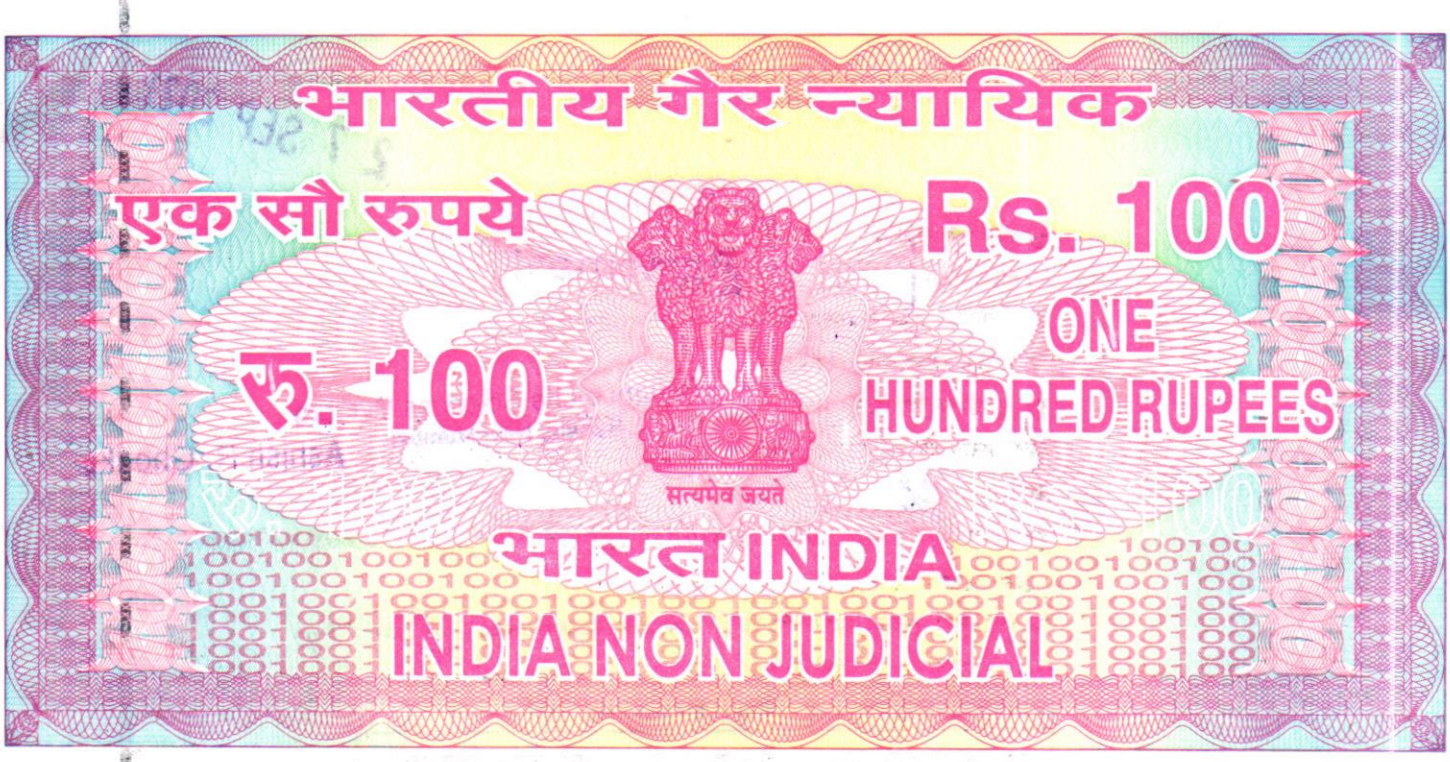

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ ZA 328107

CLINICAL TRIAL AGREEMENT

Between

Reliance Life Sciences Pvt. Ltd., ("Reliance")

AND

Dr. Anand Nikalje, ("Investigator")

AND

MGM Medical College and Hospital, Aurangabad, ("Institution")

AND

Dr. Ujwala Kulkarni, Aurangabad Healthcare and Research LLP ("SMO")

27 SEP 2021

जोडपत्र – २

मुद्रांक विक्री नोंदवही अनु.क्रमांक 192203 दिनांक .....

दस्ताचा प्रकार : Agreement

दस्त नोंदणी करणार आहेत का ? :– होय / ना ही

मिळकतीचे थोडक्यात वर्णन .....

मुद्रांक विकत घेणा-याचे नांव ..... Reliance Life Sciences Pvt. Ltd DALC, Rabale, Navi Mumbai

हस्ते असल्यास त्यांचे नाव, पत्ता ..... Ashish R. Ghodke

सही .....

दुस-या पक्षकाराचे नाव ..... Dr. Anand Nikalje, Aurangabad

मुद्रांक शुल्क रक्कम ..... 100/-.

परवानाधारक मुद्रांक विक्रेत्याची सही – (श्री. शंकर साहेबराव यादव) .....

परवाना क्रमांक – १२०१०३१.

मुद्रांक विक्रीचे ठिकाण/पत्ता : जिल्हा सत्र न्यायालय, ठाणे.

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is entered into, on the 2nd day of NOV 2021 between **1) Dr. Anand Nikalje, ("Investigator")** at **MGM Medical College and Hospital, Aurangabad** and **2) MGM Medical college and Hospital, Aurangabad, ("Institution") both** having its address at **N-6,** Cidco,Aurangabad,Maharashtra India and **3) Dr. Ujwala Kulkarni, Aurangabad Healthcare and Research LLP, ("SMO")** having its office at Aurangabad Health Care & Research LLP, Shop No.126, CTS No.12482/I Chetan Trade Centre, Opp. S. F School, Jalna Road, Aurangabad, Pin 431001, Maharashtra, India.
India and **4) Reliance Life Sciences Pvt. Ltd**., ("**Reliance**"), with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701.

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

PROTOCOL NUMBER:	**RLS/RES/2021/05**
PROTOCOL TITLE:	**A multicentre, prospective, open label, randomized comparative clinical trial to evaluate safety and efficacy of Reliance Life Sciences' Bevacizumab (R-TPR-023) plus standard of care and standard of care alone in COVID 19 Acute Respiratory Distress Syndrome (ARDS) Patients with non-invasive ventilation.**
STUDY PRODUCT:	**R-TPR-023 (containing Bevacizumab for intravenous infusion)**
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	***Dr. Anand Nikalje***
INSTITUTION/SITE:	***MGM hospital, Aurangabad***

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

WHEREAS, Reliance wishes to engage the Investigator, SMO and Institute to carry out Reliance's designated clinical study set out and described in protocol **RLS/RES/2021/05** and the Investigator is able and willing to conduct a clinical study (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator for conducting the Study at the Institution.

WHEREAS, the Investigator, the SMO is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study; The Institution and the Principal Investigator having each reviewed the Protocol for the Study and

sufficient information regarding the Investigational Product to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study.

WHEREAS, the institution has engaged **Dr. Ujwala Kulkarni, Aurangabad Healthcare and Research LLP, ("SMO")** a Site Management Organization having its address at **Aurangabad Health Care & Research LLP, Shop No.126, CTS No.12482/I Chetan Trade Centre, Opposite S. F School, Jalna Road, Aurangabad, Pin 431001**, **Maharashtra, India**, authorized to facilitate the clinical trial study, Pursuant to the terms of this agreement and the study. Institution shall has the right to enlist the services of the SMO as its representative agent to, manage, oversee, and otherwise perform functions related to the study as permitted by applicable law. The institute shall be responsible for activities delegated to SMO and risk associated, herein mentioned in the agreement, with SMO functioning.

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

CONFORMANCE WITH LAW AND GUIDELINES

The Institution, Principal Investigator and SMO shall carry out the Study in accordance with:

a) the Protocol as amended from time to time,
b) Good Clinical Practice;
c) the Declaration of Helsinki;
d) New Drug and Clinical Trial Rules, March 2019.
e) Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research
f) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

NOW THEREFORE, the parties have agreed as follows:

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

Helsinki, National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017), New Drugs and Clinical Trials Rules, 2019 and all applicable laws and regulations and amendment to these that arise from time to time (hereinafter "Applicable Laws and Requirements", and the approval of the Ethics Committee ('EC') of the Institution. The Investigator, SMO hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

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

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

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

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

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

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

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and Applicable Laws and Requirements", including:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Enrolment; Notices; Informed Consent; Authorization:

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

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

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

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

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

or in part from the Study or any Confidential Information, but the Investigator, SMO and Institution shall offer Reliance the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

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

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

7. Publication. The results of the Study including all obtained data will be the property of Reliance. The Investigator, SMO and Institution should not publish or communicate the data in public without written authorisation by Reliance, unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of Reliance. The Investigator, SMO and /or Institution may have access to the Study data resulting solely from his/her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by Reliance he/she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission

to any third party, for review and comment. Within these sixty (60) days period, Reliance shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Reliance desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Reliance requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patent applications before publication or release, Investigator shall take the requested action.

8. Subject Injury Reimbursement

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

9. Inspection and Debarment.

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not

required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study Subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the Subject in the signed Informed Consent Form.

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

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

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

10. Study Term and Termination.

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

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

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

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

iii) If no subjects have been enrolled, or the Investigator recruits no subjects, or recruits such a low number (less than 2 in number) of subjects that it can be assumed that the agreed number of subjects will not be reached during the planned recruitment phase;

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

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

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

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

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

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

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

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

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the Principal Investigator, the Institution, its officers, agents, and employees; and the Ethics Committee that approved the Study (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, and expenses to the extent that it relates to the death of a Subject caused by: a) the

administration of Reliance Study Product (b) a properly-performed Protocol-required procedure, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

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

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

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

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

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

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

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

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

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

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

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

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

11.2 Investigator, SMO and Institution shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their

respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain a signed Informed Consent Form in compliance with the terms of this Agreement or otherwise fails to comply with Applicable Laws and Requirements provided:

a. Investigator, SMO and Institution are promptly notified in writing of any such claim or suit;

b. Reliance cooperates fully in the investigation and defense of any such claim or suit;

c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and

d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Reliance's behalf without Reliance's advance written permission.

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

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

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

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

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

15. Publicity.

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

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

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

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

16.0 Additional Contractual Provisions.

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

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

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

16.4 During the term of this Agreement, neither Investigator, SMO nor Institution shall directly or indirectly conduct any study as set out in the protocol no. RLS/RES/2021/05 and any subsequent amendments thereto or participate in the study, which is same or similar to Reliance designated study mentioned in this Agreement, without prior written approval of Reliance.

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

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

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

16.8 Force Majeure "Neither party of this agreement shall be liable for failure to perform if the failure is attributable to any cause which is reasonably beyond the party's control including:

(i) War (declared or undeclared), riot, political insurrection, rebellion or revolution.

(ii) Acts or order if, or legislation by government prohibiting the sale of the goods covered hereby, or imposing any restriction thereof.

(iii) Epidemics, pandemics or Quarantine restrictions.

(iv) Fire, flood, explosion, earthquake, tornadoes or other natural events: and

b) Any party claiming an event or force majeure shall promptly notify the other parties in writing and provide full particulars of the cause or event and the date of first occurrence thereof as soon as possible. If conditions of

force majeure continue for a period of more than 60 days thereby affecting performance of the notifying parties, either party shall have an option to terminate this agreement by giving a 30 days' notice to the other party.

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

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

16.11 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof, shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties. The place of Arbitration shall be at Aurangabad and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

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

Please sign

ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

Reliance Life Sciences Pvt. Ltd. Navi Mumbai

By: _____

Name: Dr. Ajaykumar Yadav

Title: Head-Clinical Research

Date: 02-NOV-2021

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Dr. Anand Nikalje
M.D. (Medicine)
Associte Professor & Intensivist
MGM Medical College & Hsoptial A'bad.
Reg.No.67939

Name: Dr. Anand Nikalje

Title: Principal Investigator

Date: 03-NOV-2021

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

By: _____ 3/11/21

Name: Dr. Deepak Bhosale

Title: Professor & HOD, Pharmacology Department, MGM College and Hospital, Aurangabad

Date: _____

ACKNOWLEDGED AND AGREED BY SMO:

Aurangabad Health Care & Research LLP
Shop No. 126, CTS No. 1248211, Chetan
Trade Centre Opp. S.F. School, Jalna Road,
Aurangabad MH India,

By: _____

Name: Dr. Ujwala Sudhir Kulkarni

Title: Head- Clinical Operations, Aurangabad Health Care & Research LLP

Date: 03-NOV-2021

03/Nov/2021

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Appendix 1 to Clinical Trial Agreement

Investigator have designated **"Aurangabad Healthcare and Research LLP"** i.e. **("SMO")** as a Payee 1 to receive all the payments under Appendix A to this Agreement and "**MGM Medical College", ("Institute")** as a Payee 2 to receive payment for Archival Charges. The details of the Payee designated to receive all of the payments for the services performed under this Agreement are given below.

Payee 1:

PAYEE NAME:	**Aurangabad Healthcare and Research LLP ("SMO")**
PAYEE ADDRESS:	**Aurangabad Healthcare and Research LLP, ("SMO") a Site Management Organization having its address at Aurangabad Health Care & Research LLP, Shop No.126, CTS No.12482/I Chetan Trade Centre, Opposite S. F School, Jalna Road, Aurangabad, Pin 431001, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**ABRFA2186R**
GSTIN number	**27ABRFA2186R1ZJ**

Payee 2:

PAYEE NAME:	**MGM Medical College**
PAYEE ADDRESS:	**MGM Medical College & Hospital, N-6 CIDCO, Aurangabad, 431003,MH,India, Aurangabad, Pin 431003, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**AAATM4256E**
GSTIN number	**Not Applicable**

The payments under Appendix A will be made by account payee through e-payment in favor of the Payee 1, **Aurangabad Healthcare and Research LLP ("SMO")** and the payment for archival charges will be made in the favor of the Payee 2, **MGM Medical College, ("Institute")** in Indian Rupees.

The Parties agree that the payees designated herein is the proper payee for this Agreement, and that payments under this Agreement will be made only to the designated payee ("Payee 1" & "Payee 2").

Agreement Clauses

1) For the amount designated as per-subject budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of subjects who have completed

these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an Ethics Committee -approved Informed Consent Form, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

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

6) Matters in dispute shall be payable upon mutual resolution of dispute.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Product, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701, Maharashtra
Attn: Dr. Ajaykumar Yadav, Tel: 91-02279649408,

The Payee will have 30 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961

Appendix A

A.1. Financial Summary

SITE BUDGET SHEET					
Project Code:	**R002**				
Protocol Number	**RLS/RES/2021/05**				
Investigational Product	**Bevacizumab**				
Number of patients in study	**44**				
Principal Investigator's Name	**Dr. Anand Nikalje**				
Number of patients expected at site	**10**				
Number of visit per patient	**07**				
	Unit Cost (INR)	**No. of Units per subject**	**No. of Patients**	**Sub Total**	**Total (INR)**
Site Related Costs (A)					
Investigator Fees					**6,32,500**
Principal Investigator (PI) Fees	5000	7	10	350000	
Administrative Overhead (25%) on PI Fees	1250	7	10	87500	
Phlebotomist	400	5	10	20000	
Study coordinator	2500	7	10	175000	
Patient Related Expense					**35,000**
Travel reimbursement	500	7	10	35000	35,000
Sub-Total site related cost (A)					**6,67,500**
Local Laboratory Testing Charges (B)					**3,12,000**
12 Lead ECG	500	1	10	5000	
HRCT (Chest)	8500	1	10	85000	
X-Ray	500	1	10	5000	
Hematology	350	3	10	10500	
Bilirubin	750	2	10	15000	
Platelets	350	2	10	7000	
Creatinine	350	2	10	7000	
Serology	1600	1	10	16000	
Biochemistry	1950	3	10	58500	
UPT	250	2	10	5000	
Urinalysis	250	3	10	7500	
IL-6	2900	1	10	29000	
Procalcitonin	600	1	10	6000	
D-Dimer	2000	1	10	20000	
Ferritin	1600	1	10	16000	
RTPCR	1200	1	10	12000	
CRP	750	1	10	7500	
Sub Total Laboratory Testing Charges (B)					**3,12,000**
Budget Per Subject					**97,950**
GST (18%) on Per subject budget					**17,631**
Total Budget Per Subject including GST (18%)					**1,15,581**
Total Site Budget including GST (18%) for 5 subjects					**11,55,810**

A.2. Payment Schedule for Per Subjects

Assessment	Screening	Day 0	Day 1	Day 2	Day 7	DAY 14	Day 21	Wk 28 / Withdrawal visit	Total
Principal Investigator Fees	2500	2500	5000	5000	5000	5000	5000	5000	35000
Institute Overhead (25% on PI Fees)	625	625	1250	1250	1250	1250	1250	1250	8750
Phlebotomist	400	400			400	400		400	2000
Clinical Research coordinator Fees	1250	1250	2500	2500	2500	2500	2500	2500	17500
Patient Travel expense									
Travel Reimbursement	500		500	500	500	500	500	500	3500
Lab Test									
Haematology	350					350		350	1050
12 Lead ECG	500								500
HRCT (Chest)	8500								8500
X-Ray	500								500
Bilirubin		750			750				1500
Platelets		350			350				700
Creatinine		350			350				700
Serology	1600								1600
Biochemistry	1950					1950		1950	5850
UPT	250							250	500
Urinalysis	250					250		250	750
IL-6	2900								2900
Procalcitonin	600								600
D-Dimer	2000								2000
Ferritin	1600								1600
RTPCR	1200								1200
CRP	750								750
Per Visit Cost in INR	28225	6225	9250	9250	11100	12200	9250	12450	**97950**
Per Visit 18%GST Cost in INR	5080.5	1120.5	1665	1665	1998	2196	1665	2241	17631
Per Subject Budget in INR with 18%GST	33305.5	7345.5	10915	10915	13098	14396	10915	14691	**115581**

Note:

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

In addition to the above

- It is expected that the site will enroll **at least 10 subjects.**
- Reliance will not pay screening fees for screen failure subjects.
- Reliance will pay only Laboratory assessment cost on actual for Screen Failures as per A.1 & A.2 Payment schedule, However site need to send pre-screening documentation to Reliance before performing the actual screening.
- Ethics Committee protocol review fee will be paid as per actuals and applicable TDS will be deducted.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.1 & A.2 Payment schedule under this Agreement. However, Reliance's prior approval should be taken for such visits and procedures (on a case to case basis).

Please note the following:

- The per visit activity cost will be paid on the completion of the corresponding activity and the completion of the corresponding CRF.
- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuation will be paid through last completed "visit".
- The investigator must present a statement on letterhead for claiming any above mentioned payment under section A.1 & A.2 as per tax-compliant formats.
- If the study is prematurely terminated, the total payment to the Payee will be made for those evaluable subjects enrolled by the Investigator in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Forms. The Investigator agrees to refund any excess amount previously paid, and Reliance agrees to promptly pay any amount owing to the receipt of acceptable CRFs at Reliance, and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from Reliance. The total grant will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subject budget originally reserved for this site to other sites if site is having difficulty in enrolling and qualifying subjects.
- The archival of the study documents after the close-out visit will be the responsibility of Investigator site **"MGM Medical college and Hospital", N-6, Cidco, Aurangabad, Maharashtra, India.** One time archival charges of **INR 60,000/- for 15 years** would be provided to "Payee 2" i.e. **MGM Medical College and Hospital**. GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.
- Along with invoice raised, GSTR1 and GSTR3B forms to be shared for the entire amount claimed in invoice. Upon failure of sharing GSTR1 and GSTR3B forms, GST amount would be kept on hold and the applicable visit related payment would be released. If payee is GST defaulter, then the entire of amount of invoice will be kept on hold till the GST is paid and details are shared with Reliance.