CLINICAL TRIAL SERVICES AGREEMENT

This Agreement is made and entered into this DD/MM/YYYY by and between:
Principal Investigator
Dr. Kelkar Vasanti Prabhakar
Mahatma Gandhi Mission's Medical College and Hospital
N-6 CIDCO, Aurangabad-431003, Maharashtra

Head of Institute
Dr. Rajendra Bohra
Mahatma Gandhi Mission's Medical College and Hospital
N-6 CIDCO, Aurangabad-431003, Maharashtra

And

CRO:
Biosphere Clinical Research Pvt. Ltd.,
SB - 02, 03 & 04, Second Floor,
Highland Corporate Centre,
Kapurbawdi Junction, Thane (W)-400607,
Maharashtra, India.

For study titled "A Phase III, Multicentre, Randomized, Double Blind, Parallel group, Comparative Clinical Study to evaluate Efficacy and Safety of Ropivacaine Hydrochloride 0.75% (7.5mg/mL) in Dextrose 8% (80mg/mL) injection compared to Bupivacaine Hydrochloride 0.5% (5mg/mL) in Dextrose 8% (80mg/mL) injection for subjects undergoing lower limb orthopaedic surgeries under spinal anaesthesia."

WHEREAS CRO is engaged in the business of clinical trials management as a Clinical Research Organization and intends to carry out the Phase III Clinical Study (here in after "the Study" / "Clinical trial") and is acting on behalf of Neon Laboratories Limited.

WHEREAS, the CRO has represented that it has entered into an agreement with the SPONSOR whereby the terms and conditions governing the conduct of the clinical trial at the INSTITUTION have been incorporated.

Subject to the condition of obtaining the pertinent ethics committee approval and the regulatory authority's authorization, the parties intend to participate in the Study by rendering their

services and agree to the following:

1. **INSTITUTION:** The CRO has approached the INSTITUTION on behalf of the SPONSOR, as the

SPONSOR desires the INSTITUTION to perform the study in regards to the said Investigational Product in accordance with the following standards:

(a) The current World Medical Association Declaration of Helsinki titled "Ethical Principles for Medical Research involving Human Patients";

(b) The current ICH Harmonized Tripartite Guideline for Good clinical Practice (CPMP/ICH/135/95);

(c) The current Indian Ministry of health and Family Welfare Guidelines for good clinical practice titled, "Good Clinical Practices for Clinical Research in India";

(d) The current Indian Council of Medical Research on Human Patients;

(e) New Drugs and Clinical Trials Rules, 2019

(f) The written requirements of all reviewing institutional ethics committees;

(g) The Principal Investigator requirements;

(h) All policies and procedures of the INSTITUTION;

(i) All current and applicable permission, licenses, approvals, federal wide assurance and certifications and (1) all current and applicable laws and regulations (such as standards set forth in Sections 2(a) – (i) collectively referred to hereafter as the Standards) and;

(j) In accordance with the final protocol, patient information sheet, informed consent documents and case report forms for the above-referenced clinical study (collectively, the Clinical Trial Protocol, acurrent version of which is attached hereto, which attachment shall be replaced in the final version and all amended versions, if any).It is understood and agreed that, in the event of a conflict among any of the standards, the most stringent standard shall apply.

2. **PERFORMANCE:**

a) Protocol and Standards: Principal investigator who will supervise and direct the work of the INSTITUTION and the Dean of the INSTITUTION, hereby confirm that they have read and understood the Clinical Trial Protocol for the Study to be conducted in 206patients and further confirm that their research team is properly trained concerning the clinical trial Protocol and Standards. All amendments have also been read and understood. The Principal Investigator and the INSTITUTION agree to the final Clinical

Trial Protocol and to perform the study in strict accordance with this Agreement.

b) Subcontracting: Services of Principal Investigator: The INSTITUTION shall not subcontract the performance of any or all of its obligations under this Agreement to any third party (including to any affiliate). The services of the Principal Investigator are considered essential for the performance of this Agreement. If for any reason the Principal Investigator becomes unavailable or otherwise unable to supervise and direct the activities under this Agreement, INSTITUTION shall promptly notify the CRO/SPONSOR. If a mutually acceptable successor is not promptly identified, this Agreement may be terminated by the CRO.

c) Study Duration: It is anticipated that the Clinical Study will commence upon execution of this Agreement, that subject enrollment will be completed approximately in four months from the date of Site Initiation Visit, and that the Clinical Study will be completed as per the study schedule, unless otherwise terminated in accordance with Section 7.

d) Recruitment: The Principal Investigator understands and agrees that the CRO/SPONSOR requires at least 206 evaluable patients at the conclusion of the Study from approximately 8-10 sites, hence it will be necessary for the INSTITUTION to enroll 25-30 patients (considering a drop-out rate of 10%) to achieve the targeted number of patients who satisfy all enrollment criteria specified in the Clinical Trial Protocol, within a period of 2-3 months approximately after the SPONSOR authorizes commencement of the study.

e) Confidentiality:

i. Definition: During the term of this agreement (period of five years thereafter), the INSTITUTION and Principal Investigator may have access to information, know-how, knowledge and data in oral, written, electronic, graphic or other tangible form, confidential or proprietary to SPONSOR or to SPONSOR's other collaborators (other than the INSTITUTION) and is, therefore of a confidential nature (confidential information). Confidential information shall include the Clinical Trial Protocol, SPONSOR's Investigator's Brochure concerning the Investigational Product data, all Study Data, all documents maintained in the Clinical Trial Record Binder (site documentation), any other data emerging out of the protocol, any other information supplied by SPONSOR/CRO during the course of the study and clinical development plan, except the information already existing in the public domain, and all results and reports obtained, collected, conceived, processed and developed pursuant to this Agreement.

ii. Use: The INSTITUTION shall hold all confidential information and shall disclose confidential information only to its Principal Investigator, Co-Investigators, hospital staff and employees who have a need to know such confidential information for the purpose of this agreement and who agree in writing to keep such confidential information, confidential under terms substantially similar to those set forth herein. The INSTITUTION shall use confidential information for the sole purpose of providing services under this Agreement and shall not use confidential information

for the INSTITUTION's own benefit at any time. No right or license under any patent application, trade secret or other proprietary right now or hereafter owned or controlled by the SPONSOR or other collaborators is granted to the INSTITUTION from the provision of confidential information hereunder. The INSTITUTION shall comply with the Study Data Confidentiality conditions.

iii. Provision to CRO/SPONSOR: The INSTITUTION agrees that, at any time upon CRO/SPONSOR's request, it shall promptly provide to the CRO/SPONSOR respectively, copies of all Confidential Information under this Agreement. The INSTITUTION further agrees that upon any termination or expiration of this Agreement, it shall at CRO/SPONSOR's election, return to the CRO/SPONSOR or destroy all copies of all Confidential Information; however, that the INSTITUTION may retain two (2) archival copies, with obligation to maintain the confidentiality of such confidential information.

f) Work Product:

i. Definition: The Parties agree that all work performed by the INSTITUTION hereunder including, without limitation, all study data, results, reports, inventions, discoveries, new uses or know-how obtained, collected, conceived, processed, developed, improved or reduced to practice by Principal Investigator or the INSTITUTION's other hospital staff or employees pursuant to this Agreement (collectively, work product) shall be the property of the SPONSOR.

ii. Disclosure, Assignment and Provision to CRO/SPONSOR: The parties agree that the INSTITUTION shall promptly disclose to the CRO/SPONSOR any and all work related to the product comprising inventions, discoveries, new uses or know-how obtained. As per the agreement, the CRO/SPONSOR can review and obtain copies of all work related to the product including and without limitation, all study data, in an agreed–upon format and with a complete glossary of terms used for such data.

iii. Materials: The study medication, blood samples from patients under the study and all other tangible material provided to or obtained by the INSTITUTION under this Agreement (Collectively the Materials) shall be the property of the SPONSOR and/or SPONSOR's other collaborators (other than the INSTITUTION). The INSTITUTION shall use the Materials for the sole purpose of providing services under this agreement and shall not use the materials for its own benefit at any time. No right or license, any patent, patent application, trade secret or other proprietary right now or hereafter owned or controlled by SPONSOR or SPONSOR's other collaborators is granted to the INSTITUTION from the provision of materials hereunder. Upon any remaining Investigational Product and other Materials received or obtained hereunder in accordance with the Protocol, standards and the directions of CRO/SPONSOR.

g) Human Patients: The INSTITUTION shall be responsible for safeguarding the rights and welfare of patients in the study. The INSTITUTION shall ensure (i) the rights and welfare of each such patient are protected, (ii) informed consent of each such patient is

freely and knowledgeably given: (A) to participate in the study and (B) for the collection by, processing by and disclosure to and between the CRO representatives of SPONSOR, Principal Investigators and Researcher, Study Monitors, Study Laboratory Personnel, Study Data Analysts, members of the Independent Ethics Committees and representatives of governmental and inter-governmental agencies in India; (iii) the balance between risk and potential benefit from participating in the study has been assessed and deemed acceptable; and (iv) the SPONSOR/CRO has made appropriate arrangements to eliminate, mitigate and/or compensate for the consequences to such patients and their families in case of any death, injury or illness which has causal relationship with the spinal anaesthesia for lower limb orthopaedic surgeries for which the SPONSOR/CRO has agreed to assume liability. Such arrangements shall include medical treatment and financial relief as per the Policy provided by Sponsor.

h) Ethical Approval: The INSTITUTION shall petition for written certification of ethical approval of the Study from its Institutional Ethics Committee. The INSTITUTION shall keep the CRO/SPONSOR fully advised of the progress of such submission and shall upon request, provide the CRO/SPONSOR with all correspondence relating to such submission. The INSTITUTION shall obtain such certification prior to screening any patients for the Study, annually after obtaining such certification, and prior to implementing any changes to the Clinical Trial Protocol. Upon receipt of such certification, the INSTITUTION shall promptly provide a copy to the CRO/SPONSOR.

i) Case Report Form Handling: The Principal Investigator shall be responsible for providing correct Case Report Forms ("CRF") according to the following:

i. The main objective of the CRF is to obtain those data required by the Protocol in a complete, accurate, legible and timely fashion. The data in the CRF must be consistent with the relevant source documents, and they must be suitable for submission to authorities.

ii. The data recorded in the course of the Study shall be documented in the CRFs and, as necessary, on the SAE report. They will then be forwarded to CRO/SPONSOR for data management and biometric analysis.

iii. The data in the CRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither CRFs nor other documents that will be forwarded to the CRO/SPONSOR.

iv. Wherever possible, all data obtained in the course of the Study must be recorded in the original patient files. Data to be recorded directly on the CRFs and considered as source data will be identified as such. All data in the CRFs must correspond exactly with data recorded in the source documents.

iv. If CRFs are not complete the Principal Investigator shall be obliged to complete them on request of CRO/SPONSOR.

j) Drug Safety: The recording of Adverse Events (AEs) is an important aspect of 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 CRO/SPONSOR Medical Monitors concerning any AEs. 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 patient 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 the Protocol), which occur during the course of the Study and up to the date of the patient´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 sent to **CRO** for onward transmission to SPONSOR:

Name: Dr. Neeta Nargundkar
Telephone Numbers: (022) 41006794
E-mail: drneeta@biospherecro.com

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the study medication CRO shall be informed immediately by telephone and followed immediately by mail. CRO will be responsible to notify on-time the health authorities in India.

k) Source Data: The Principal Investigator shall be responsible for providing the Source Data according to the following regulations. Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically, but not limited to they comprise:

i. Signed Informed Consent Form
ii. Patient hospital file and individual clinical notes
iii. Laboratory Reports
iv. Pharmacy Records
v. Study specific source documents
vi. Appropriate sections of the CRF, where data are recorded directly onto specific forms
vii. Other reports and records of any procedure performed in accordance with the Protocol

l) The Principal Investigator shall safely maintain the original study documentation together with all source data for the maximum period of time permitted by the hospital, research institute or practice in question, but not less than 5 years after the clinical part of the trial has been completed. If archiving can no longer be maintained at site, the Principal Investigator will notify CRO/SPONSOR.

m) Investigator Study File and Archiving: The INVESTIGATOR shall prepare and maintain complete and accurate study documentation in compliance with ICH-GCP standards and

local regulations. Therefore, an investigator study file shall be prepared which contains all relevant documents necessary for the conduct of the study:

i. Signed Protocol and Amendments
ii. Investigator's Brochure and Updates
iii. EC Composition, approval(s)/opinion correspondence/reporting
iv. Notifications of regulatory authorities
v. CVs and signature sheet for key study personnel (e.g. Investigators, Study Nurses)
vi. Signed study agreements including financial agreement.
vii. Trial Initiation Report
viii. Approved and signed Informed Consent Forms
ix. Patient Insurance Certificate
x. CRFs (Investigator's copy)
xi. Data Clarification Forms (copies)
xii. SAE documentation and related correspondence/reporting
xiii. Shipping/accountability/destruction records for investigational product.
xiv. Certificate of Analysis
xv. Instructions for handling of investigational product.
xvi. Laboratory accreditation/certification and up-to-date reference ranges of normal values, Screening, enrollment and monitoring logs and subject identification code list
xvii. Appointment diaries
xviii. Study related correspondence with CRO/SPONSOR

n) Documentation and Material (Supplies): All supplies provided to the Principal Investigator for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

o) The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of unused material for the Study, supplied by the CRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to the CRO/SPONSOR. In the latter case, the identification and quantity of each unit of study medication and the person in charge must be documented.

p) Monitoring, Quality Assurance and Inspection by Authorities: The Study will be monitored by the CRO. Its representatives (alone or together with representatives from SPONSOR) will be allowed access to all information resulting from this Study and SPONSOR will have an unrestricted right to use such information. CRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring and remote monitoring throughout the Study. The tasks of the monitor comprise the following:

i. to ensure Protocol adherence
ii. to verify the data in the CRFs against source documents (SDV)

iii. to check progress of the study and to motivate, if necessary
iv. to review the CRFs for complete and accurate capture of data, including laboratory test reports and other patient records
v. to check all data for possible SAEs and AEs
vi. to review signed informed consent forms for signatures and date of consent
vii. to ensure accurate record of drug accountability
viii. to ensure adequate storage of study supplies
ix. to collect completed CRFs
x. to discuss and help resolve any problems

q) Source Data Verification (SDV) shall be performed on 100% of key data such as informed consent, demographics, and inclusion/exclusion criteria, parameters for the evaluation of the main endpoints, safety evaluation and drug accountability.

The visits shall involve the Principal Investigator or his appointed representative(s) and any other staff, as required. The Principal Investigator shall ensure that sufficient time is allowed for monitoring visits. Follow-up correspondence between the Site and the CRO relating to apparent inconsistencies or clarification of CRF entries will be kept on file at both CRO and the Site.

r) Study Protocol, Patient Information Leaflet/Consent Forms, CRF and Trial Report as well as each step of data recording, monitoring and processing shall be subject to the independent Quality Assurance at CRO.

s) This Study shall be audited on behalf of SPONSOR to assure GCP compliance as well as validity of the study data according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of the CRO/SPONSOR.

t) For monitoring visits and in case of audits and inspections by authorities, the Principal Investigator must provide direct access to the complete study records including CRFs, original source data, study documentation, and, if necessary, any additional background data. Furthermore, access to Study related facilities must be ensured.

u) Confidentiality of Patient Records: The INSTITUTION and the Principal Investigator must assure that Study patients' anonymity will be maintained, and that their identities will be protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On CRFs or other documents removed from the INSTITUTION, patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator is obliged to maintain a subject identification code list showing the patients' full name and date of birth together with the corresponding patient identification number to allow revealing identity of any subject.

v) The Principal Investigator agrees that representatives of CRO/SPONSOR, of the responsible IEC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and CRO guarantee for their representatives that patient data will be treated confidentially. Monitors and

Auditors are further bound to secrecy.

4. **AMENDMENTS:** The CRO, on behalf of the SPONSOR, may from time to time, make changes to the Protocol. Changes in the Protocol must take the form of written amendments and shall be approved by all signatories of the final version of the Protocol. Any amendments to the Protocol which affect the patient (e.g. changes in procedures/assessments or matters relating to patient safety) require approval of the relevant ethics committee as well as further informed consent from each concerned patient prior to implementation. The Principal Investigator shall obtain such approval. Changes of purely administrative nature shall be notified to the committee by the Principal Investigator, but do not require formal approval.

5. **INSPECTIONS:**

a) By Representatives of CRO/SPONSOR: The INSTITUTION agrees that CRO/SPONSOR's representatives and clinical monitors for the Study will have free access to the INSTITUTION's facilities and all documents pertaining to the Study during normal business hours, after provision of prior written notice, as is necessary to ensure that the Study is conducted in accordance with this Agreement. In the event any such representative or monitor observes non-compliance with this Agreement, incomplete, illegible or inaccurate recording of Study data, or other matters of concern relating to the Study, the INSTITUTION shall, in cooperation with such representative or monitor, promptly remedy such non-compliance, Study data recording problems or matters of concern and shall promptly notify such representative or monitor of such remedial actions taken.

b) By Governmental Representatives: The INSTITUTION agrees that representatives of the government will have access to its facilities and such documents pertaining to the study as may be legally requested by such representatives. The INSTITUTION shall not disclose individually- identifiable personal information, individually-identifiable health care information or other Confidential Information to such governmental representatives except as required by law, and if the INSTITUTION discloses such individually-identifiable information or other Confidential Information to such governmental representatives, the INSTITUTION shall seek an appropriate, written agreement of confidentiality from such governmental representatives prior to making such disclosure. The INSTITUTION shall promptly provide copies to the CRO/SPONSOR of any notices, correspondence and other documentation received or prepared by or on behalf of the INSTITUTION in connection with any governmental inspection, action; inquiry or correspondence relating to or that may affect the INSTITUTION's activities under the Study. The INSTITUTION shall take all actions necessary to remedy any non-compliance cited by governmental authorities and shall promptly notify CRO/SPONSOR of such remedial actions taken.

6. **WARRANTIES AND DISCLAIMER OF WARRANTIES:** INSTITUTION warrants that all services provided under this Agreement will be provided in a professional and workmanlike manner, in compliance with the Standards and the terms of this Agreement.

7. AGREEMENT TERM AND TERMINATION:

a) This Agreement is effective as of beginning of the study, and shall continue until 5 (five) years after completion of study, unless terminated sooner in accordance with this Article 7 or unless extended for a defined period by a signed written amendment in accordance with Article 14.

b) The Study and this Agreement may be terminated by written notice from the SPONSOR/CRO to the INSTITUTION for any of the following reasons:

i. Notification to CRO/SPONSOR from applicable regulatory authorities to terminate this Study.
ii. Determination by CRO/SPONSOR that the INSTITUTION is not performing the Study as required in the Agreement and/or is not meeting the agreed upon patient enrollment requirements set forth in Section 7(c) herein.
iii. Failure of the Principal Investigator and/or the INSTITUTION to provide access to the SPONSOR monitors or SPONSOR representatives to the INSTITUTION's facilities and all original medical records and Study-related documents necessary to verify entries on Study Case Report Forms and the INSTITUTION's compliance with this Agreement.
iv. Failure of the Principal Investigator or associated staff or any other person engaged in the Study (excluding patients) to be available, upon reasonable notice and by prior mutually convenient time appointment by CRO/SPONSOR, to meet with the CRO/SPONSOR monitors or CRO/SPONSOR representatives during the course of the Study as necessary to discuss information relevant to the Study.
v. Unauthorized replacement of Principal Investigator, in accordance with Section 7(b) herein.
vi. Determination by SPONSOR that business or scientific considerations require termination.
vii. Case Report Forms provided to the Principal Investigator by the CRO/SPONSOR for use in the Study are not completely, accurately and/or legibly completed and/or forwarded to the CRO/SPONSOR's designated representative, as appropriate, within one (1) week of each patient's visit date.

c) The INSTITUTION may terminate this Agreement by written notice from the INSTITUTION to the CRO/SPONSOR for any of following reasons:

i. SPONSOR does not comply with the Clinical Trial Protocol provisions related to supply of Investigational Product for the Study, or the CRO/SPONSOR does not supply other agreed-upon study related material.
ii. The Principal Investigator reasonably suspects an adverse reaction/adverse event related to the Study procedure and of serious nature, after informing the Institutional Ethics Committees and the CRO/SPONSOR.

d) In case of any termination or expiration of this Agreement:

i. Responsibility for treatment of enrolled patients will be as specified in the Standards;

ii. The INSTITUTION shall cooperate with the SPONSOR/CRO for an orderly wind-down of activities, with due regard for patient safety and welfare;
iii. The INSTITUTION shall return or destroy all Confidential Information to CRO/SPONSOR, at the CRO/SPONSOR's election, in accordance with Section 7(d)(iii) herein;
iv. The INSTITUTION shall promptly provide all Agreement deliverables due to the CRO/SPONSOR and, if requested by the CRO/SPONSOR, provide copies of all Work Product (including without limitation all Trial Data) to CRO/SPONSOR, in accordance with Section 7(d) (ii) herein;
v. The INSTITUTION shall return and/or dispose off all remaining Investigational Product or other Materials received or obtained hereunder, in accordance with the Protocol, Standards and the directions of CRO/SPONSOR, in accordance with Section 7(d) herein;
vi. The INSTITUTION shall, within thirty (30) days after such termination or expiration, provide a final invoice to the CRO; and
vii. The INSTITUTION shall, notwithstanding such termination or expiration, remain responsible for compliance with all Standards.

e) The provisions of Articles 5, 6, 7, 8, 9, 10, 12 and 13 herein shall survive any termination or expiration of this Agreement, as shall such other provisions as, by their context, are intended to survive such termination or expiration.

Effect of Termination

The Institution shall comply all the standard procedures required for study close out

8. **RECORDS:** The INSTITUTION shall maintain in the English language (a) all Work Product; and (b)complete, accurate and legible scientific and clinical documents, books and records pertaining to all activities performed and all Materials provided or obtained under this Agreement. The other Study materials will be archived at the INSTITUTION for the period set forth in the Clinical Trial Protocol and originals given to the CRO for the purposes of data analysis.

9. PUBLICATION OF RESULTS:

a) Both the INSTITUTION and CRO shall treat matters of authorship in a proper, collaborative spirit, giving credit where it is due and proceeding in a manner that fosters cooperation and communication.

b) It is hereby expressly made clear that all Intellectual Property Rights in the final test report as well as in the material generated during the process of Clinical trial will reside with the SPONSOR. CRO.

10. FINANCE:

a) The expenses of the Study, as set forth in the total projected budget, shall be paid by the CRO and are estimated not to exceed the amount mentioned in the total projected budget,

in case it exceeds it will be mutually agreed upon on reasonable grounds and documented appropriately. The CRO's payment to INSTITUTION is contingent upon the CRO receiving payment from the SPONSOR. Funds shall be paid by the CRO to the INSTITUTION for the satisfactory and timely performance under this Agreement, as per the payment details, terms and conditions laid out in

b) ***Annexure A.***

All payments will be based on actual patient visits for every 3 months.

Method of payment

CRO, on behalf of the Sponsor shall pay the relevant cost and fee as set out in Annexure A to the Institution and Institution will pay Principal Investigator.

Details of Payee are: All the site payments including investigator and co-investigator fees, Lab charges, Subject travel reimbursement and Institutional overhead charge will be paid on below mentioned payee name.

Payee Name	MGM Medical College, Aurangabad
Address	Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra.
PAN Number	AAATM4256E
Bank Account Number	0376t04000000107
Bank IFSC Code	IBKL0000376
GST NO	-
Name of the Bank	IDBI Bank.

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country and CRO will deduct the tax at the time of making payments unless a valid Certificate) from tax authority is made available.

c) An insurance policy, as relevant, for the participating patients covering any injury or illness suffered as a direct result of their participation in this Clinical Study shall be taken out by the SPONSOR/CRO. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage.

11. PUBLICITY, PRODUCT PROMOTING ACTIVITY AND COMMUNICATION GUIDELINES:

a) The SPONSOR shall not identify or use the names, trademarks, trade names or symbols of the institution, Principal Investigator or his research team under the study without the prior written permission of the Principal Investigator and head of the institution for claims, publicity or any product promoting activity. because the SPONSOR is a publicly funded organization that must maintain a certain level of transparency about its

collaborations, SPONSOR may disclose the identity of the INSTITUTION, publicly available information about the INSTITUTION and the broad purpose of the collaboration under this Agreement to third parties such as a Court of Law, regulatory agencies, governmental or legal agencies, other collaborators, other investigators involved in the project and the organization (profit or non-profit) funding the development of the Investigational Product. Also such details can be shared in scientific forums and with other medical professionals, if questioned.

b) The INSTITUTION shall not identify or use the names, trademarks, trade names or symbols of the SPONSOR, the SPONSOR's employees or affiliates, SPONSOR, SPONSOR's employees, donors or affiliates or any other author of the primary collaborative publication described in Section 11(b) herein for publicity or product promoting activity.

c) Prior to the beginning of the Study, the CRO/SPONSOR shall develop external communication guidelines for use by the INSTITUTION. The INSTITUTION agrees to comply with such guidelines. The INSTITUTION shall not issue any press release concerning the Study or this Agreement without the prior, express written approval of SPONSOR.

12. **LIMITATION OF LIABILITY:** The parties expressly agree that there shall be no limitation on either Party's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the services performed hereunder. IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OF USE OF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE PATIENT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK. Any disputes that arise during the study between SPONSOR/CRO and Principal Investigator will be under the jurisdiction of Mumbai courts.

i. **APPLICABLE LAW AND ARBITRATION**: This Agreement is entered into and will be deemed for all purposes to have been made in Mumbai, India and shall be governed and construed in accordance with the laws of India applicable to contracts and agreements. The parties shall share equally the costs of the Arbitration unless determined otherwise.

13. **AMENDMENTS:** This Agreement may only be amended by and to such degree as specified by the mutual written consent of the parties hereto.

14. **ENTIRE AGREEMENT:** This Agreement, contains the entire understanding of the parties with respect to the subject matter hereof and except as expressly set forth herein, all express or implied agreements, representations and understandings, either oral or

written, made prior to this Agreement are hereby expressly superseded by this Agreement. In the event there is a conflict between the Clinical Trial Protocol and the terms in the body of this Agreement, the terms in the body of this Agreement will govern with respect to commercial and contract terms, but such Protocol will govern with respect to the conduct of the Study and with respect to serving the welfare of patients of the Study. This Agreement may only be amended by a written instrument executed by the parties hereto, and CRO must approve any such amendment in writing prior to such amendment becoming effective.

15. **SEVERABILITY:** The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

16. **ASSIGNMENT:** The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of the CRO. The CRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates.

17. **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 the same term, provision or condition, or of any other term, provision or condition of this Agreement.

18. **NOTICE:** Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by registered or certified mail, postage prepaid, return receipt requested, or received by facsimile 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:

WHEREOF, the parties hereto have executed this Agreement in tripartite by proper persons thereunto duly authorized.

If to Principal Investigator: Name of the principle investigator **Dr. Kelkar Vasanti Prabhakar** Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra	**If to INSTITUTION:** Name of the Institute medical Director **Dr.Rajendra Bohra** Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra
If to CRO: **Dr. Neeta Nargundkar** **Biosphere Clinical Research Pvt. Ltd.,** Highland Corporate Centre, SB 02,03 & 04, Second Floor, Near Kapurbawdi Junction, Thane (W)400 607.	

Annexure A

Name of the Site:
Provisional Investigator Site Payment-Per Patient cost is as follows:

Visit Number	Payments INR
Visit 1 –Screening Visit/ -5 days	3000
Visit 2 –Randomization Visit / Day 1	3000
Visit 3–Follow up visit / 12 ± 4 Hours post administration of IP	1000
Visit 4 –Follow up visit / 24 ± 6 Hours post administration of IP	1000
Visit 5- End of study visit/ 48±6 Hours post administration of IP or at the time of discharge whichever is earlier.	2000
Total	10,000 INR

Note 1: The above payments are inclusive of Investigator Fees, Sub-Investigator Fees, Subject Travel Reimbursement, Laboratory cost and Institutional Overheads.

Note 2: Clinical Research Site Coordinator Fees 8,000 INR/month will be paid from Site Initiation Visit till completion of study activities. (Up to 4 Months)

Note 3: Screen failure subjects will be paid only up to 10% of the total enrolled completed subjects at the site.

Note 4: For drop-out subject payment will be made as per completed visit on pro-rata basis.

Note 5: All the site payments will be released upon receipt of original invoice signed by authorized signatories.

Note 6: All the payments made to the payee are subject to Tax Deducted at Source (TDS) and Goods and Services Tax (GST) as per the applicable existing tax laws in the country and CRO will deduct the tax at the time of making the payments.