CLINICAL STUDY AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made and entered into on this 6th day of November,2023 ("**Effective Date**") by and between:

A. Jehangir Clinical Development Centre Private Limited, a company incorporated under the Companies Act, 1956 and having its registered office at 32 Sassoon Road, Pune 411001(hereinafter referred to as "**JCDC**");

AND

B. Dr. Shyamasunder Bhat N, Professor and Head, Department of Orthopaedics, Kasturba Medical College, Manipal, Manipal Academy of Higher Education, Karnataka (hereinafter referred to as the **"Principal Investigator" or "PI");**

AND

C. Manipal Academy of Higher Education (MAHE), on behalf of its constituent unit Department of Orthopaedics, Kasturba Medical College Hospital (KMC), having its registered office at manipal.edu Building, Madhava Nagar, Manipal 576104 represented by its Registrar Dr P Giridhar Kini (hereinafter referred to as "**Institution**")

AND

D. Serigen Mediproducts Private Limited, **(Previously known as BiolMed Innovations Private Limited)** a company registered under the Companies Act, 2013 and having its registered office at 1006-B, Anusha Residency, Sus Road Sutarwadi, Pune-411021, Maharashtra, India and corporate office at 100, NCL Innovation Park, Dr Homi Bhabha Rd, Pashan, Pune, Maharashtra 411008 and include its successors and assignees. (hereinafter referred to as ("**Sponsor**").

Each a "Party" and together the "Parties".

Protocol Number:	SMPL/SM/003
Protocol Title:	Title: A prospective, interventional, randomized, comparative open label pivotal clinical study to assess the efficacy of Serioss® as bone void filler/bone substitute.
Protocol Date:	10-01-2023
Sponsor:	Serigen Mediproducts Pvt. Ltd.
Country where Institute is Conducting Study	India

Site Investigator:	Dr. Shyamasunder Bhat N
IRB/IEC	Kasturba Medical College and Kasturba Hospital

RECITALS:

WHEREAS, JCDC is providing specific clinical research services to the Sponsor with respect to the said Study, under a separate agreement 31-Mar-2023 between JCDC and Sponsor ("Service Agreement"). Under the said Service Agreement, JCDC's services inter alia include Project management, monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution, **Manipal Academy of Higher Education (MAHE),** on behalf of its constituent unit Department of Orthopaedics, **Kasturba Medical College Hospital (KMC)** which is a recognized well equipped, multispecialty hospital. Kasturba Medical College Hospital and Investigator (hereinafter jointly the "**Site**") are willing to conduct the Study and JCDC requests the Site to undertake such Study, subject to terms and conditions as stated Agreement, the Protocol and the Applicable Law.

WHEREAS Dr. Shyamasunder Bhat N, Professor and Head, Department of Orthopaedics, Kasturba Medical College, Manipal Academy of Higher Education, Manipal, Karnataka at the Institute has been appointed as the **Principal Investigator (PI)** for the Study by the Institution.

AND WHEREAS, **Serigen Mediproducts Private Limited** and **Kasturba Medical College Hospital (KMC)** have already signed a Clinical Trial Agreement dated 9th March 2023, which would cease to exist with effect from signing date of this agreement.

NOW THEREFORE, it is hereby agreed by and between the parties as follows:

1. DEFINITIONS

The following additional definitions shall apply to this Agreement:

1.1 Applicable Law: 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.

1.2 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 within the Territory or elsewhere, having jurisdiction over the Parties.

1.3 Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

1.4 Case Report Form (CRF): case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to JCDC / Sponsor on each Study Subject (defined below).

1.5 Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the Investigational Product identified in the Protocol.

1.6 Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

1.7 Study Staff: the individuals involved in conducting the Study under the direction of the Investigator including the site staff.

1.8 Investigational Product: the Investigational Product identified in the Protocol that is being tested in the Study.

1.9 Good Clinical Practices or GCPs: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonized Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

1.10 Sponsor: the sponsor of the Study.

1.11 Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs, other diagnostic images and any other notes or reports whatsoever relating to the Study.

1.12 Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be

delivered to JCDC / Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

1.13 Government Official: insofar as s/he is directly connected with the Study and over which his/her position has jurisdiction any one or more of the following : officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

1.14 Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

1.15 Dual Capacity: the capacity of holding a Government Official position and being a party to this Agreement.

1.16 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.

1.17 MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

1.18 Visits: also referred to as Time points during the Study when clinical and laboratory data of the enrolled patient will be recorded as per the Study Protocol.

2. Conduct of the Study

2.1 Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws, regulations and guidelines, including in particular, but without limitation, GCPs, MCI Regulations, and state and local tax and finance regulations. Site and Study Staff acknowledge that JCDC and Sponsor and Sponsor, and their respective affiliates, need to adhere to the provisions of applicable anti-corruption legislation.

2.2 Obligations of Site.

Site shall be responsible for strict compliance by all Study personnel, including the Investigator and the sub investigators and Study Staff, with the terms of this Agreement. Institution shall ensure that any 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. Institution will assume all those responsibilities assigned to clinical study sites under all Applicable Laws including without limitation all relevant International Conference on Harmonization Good Clinical Practice ("ICH GCP") guidelines and standards, and all Applicable Laws relating to the confidentiality, privacy and security of patient information. The Investigator shall be responsible and liable for performance of the obligations under this Agreement by the Study Team. Any breach committed by the Study Team shall be deemed to be a breach committed by the Investigator.

2.2.1 Protocol. Institution shall and agrees to ensure that the Investigator and the Study Staff conducts the Study in accordance with the Protocol (Attachment A).

2.2.2 Amendments. The Protocol may be modified only by a written Amendment, signed by both Sponsor, Sponsor and the Investigator. The Parties acknowledge that Protocol Amendments are also subject to approval by the responsible Independent Ethics Committee ("IEC").

2.2.3 Emergency Amendments. If it is necessary to change the Protocol on an emergency basis for the safety of the Study Subjects, Institution will notify JCDC 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 Sponsor and the Investigator.

2.2.4 No Additional Research. Institution confirms that no additional interventional clinical trials will be conducted on the Study Subjects during the conduct of the Study, unless it is approved by JCDC and documented as a companion protocol or an Amendment to the original Protocol.

2.2.5 Institution Ethics Committee. Before the Study is initiated, the Institution will ensure that both the Study and the informed consent form are approved by an IEC that complies with all applicable regulations. Institution will further ensure that the Study is subject to continuing oversight by the IEC throughout the duration of conduct of the study.

2.2.6 Study Disapproval. If, through no fault of Institution, the Study is disapproved by the IEC, this Agreement will immediately terminate with no penalty to the Institution, as outlined below.

3. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("IRB") or Independent Ethics Committee ("IEC") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.

4. Medical Records and Study Data

Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall:

i. maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with Applicable Laws, regulations and industry standards; and

ii. Protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by JCDC, Site will submit Study Data using the electronic system provided by JCDC or their designated representative and in accordance with JCDC's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords.. Site shall ensure the prompt submission of Source and CRFs; and take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by Applicable Laws

iii. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the JCDC, and Institution shall continue to store Medical Records and Study Data for any period that the JCDC may request in writing after retention is no longer required by any Applicable Law.

iv. If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

4.1 Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

4.2 Access, Use, Monitoring and Inspection. Upon reasonable request, Site shall provide original copies (as the case may be) of all Study Data and other Study records (including Study Subject records and medical charts, Study Subject consent documents; Study Product receipt and disposition logs) to JCDC for Sponsor's use. Site shall afford Sponsor and JCDC and their representatives and designees reasonable access to Site's facilities to examine and inspect the facilities and other activities relating to the Study or the IEC; and to Medical Records and Study Data so as to permit Sponsor and JCDC and their representatives and designees to monitor and observe the conduct of the Study.

- Site shall afford regulatory authorities, a reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.
- The Site agrees to ensure the full cooperation of the Site´s staff, and IEC members with any such inspection and with the representatives of JCDC and Sponsor and Site will ensure timely access to applicable records and data to inspections, JCDC and Sponsor. Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives. Site will promptly resolve any discrepancies that are identified between the Study Data and the Study Subject's medical records. , The site agrees to resolve the queries within 2 working days.
- Site will promptly forward JCDC copies of any inspection findings that Site receives from a regulatory agency in relation to the Study. Whenever feasible, Site will also provide JCDC and Sponsor with an opportunity to prospectively review and comment on any Site responses to regulatory agency inspections in regard to the Study.
- Site will inform JCDC within twenty-four (24) hours of, and provide JCDC and Sponsor copies of, any effort, inquiries, correspondence or communications to or from any governmental or regulatory authority or other persons to inspect or contact the Site or research staff relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit JCDC and Sponsor to attend any such inspections; and will provide Sponsor and JCDC the opportunity to participate in any proposed or actual responses by Site to such communications. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

4.3 Archival. All the study data including source documents and related records shall be maintained by the site for a period not less than 15 years/ as per applicable regulations

4.4 Survival. This section 4 4.0 “Medical Records and Study Data” shall survive termination or expiration of this Agreement

5. Duties of Investigator

- The site will ensure that only individuals who are appropriately trained and qualified assist in the conduct of the Study as sub investigators or Study Staff.
- The Investigator shall be responsible and liable for performance of the obligations under this Agreement by the Study Staff. Any breach committed by the Study Staff shall be deemed to be a breach committed by the Investigator.
- The Investigator is responsible for the conduct of the Study at Institution. In particular, but without limitation, it is the Investigator’s duty to review and understand the information in the Study Protocol, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.
- The investigator agrees to provide a written declaration revealing Investigator’s possible economic or other interests, if any, in connection with the conduct of the Study or the Study Product.
- The Investigator agrees to provide a written declaration revealing Investigator’s disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.
- The Site agrees to provide prompt advance notice to JCDC if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of JCDC.
- The Site agrees to enroll upto 20 subjects in strict adherence to the Protocol, study recruitment is competitive. Site shall stop enrollment immediately upon notice from JCDC.
- The Investigator is responsible and shall ensure that the Study Data is fully and correctly entered in the CRF / e-platform provided by JCDC for collecting the Study Data. The Study Data is to be entered simultaneously with the study activity on the E-platform and the same is verified by JCDC and queries if any are resolved to JCDC’s satisfaction. The query raised has to be properly resolved within 48 hours. JCDC holds the right to reject payment for the activity for which data is not entered within the timeline as mentioned here.

6. Adverse Events

- The Site shall report adverse events and serious adverse events as directed in the Protocol and by Applicable Laws within 24 hours of the occurrence of the event. The

Site shall cooperate with JCDC in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

- JCDC will promptly report to the Site, the Site's IRB/IEC any finding that is reported to it, that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

7. Use and Return of Investigational Product and Equipment

- JCDC or a duly authorized agent of JCDC shall supply Institution or Investigator with sufficient amount of Study Product.
- The Site shall use the Study Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by JCDC and according to Applicable Laws, including storage in a locked, secured area at all times and will not administer or dispense it to anyone who is not a Study Subject, or provide access to it to anyone except Investigator, sub investigators, or Study Staff.
- Upon completion or termination of the Study, the Site shall return / destruct the unused Investigational Product comparator products and materials and return all Confidential Information (as defined below). Site shall produce the certificate of destruction of the Investigational Product as required under application standards.
- Institution and Investigator will use Study Product or comparator products only as specified in the Protocol. Any other use of Study Product or comparator products constitutes a material breach of this Agreement. Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Study Product and any instructions from JCDC that are not inconsistent with such laws and regulations.
- The Site shall return any equipment or materials provided by JCDC for use in the Study as per discretion of Sponsor/CRO.
- Study Product is and remains the property of Sponsor. Institution and Investigator have no express or implied intellectual property rights or any other rights (including any moral rights) in and to the Study, Study data, Study methodology, the Study Product or in any methods of making or using the Study Product (jointly and severally "Sponsor Property") all of which intellectual property rights and other rights, are and shall remain exclusively and absolutely owned by Sponsor. Nothing in this Agreement shall be deemed to grant, assign, convey, or transfer to any one or more of the other Parties hereto (or to any other party as of the date hereof), any right, interest, or license, in whole or in part, in and to such Sponsor Property as mentioned herein or elsewhere in this Agreement.

8. Key Enrolment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject within 01 month of SIV then JCDC may terminate this Agreement in accordance with Section 18 "Term & Termination"/JCDC has the right to limit enrollment at any time.

9. REPRESENTATIONS AND WARRANTIES

9.1 The Institution and the Investigator hereby jointly and severally represent and warrant to JCDC the following:

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

b. Sufficient resource and time is available and shall continue to be available to Investigator for dedicated, proper and punctual performance of the Study in accordance with the Protocol requirements, the terms of this Agreement, the Protocol, ICH GCP and/or other nationally established guidelines and the approval of the EC;

c. Investigator and Study Staff possess requisite experience, qualifications, capability and resources including but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol and regulatory requirements;

d. Investigator shall perform the Study in an efficient and professional manner and shall complete the Study within the time period as informed by JCDC from time to time;

e. Investigator and Study Staff shall duly observe and follow all directives, conditions and restrictions, if any imposed by the respective authority(ies) under the applicable regulatory approvals;

f. Investigator and the Study Staff shall conduct the Study under the review and supervision of JCDC, the EC, or an appropriate independent review committee of scientists or other qualified individuals or any such board, body or committee authorized to coordinate, review and safeguard the rights, safety and well-being of the Study Subject;

g. The representation, warranties set out hereunder may be relied upon in any applications to any of the regulatory authority(ies);

h. They 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 / laws or statutes from undertaking or performing the Study or the obligations hereunder;

i. They shall ensure the safe custody of the Study Product in accordance with the Protocol and shall not use the Study Product for any purpose other than the purpose of this Agreement;

j. They shall notify JCDC of any change in the truth of any of the aforesaid representations;

k. They shall take necessary and appropriate steps to inform its Study Staff of the terms and conditions of this Agreement and to ensure that such persons comply with the terms and conditions of this Agreement;

l. They shall be accountable to JCDC and to Sponsor for any and all breach, action, inaction or omission, committed by the Study Staff, support staff and personnel provided by it for conducting the Study;

m. In the event the study site is inspected and the Study Data are audited / examined by any regulatory authority(ies) having competent jurisdiction under the regulatory requirements or Applicable Laws, Investigator shall forthwith notify JCDC of such inspection, inquiry, audit or examination conducted by such regulatory authority(ies);

n. They 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 them, in a timely manner, in accordance with the regulatory requirements and Applicable Law;

o. They shall apply for, and obtain, maintain, renew all the applicable approvals during the term of the Agreement;

p. They shall perform such other roles, responsibilities and duties as may be required by JCDC from time to time; and

q. They 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.

r. The Site has the necessary infrastructure including but not limited to the computers and high speed internet access for conducting the study in an efficient and compliant manner.

The Job Description of Principal Investigator is attached in Attachment D

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

a. it has taken all necessary action on its part required to execute, deliver and perform its obligations under 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.

10. Payment

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment B, with the last payment being made after the Site completes all its obligations hereunder, and JCDC has received all properly completed CRFs and, if requested, all other Confidential Information (as defined below).

11. Confidentiality

11.1 Definition

"Confidential Information" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by Sponsor or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 12) of Sponsor, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 12).

Confidential Information shall not include information that:

i. can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;
ii. can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;
iii. can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel without reference to any Sponsor Property; or
iv. is permitted to be disclosed by written authorization from Sponsor.

11.2 Obligations

Site and Site's personnel, including Study Staff shall not directly or indirectly,

i. Use Confidential Information for any purpose other than the performance of the Study or
ii. Disclose Confidential Information to any third party, except as permitted by this Section 5 or by Section 7 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

i. limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;
ii. advise all Study Staff who receive Confidential Information of the confidential nature of such information; and
iii. Use reasonable measures to protect Confidential Information from disclosure.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 13"Publication Rights."

11.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall promptly, but not later than three (3) days of receipt of such notice, notify Sponsor so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

11.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

11.5 Survival

This Section 11 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

12. Intellectual Property

12.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "Pre-existing Intellectual Property"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

12.2 Inventions

For purposes hereof, the term "Inventions" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall absolutely and exclusively own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

12.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor any and all of its rights, title and interest whatsoever in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site and/or its personnel hereby expressly agree that Sponsor shall have full, exclusive, and absolute ownership rights in and to Invention(s). Accordingly, Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions. In the event that Institution and/or its personnel is unable, neglect, or fail for whatever reason to execute such documents as are reasonably necessary in Sponsor's sole judgment to

file, prosecute, claim, defend any of the assigned rights herein, or to more perfect Sponsor's claim(s) to such assigned property(s), Institution on behalf of itself and its personnel, hereby appoints Sponsor and each of Sponsor's agent nominated by Sponsor from to time, as Institution's (and its personnel) Attorney-in-Fact to act in place of Institution and/or its personnel, to file and execute such documents as may be required to file, defend, claim, or make more perfect Sponsor's claim(s) to such assigned property(s).

12.4 Patent Prosecution

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

12.5 Survival

This Section 12 "Intellectual Property" shall survive termination or expiration of this Agreement.

13. Publication Rights

13.1 Publication and Disclosure

Subject to Sponsor's prior written approval, Institution and Investigator may publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Institution and Investigator agree to submit any proposed publication or presentation to Sponsor for review at least thirty (30) days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, Sponsor through JCDC shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. Sponsor shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Sponsor to seek patent protection for Inventions.

13.2 Multi-Center Publications

If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the Sponsor's prior written consent, independently publish, present or

otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until a multi-center publication is published solely in accordance with the provisions of Section 13.3 "Confidentiality of Unpublished Data." and 13.1 "Publication and Disclosure"

13.3 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 13.1 or Section 7.2 ("Unpublished Data") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 13.1 or Section 13.2.

13.4 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of JCDC. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

13.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or JCDC's name or Sponsor's /Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and JCDC may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. JCDC /Sponsor will register the Study with a public clinical trials registry in accordance with Applicable Laws and will report the results of the Study publicly when and to the extent required by Applicable Laws.

13.6 Survival

This Section 13 "Publication Rights" shall survive termination or expiration of this Agreement.

14. Personal Data

14.1 Study Team Member Personal Data

Both prior to and during the course of the Study, the Investigator and his/her teams may be called upon to provide personal data. This data falls within the scope of the law and regulations relating to the protection of personal data.

For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to potential Dual Capacity conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

i. the conduct of clinical trials;
ii. verification by governmental or regulatory agencies, the Sponsor, Sponsor, JCDC, and their agents and affiliates;
iii. compliance with legal and regulatory requirements;
iv. publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
v. storage in databases to facilitate the selection of investigators for future clinical trials; and
vi. Anti-corruption compliance.

Names of members of Study Staff may be processed in JCDC/Sponsor'/ Sponsor's study contacts database for study-related purposes only.

14.2 Study Subject Personal Data

The Investigator shall obtain Study Subject written consent for the collection and use of Study Subject personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable data protection provisions.

14.3 Survival

This Section 14 "Personal Data" shall survive termination or expiration of this Agreement.

15. Study Subject Injury

15.1 The Site shall promptly notify JCDC in writing of any claim or probable claim of illness or injury or death actually or allegedly due to an adverse reaction to the Study Product and cooperate with JCDC in the handling of the adverse event.

Sponsor through JCDC shall reimburse Institution for the direct 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, specifically due to administration of Study Product 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 this Agreement, the Protocol, any written instructions of JCDC concerning the Study, or any Applicable Law, including GCPs, issued by any regulatory authority, or
b. negligence, fraud or wanton or willful acts amounting to misconduct by Institution, Investigator or any of their respective personnel, or
c. Failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

Sponsor will compensate as required by the current compensation guidelines notified vide Gazette dated Rules 2019 G.S.R. 227 (E), as amended from time to time containing directives regarding compensation for injury and death during the clinical trials and any amendment or new pronouncement notified by the Competent authority.

This Section 15 “Study Subject Injury” shall survive termination or expiration of this Agreement.

16. Insurance.

The Site will secure and maintain in full force and effect throughout the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage for medical professional liability with limits in accordance with the Applicable Laws for all medical professionals conducting the Study. Sponsor and / JCDC shall not be liable for any liability arising out of the exposure of Investigator or site Study staff to COVID-19.

So also, Sponsor will secure and maintain in full force and effect throughout the performance of the Study a Clinical Trial Insurance Policy for damages in respect of any claim made by Study Subject for any loss suffered by them on account of their participation in this Study.

17. JCDC Disclaimer

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

This Section 17 "JCDC Disclaimer" shall survive termination or expiration of this Agreement.

18. Consequential Damages

Neither JCDC nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to JCDC or Sponsor for any lost profits, lost opportunities, or other consequential damages.
Notwithstanding anything contained herein the Institution shall be liable for any act or omission of the Investigator with respect to the payment received by the Investigator in the capacity of the Payee.
This Section 18 "Consequential Damages" shall survive termination or expiration of this Agreement.

19. Debarment

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify JCDC immediately if any such investigation, disqualification, debarment, or ban occurs. Site also certifies that it is not excluded from any governmental health care program; Site further certifies that that it is 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, Site will notify JCDC 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 Site becomes aware of any material issues related to the medical licensure of any associated Study researchers (including the Investigator).
This Section 19 "Debarment" shall survive termination or expiration of this Agreement.

20. **Financial Disclosure and conflict of interest**

Upon JCDC's request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to JCDC a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

JCDC may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.
Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Sponsor, JCDC, and their agents, and the Site consents to such review.

This Section 20 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

21. Anti-kickback and Anti-Fraud

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

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

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from JCDC, or which are not part of the ordinary care they would normally provide for the Study Subject.

22. Anti-bribery

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision

that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist JCDC /Sponsor / Sponsor to secure an improper advantage or obtain or retain business.

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

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

23. Independent contractors

The Investigator and Institution are acting as independent contractors of JCDC and shall not be considered the employees or agents of JCDC or Sponsor.

Neither JCDC nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or their staff.

24. Term & Termination

24.1 Term

This Agreement will become effective on the date of approval of the relevant IEC / IRB or the date on which it is last signed by the parties, whichever date is later, (the "Effective Date") and shall continue until completion or until terminated in accordance with this Section 18 "Term & Termination".
One of more copies of this Agreement may be countersigned by one or more Parties hereto and all such countersigned copies shall together nevertheless constitute only one single document and each countersigned document containing at least one original signature, may be considered to be an original copy of the Agreement provided that copy(s) of the original signature of the other Party(s) are also affixed thereto.

24.2 Termination

JCDC may terminate this Agreement for any reason or for no reason effective immediately upon written notice. The Site may terminate this Agreement upon 30 days written notice if circumstances beyond the Site's reasonable control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and JCDC on behalf of the Sponsor shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment B; provided, however, that final payment will be withheld until final acceptance of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, JCDC may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

25. Inspections and Audits.

a. Access. Upon reasonable request, JCDC, authorized representatives of JCDC, and/or authorized representatives of the applicable regulatory 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 the conduct of the Trial.

b. Notice. Site will inform JCDC within twenty-four (24) hours of any effort or request by regulatory authorities or other persons to inspect or contact the Site or research staff with regard to the Trial; will provide JCDC with a copy of any communications sent by such persons via physical delivery, speed-post or email; and will provide Sponsor or JCDC the opportunity to participate in any proposed or actual responses by Site to such communications.

c. Cooperation. Site will ensure the full cooperation of the Site researchers, and IEC members with any such inspection and will ensure timely access to applicable records and data. Site will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records. Site will promptly forward JCDC copies of any inspection findings that Site receives from a regulatory agency in relation to the Study. Whenever feasible,

Site will also provide JCDC with an opportunity to prospectively review and comment on any Site responses to regulatory agency inspections in regard to the Trial.

26. Notice

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered

(a) In person,
(b) By certified mail, postage prepaid, return receipt requested,
(c) By e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
(d) By a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Investigator	Dr. Shyamasunder Bhat N Professor and Head Department of Orthopaedics Kasturba Medical College, Manipal Manipal Academy of Higher Education KARNATAKA, INDIA. PIN - 576 104 Ph: +91 820 2922929, +91 820 2922754 E-Mail: shyambhat.n@manipal.edu
To Institution	Dr. P Giridhar Kini Registrar Manipal Academy of Higher Education, Kasturba Medical College, Manipal, KARNATAKA, INDIA. PIN - 576 104 +91 820-2922323 registrar@manipal.edu copy to: legal.mahe@manipal.edu
To JCDC	Mrs. Geeta Divate Jehangir Clinical Development Centre Pvt.Ltd. Jehangir Hospital Premises 32 Sassoon Road, Pune-411001 MAHARASHTRA Tel:020 6726 8800
To Sponsor	Dr Swati Shukla 1006-B, Anusha Residency, Sus Road Sutarwadi, Pune- 411021, MAHARASHTRA

27. Force Majeure

The performance by any Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

28. Miscellaneous

a. Entire Agreement
This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties as to the subject of the Study herein and replaces all other written and oral representations thereto.

b. No Waiver/Enforceability
Failure to enforce any right of this Agreement shall not constitute a continuing waiver of such right or a waiver of any other right.

If any provision or part(s) of provision of this Agreement is found to be unenforceable or invalid, the remaining provisions of this Agreement shall continue to remain in effect.

c. Assignment of the Agreement
This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of JCDC.

Upon Sponsor's / Sponsor's request, JCDC may assign this Agreement to Sponsor or to a third party, and JCDC shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

d. Third Party Beneficiary
The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor / Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

e. Applicable Law and Arbitration
This Agreement shall be interpreted under the laws of India with the exclusive jurisdiction of Courts of Pune.

For any dispute, commercial or otherwise, that may arise in future, all parties agree to resolve the same amicably within a period of 30 days from the date of written notice by the aggrieved party to the others. Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, which still remains unresolved after above-mentioned period of 30 days, shall be referred to a sole arbitrator under the provisions of the Arbitration and Conciliation Act 1996 and its subsequent amendments. The arbitration proceedings shall be conducted in the English language and venue for arbitration proceedings shall be Pune. Decision of the Ld. Arbitrator shall be binding and final upon all parties and courts of Pune shall have exclusive jurisdiction in all such disputes.

f. Conflict with Attachments
To the extent that terms or provisions of this Agreement conflict with the terms and provisions of the Protocol, the terms and provisions of this Agreement shall prevail in relation to legal and business matters, and the terms and provisions of the Protocol shall prevail in relation to technical research and scientific matters unless expressly agreed in a writing between the parties.

g. Survival:
The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

29. Indemnification

29.1 Indemnity: The Sponsor will defend, indemnify and hold harmless the Principal Investigator, Institutions, JCDC and any of their agents, sub-contractors, directors employees and other representatives ("Site Indemnitees") from any and all liabilities, claims, actions or suits in relation to the Study to the extent the claim is not based on the Site Indmenitee's negligence and/or willful misconduct or material breach of this Agreement. This indemnification is subject to the conditions stated in Clause 29.6.

29.2 The Principal Investigator/ Institution shall promptly notify the JCDC and the Sponsor of any claim for which indemnity may be sought. The Principal Investigator / Institution shall fully cooperate with the Sponsor and its legal representatives in the investigation and defense of any claim or suit covered under this Agreement

29.3 Site Indemnification Liability: The Principal Investigator and/or Institution shall also indemnify, defend, and hold the Sponsor / Sponsor, JCDC and its affiliates, directors, officers, employees and other representatives ("Sponsor's Indemnified Parties") harmless and against any and all loss, costs, claims, actions, liability and/of suits, including without limitation, interest, penalties and reasonable attorneys' fees ("Sponsor's Claims"), incurred by the Sponsor's Indemnified Parties that arose from or was a result of (a) any material breach by Principal Investigator and/ or Institution under this Agreement; (b) the failure to act, omissions, gross negligence or intentional misconduct of Principal Investigator and/or Institution in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement; (c) Principal Investigator's and/or Institution's violation of any and all applicable Federal, State or Local laws rules and regulations of India, (d) Principal Investigator's and/or Institution's breach or default in performance of its obligations in connection with this Study; (e) Principal Investigator's and/or Institution's material deviation from the Protocol or other written recommendation or instructions furnished by Sponsor through JCDC to Principal Investigator and the Institution for this Study; (f) Claims attributable solely to Principal Investigator's and/ or Institution's willful misconduct, gross negligence, failure to comply with its obligations under this Agreement.

29.4 Exclusions from Indemnification: The Sponsor's/ Sponsor's obligation to indemnify Site Indemnitees in accordance with Clause 29.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject against liability, damage, loss or expense incurred by or imposed on the Site Indemnitees or any one of them in connection with any claim, suit, action, demand or judgment arising:

(i) from malpractice, gross 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 other information provided to any Site Indemnitee in connection with the Study or the Product, including, but not limited to information provided in the relevant product related information;
From any unauthorized representations and/or warranties made by any Site Indemnitee concerning the Study Product;
(iv) 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 Indemnitee shall indemnify, defend and hold harmless Sponsor, Sponsor, JCDC and their employees, officers, directors, contractors, successors, assigns, representatives or agents;
No party however shall in any event be liable whether in contract, tort, misrepresentation, negligence or otherwise, for any loss of profit, 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.

29.5 The Indemnity obligation shall survive the expiration or termination of this agreement or the Clinical Study agreement.

29.6 Insurance

29.6.1 Sponsor's Insurance: The Sponsor represents and warrants that it has and during the term of Study shall maintain the following insurance coverage:

a. An insurance coverage under a human clinical trial insurance policy adequate to cover its obligations and liability in relation to the study.
b. Professional liability insurance

29.6.2 The Sponsor shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 29.4.1 to the Site and Institute, PI and IRB/ ethics Committee.

29.6.3 Site and Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Site contained in the Clinical Trial Agreement.

29.7 Entire Obligation

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

29.8 Miscellaneous

29.8.1 Amendment: No Party may amend the terms of this Agreement except by a written instrument signed by the Parties. In addition, any amendment to the protocol must be approved in writing by the Sponsor [and the appropriate Institutional Review Board / Ethics Committee].

29.8.2 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 Site and the Clinical Trial shall remain employees/ consultants of the Site and performance of services under this Agreement shall not be construed as transfer of their employment to the Sponsor / JCDC.

29.8.3 Assignment: This Agreement may be assigned by the Sponsor to any of its Affiliates or to any third party, with prior written information to the Parties, and the site hereby consents to such an assignment provided that site will be given prompt notice of such assignment and fat such assignment in no event shall adversely affect the rights and benefits of the Site entitled by this agreement. The successor shall take full responsibility of the duties and liabilities as per this agreement.

29.8.4 Termination: This Agreement shall be coterminous with the Clinical Study Agreement.

29.8.5 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 shall be excused for the period of such Disability. The Party incurring the Disability shall provide notice to the other of i.e. commencement and termination of the Disability. In case a Disability continues for more than three (3) months, the Party 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.

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

29.10 Policy Compliance:

29.10.1 Institution & PI shall comply fully at all time with Sponsor's business conduct policies and all applicable laws and regulations, including but not limited to applicable anti-corruption laws, of the territory in which Institution & PI conducts business for the Sponsor.

29.10.2 Sponsor shall be entitled to terminate this Agreement immediately on written notice to Institution & PI, if Institution & PI fails to perform its obligations in accordance with this Clause. Institution & Pl shall have no claim against the Sponsor or Sponsor or JCDC for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Clause.

29.11 Governing Law: This Agreement shall be governed by the laws of India.

29.12 That nothing herein under shall make any clause in the Clinical Study Agreement inoperative or ineffective unless expressly stipulated herein and all the other clauses in the Clinical Study Agreement shall remain valid and effective without any hindrance or impediment. In case of any conflict between this Agreement and the Clinical Study Agreement, in respect of the clauses stipulated herein this Agreement shall prevail over the Clinical Study Agreement as the case may be.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement on the date and the year first hereinabove written.

For JCDC Pvt. Ltd.,

Dec 03 2023 17:54 IST

Mrs. Geeta Divate

Title: Director (Finance)

For Principal Investigator,

Dec 01 2023 16:15 IST

Dr. Shyamasunder Bhat N

Title: Principal Investigator

For Sponsor,

Serigen Mediproducts Pvt. Ltd.

(Previously Known as BiolMed Innovations Pvt. Ltd)

Dec 04 2023 10:44 IST

Dr. Swati Shukla

Title: Co-founder and COO

For Institute,

Manipal Academy of Higher Education

_____

Dr. Giridhar Kini

Title: Registrar

ATTACHMENT A

STUDY PROTOCOL

Attachment B
Budget & Payment Schedule

. Payee details

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 ("Payee):

Payee Name	Manipal Academy of Higher Education
Payee Address	manipal.edu Building, Madhava Nagar, Manipal – 576104
Bank Name	State Bank of India
Bank Address	Manipal Branch, Madhuvan Serai, Ground Floor, Near Smriti Bhavan, Tiger Circle, Manipal – 576104, Karnataka
Bank Account IBAN Number or branch number	37983533287
IFSC Code	SBIN0004426
Permanent Account Number	AAETM8695B
GST Number	29AAETM8695B1Z4

In case of changes in the Payee's bank details, Site is obliged to inform JCDC in writing. The Parties agree that in case of changes in bank details which do not involve a change of Payee/Bank Account Name or change of country location of bank account, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.
If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by JCDC to the Payee.
Investigator acknowledges that if Investigator is not the Payee, JCDC will not pay Investigator even if the Payee fails to reimburse Investigator

B. Payment Term

JCDC on behalf of Sponsor will pay the Payee monthly, on a completed visit per enrolled subject basis in accordance with the attached budget. The completed visits shall mean visits that are properly conducted in strict adherence to the protocol, are fully entered in the CRF / e-platform provided on the day of the visit by JCDC for collecting the Study Data and the same is verified by JCDC and queries if any, are resolved to JCDC's satisfaction. The data is to be entered simultaneously / on-line with the study activity on the E-platform. The query raised has to be properly resolved within 48 hours. JCDC holds the right to reject payment for the activity for which data is not entered within the acceptable timeline as mentioned here.

Non-evaluable data is not payable.

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

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

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

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

Major, disqualifying Protocol violations are not payable under this Agreement.

C. Minimum Enrolment Goal

Site acknowledges that Site's minimum enrollment goal is 20 and that Site will use best efforts to reach the enrollment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle JCDC /Sponsor may reconsider Site's suitability to continue participation in the Study.

D. Discontinued or Early Termination

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

E. Invoices

Original Invoices pertaining to this Study for the following items must be submitted to JCDC for reimbursement at the following address:

Jehangir Clinical Development Centre. Pvt. Ltd.
Jehangir Hospital Premises 32 Sassoon Road, Pune-411001.
Attention: Geeta Divate
GST No 27AABCJ7402M1ZF

Please note that invoices will not be processed unless they reference the JCDC name, Protocol number and Investigator name and site number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

F. EC/IRB/IEC FEES

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made by the JCDC on behalf of the Sponsor directly to the EC/IRB/IEC. Any subsequent re-submissions or renewals, upon prior approval by JCDC, will be reimbursed upon receipt of appropriate documentation.

G. Budget table

Principal Investigator Visit Fee Structure (Per Patient)

1. Budget for per Subject grant.

Particulars	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Total
PI Grants	2500	7500	2000	2000	1200	2000	17200
Institution Overhead	500	1500	400	400	240	400	3440
Subject Travel Reimbursement	500	500	500	500	500	500	3000
TOTAL	**3500**	**9500**	**2900**	**2900**	**1940**	**2900**	**20640**

2. Surgery Cost: Rs. 25,000 per subject will be paid as a fixed cost to the patient by the Institution. A separate invoice would be raised by the Institution, which will be paid by JCDC after approval and funds received from the Sponsor. Bone void filler will be provided free by the Sponsor.
3. A renumeration of Rs. 25,000/- per month will be paid to the site for the CRC services for an initial period of 6 months starting from 1st Dec 2023. The decision to continue

the services after 6 months would taken by the Sponsor and notified to JCDC in written communication.

4. Local Laboratory Tests Cost:

Test Name	Cost per Test
CBC	280
UREA, CREAT	220
TOTAL PROTEIN	90
LFT (MINI)	480
CAL, PHOS, ALP	330
VIT D	1140
CRP	240
XRAY KNEE, HIP, ANKLE, WRIST, SHOULDER (SMALL) AP/LAT	400
CT SCAN	4020

JCDC on behalf of the Sponsor will pay for the Local laboratory assessments mentioned below:

The billing shall be as per the actual test cost provided by the Site which shall be study specific as per approved protocol scheduled visit and shall not be changed throughout the study. Any investigation performed which is not mentioned in Protocol, needs a prior approval from the Sponsor.

JCDC shall make the payments to the site only if the payment has been approved by the Sponsor and the funds for the payment have been received from the Sponsor.

5. Authorship: To all Investigators in Publication.

H. STUDY SUBJECT REIMBURSEMENT

There is no provision of any payment by Sponsor or JCDC to Study Subject for participating in the trial or reimbursement of hospital bills/laboratory charges of the Subject by Sponsor or JCDC in this Study, except as under the provisions of Clause 9.1 (Study Subject Injury and Indemnification).

ATTACHMENT C

EC APPROVAL LETTER

Kindly Note:
1.Number of subjects enrolled will be 20 in total duration of maximum 3 months (as confirmed with the PI). 2. Payments will be done within 45 days upon receipt of signed correct invoices based on CRF completion and no queries in system. 3. All the above-mentioned amounts are in **INR.** 4. Archival fees is included in the PI Grant for the study. 5. GST shall be paid only if the proper GST Invoice is provided, taxes are paid and returns are submitted in accordance with applicable rules & GST credit is received by JCDC as per rules. 6. The payment of the GST portion in the invoice will be released only after the GST Return is filed and the credit is reflected on the portal in the name of JCDC. 7. This compensation is payable to the Site for the Investigator and his Study Staff conducting the Study as per the Study Protocol and this Agreement 8. JCDC shall pay on a per subject per visit cost for each satisfactorily completed enrolled subject visit. Only if a subject is discontinued for reason stipulated in the Protocol, the Principal Investigator shall be paid a prorated rate for work completed as per visits outlined in Principal Investigator Visit Fee Structure hereinabove.

ATTACHMENT D

(Undertaking to be Signed by PI)

Responsibilities of PI:

1. I have sufficient time, adequate staff, and appropriate facilities to conduct and complete the clinical Study. I agree to make these resources available for the duration of the study and agree that other Studies will not divert essential subjects or facilities away from this trial.

I assure JCDC Pvt. Ltd., that no other Clinical Study conducted by me shall give rise to a conflict of interest or interfere with this Clinical Trial.

I will endeavor to ensure an adequate recruitment rate during the clinical trial.

2. JCDC Pvt. Ltd. will furnish me with copies of the Investigator's Brochure and the Study Plan and Protocol and I agree:

. i. To become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the pre-clinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and

ii. To become well acquainted with the Study Protocol and Plan before signing it.

3. I agree to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the Study.

4. I understand that I shall have primary responsibility for the accuracy, legibility, and security of all Study data, documents, and subject records both during and after the Study. I will be responsible for signing the Case Report Forms (CRFs). Any alteration of the raw/source data shall be signed and dated, without obliterating the original entry.

I agree to abide by the following conditions governing my handling of the data associated with this Study.

a) I am required to maintain adequate records regarding all investigational product received and used by me including batch numbers, dates, and quantities. If the Study is terminated, suspended, discontinued, or completed, I shall return to JCDC Pvt. Ltd./ Sponsor, any unused supplies unless other arrangements are made by JCDC Pvt. Ltd/ Sponsor.

b) I am required to prepare and maintain adequate and accurate subject's case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the Clinical Study.

c) I understand I am to furnish my records of the Study to JCDC Pvt. Ltd/ Sponsor.

d) I will maintain records of the disposition of the investigational product and other records for the duration longer than the following periods:

i. the period defined by national or local law and rules
ii. five years after the Study is terminated or computed, or

iii. five years after the records are no longer required for purposes of supporting the relevant United States, other national, European (EU), or other international regulatory applications.

iv. to avoid any possible errors I will contact JCDC Pvt. Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e) I agree to provide accurate information to the Ethics Committee upon request. I also agree to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies' authorities and my ethical obligations, as set forth below:

- Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, I will make records related to the Clinical Study available for inspection and copying.

- The subject's identity will not be released except where data verification procedures demand inspection of subject's personal identity or personal medical information. In this case this inspection may be performed only by a properly authorized person.

- The subject's identity shall not be released to third parties without the subject's or subject's legal representative's prior consent. Accordingly, the study subject's or subject's legal representative's consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

5. I agree to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to JCDC Pvt. Ltd/ Sponsor.

I shall not commence the Study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject recruitment procedures, and any written material to be provided to the subject or the Subject's legal representative.

I shall provide the Ethics Committee or Institutional Review Board with all required information.

6. I certify that the investigational product for clinical investigation will be provided only to subjects under my personal supervision (add any additional names on a separate sheet, if needed):

I further certify that the investigational product will not be supplied by me to any investigator, or to any clinic, medical facility, or study site for use.

7. I agree with the policy that no procedure will be performed until all personnel have been properly trained.

8. I agree to be responsible for the personal safety and well-being of the subjects. To this end, I agree to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:

Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with a dated signature.

a) I will ensure that subject/ subject's legal representative or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the subject / subject's legal representative.

The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.

b) I will ensure that the subject / subject's legal representatives are given the opportunity to inquire about the details of the Clinical Study. The information given to the subject /subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the Clinical Study at any time without any sanction. I will make an effort to ascertain the reasons for any withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.

c) I will ensure that the subject / the subject's legal representatives are provided adequate time to decide whether or not they wish to participate / wish their ward to participate in this clinical investigation.

I will discuss with JCDC Pvt. Ltd. and Sponsor any question of modification of the Study Plan and obtain JCDC Pvt. Ltd. and Sponsor's / Sponsor's written agreement and also approval from the ethics committee prior to implementation of any modification. I will not proceed with a non-emergency deviation from the Clinical Protocol without approval from Sponsor and JCDC Pvt. Ltd. and as needed the Ethics Committee. It is my responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by JCDC Pvt. Ltd., including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

9. I will report all adverse events to JCDC Pvt. Ltd./ Sponsor within the prescribed time limit specified.

a. I will promptly report:

- Deviations from or changes to the protocol to eliminate immediate hazards to the study subjects.
- Changes increasing the risk to subjects and/or affecting significantly the conduct of the study.
- All adverse drug reactions (ADRs) and Adverse Events (AEs) that are both serious and unexpected.
- New information that may affect adversely the safety of the subjects or the conduct of the study.

b. The Investigator will maintain a list of appropriately qualified persons to whom the Investigator has delegate significant trial related duties I will assure that all staff in contact with the subject should be aware of their responsibility to note and report all adverse events reported by the Subjects / subject's legally acceptable representative.

c. The Investigator or designate shall assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d. All serious adverse events (SAEs) shall be reported to JCDC within 24 hours. Additionally, these will be notified to the Ethics Committee with 7 working days of the occurrence.

e. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

f. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the study subjects rather than by the subjects' names, personal identification numbers and/or addresses.

g. Adverse events and/or laboratory abnormalities identified in the protocol as critical to safety evaluations should be reported to JCDC according to the reporting requirements and within the time periods specified by JCDC in the Protocol.

10. I will report all deviations from the protocol to JCDC Pvt. Ltd. and to the Ethics Committee.

11. I will notify Sponsor and JCDC Pvt. Ltd., immediately, but in no event in more than five working days, about withdrawal of approval by the reviewing Ethics Committee of my part of the Clinical Study.

12. I will comply with any request by JCDC Pvt. Ltd. to return or dispose off, investigational product upon termination or completion of the clinical study. I understand that JCDC Pvt. Ltd. is required by law to discontinue shipments of investigational product to me if I fail to comply with the Study Protocol or with any applicable laws or regulatory requirements applicable to the investigation, including national guidelines.

13. I agree to permit personnel from JCDC Pvt. Ltd. and/or the Study Monitor/auditor to visit me and/or the Study Site to monitor my compliance with the protocol and/or audit the investigational records. To facilitate JCDC. Pvt. Ltd., or the Study Monitor's audit, I further agree to make records related to the Clinical Study available for inspection and copying.

14. I agree to maintain confidentiality regarding all information generated in the course of this Clinical Study. I further agree to ensure that the confidentiality of all information about subjects and the information supplied by JCDC Pvt. Ltd./Sponsor is respected by all persons, with the limitations discussed above.

15. I agree to submit and sign a Final Report of the Clinical Study after it is submitted by sponsor to me after termination or completion of the Clinical Study to the Ethics Committee.

16. I shall provide all care possible and appropriately guide the patient in coordination with the Hospital to save the life of the patient and stabilize the patient in case of an adverse event.

17. In case of termination of the agreement as per clause 6 above, I shall take due medical care of the participants.

18. I agree that I will not charge the subjects directly for any procedure or consultation which is covered under the protocol.

I agree to abide by this Investigator Agreement.

Investigator Signature:  Date Signed: Dec 01 2023 16:15 IST