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 …….2014 **AMONG**

……., a company originally incorporated in …… and registered under section 592 of Companies act, 1956 as having "…… and one of its office is located at ……. through it……..".……..".……. "Sponsor"] of the First part.

AND

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

AND

Dr. ……a **……, Department of ……..**, **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: _____

Entitled……..".……

……..**" [Hereafter referred to as "Study"]** described in StudyProtocol;

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

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

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

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

2.0 Obligations and Responsibilities of the Principal Investigator

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

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

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

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

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

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

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

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

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

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

2.11 The Principal Investigator will be responsible for proper account of receipt, utilization and return of unused sample of trial 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 Patient Information Sheet (PIS).

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

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

3.0 Obligation and Responsibilities of the Institute:

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

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

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

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

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

3.6 Necessary infrastructure support to PI.

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

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

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

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

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

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

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

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

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

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

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

3.18 Review of final report.

3.19 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.

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.

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

4.5 Not to send samples for Pharmacogenetic study abroad.

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

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

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

4.9 To define and follow procedure for premature termination.

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

5.0

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

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

(b) Violation of the approved Protocol;

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

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

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

(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).

9.0 Administration

9.1 Overall responsibilities of the Study will rest with PrincipalInvestigator, 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.

(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.

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

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

14.0 Trial Results and Inventions

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

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

15.0 Payment

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

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

(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 PrincipalInvestigator/s and other Institute's Study personnel
- All manpower cost involved in the Study conduct
- All diagnostic test and other investigations (ECG, Chest X-ray, Spinal X-ray etc.)
- Housing or hospital stay for patients including meals
- Patient reimbursement/ Compensation
- All overhead costs
- Usage of Instruments/ equipments which during the Study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Institute infrastructure).

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

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

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

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

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

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

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

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

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

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

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

Principal Investigator Fee/ Clinical Trial Subject Reimbursement and Hospitalization:

Payee Name (Account name)	**Director, SGPGIMS, Research a/c**
Account Number	**10095237491**
Bank Name	**State bank of India**
Branch Name	**SGPGI Branch, Lucknow**
Swift/IFSC Code	**SBIN0007789**
PAN Number*	**AAAJS3913N**
Send to <<Cheque Delivery Address>>	**Dr. ……..** **……., 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 PrincipalInvestigator for each Clinical Trial Subject, i.e., **Rs. ……**as per the Study schedule. However, it will be the obligation of PrincipalInvestigator to pay the Clinical Trial Subject reimbursement on a pro rata basis (**Rs……..-** per visit). **Sponsor will provide an amount of ……. 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. ……..** (…….. rupees) only for his/her efforts contribution to the Study. This payment would be exclusive 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.

17.0 No joint venture etc.

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

18.0 Insurance and Indemnification

Insurance:

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

Indemnification:

Sponsor shall, at all times to come, indemnify the Principal Investigator and Institute without demure for any damages and liabilities including reasonable attorney fees as a result of any claim or lawsuit against Investigator or Institute arising directly or indirectly out of the performance of the Study pursuant to the Protocol and SOP.

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

19.0 MONITORING; AUDIT; REGULATORY INSPECTIONS

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

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

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

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

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

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

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

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

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

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

20.4 This Agreement may be terminated by any party upon giving at least a thirty (30) days written notice to that effect to the other parties. The day following the 30^{th} 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 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,

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…….) which covers per patient amount (……..per patient limit). This insurance is valid from the period from ……) to (…….). 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 Lucknow, notwithstanding any other provision to the contrary in any law in this regard.

27.0 Arbitration

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

28.0 Amendment

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

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. ……
(Name)
Title/Designation: …….Department of……..

2. Director/his nominee, Sanjay Gandhi Post Graduate Institute of Medical Sciences, Lucknow
Signature and date: _____

Dr. ……
(Name)
Title/Designation: ……
(Director/his nominee)

3**. Sponsor**
Signature and date: _____

Mr. /Dr. ……
(Name)
Title/Designation: …….……..

OR
…….Clinical limited
Signature and date: _____

Mr./Dr. ……
(Name)
Title/Designation: …….……..

ANNEXURE- A

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 X-ray 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

Principal Investigator Grant	INR ……..Per completed Clinical Trial Subject
Coordinator Payment	INR ……. per month (From Investigation Site Initiation to Investigation Site Closeout)
Investigational Cost	This amount is included in per Clinical Trial Subject amount
Hospitalization Cost	INR …….. per Clinical Trial Subject
Stationary and Miscellaneous	This amount is included in per Clinical Trial Subject amount
Patient Travel convenience	INR ……. per Clinical Trial Subject patient
Patient Future treatment Reimbursement	INR …….. per Clinical Trial Subject completed the Study

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