: For Accutest Research Laboratories (I) Pvt. Ltd: Signature and Date Rajendra Talele 20-Apr-2018 Mr. Rajendra Talele, Head- Clinical Development Services	2) PRINCIPAL INVESTIGATOR: Signature and Date 21/7/18 Dr. Usha kant Misra **Co- Investigator:** Signature and Date 21/7/18 Dr. Jayantee Kalita
3) INSTITUTE: For Signature and Date 23/01/19 DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA Name & Designation: Dr. Rakesh Kapoor- Director	

a/c

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

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APPENDIX II

Visit	**Amount(INR)**
Screening	8000
Visit 1 (Enrollment)	3800
Visit 2 (Month 1)	3500
Visit 3 (Month 2)	3500
Visit 4 (Month 3)	3500
Visit 5 (Month 4)	3500
Visit 6 (Month 5)	3500
Visit 7 (Month 6)	3500
Total PI Grant (a)	32800
Institutional overhead (25%) (b)	8200
TOTAL (a+b)	41000
TDS 10% (c)	4100
Grand Total (a+b+c)	45100
TOTAL PI GRANT	45100

Payment Details & Milestone:

1. Principal Investigator Fees will be **INR 32800 /-** per completed patient (Including Clinical Research Coordinator payment and excluding institutional overhead and goods and service tax and/or other taxes if applicable). The taxes may be revised and shall be applicable as per the Government norms from time to time.

   All local investigations (local lab tests, CT scans,any diagnostic assessments etc.) will be paid to the payee mentioned for "PI/ institute payment"on Actuals on Production of the Bills/Invoice/Proof.

   CRC payment of INR 16000/- per month will be adjusted by the PI from the PI grant. The PI grant of INR 45100/- per patient is inclusive of CRC payment.

The above payment also includes following charges:

a) Investigator(s) and other team members fees
b) Stationary, cupboard, courier, telephone, fax, internet and electricity bills, etc.
c) Patient recruitment
d) Electronic Case Report Form/Case Report Forms (CRF/ eCRFs) completion and correction
e) Data Clarification Form (DCF) resolution
f) Consultation charges
g) Document archival

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2. Ethics Committee fee will be paid on actual on the production of Bill/proof/invoice.
3. Institutional Overhead will be paidon production of Bill/proof/invoice
4. Per patient cost will be paid as mentioned above upon confirmation by site monitor of receipt of legible and accurately completed CRF/eCRF for a properly qualified subject.
5. INR 2000/- for screen failure patient.
6. Expense towards the medical management of serious adverse events will be made as per actual.
7. INR 1000/- for unscheduled patient visit.

The following are the milestone for the payments:

1. Every month from SIV, site personnel is supposed to raise invoice.
2. Invoice should be 90% of the SDV completed at the site by the ARL monitor.
3. Rest 10% of study payment will be made after study close out visit once all documents and activities (related to site) are completed.

NOTE: *If above milestones are not achieved than proportionate amount will be paid based on patient randomized and visit completed by the patient.*

Principal Investigator agrees that before incurring any of the aforesaid expenses it shall obtain prior written approval from the Sponsor. Sponsor will generally provide procedural material required by the protocol for the study. However, in the event Sponsor requires Principal Investigator to procure aforesaid items, it shall reimburse the actual cost incurred by Principal Investigator in connection in addition to that.

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) Accutest will pay a sum for every complete and evaluable patient.

b) A complete and evaluable patient is defined as follows:
   - All procedures must be performed according to the protocol
   - A patient will only be included according to the inclusion/exclusion criteria
   - All data are documented completely and accurately

c) All payments will be on a pro rata basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit, then an equivalent amount mentioned in the above budget will be deducted.

d) An invoice will be generated/ requested for payment on a monthly basis according to the actual work performed (after source data verification and CRF/eCRFs review for completed visits). An invoice will be generated/ requested according to days completed by the patient as specified above.

e) If the patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without a waiver, if applicable), then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

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f) Patient conveyance/ compensation will be paid by Accutest on behalf of the Sponsor and is included in the budget as mentioned. The TDS will not be deductedon payment released for patient compensation.

g) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

h) If the trial terminates prematurely, any payments made by Accutest exceeding the amount earned will be promptly refunded to Accutest (minus Ethics Committee fees, and patient conveyance/compensation).

i) Payment would be done on the basis of invoices generated by the site in consultation with site CRA on every monitoring after checking the CRF/eCRF completion.

NOTE: Site should generate a monthly invoice and should consider completed milestone from above at the time of invoicing.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date Rajendra Talele 20-Apr-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date 17/10 **Dr. Usha kant Misra** **Co- Investigator:** Signature and Date 27/7/18 **Dr. Jayantee Kalita**
3) INSTITUTE: Signature and Date DIRECTOR Sanjay Gandhi Post Graduate Institute of Medical Sciences LUCKNOW-226 014, INDIA 23/10/2018 **Name & Designation: Dr. Rakesh Kapoor-Director**	

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

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