

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("Agreement") by and between **Johnson & Johnson Private Limited** ("Sponsor"), with offices at Arena Space, Behind Majas Bus Depot, Off Jogeshwari Vikhroli Link Road Jogeshwari (E), Mumbai 400 060, Maharashtra, India

and

Tata Medical Center having their address at 14 MAR (E-W), New Town, Rajarhat, Kolkata - 700 160, West Bengal, India ("Institution") represented by Dr. P Arun (authorized representative), designated as Director

and

Dr. Jeevan Kumar ("Principal Investigator"), an employee of the Institution, working at 14 MAR (E-W), New Town, Rajarhat, Kolkata - 700 160, West Bengal, India ("Study Site")

is made and effective as of the date that the last party signs below (hereinafter "Effective Date").

(Sponsor, Institution and Principal Investigator may each be referred to herein as a "Party", and collectively as the "Parties")

Background

WHEREAS, the Sponsor has requested Institution and Principal Investigator, to conduct a clinical research study as described herein (the "Study") involving the investigational product(s) **JNJ-79635322** ("Investigational Product") according to the protocol **79635322MMY3002** titled "**A Phase 3 Randomized Study Comparing JNJ-79635322 versus Teclistamab in Participants with Relapsed or Refractory Multiple Myeloma after 1 to 3 Prior Lines of Therapy, Including an Anti-CD38 Antibody and Lenalidomide**", including any subsequent amendments thereto (collectively, the "Protocol"), which is incorporated herein by reference; and

WHEREAS, the Principal Investigator is a qualified medical practitioner and an employee of the Institution; and

WHEREAS, the Institution is qualified and equipped with adequate facilities, equipment and personnel to undertake the Study, and

WHEREAS, the Institution and the Principal Investigator have agreed to perform the Study on the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants expressed herein, the Parties agree as follows:

1. Performance of the Study.

A. Compliance with this Agreement, Protocol and Applicable Law.

- (i) The purpose of this Agreement is to conduct the Study at the Study Site of the Institution. The Institution and the Principal Investigator shall perform the Study and maintain all Study records in compliance with the Protocol, the terms and conditions of this Agreement including any amendments thereto, the Drug Controller General of India ("DCGI") and Ethics Committee ("EC") approval and all applicable legal and regulatory requirements, including without limitation, the New Drugs and Clinical Trial Rules 2019, the Drugs & Cosmetic Rules 1945

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including any amendment(s) thereof, Drugs & Cosmetics Act 1940 including any amendment(s) thereto, Guidelines of Indian Council for Medical Research, Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations 2002, Indian Good Clinical Practice of the Central Drugs Standards Control Organization, ICH Guidance for Good Clinical Practice, as well as with generally accepted conventions such as the Declaration of Helsinki and the ICH-GCP guidelines, Prevention of Corruption Act 1988 (India), Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules 2011 (as amended from time to time), Digital Personal Data Protection Act 2023, including any law, rules, guidelines, regulations that also may be introduced in the future, in relation to Study participants personal data, confidentiality and consent. For the avoidance of doubt, "Study participant" shall mean those individuals or patients who agree to and have consented to participate in the Study.

- (ii) The Institution shall comply with all applicable labour legislation and other applicable laws and undertakes to make all statutory payments on time, including but not limited to minimum wages, ESI, PF, bonus, gratuity and other benefits, as may be due. Further, the Institution undertakes to maintain all the statutory records for its personnel and the Institution will be responsible and/or liable for non-compliance of these obligations by the Institution. In the event the Institution engages personnel of any vendors to provide the services under this Agreement, the Institution shall be responsible for and shall ensure that those vendors, their employees and/or persons engaged by them, comply with all applicable labour legislation. Notwithstanding anything contained in this Agreement, the Sponsor shall not be responsible for any claims that may arise with regards to payment of statutory dues by the Institution.
- (iii) Institution and Principal Investigator will not deviate from the Protocol without the advance written consent of Sponsor, unless in the good medical judgment of the Principal Investigator, a deviation is necessary to protect the safety of the Study participants due to emergent or urgent medical conditions, in which case Principal Investigator or Institution shall notify Sponsor orally of such deviation and the reason for such deviation within twenty-four (24) hours after its occurrence and provide a written report to Sponsor within five (5) business days after the occurrence of such deviation. Neither Institution nor Principal Investigator shall conduct or facilitate any research not required by the Protocol (i) on Study participants that interferes with the conduct of the Study or (ii) on biological samples collected from Study participants that relates to the Investigational Product.

- B. Institution Staff. Institution shall ensure that all individuals engaged by Institution or Principal Investigator to conduct the Study (collectively "Institution Staff") are appropriately licensed and credentialed and shall conduct the Study in compliance with the terms of this Agreement. Institution shall be liable for any breach of this Agreement by Institution Staff.
- C. Principal Investigator. The Principal Investigator will personally supervise the Study at Institution and may not delegate this duty of Study supervision to any other individual without the Sponsor's prior written approval. Principal Investigator may, however, delegate other duties as necessary to Institution Staff in accordance with regulatory requirements and as described on a delegation log. The Institution may not replace the Principal Investigator without the Sponsor's prior written approval. If the Principal Investigator is to be temporarily absent from the Institution, the Institution shall designate an investigator qualified and trained to assume such responsibilities to temporarily supervise the Study on the Principal Investigator's behalf. The Institution shall document this designation and if applicable, report to the DCGI and/or EC, and notify the Sponsor in writing of such designation prior to its commencement. In the event that the Principal Investigator is no longer affiliated with Institution, Institution shall provide written notice to Sponsor within three (3) days of such departure. Sponsor shall have the right to approve any new Principal Investigator designated

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by Institution. The new Principal Investigator shall be required to agree to the terms and conditions of this Agreement.

- D. Principal Investigator and Institution Staff Training and Meetings. The Institution shall ensure that the Principal Investigator and applicable Institution Staff attend all trainings and meetings (including an investigator meeting) conducted by the Sponsor relating to the performance of the Study or any other applicable guidelines as determined by the Sponsor to be relevant to the conduct of the Study. If an investigator meeting requires travel, Sponsor shall provide and pay all reasonable and appropriate travel expenses, including modest lodging and meals associated with such meeting in accordance with Sponsor's travel and expense policy and guidelines as communicated when applicable.
- E. Use of Investigational Product, Equipment and Study Materials. Neither the Institution nor Principal Investigator shall make any use of the Investigational Product, documents, any other Study materials (including any comparator/combination drugs, or other product(s)) provided by or paid for by Sponsor (collectively, "Study Materials"), or biological samples collected pursuant to the Protocol other than for the performance of the Study in accordance with the Protocol and the terms and conditions of this Agreement. Equipment provided or reimbursed by Sponsor shall be returned or maintained by Institution in accordance with Exhibit A of this Agreement.
- F. Additional Study Services. Sponsor may offer additional services to assist in the conduct of the Study. Institution, in its discretion, may elect to utilize such services. In such event, the terms and conditions applicable to such services are attached hereto as Exhibit G and incorporated herein.

2. Term and Termination.

- A. Term. The term of this Agreement shall begin on the Effective Date and shall end on the later of six (6) months following final database lock. The Parties may extend the term of this Agreement by mutual written agreement.
- B. Termination. Sponsor may terminate this Agreement at any time in the exercise of its sole discretion upon fifteen (15) days prior written notice to the Institution. The Sponsor or Institution may terminate this Agreement upon written notice to the other Party (i) if either the Sponsor or Institution determine Study participant safety may be at risk, so long as in the case of termination by Institution, Sponsor is consulted regarding safety-related issues prior to Institution providing notice of termination; (ii) if the EC withdraws approval of the Study at Institution; (iii) if the Principal Investigator is no longer affiliated with Institution and the Sponsor and Institution are unable to agree on a replacement for the Principal Investigator after Institution's good faith efforts to identify a suitable replacement for a period of at least thirty (30) days.

In the event of a material breach: (i) by the Institution and/or Principal Investigator, which has not been cured within thirty (30) days of Sponsor notifying Institution and/or Principal Investigator of such breach, the Sponsor may terminate this Agreement by providing written notice to the Institution; (ii) by the Sponsor, which has not been cured within thirty (30) days of Institution notifying Sponsor of such breach, the Institution may terminate this Agreement by providing written notice to the Sponsor.

If no Study participants have been recruited at the Study Site within 6months following the initiation of the Study at the Institution, Sponsor may terminate this Agreement upon written notice to the Institution

- C. Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or

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obligations which have accrued prior thereto or any other rights or remedies provided at law or equity which any Party may otherwise have. Upon termination of this Agreement, Institution and Principal Investigator shall promptly terminate the conduct of the Study to the extent medically permissible for all Study participants.

- D. Disposition of Investigational Product, Study Materials and Sponsor Confidential Information. In accordance with Sponsor's written instructions, Institution and Principal Investigator shall account for and return to Sponsor, or otherwise dispose of or maintain in accordance with this Agreement and the Protocol, (i) any unused Investigational Product and Study Materials, (ii) any biological samples collected pursuant to the Protocol, and (iii) all Sponsor Confidential Information, as defined in the Confidentiality Section of this Agreement, at the earlier of the conclusion of the Study or early termination of this Agreement. In the event that unused Investigational Product or Study Materials is destroyed at the Institution, the Institution shall promptly provide the Sponsor with written evidence of its destruction.

3. Institutional Ethics Committee and Informed Consent.

- A. Institutional Ethics Committee. In accordance with applicable laws and regulations, the Institution and the Principal Investigator shall be responsible for obtaining EC approval of the Protocol and its amendments, informed consent document(s), Study advertisements (if any), Study recruitment procedures (e.g., announcements, financial statements, waiver of any patient authorization permitting the disclosure of confidential patient information in connection with the Study if any), all in the form as approved by Sponsor. In the event the EC requires changes in the Protocol, informed consent document(s), and/or Study advertisements, such changes shall not be implemented until the Sponsor is notified and gives its written approval. The Protocol, the informed consent document(s), and any advertising or recruitment procedures shall not be revised without the prior written agreement of the Sponsor and the EC.
- B. Informed Consent. Prior to each Study participant's enrollment in the Study, Institution and Principal Investigator shall ensure EC-approved informed consent document(s) are signed by or on behalf of each Study participant, as per the applicable guidelines, rules and regulations. The informed consent document shall include the right for the Sponsor and applicable government authorities to review source documents as defined by section 1.52 of the ICH-GCP guidelines ("Source Documents"), in all monitoring, auditing and inspection activities.
- C. Sponsor shall be responsible for the fulfillment of all other authorization formalities related to the conduct of the Study (such as submitting a clinical trial application) and related to the manufacturing, supply and/or importation of the Investigational Product and, if required, for obtaining the written authorization from the competent health authorities prior to commencement of the Study.

4. Data and Sponsor IP.

- A. Data. Sponsor shall own all data, test results, case report forms and other reports required by the Protocol to be collected or generated by the Institution, Principal Investigator, Institution Staff, or Study participants ("Data"). Without limiting the foregoing, original medical and patient records ("Medical Records") shall remain the property of the Institution or Principal Investigator.
- B. Sponsor Intellectual Property (IP). Sponsor shall own all rights to any invention or discovery arising from the conduct of the Study by Institution or Principal Investigator that relates to the Investigational Product (including but not limited to its formulation and use alone or in combination with other drugs) and/or the Protocol ("Sponsor IP"). Institution and Principal Investigator shall disclose all Sponsor IP promptly and fully to Sponsor in writing. Institution and Principal Investigator, on behalf of itself

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and Institution Staff, hereby assigns to Sponsor all of its rights, title and interest in and to Sponsor IP, including all patents and other intellectual property rights therein. Institution and Principal Investigator shall cooperate and assist Sponsor by executing, and causing Institution Staff to execute, all documents necessary for Sponsor to secure and maintain Sponsor's ownership rights in Sponsor IP. Institution warrants that Principal Investigator and any other persons involved in conducting the Study under this Agreement on behalf of Institution (including Institution Staff) are obligated to assign to Institution all inventions made in the course of their engagement by Institution or Principal Investigator, either by written agreement or by the terms of their employment.

- C. Institution Use of Data. Sponsor hereby grants to Institution and Principal Investigator a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use the Data, subject to the obligations set forth in the Confidentiality Section of this Agreement, for internal, non-commercial research and for educational purposes.

5. Confidentiality.

- A. Sponsor Confidential Information. Institution and Principal Investigator will (and will cause Institution Staff to) keep confidential and not disclose any information provided by or on behalf of Sponsor or that is generated by the Institution, Principal Investigator, and/or Institution Staff pursuant to the Protocol (other than Medical Records), including the Protocol, Data, Sponsor IP ("Sponsor Confidential Information") and the terms and conditions of the Agreement. Sponsor shall endeavor to mark tangible Sponsor Confidential Information provided to Institution and Principal Investigator as "Confidential" and to confirm verbally disclosed Sponsor Confidential Information as confidential in writing within a reasonable period of time, given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Except as provided for in this Agreement, Institution and Principal Investigator will use, and will cause Institution Staff to use, Sponsor Confidential Information only for purposes of the Study and for no other purpose.
- B. Institution Confidential Information. During the conduct of the Study by Institution under this Agreement, Sponsor and/or its representatives may be provided or otherwise gain access to information relating to Institution's business operations, policies, procedures or financial information ("Institution Confidential Information"). Neither Sponsor nor its representatives shall use or disclose Institution Confidential Information except as required to conduct and monitor the Study or to the extent required by applicable laws and regulations, including as may be required in connection with any regulatory filings related to the Study or Investigational Product.
- C. Exceptions. Sponsor Confidential Information and Institution Confidential Information (collectively, "Confidential Information") will not include information that: (i) is or becomes publicly available through no fault of the receiving Party; (ii) was known to the receiving Party without obligation of confidentiality prior to receiving it either directly or indirectly under this Agreement, (iii) is disclosed to the receiving Party, without any obligations of confidentiality, by a third party having a right to do so; or (iv) was independently developed by the receiving Party without reference to or reliance upon such information.

Institution and/or the Principal Investigator may disclose Confidential Information to its employees, its agents or consultants to the extent required on a need-to-know basis to accomplish the purposes of this Agreement provided that Institution and/or the Principal Investigator obtains prior written agreement from such employees, agents and consultants to whom disclosure is to be made to be bound by obligations of confidentiality and non-use at least as stringent as those set out in this Agreement and to not make use of such Confidential Information for any purpose other than those permitted by this Agreement. The Institution and Principal Investigator warrant the compliance of all

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such employees, agents, and consultants involved in the Study with the provisions of this Section.

- D. Compelled Disclosures. In the event that the receiving Party (or any person to whom it has transmitted Confidential Information received hereunder) is required by law or legal process to disclose any of such Confidential Information, or the terms and conditions of this Agreement, the receiving Party will (i) provide the disclosing Party with prompt notice of such event, and (ii) use reasonable efforts to ensure that confidential treatment will be afforded to the Confidential Information to be disclosed. The receiving Party shall furnish only that portion of the Confidential Information which is legally required to be disclosed.
- E. Term of Confidentiality and Non-Use. The obligations of this Section will survive for a period of five (5) years after the termination or expiration of this Agreement.

6. Publication and Registration.

- A. Publication. Sponsor shall have the right to publish, present in public or post the Data and results without approval from the Institution or Principal Investigator, and may do so in a timely manner to meet obligations for such data disclosure under the applicable laws or regulations. Institution and Principal Investigator shall have the right to publish the Data and Institution's results of the Study in accordance with this Section. Principal Investigator will submit all proposed publications along with the name of the intended scientific journal, forum or conference, to Sponsor thirty (30) days prior to submission. No publication that incorporates Sponsor Confidential Information (other than the Data and Institution's results of the Study) will be submitted for publication. At Sponsor's request Principal Investigator shall delay a proposed publication for an additional sixty (60) days to allow for filing of a patent application. If the Study is part of a multicenter study, the Institution agrees that the first publication of the results of the Study shall be made as a joint, multicenter publication, with investigators and institutions from all participating sites contributing data. If a multicenter publication is not submitted within twelve (12) months after conclusion, abandonment or termination of the Study at all sites, Institution and Principal Investigator, may publish the results from the Institution individually in accordance with this Section. Authorship of a multicenter publication shall be determined in accordance with the criteria established by the International Committee of Medical Journal Editors ("ICMJE") guidelines. If the Principal Investigator is not chosen as an author, then Sponsor may acknowledge Principal Investigator as contributing to the data collection for the study. If Principal Investigator does not wish his or her name to appear as part of the acknowledgments, he/she shall submit this request in writing to the Sponsor. All publications by Principal Investigator will include a statement that the Study was supported by Sponsor.

Institution and Principal Investigator warrant the compliance of all co-investigators and other personnel involved with the Study with the provisions of this Section 6.

- B. Study Registration. Prior to the initiation of enrollment, Sponsor shall have the right to register the Study with the website of Clinical Trial Registry of India (www.ctri.in). For potential Study participants screened as potentially eligible in the Institution's geographical area, the Institution may receive a report with the completed screen and the potential Study participant's contact information. Institution shall use reasonable efforts to contact the potential Study participant and shall document such attempt.

Protocol summaries requiring disclosure on CTRI shall always be disclosed in alignment with the CTRI dataset requirements and with the WHO International Clinical Trials Registry Platform (ICTRP) dataset requirements.

In addition to the registration on CTRI, studies will/can also be registered on:

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- www.clinicaltrials.gov; when in scope of the Sponsor's company policy,
- other clinical trial registries; when mandated by a local disclosure requirement, and
- Sponsor's websites.

7. Reporting of Data.

- A. Data Entry. Institution and/or Principal Investigator will deliver Data to Sponsor in the form and manner described in the Protocol and will comply with the Protocol, Sponsor's written instructions and any applicable laws and regulations in the use of any electronic data capture ("EDC") system provided by Sponsor. Unless otherwise instructed in writing by Sponsor, Institution and/or Principal Investigator will use reasonable best efforts to deliver the Data to Sponsor, or, if an EDC system is used for the Study, enter the Data into Sponsor's EDC system, within five (5) working days after Study visit procedures have been completed and results are available. The Institution and/or Principal Investigator shall prevent unauthorized access to the Data by maintaining physical security of any computers used to access an EDC system and shall ensure that Institution Staff maintain the confidentiality of their passwords used to access the system. Institution and/or Principal Investigator shall collect all Data in Source Documents (electronic or paper) prior to entering the Data into Sponsor's EDC system or otherwise delivering the Data as directed by Sponsor. Institution and/or Principal Investigator represents and warrants that in the event it uses an electronic medical records ("EMR") system for the collection of Source Documents, such system complies with all applicable laws and regulations.
- B. Query Response. Sponsor may issue queries to Institution and/or Principal Investigator to resolve discrepancies in the Data. Institution and/or Principal Investigator shall provide appropriate responses to such queries within five (5) working days of receipt, unless otherwise instructed by Sponsor in writing.
- C. Effect of Noncompliance. In the event the Institution and/or Principal Investigator does not deliver Data to Sponsor or respond to queries in the timeframe set forth above, Sponsor may, in its sole discretion, immediately take corrective actions. These actions may include but are not limited to, temporary suspension of screening or enrollment, additional monitoring visits, consideration of an audit, and possible termination of Institution's and Principal Investigator's participation in the Study.
- D. Adverse Event Reporting. The Principal Investigator and the Institution agree to report to the Licensing Authority as defined in clause (b) of Rule 21 of Drugs and Cosmetic Rules 1945 including any amendment thereof, EC and the Sponsor immediately but no later than twenty-four (24) hours or within such other mandatory timelines as amended from time to time and specifically mentioned under New Drugs and Clinical Trials Rules 2019 of the Drugs and Cosmetics Rules 1945, after learning of any events and all other important medical events, including but not limited to adverse reactions, as identified in the Protocol affecting any Study participant. Principal Investigator and Institution further agree to follow up such report with detailed written reports in compliance with all applicable legal and regulatory requirements, Safety/SAE management for a Study participant enrolled in the Study must be carried out in accordance with the New Drugs and Clinical Trials Rules 2019. Compensation to a Study participant in case of injury/disability/death shall be calculated pursuant to section 39 of the New Drugs and Clinical Trials Rules 2019 or as per the DCGI Directives.
- E. Archiving of Study Documents. The Institution and the Principal Investigator shall be responsible for (i) archiving the "Study Documents" for at least fifteen (15) years after the completion of the Study at the Study Site or (ii) disposing the Study Documents at the direction and written request of the Sponsor, unless the Study Documents are otherwise required to be stored or maintained by the Institution and the Principal Investigator subject to the applicable laws and regulations. The Institution and Principal Investigator agree to retain Study Documents for such longer period as

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reasonably required by the Sponsor. "Study Documents" means all documents related to the Study, required to be maintained at the Study Site including but not limited to signed informed consent documents, case report forms, Protocol, information relating to the Investigational Product excluding hospital patient records, provided that, subject to all applicable laws, regulations, codes and guidelines, the Institution and the Principal Investigator, if applicable, shall ensure that a copy of the relevant hospital patient records is included in the Study Documents. Under no circumstances shall any Study Documents be destroyed before or after the expiration of this time period of fifteen (15) years without giving the Sponsor thirty (30) days prior notice of an intent to do so and obtaining written approval of the Sponsor. In the event that the Institution or the Principal Investigator is unable to retain the Study Documents for the agreed period herein from the completion of the Study at the Study Site owing to a lack of storage space or any other reason, the Institution or the Principal Investigator shall notify the Sponsor as soon as possible, and mutually agree on alternative methods of storing the Study Documents in writing.

8. Monitoring, Inspections, and Audits.

- A. During and after the term of this Agreement, the Principal Investigator and the Institution agree to permit representatives of the Sponsor, Central Drugs Standard Control Organization ("CDSCO") and/or any other regulatory authority having jurisdiction under applicable law(s) (including, but not limited to, India, the United States Food and Drug Administration ("US FDA") and/or European Medicines Agency) to examine at any reasonable time during normal business hours:
- (i) the facilities where the Study is being conducted,
 - (ii) all Source Documents relating to the Study including original Study participant records or certified copies of such original Study participant records, if allowed under the terms of the informed consent document(s) and the applicable laws, and
 - (iii) any other relevant information necessary to confirm that the Study is being conducted in compliance with the Protocol, this Agreement and in compliance with applicable legal and regulatory requirements, including privacy and security laws and regulations and ICH-GCP.
- B. The Institution and the Principal Investigator shall immediately notify the Sponsor if (i) representatives of CDSCO and/or any other regulatory authority having jurisdiction under applicable law(s) takes regulatory action against the Institution, Principal Investigator, or EC which could materially impact the Study, or (ii) any other third-party begins an audit or inspection of Institution or Principal Investigator which attempts to expose Sponsor Confidential Information. In the event a regulatory authority schedules or, without scheduling, begins an inspection of Institution or Principal Investigator relating to the Study, Institution and/or Principal Investigator shall promptly, upon issuance, provide the Sponsor a copy of CDSCO's and/or any other regulatory authority having jurisdiction under applicable law(s) correspondence resulting from any such regulatory action or inspection. In addition, the Sponsor shall have the right to review and approve any correspondence, including any corrective action plans, by Institution planned for submission to CDSCO and/or any other regulatory authority having jurisdiction under applicable law(s) which relates to the Study or a regulatory action which could materially impact the Study prior to submission of such correspondence by Institution, Principal Investigator or Institution Staff.
- C. Corrective Action. The Institution and the Principal Investigator agree to take all reasonable actions requested by the Sponsor to cure deficiencies noted during an audit or inspection.
- D. The provisions and obligations set forth in this Section shall survive the termination or expiration of this Agreement.

9. Privacy Laws.

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- A. Each Party agrees that its collection, processing and disclosure of any data relating to an identified or identifiable individual ("Personal Information") in connection with this Agreement is and will be in compliance with the ICH-GCP guidelines and applicable data protection laws protecting Personal Information, and that it has obtained all rights and consents necessary to collect, process and disclose the Personal Information. When collecting and processing Personal Information, the Parties agree to take appropriate measures to safeguard the Personal Information, to maintain the confidentiality of Study participant's related health and medical information, to properly inform and obtain written consent (including audio video recording, if applicable) in accordance with applicable data protection laws the concerned Study participants about the collection and processing of their Personal Information, to grant Study participants access to their Personal Information, to address other data subject rights of the Study participant as per applicable laws and to prevent access by unauthorized persons.
- B. Institution and Principal Investigator will implement appropriate physical, human, technical, and organizational security control measures to ensure a level of security for Personal Information processed in connection with the Agreement that is appropriate to the risk.
- C. Institution and Principal Investigator represent, warrant, and covenant that Personal Information related to Study participants, when supplied to Sponsor, will be de-identified to replace any information that directly identifies a Study participant with a participant identification code. Principal Investigator will not provide Sponsor with the key or code that enables Study participant to be re-identified. Institution and Principal Investigator will notify Sponsor immediately if Institution and/or Principal Investigator discovers that any Personal Information concerning Study participants provided to Sponsor does not satisfy this requirement. Principal Investigator will cooperate with all Sponsor requests to mitigate any harm resulting from any such disclosure of Personal Information. In such an event, Institution and Principal Investigator will deliver corrected Personal Information to Sponsor as promptly as possible at no extra expense to Sponsor.
- D. In case of a breach by Principal Investigator and/or Institution of security, leading to an accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Information data transmitted, stored or otherwise processed ("Privacy Incident"), Institution and/or Principal Investigator will immediately after becoming aware of a Privacy Incident notify Sponsor. Such notification shall specify the nature of the Privacy Incident, the categories and approximate number of Study participants and Personal Information records impacted by such Privacy Incident. Institution and Principal Investigator agree to fully cooperate with Sponsor, investigate and resolve any such Privacy Incident and provide Sponsor any information necessary to provide notifications.
- E. Institution and Principal Investigator agree to fully cooperate with respect to any data protection impact assessments and/or prior consultations with the relevant competent authority that may be required with respect to the processing of Personal Information under the Agreement.
- F. Institution and Principal Investigator shall not engage any third-party, including any affiliate or subcontractor, as data processor (as defined under applicable data protection laws) for the performance of their respective activities under this Agreement, without Sponsor's prior written approval. In the event Sponsor consents to such third-party data processor, Institution and Principal Investigator (i) shall be responsible for ensuring that any permitted third-party data processor complies with this Agreement, the applicable data protection laws and regulations, and (ii) shall be fully liable to Sponsor for all actions of such third-party data processors.
- G. Personal Information related to Principal Investigator and any Institution Staff (e.g. name, hospital or clinic address and phone number, curriculum vitae) may be transferred to Johnson & Johnson's

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affiliates for purposes of drug monitoring, implementation, documentation and control of clinical trials, as well as for contacting them and their respective agencies around the world in case of other future studies or investigations in which they may be involved. The Parties also agree to use Personal Information provided by the Principal Investigator for managing internal studies and ensuring that contact information is contained in a faithful and complete way in other systems, in compliance with this Section.

- H. Sponsor may transmit Personal Information, including but not limited to other affiliates of the Johnson & Johnson group of companies and their respective agents worldwide. Accordingly, Personal Information may be transmitted to countries outside the Study participants country of residence, including the United States, which may provide for different data protection rules than in the Study participants country. Notwithstanding the above, Sponsor and its affiliates of the Johnson & Johnson group of companies and respective agents will apply adequate privacy safeguards to protect such Personal Information as required in the Study participant's country of residence. Personal Information may also be disclosed as required by individual regulatory agencies or applicable law, such as to report serious adverse events.
- I. Sponsor has provided certain details regarding its Personal Information handling practices concerning Personal Information related to Principal Investigator and any Institution Staff, including the data subject rights, in Exhibit D. Principal Investigator agrees to inform and obtain written consent in accordance with applicable data protection laws from all Institution Staff from whom Personal Information is collected during the course of the Study about Personal Information handling practices as specified in Exhibit D.
- J. Upon written request, the Sponsor will provide any Principal Investigator and Institution Staff with access to his or her information that is held by the Sponsor. Such Institution Staff may also request correction of information that he or she demonstrates to be inaccurate or incomplete.
- K. The Principal Investigator and the Institution shall ensure that the Sponsor may add Personal Information collected under the Study to its research databases so that it, and/or its development partner(s) with regard to the Investigational Product, may conduct additional reviews of the Personal Information in order to study the safety and effectiveness of the Investigational Product and other products and treatments, to develop a better understanding of disease, or to improve the efficiency of future clinical trials (collectively referred to as 'further research uses'). The Principal Investigator and the Institution shall obtain an informed consent document(s) signed by each Study participant in the Study that addresses such further research uses.

10. No Participation of Excluded/ Debarred Persons in Performance of this Agreement.

- A. The Institution and the Principal Investigator shall not employ, contract with or retain any person directly or indirectly to perform services under this Agreement if that person:
 - (i) is debarred by a competent health authority, or
 - (ii) has been sentenced for malpractice related to the conduct of clinical trials.
- B. In the event that the Institution or the Principal Investigator receives notice of, or otherwise becomes aware that any person identified above becomes excluded or debarred or receives notice of the threat of an action with respect to such exclusion or debarment, the Institution and the Principal Investigator shall notify Sponsor immediately and Sponsor shall have the right to immediately terminate this Agreement. Further, Institution and Principal Investigator represent and warrant that Principal Investigator and applicable Institution Staff maintain a license to practice medicine that is in good standing with relevant licensing boards. Upon written request from the Sponsor, the

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Institution and/or the Principal Investigator shall, within ten (10) calendar days, provide written confirmation that it has complied with the foregoing obligation. The obligations of this Section shall survive termination or expiration of the Agreement.

- C. Employment of Young Persons: The Institution shall comply with the Sponsor's Policy on Employment of Young Persons as set out in Exhibit E.

11. Conflicts of Interest.

- A. Institution represents and warrants Institution's, Principal Investigator's and Institution Staff's performance of the services and acceptance of compensation or reimbursement of expenses as set forth in Exhibit B is in compliance with all policies and procedures of Institution, and Principal Investigator's performance of such services does not present a conflict of interest with Principal Investigator's official duties with Institution.
- B. Institution shall require Principal Investigator to, and Principal Investigator shall, comply with all applicable disclosure obligations relating to his/her relationship with Sponsor (including, without limitation, full disclosure of the existence and nature of this relationship) that (i) may be imposed on Principal Investigator based on his/her affiliation with any formulary, pharmacy and therapeutics (P&T) committee, or committee associated with the development of treatment protocols or standards (including clinical guidelines); or (ii) are required by any health care institution, medical committee or other medical or scientific organization with which Principal Investigator is affiliated. Institution shall require Principal Investigator to, and Principal Investigator shall, abide by such committee's or medical or scientific organization's procedures, which may include recusing himself/herself from decisions relating to any product for which Principal Investigator is conducting the Study under this Agreement. If any Institution Staff are health care providers and are presently or become a member of a committee or organization as described above, Institution and Principal Investigator shall require that such Institution Staff comply with the terms of this Subsection.
- C. The Institution and Principal Investigator shall also provide all information to the Sponsor necessary to comply with any disclosure requirements mandated by any competent health authority (including, if applicable, the US FDA), relevant trade association or similar body, or other applicable national or local laws, including any information required to be disclosed in connection with any financial relationship between the Sponsor and the Principal Investigator and any other Investigator involved in the Study and any other agent or employee of the Institution and the Sponsor. This disclosure requirement may require disclosure of information involving immediate family members of those involved in the Study.
- D. The Institution and Principal Investigator represent and warrant that it is under no agreement or obligation to any third party and has no material conflict of interest that would prevent it from performing its duties and obligations under this Agreement.
- E. Position of Influence. If permitted by local laws, regulations and Institution's contractual obligations, Institution shall notify the Sponsor if the Institution or any of the directors, partners or employees of the Institution attain a position which may influence purchasing decisions of a government entity or health care related institution, owned or substantially controlled by a government or public body. Such purchasing decisions may relate, for instance, to tenders issued by health authorities or decisions of formulary committees of public hospitals. In case of such notification by Institution, the Sponsor has the right to terminate this Agreement with immediate effect by written notice. Where such notification to the Sponsor is not permitted by local laws, regulations or Institution's contractual obligations, Institution shall notify the purchase decision-maker in said government entity, institution or hospital of Institution's financial relationship with the Sponsor before any purchasing decision is

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made.

- F. Professional/Employment Rules. Where the provision of the services pursuant to this Agreement by Institution and Principal Investigator are subject to professional and/or employment rules requiring approval, the Institution and the Principal Investigator warrant that they shall obtain such approval, prior to performing the Study under this Agreement. The Institution and Principal Investigator shall provide, without delay, written evidence of the relevant approval(s).
- G. The Institution and the Principal Investigator agree and undertake that they shall observe and abide by the Sponsor's Business Conduct Policy relating to Conflict of Interest, a copy of which is set out in Exhibit F.
- H. If the Institution fails to comply with any of the provisions of this Section 11 of the Agreement (irrespective of the size, nature or materiality of such violation), such failure shall be deemed to be a material breach of this Agreement and, upon any such failure, the Sponsor shall have the right to terminate this Agreement with immediate effect upon written notice to Institution, without penalty or liability of any nature whatsoever.

12. Indemnification.

- A. Sponsor Obligations. The Sponsor shall indemnify, defend, and hold harmless Institution, its trustees, officers, agents and employees (including the Principal Investigator and co-investigators) ("Institution Indemnitees") from any and all direct losses, costs, expenses, liabilities, claims, actions and damages (collectively referred to as "Claims") based on (i) a personal injury to a Study participant directly caused by use of the Investigational Product during the course of the Study or (ii) any properly performed Protocol required procedure to which the Study participant would not have been exposed but for their participation in the Study (collectively, "Sponsor Indemnification Obligations"). Sponsor Indemnification Obligations shall not apply in the event any Claims are attributable to (i) the willful, reckless, or negligent acts or omissions or the professional malpractice of an Institution Indemnitee, (ii) the failure of an Institution Indemnitee to comply with the Protocol, any applicable laws or with Sponsor's written instructions regarding the use of the Investigational Product, or (iii) failure to comply with the Drugs & Cosmetics Act 1940 including any amendment(s) - New Drugs and Clinical Trial Rules 2019 thereof or any other applicable legal and regulatory requirements.
- B. Institution Obligations. Institution and Principal Investigator shall indemnify, defend and hold harmless the Sponsor, its trustees, officers, agents and employees ("Sponsor Indemnitees") for Claims in any way arising from or caused by (i) the willful, reckless, or negligent acts or omissions, or professional malpractice of the Institution Indemnitees, or (ii) the failure of Institution Indemnitee to comply with the Protocol, with Sponsor's written instructions regarding the use of the Investigational Product, or with any applicable legal and regulatory requirements.
- C. Sponsor Indemnitees' and Institution Indemnitees' Obligations. The obligation of the indemnifying Party hereunder shall apply only if the other Party provides prompt notification upon receipt of notice of any claim or suit, permits the indemnifying Party and its attorneys and personnel to handle and control the defense of the Claim, including pretrial, trial or settlement, and the indemnified Party fully cooperates and assists in such defense. The indemnified Party agrees that it will not settle or compromise any Claim without the prior written consent of the indemnifying Party.

13. Insurance.

- A. Institution Insurance. The Institution and the Principal Investigator shall secure and maintain in full

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force and effect through the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage for: (i) general liability; and (ii) workmen's compensation, each such insurance coverage in amounts appropriate to the conduct of Institution's and Principal Investigator's business activities and the services contemplated by the Study, and in compliance with minimum amounts of insurance required by applicable laws or regulations. For any avoidance of doubt, Institution and Principal Investigator warrant that they have sufficient financial resources to cover all liability associated with their obligations under this Agreement.

- B. Sponsor Insurance. The Sponsor shall secure and maintain in full force and effect through the performance of the Study (and following termination of the Study to cover any claims arising from the Study) insurance coverage required for clinical trials or as otherwise required by applicable law in amounts appropriate to the conduct of Sponsor's business activities and in compliance with the applicable legal and regulatory requirements.
- C. Upon request, each Party shall provide the requesting Party with certificates of insurance evidencing the required insurance coverage. The failure of any Party to secure appropriate coverage shall in no way limit the respective liability of that Party.

14. Payment.

- A. Budget and Compensation. The compensation and fees to be paid by the Sponsor for the Study is contained in the budget described in Exhibit B. Payment shall be due and payable in accordance with the schedules set forth in Exhibit B. To be eligible for payment, Study procedures must be performed in compliance with the Protocol and this Agreement, and Data must be accurate, complete, and provided to Sponsor as described in the Protocol and this Agreement. For avoidance of doubt, Institution shall be responsible for disbursing any payments received hereunder to Principal Investigator and Institution Staff. In the event a Study participant does not complete the Study, Institution shall be paid on a prorated basis according to visits completed by the Study participant and Data received by the Sponsor. In the event Sponsor makes an erroneous payment, such amount paid in error will be applied to future payments due. In the event of an erroneous payment when there are no future payments due to Institution to offset the overpayment, Institution shall promptly refund the overpayment to Sponsor in accordance with Sponsor's instructions.
- B. Reimbursement for Equipment Calibrations. Institution shall be responsible for ensuring equipment owned by Institution and utilized in the Study is serviced and maintained as per the manufacturer's recommendation or more frequently if required by Sponsor. Records verifying such equipment calibration and maintenance shall be provided to Sponsor upon request. For calibrations that are performed solely at the request of Sponsor, and that are not part of the recommended scheduled maintenance suggested by the manufacturer, Sponsor will reimburse Institution for the actual cost for each calibration.
- C. Fair Market Value and Healthcare Compliance. The Parties acknowledge and agree that the compensation and support provided by the Sponsor to the Institution pursuant to this Agreement represents the fair market value for the research services conducted by the Institution and Principal Investigator, and has been negotiated in an arms-length transaction. Accordingly, no part of any consideration paid hereunder is a prohibited payment for recommending or arranging for the referral of business, or the ordering of items or services; nor are the payments intended to induce illegal referrals of business. Nothing contained in this Agreement shall be construed in any manner as an obligation or inducement for the Institution or Principal Investigator to recommend that any person or entity purchase Sponsor's products or those of any entity affiliated with Sponsor. Institution agrees to comply with all terms in the compliance provisions in Exhibit C.

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- D. Third Party Payor Billing. Neither the Institution nor the Principal Investigator shall bill any third party for the Investigational Product or any other items or services furnished by the Sponsor in connection with the Study, or any services provided to Study participants in connection with the Study for which payment is made as part of the Study, except as may be specifically authorized by compensation standards set forth in Exhibit B.
- E. No Influence. Principal Investigator warrants that its' judgment with respect to advice to and care of each Study participant is not affected by the compensation Institution receives hereunder.
- F. Payment Upon Termination.
- (i) Services. Upon termination of this Agreement the Sponsor shall pay the Institution for services performed prior to termination of the Agreement, provided that Sponsor shall not be responsible for paying for services performed in violation of the Protocol or for Data contained in a case report form which is incomplete or inaccurate. If Sponsor has previously paid for such services, the payment shall be deducted from the final payment due under this Agreement ("Final Payment"). Further, in the event the Sponsor has prepaid any portion of payment for services that have not been performed as of the date of termination in an amount in excess of the Final Payment, Institution shall reimburse Sponsor for such unperformed service fees. No cancellation penalty payments shall apply.
- (ii) Costs and Expenses. Upon any early termination for any reason other than the breach of the Agreement by Institution, Sponsor shall reimburse Institution for pre-approved expenses and noncancellable commitments made or incurred in accordance with this Agreement, prior to Institution's receipt of a notice of termination (reduced by all applicable prior payments made by Sponsor under this Agreement). Upon receipt of such notice of termination, Institution and Principal Investigator shall use all reasonable efforts to avoid incurring additional costs and expenses. Sponsor shall not be obligated to reimburse Institution for expenses that are invoiced to Sponsor more than one hundred eighty (180) days after the termination date of this Agreement.
- G. Disclosure of Compensation. The Parties acknowledge and accept that certain countries require pharmaceutical companies to disclose information on compensation, gifts or other remuneration provided to physicians and other health care professionals if such disclosure is required by applicable local law or government authorities. In case of such request the Parties shall give each other a written notice as soon as possible. The Sponsor may report as required by law, or may voluntarily disclose or make public, information about remuneration provided under this Agreement.
15. Publicity. No Party shall use the name, logo or trademarks of any other Party for promotional purposes without the prior written consent of the Party whose name is proposed to be used except as required by law.
16. Notice. Any notices given hereunder shall be deposited in the postage prepaid, personally delivered or sent via a recognized courier service, and be directed to and addressed as follows

TO: Head, Global Clinical Operations (India)
Johnson & Johnson Private Limited
Arena Space, Behind Majas Bus Depot,
Off Jogeshwari Vikhroli Link Road
Jogeshwari (E), Mumbai 400 060, Maharashtra, India

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TO: Tata Medical Center
14 MAR (E-W), New Town,
Rajarhat, Kolkata -700 160, India

TO: Dr. Jeevan Kumar
Tata Medical Center
14 MAR (E-W), New Town,
Rajarhat, Kolkata -700 160, India

17. Dispute Resolution and Governing Law. In the event of any dispute arising between the Parties in relation to the terms of this Agreement, the Parties shall use their best endeavors to resolve the matter on an amicable basis within 30 days from the date one Party receives notice from the other Party of a dispute. This Agreement shall be governed by and construed in accordance with the laws of India without regard to any conflicts of law provisions. The Parties consent to the exclusive jurisdiction of the courts of competent jurisdiction in Mumbai for the resolution of all disputes or controversies between the Parties hereto that Parties are unable to settle amicably.
18. Warranty Disclaimer. Sponsor makes no warranty, either expressed or implied, regarding the use of the Investigational Product. Without limiting the foregoing, the Sponsor expressly disclaims any implied warranties of merchantability or fitness for a particular purpose.
19. General Provisions.
- A. Entire Agreement. It is the mutual desire and intent of the Parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. Accordingly, this Agreement (i) supersedes all previous understandings, agreements and representations between the Parties, written or oral relating to the subject matter described herein and (ii) constitutes the entire agreement and understanding between the Parties with respect to the subject matter thereof and incorporates all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, no Party makes any covenant or other commitment concerning its future action, or makes any promises, representations, conditions, provisions or terms related thereto.
- B. Conflict with Protocol. If any provision of this Agreement conflicts with a provision of the Protocol, the Protocol takes precedence on matters of medicine, science and conduct of the Study. This Agreement takes precedence in any and all other conflicts.
- C. Noncompliance, Waiver and Severability. In the event that any part of this Agreement is determined to violate local laws, rules, or regulations, the Parties agree to negotiate in good faith revisions to the provision or provisions that are in violation. In the event that a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the validity of the remaining provisions of this Agreement, and they shall continue in full force and effect. In the event the Parties are unable to agree to new or modified terms as required to bring the entire Agreement into compliance, the Sponsor or Institution may terminate this Agreement on sixty (60) days written notice to the other Parties. No waiver by any Party of a breach of any provision hereof shall constitute a waiver of any other breach of that or any other provision hereof.
- D. Headings. Headings used in this Agreement are for the purpose of convenience only and do not affect the interpretation or construction of the Agreement itself.

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- E. Agreement Modifications. Except as stated herein, this Agreement and its exhibits may not be altered, amended or modified except by a written document signed by all Parties hereto.
- F. Assignment. The Sponsor shall have the right to assign this Agreement and shall use reasonable efforts to provide written notice thereof to the Institution. Neither Institution nor Principal Investigator shall assign its rights or duties under this Agreement without the prior written consent of the Sponsor. This Agreement shall bind and inure to the benefit of the respective Parties and, subject to the foregoing limitation on assignment, their successors and assigns.
- G. Force Majeure. If the performance of this Agreement by the Parties is prevented, restricted, interfered with or delayed, (either totally or in part) by reason of any cause beyond the reasonable control of the Parties (such as acts of God, explosion, disease, epidemic, pandemic, lockdown, natural calamities, war, terrorism, insurrection, civil strike or riots lasting over thirty (30) days), the Party so affected shall, upon giving written notice to the other Party, be excused from such performance to the extent of such prevention, restriction, interference or delay, provided that the affected Party shall use its reasonable best efforts to avoid or remove such causes of non-performance and shall continue performance with the utmost dispatch whenever such causes are removed. For purposes of this Section, a lack of funds shall not be considered a cause beyond the reasonable control of the Parties.
- H. Independent Contractor. The Institution and the Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees or agents of the Sponsor. Neither Institution nor Principal Investigator shall make any claim against the Sponsor for compensation, other than that set out in Exhibit B, including but not limited to vacation pay, sick leave, retirement benefits, social security benefits, workers' compensation, disability or unemployment benefits or employee benefits of any kind.
The Institution and the Principal Investigator shall conduct the Study as independent contractors and not as partners of Sponsor and shall not be nor hold them out to be agents of Sponsor and shall have no power to bind Sponsor.
- The Principal Investigator or any other investigational staff on the Study shall not be considered, under the provisions of this Agreement or otherwise, as having an employee status with the Sponsor and the Sponsor shall not be obligated to pay or withhold any income, social security contributions, unemployment or other employee tax for amounts payable to Institution.
- The Parties have entered into this Agreement on the understanding that the Study shall involve the personal direction and effort of the Principal Investigator. Consequently, it is agreed that the work may not be assigned or delegated to any third party without the prior written approval of the Sponsor.
- I. Authorized Representatives. Each signatory to this Agreement personally represents that the individual has authority to legally bind that individual's respective Party to this Agreement.
- J. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be an original and all such counterparts together shall constitute the entire Agreement.
20. Survival. The following provisions and any other term or condition which by its nature is clearly intended to survive the termination or expiration of this Agreement will survive the termination or expiration of this Agreement: 2.D, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14.C, 14.G, 15, 17, 18, 19.A, 19.F and 20.

[Signatures follow on the next page.]

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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives.

Johnson & Johnson Private Limited

Signature_____ Date and Stamp_____
Darshana Dholakia
Senior Manager, Global Clinical Operations-India

Tata Medical Center

Signature_____ Date and stamp_____
Dr. P. Arun
CEO-Tata Medical Center

Dr Jeevan Kumar

Signature_____ Date and stamp_____
Principal Investigator

Attachments:

- Exhibit A: Equipment
- Exhibit B: Budget and Payment Schedule
- Exhibit C: Healthcare Compliance
- Exhibit D: Personal Information concerning Principal Investigator and any Institution Staff
- Exhibit E: J & J's Policy on Employment of Young Persons
- Exhibit F: Code of Conduct-Conflict of Interest
- Exhibit G: Additional Study Services

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Exhibit A**Equipment**

Sponsor will provide Institution with equipment valued at the corresponding rates(s) in the table below for use as called for in the Protocol. Upon termination of the Study at Institution, such equipment will be returned in accordance with Sponsor's instructions.

Equipment	Value in INR
eCOA	87,997/-
Thermohydrometer	3,480/-

Institution shall (i) promptly inspect any equipment provided by Sponsor following receipt and notify Sponsor upon becoming aware that any equipment is damaged or malfunctioning; (ii) use the equipment only for the purposes described in the Protocol, in accordance with the user manual, and any other instructions provided with the equipment; and (iii) restrict access to and use of the equipment to Institution Staff for whom such access and use is required to conduct the Study. Institution shall maintain such equipment in a secure manner designed to protect such equipment from unauthorized use, theft, or damage and shall exercise the same degree of care with respect to the equipment that Institution exercises with respect to its own equipment of similar type and value. If any of the equipment described herein is lost, stolen, or damaged, then Institution shall pay the reasonable cost of replacement or repair, as applicable, which shall not exceed the value set forth above.

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Exhibit B**Budget and Payment Schedule**

Protocol Number	79635322MMY3002
Protocol Version	Amendment 1

1. Per Participant Visit Totals

Attachment 1 of this Exhibit B shows which procedures and research services are included in the milestones below.

Arm A

<u>MILESTONES</u>	<u>Visit Amount (Rs)</u>	<u>Overhead 40 % (Rs)</u>	<u>Total Visit Amount (Rs)</u>
Screening	34,650	13,860	48,510
Step-up Dose 1	30,575	12,230	42,805
Step-Up Dose X (Optional, Repeatable)	28,475	11,390	39,865
Cycle 1 Day 1	24,025	9,610	33,635
Cycle 2 Day 1	24,575	9,830	34,405
Cycle 3 Day 1	22,475	8,990	31,465
Cycle 4 Day 1	24,575	9,830	34,405
Cycle 5 Day 1	22,475	8,990	31,465

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<u>MILESTONES</u>	<u>Visit Amount (Rs)</u>	<u>Overhead 40 % (Rs)</u>	<u>Total Visit Amount (Rs)</u>
Cycle 6 Day 1	24,575	9,830	34,405
Cycle X Day 1 Odd (Repeatable) (Subsequent Odd-numbered Cycles, starting at Cycle 7 Day 1)	19,675	7,870	27,545
Cycle X Day 1 Even (Repeatable) (Subsequent Even-numbered Cycles, starting at Cycle 8 Day 1)	21,675	8,670	30,345
End of Treatment	20,925	8,370	29,295
Pre-PD Follow-Up Q4W: Onsite (Repeatable)	10,825	4,330	15,155
Pre-PD Follow-Up Q4W: Phone (Optional, Repeatable) (To be paid in lieu of Pre-PD Onsite visit if visit is performed via phone or video conferencing)	1,500	600	2,100
Post-PD Follow-Up Q4M: Onsite (Repeatable)	8,525	3,410	11,935
Post-PD Follow-Up Q4M: Phone (Optional, Repeatable) (To be paid in lieu of Post-PD Onsite visit if visit is performed via phone or video conferencing)	1,500	600	2,100
Per-Subject Fee (Excluding Optional)	289,550	115,820	405,370

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Arm B

<u>MILESTONES</u>	<u>Visit Amount (Rs)</u>	<u>Overhead 40 % (Rs)</u>	<u>Total Visit Amount (Rs)</u>
Screening	34,650	13,860	48,510
Cycle 1 Day 1 (Step-up Dose 1)	26,875	10,750	37,625
Cycle 1 Day 3 (Step-up Dose 2)	22,175	8,870	31,045
Step-up Dose X (Optional,Repeatable)	22,175	8,870	31,045
Cycle 1 Day 5	22,975	9,190	32,165
Cycle 1 Day 12	11,175	4,470	15,645
Cycle 1 Day 19	11,175	4,470	15,645
Cycle 2 Day 1	22,475	8,990	31,465
Cycle 2 Day 8	11,175	4,470	15,645
Cycle 2 Day 15	11,175	4,470	15,645
Cycle 2 Day 22	11,175	4,470	15,645

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<u>MILESTONES</u>	<u>Visit Amount (Rs)</u>	<u>Overhead 40 % (Rs)</u>	<u>Total Visit Amount (Rs)</u>
Cycle 3 Day 1	22,475	8,990	31,465
Cycle 3 Day 15	11,175	4,470	15,645
Cycle 4 Day 1	22,475	8,990	31,465
Cycle 4 Day 15	11,175	4,470	15,645
Cycle 5 Day 1	22,475	8,990	31,465
Cycle 5 Day 15	11,175	4,470	15,645
Cycle 6 Day 1	22,475	8,990	31,465
Cycle 6 Day 15	11,175	4,470	15,645
Cycle X Day 1 (Repeatable)	21,675	8,670	30,345
End of Treatment	14,075	5,630	19,705
Pre-PD Follow-Up Q4W: Onsite (Repeatable)	10,825	4,330	15,155

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<u>MILESTONES</u>	<u>Visit Amount</u> <u>(Rs)</u>	<u>Overhead</u> <u>40 % (Rs)</u>	<u>Total Visit Amount</u> <u>(Rs)</u>
Pre-PD Follow-Up Q4W: Phone (Optional,Repeatable) (To be paid in lieu of Pre-PD Onsite visit if visit is performed via phone or video conferencing)	1,500	600	2,100
Post-PD Follow-Up Q4M: Onsite (Repeatable)	8,525	3,410	11,935
Post-PD Follow-Up Q4M: Phone (Optional,Repeatable) (To be paid in lieu of Pre-PD Onsite visit if visit is performed via phone or video conferencing)	1,500	600	2,100
Per-Subject Fee (Excluding Optional)	374,725	149,890	524,615

Long-term Extension

<u>MILESTONES</u>	<u>Visit Amount</u> <u>(Rs)</u>	<u>Overhead</u> <u>40 % (Rs)</u>	<u>Total Visit Amount</u> <u>(Rs)</u>
Arm A & Arm B: LTE ICF (To be paid in conjunction with Cycle X Day 1 Visit from Open-label Treatment Phase or LTE Cycle X + 1 Visit if occurring on the same day)	1,500	600	2,100
Arm A: LTE Cycle X Day 1 without Study Treatment (Repeatable)	8,275	3,310	11,585
Arm A: LTE Cycle X Day 1 with Study Treatment (Repeatable)	18,525	7,410	25,935
Arm B: LTE Cycle X Day 1 with Study Treatment (Repeatable)	18,525	7,410	25,935

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<u>MILESTONES</u>	<u>Visit Amount (Rs)</u>	<u>Overhead 40 % (Rs)</u>	<u>Total Visit Amount (Rs)</u>
Arm A: LTE End of Treatment	16,525	6,610	23,135
Arm B: LTE End of Treatment	11,775	4,710	16,485
Arm A & Arm B: LTE Survival Status Phone (Repeatable) (Q4M for Participants off Study Treatment)	1,500	600	2,100
Arm A & Arm B: LTE Survival Status Onsite (Repeatable) (Q4M for Participants off Study Treatment)	3,275	1,310	4,585

- **Local Laboratory Assessments by Third Party:** If a scheduled or unscheduled site visit cannot be performed, due to natural disaster/pandemic related restrictions, fees for the assessments below will be paid at actual cost without markup up to the maximum rates in the table below. May not be invoiced in conjunction with Items from Conditional Invoiceable Table above. Procedures should be performed in accordance with the Protocol. Processing of payment will begin upon receipt of original invoice or alternative supporting documentation in accordance with Section 5 below and approval by the Sponsor. These fees may be discontinued or increased at the discretion of the Sponsor without an amendment to the agreement. The Sponsor will notify the Institution of the discontinuation or increase in writing. Approved costs incurred for this task prior to the date of notice of discontinuation will be paid per the invoice process documented below.

<u>Item</u>	<u>Maximum Rs.</u>
Local CBC with Differential/Hematology	700
Local Chemistry	1,800
Local Direct Bilirubin	500
Local Coagulation	1,250
Local Serum B2-microglobulin	1,800
Local Quantitative Immunoglobulins (each)	1,200
Local SPEP	2,200

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Local SIFE	3,200
Local Serum FLC	1,200
Local 24-hour UPEP	550
Local UIFE	3,000
Blood Sample Collection	700
Urine Sample Collection	300

3. Conditional Study Participant Costs

- Medical treatment costs incurred as a result of the immediate treatment of an adverse event to the Subject as permitted in the Subject Injury Reimbursement Section of this Agreement must be itemized and submitted in a separate invoice to Sponsor for evaluation and approval through its internal Medical Expense Reimbursement (MER) Program. Eligible costs will be processed through the payment process outlined in this Agreement or Sponsor's clinical trial insurance as appropriate per Sponsor's internal approval process and applicable local regulations (e.g.- New Drugs and Clinical Trial Rules 2019).
- Processing of payment for Other Compensation will begin upon receipt of invoice in accordance with Section 5 below and approval by the Local Trial Manager. Other Compensation items will be reimbursed at the rates in the table below. To be eligible for reimbursement, Other Compensation items must be performed in accordance with the Protocol and outside of the timepoints delineated in Attachment 1

Conditional Invoiceable Table

<u>Item</u>	<u>Additional Information</u>	<u>Total Amount (inclusive of institutional overhead) (Rs)</u>
Participant contact (conducted via phone, video conference or electronic means)		1,000
LTE Survival Status Chart Review		1,000
Hospitalization	1. Per night fee includes hospital overhead, staffing, patient monitoring and meals. 2. Not to be invoiced in conjunction with Daily Facility Charge.	5,500

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<u>Item</u>	<u>Additional Information</u>	<u>Total Amount (inclusive of institutional overhead) (Rs)</u>
Unscheduled Visit	1. Visit cost to be paid in conjunction with any other assessments listed below when conducted outside of a regularly scheduled visit. 2. This fee covers the cost of Staff time.	6,070
Re-Consenting of a Participant		1,500
Repeat/Additional ePRO		800
Repeat/Additional ECOG Status		700
Repeat/Additional Symptom-Directed Exam	Includes Vital Signs	1,500
Repeat/Additional Vital Signs		1,000
Repeat/Additional Neurological Examination	Includes ICE Tool	2,000
Repeat/Additional 12-lead ECG	Includes Tracing, Interpretation & Report	1,500
Repeat/Additional Blood Sample Collection		700
Repeat/Additional Urine Sample Collection		300
Repeat/Additional Sample Handling and Shipping to Central Lab		450
Repeat/Additional Local CBC with Differential/Hematology	Includes local processing	700
Repeat/Additional Local Chemistry	Includes local processing for all Clinical Chemistry Labs	1,800
Repeat/Additional Local ALT/AST	Includes local processing for ALT/AST only	800
Local Direct Bilirubin	Includes local processing	500
Repeat/Additional Local Coagulation	Includes local processing	1,250
Repeat/Additional Local Serology (HBV, HCV)	Includes local processing	2,000

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<u>Item</u>	<u>Additional Information</u>	<u>Total Amount (inclusive of institutional overhead) (Rs)</u>
Local CD4	Includes local processing	2,200
Local HIV Viral Load	Includes local processing	4,500
Local HCV-RNA	Includes local processing	5,500
Local HBV-DNA	Includes local processing	3,500
Repeat/Additional Serum Pregnancy Test	Includes local processing	1,500
Repeat/Additional Urine Pregnancy Test	Includes local processing	500
Local Follicle Stimulating Hormone (FSH)	Includes local processing	2,500
Local Serum Beta-2-Microglobulin	Includes local processing	1,800
Local Serum Calcium Corrected for Albumin	Includes local processing	550
Local Serum Quantitative Immunoglobulins	Includes local processing	1,200
Local SPEP	Includes local processing	2,200
Local SIFE	Includes local processing	3,200
Local Serum FLC	Includes local processing	1,200
Local 24-hour UPEP	Includes local processing	550
Local UIFE	Includes local processing	3,000
Repeat/Additional PK, Immunogenicity Collection		1,000
Repeat/Additional PK, Immunogenicity Central Sample Processing		800
Archived Bone Marrow Sample Retrieval		3,000
Bone Marrow Biopsy		6,500
Bone Marrow Aspirate		6,500
Daily Facility Fee	Not to be paid in conjunction with Overnight Hospitalization	6,000

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<u>Item</u>	<u>Additional Information</u>	<u>Total Amount (inclusive of institutional overhead) (Rs)</u>
Moderate sedation services: initial 15 minutes of intraservice time		1,500
Moderate sedation services: each additional 15 minutes intraservice time		1,000
Physician: Pathology - Per Hour		3,000
Bone Marrow sample: Staining and preparation of the slides including shipping and handling		2,500
Local Morphology		8,000
Local Cytogenetics		26,000
Local Cytogenetics by FISH	Includes Interpretation & Report	10,500
Local Immunohistochemistry		4,500
Local Immunofluorescence		3,500
Local Flow Cytometry: First Marker		6,000
Local Flow Cytometry: Each Additional Marker		3,000
Local Flow Cytometry: Interpretation 2-8 Markers		3,500
Repeat/Additional Oral Drug Dispense		800
Repeat/Additional SC/IV Drug Dispense		1,000
Repeat/Additional Subcutaneous Drug Administration		1,500
SC via Manual Push Drug Administration		2,500
Repeat/Additional IV Infusion Drug Administration (Initial, up to 1 hour)		4,000
Repeat/Additional IV Infusion Drug Administration (Each additional hour)		1,500

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<u>Item</u>	<u>Additional Information</u>	<u>Total Amount (inclusive of institutional overhead) (Rs)</u>
MRI Whole Body		60,000
MRI Brain		35,000
CT Whole Body		30,000
CT Brain		20,000
PET-CT Whole Body		50,000
FDG-PET/CT Whole Body		65,000
Specialist Consult		5,500
Photography		1,000
Skin Biopsy		6,000
Local Lumbar Cytology	Includes local processing only	7,500
Lumbar Puncture		9,000
CSF Fluid Collection		1,000
Echocardiogram	Includes Interpretation & Report	25,000
Local B-type Natriuretic Peptide Assessment	Includes local processing	2,200
IV Fluids (Initial, up to 1 hour)		2,500
IV Fluids (Each additional hour)		2,000
Supplemental Oxygen		4,500
Local Arterial Blood Gas	Includes local processing	1,000

Supportive Medication Reimbursement: : Institution shall be reimbursed actual costs without markup to a maximum per subject for the purchase of the below listed supportive medications required per the Protocol. Institution agrees to purchase the minimum number of units of supportive medication as required to administered to such Study subject at each Protocol visit (i.e., bulk supportive drug purchases are not permitted) and to use any such purchased medications solely as required for the performance of the Study. Drug accountability for such purchased supportive medications will be performed by Institution in accordance with the Agreement and the Pharmacy Manual or Sponsor's written instructions. At the conclusion of the Study any such unused purchased supportive medications will be destroyed or returned to Sponsor in accordance with the Pharmacy Manual Sponsor's written instruction. Processing of payment will begin upon receipt of invoice in accordance with Section 5 below and approval by the Local Trial Manager. Supportive medications listed below are not permitted to be submitted for reimbursement

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to a Study subject's insurance. All such costs should be submitted to Sponsor for reimbursement for all subjects participating in the Study (i.e., invoicing for such supportive medications must be consistent for all Study subjects). The Per subject maximum allowance in the table may be increased at the discretion of the sponsor upon written notification to the Institution.

Medication	Per Subject Maximum*	Estimated Unit Price (INR)
Tocilizumab	XX	XX
IVIg	XX	XX
Dexamethasone or equivalent	XX	XX
Diphenhydramine or equivalent	XX	XX
Acetaminophen/Paracetamol or equivalent	XX	XX

4. Site Cost Table

- Local Ethics Committee/Institutional Review Board (EC/IRB) Fees:** Sponsor shall reimburse all local EC/IRB fees, including amendment review fees, based on the current fee schedule at the time of invoicing. Processing of payment will begin upon receipt of original invoice and where applicable supporting documentation detailing actual charges without mark-up and approval of the Local Trial Manager.
- Screen Failure Payments:** Sponsor shall reimburse Institution for screen failures at a rate listed for Screening Visit in the corresponding milestone tables in Section 1 above per screen failure. Processing of payment shall begin upon receipt of invoice detailing subject number and date of screen failure and in accordance with Section 5 below and upon approval by the Sponsor.

<u>Item</u>	<u>Additional Information</u>	<u>Amount (Rs)</u>
Subject Travel Reimbursement	Subject Travel Reimbursement: Sponsor shall reimburse Institution upon receipt of invoice and log (capturing Subject ID, date of visit and amount), of Rs 1,500 per Subject, per visit for the costs incurred by the Subject relating to attendance at the study visit. This allowance per visit is intended to offset the Study subject's costs associated with travel expenses and meals, where appropriate, incurred as a result of Study participation. This reimbursement shall be reflected in the Informed Consent Form as it will be provided to the Study subject. If the Subject travel reimbursement of Rs 1,500 is not sufficient to cover the study subject costs, the Institution may apply to the Sponsor for written approval of a higher amount.	1,500

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Caregiver Travel Reimbursement	Sponsor shall reimburse Institution upon receipt of invoice, with adequate documentation, for the costs associated with a Study caregiver reimbursement on actual up to maximum of Rs 1,500 per visit. This allowance per visit is intended to offset the Study caregiver's expenses (i.e., meals, tolls, parking, etc.), incurred as a result of Study participation. A caregiver may accompany the subject in the same vehicle but is not eligible for separate cab or similar shared transport service. This reimbursement shall be reflected in the informed consent form as it will be provided to the Study caregiver. Processing payment will begin upon receipt of Institution invoice. The institution shall be responsible for keeping records of reimbursement payments made to Study caregivers. Records of reimbursement payments shall be provided to the Sponsor for review upon request	1,500
Start-Up (Including Initial Submission of documents to the IRB/EC)	Start-up Payment: A non-refundable payment of Rs 100,000 (Inclusive of Institutional Overheads) for start-up related activities (e.g. preparation of regulatory documents, preparation, administration, and submission of protocol and related documents to the Institutional Review Board (IRB), etc. will be processed upon receipt of invoice from the Institution, confirmation of EC approval, and approval by the Local Trial Manager, in accordance with Section 5 below. This payment is considered full and final compensation for all activities associated with study initiation	100,000
Annual Record Retention/Document Storage	Sponsor will pay the Institution onetime cost of Rs 75,000 (Inclusive of Institutional Overheads) upon completion of the Study for archival of study documents/Record Retention based upon subject contribution from the site. Complete archival cost would be paid if randomization has happened at the site. however, in case of screening do not turn into randomization; partial or 50% of archival cost would be reimbursed. Site can raise consolidated invoice (15 X 5,000=Rs. 75,000) for archival of study documents for 15 years at the close out visit. Processing of payment will begin upon receipt of invoice in accordance with Section 5 below and approval by the Local Trial Manager.	5,000

Hotel Accommodations	1. Per night, for Study participants living more than 160 kilometers (or 2 hours) one-way from the study site. 2. Per night, when the subject must stay within 30 minutes of the Institution, and in the company of a companion, post step-up dosing and first treatment dose of JNJ-79635322. 3. Hotel must be within 8 kilometers of the study site; no resorts, spas casinos or any establishment offering entertainment. Study participant and caregiver, if applicable, must stay together in one room.	On actuals with prior approval up to a maximum of Rs. 3,000
Exceptions	Exceptions: Sponsor will review subject/caregiver requests for exceptions (e.g., unscheduled on-site visits, extended hotel stays) that fall outside of the program scope above on a case-by-case basis. Institution should submit requests for consideration to the Local Trial Manager. Approved requests will be paid in accordance with Section 5 below and approval by the Local Trial Manager.	

5. Payment Terms

Terms Table

Name	Value	Comments
Target Number of Patients	06 valid subjects	The study is being conducted under a policy of competitive enrollment. Sponsor may increase or decrease target enrollment number by providing written notice to Institution.
Visit Payment Frequency	Quarterly	Payments will include milestone payments, as well as, all invoiced and approved costs from the prior payment cycle. Costs are inclusive of any applicable overhead. Ongoing reconciliations will be performed during the course of the Study.
Invoiceable Payment Frequency	Quarterly	Payments will include milestone payments, as well as, all invoiced and approved costs from the prior payment cycle. Costs are

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Name	Value	Comments
		inclusive of any applicable overhead. Ongoing reconciliations will be performed during the course of the Study.

- a. These payments will be initiated by Sponsor via Payment Request form which will include milestone payments, as well as, all invoiced and approved costs from the prior payment cycle. Original invoices pertaining to this Study should be submitted for reimbursement to the following address:

&J AP Central Receiving Unit, Johnson & Johnson Pvt Ltd, 501, Arena Space, Off J.V. Link Road, Behind Majas Bus Depot, Jogeshwari (E), Mumbai 400060, India
AND

A copy of the invoice, together with the supporting documentation, should be emailed to JNJINDIA-GCOCCSPayments@its.jnj.com and failure to do so, might delay the payment process

Please note that invoices must contain the following information or they will be returned, delaying payment:

- Institution name
- Principal Investigator name
- Protocol number
- Invoice number and date
- Date & description of services provided
- Supporting documentation (i.e. third-party invoices, receipts)
- **Important clarification:** If applicable, the Institution and pharmacy involved in the Study shall follow the Site Blinding (Masking) Plan in order to maintain blinding for the Study. **Blinding must also be maintained in any invoices issued to Sponsor or its designee.** If unblinded information is included in such invoice it will be returned to Institution for correction and must be resubmitted, in accordance with this Agreement and applicable laws and regulations.
- Any claims for reimbursement of adverse events must be submitted in a separate invoice.
- Site Purchase Order (PO) number
- JNJ GST Number - 27AAACJ0866E1ZR
- PAN (permanent account number)
- Site (micro, small and medium enterprises) MSME number (If applicable)
- Site GST number (if applicable)
- HSN/SAC (Harmonized System of Nomenclature/ Service Account Code)

The Parties agree the payee designated below is the proper payee for this Agreement and payments under this Agreement will be made only to the following payee:

PAYEE NAME: <i>(This should be a business name and must match the business name used to file for</i>	M S Ramaiah Clinical Research Centre
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<i>your tax EIN or other tax ID number)</i>	
TAX ID NUMBER: <i>(Tax ID must exactly match the payee name indicated above)</i>	PAN NO: AAATG1779Q GST NO: 29AAATG1779Q1ZW
CONTACT INFORMATION: <i>(Name, phone number, e-mail address)</i>	Dr Vishwanath Krishnamurthy +919632611288 hod@msrcrc.com
PAYEE ADDRESS:	M S Ramaiah Medical College and Hospitals, M S Ramaiah Nagar, MSRIT Post, Bangalore560054, Karnataka, India
Institution will have thirty (30) days from the Last Subject Out (LSO) date of the Study to resolve any payment discrepancies, which have arisen during the course of the Study.	

- b. Investigator Meetings: Sponsor may recommend or require the Principal Investigator, or a Sponsor-approved Sub-Investigator designee, and a Study nurse/coordinator to attend meetings, including but not limited to an Investigator's Meeting. Sponsor shall provide and pay all reasonable and appropriate travel expenses in accordance with Sponsor's travel policy, including modest lodging and meals associated with such meetings. The parties agree that attending such meetings is reasonable and necessary to ensure all parties engaged in the Study have a clear understanding of the Protocol and its requirements. Processing of payment will begin upon receipt of invoice and supporting documentation in accordance with paragraph (a) above.
- c. The parties agree this EXHIBIT B is part of the Agreement and clarifies the payment schedule associated with this Agreement. Payments shall be made in accordance with the provisions set forth in this EXHIBIT B, with the last payment being made after the Institution completes all of its obligations under the Agreement and any exhibits thereto.

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PART- 2 TAXES

1. Notwithstanding anything contained in the Agreement, the Institution agrees that it is eligible to receive part of the consideration being the Goods and Services Tax(GST) charged in respect of the supply only after the details of such supply are uploaded by the Institution in the Form GSTR-1(or such other form as may be notified in lieu thereof from time to time), which is subsequently reflected in Form GSTR-2A(or such other form as may be notified in lieu thereof from time to time), made available electronically to the Sponsor, and are considered as matched with the corresponding details furnished by the Sponsor in its returns, in terms of the relevant provisions of the GST laws.
2. The Institution agrees to indemnify the Sponsor and keep it indemnified from and against any or all Liabilities, as defined in Explanation below, that may accrue or be demanded by a Taxing Authority, in respect of or in connection with the execution of scope of work or payments made/due to the Institution, arising under the said Agreement or anything done pursuant to the same. Any such compensation towards indemnification of Liabilities by the Institution to the Sponsor will be made within 15 days of the Liabilities accruing / demanded raised by Tax Authorities on the Sponsor either by way of issuance of demand or show cause notice or order or decree.

Explanation –

- i. 'Liabilities' in this Agreement means, "any kind of taxes / duties, disallowance of input tax credit, loss, damage, legal expenses, demands, claims, costs, interest, penalties including in relation to compliances arising under respective Taxing Statute in course of execution of scope of work"
- ii. 'Liabilities accruing / demanded' in this Agreement means, "any Liabilities proposed to be imposed either during investigation or audit or by way of issuance of show cause notice, or demanded by way of issuance of order or decree by Taxing Authority."
3. The Institution undertakes to be compliant with the anti-profiteering provision under Section 171 of the Central Goods and Services Act, 2017.
4. Other terms:
 - a. The consideration payable under this Agreement shall be exclusive of applicable Goods and Services Tax (GST) including but not limited to CGST and SGST/UTGST or IGST, and/or applicable cess, as the case may be.
 - b. The Institution shall periodically pay its tax liabilities in compliance with the GST Laws in connection with the goods / services supplied under this Agreement, such that the Sponsor is entitled to claim such credit of input tax with respect to the goods/services supplied under this Agreement as permitted under the GST Laws.
 - c. The Institution hereby undertakes that it will make timely payments of all taxes, duties, levies imposed by Government (including but not limited to GST), be responsible for filing of all necessary tax returns and undertake all necessary compliances in accordance with applicable statutory requirements under the relevant statute in relation to sum received from the Sponsor.
 - d. The Institution hereby undertakes that it will issue the tax invoices within the statutory time limits as prescribed under the GST laws and in the manner and with all the prescribed particulars as are required to be specified as per the GST Laws.
 - e. The Institution hereby undertakes that 'the address / location' of the Sponsor to which the invoice will be issued by the Institution will be as per the address mentioned in the Purchase Order (PO) issued by the Sponsor. Separately, prior to issue of an invoice, the Institution shall intimate the Sponsor about 'the address / location' of the Sponsor to which the invoice will be issued and a prior approval from the Sponsor in this respect will be taken by the Institution.
 - f. The Institution undertakes that a debit note/ supplementary invoice/credit note with appropriate references to the original invoice will be issued only in such circumstances as agreed between the parties.
 - g. Post supply of goods / services under this Agreement, the Institution shall cooperate with the Sponsor and provide any information that may be reasonably requested by the Sponsor in connection with claiming such credit of input tax under the GST Laws such as tax invoice or

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- debit note issued by the Institution or such other taxpaying document(s) as may be required as proof of payment of applicable GST by the Institution
- h. Where, transactions in respect of which the Sponsor has claimed input tax credit are notified as unmatched vis-à-vis the corresponding disclosures made by the Institution in his periodic returns, the Institution would extend necessary assistance including inter alia carrying out revision/ rectification of its returns, to enable the Sponsor to retain such claimed credits
 - i. The Institution undertakes that it has secured required GST Registration(s), which is/are in full force and effect and no action or claim is pending nor threatened to revoke or terminate such registration(s) or declare such registration(s) as invalid.
5. All fees/payments are subject to standard deductions as prescribed under the Indian Income Tax.

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Exhibit C

Healthcare Compliance

Institution represents and warrants that neither the Institution, nor any of its affiliates, nor any of their respective directors, officers, employees or agents (all of the foregoing, including affiliates collectively, "Institution Representatives") has taken any action that would result in a violation by such persons of local or international anti-bribery laws, rules or regulations applicable to either or both the Institution and Sponsor (collectively the "**Anti-Corruption Laws**").

Institution shall not, directly or indirectly, make any payment, or offer or transfer anything of value, or agree or promise to make any payment or offer or transfer anything of value, to a government official or government employee, to any political party or any candidate for political office or to any other third party with the purpose of influencing decisions related to the Sponsor and/or its business in a manner that would violate Anti-Corruption Laws.

Institution and Institution's Representatives have conducted and will conduct their businesses in compliance with the Anti-Corruption Laws, and Institution will have necessary procedures in place to prevent bribery and corrupt conduct by Institution Representatives, which includes anti-corruption training.

Institution shall maintain effective internal accounting control, and shall make sure all aspects of this Study are recorded in its books and records in an accurate, complete and truthful way and that the documents on which such books and records are based are in all major aspects accurate, complete and true. Institution shall maintain and provide Sponsor and its auditors and other representatives with access to records (financial and otherwise) and supporting documentation related to the subject matter of the Agreement as may be requested by Sponsor in order to document or verify compliance with the provisions of this Exhibit; and

Notwithstanding Section 2.B Termination and Section 12 Indemnification, if Institution fails to comply with any of the provisions of this Exhibit, such failure shall be deemed to be a material breach of the Agreement and, upon any such failure, Sponsor shall have the right to terminate the Agreement with immediate effect upon written notice to Institution without Sponsor having any financial liability or other liability of any nature whatsoever resulting from any such termination.

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Exhibit D

Personal Information concerning Principal Investigator and any Institution Staff

The Parties agree that the terms of this Exhibit shall apply to the processing of Personal Information related to Principal Investigator and Institution personnel, including [its] employees, investigators, contractors and agents performing study-related services ("Institution Staff"). The Parties agree in particular that:

- a. Principal Investigator and Institution are responsible for informing and obtaining written consent, in accordance with applicable data protection laws, from Institution Staff of the processing of their Personal Information by Sponsor, and for ensuring the lawful sharing of such information with Sponsor, including by providing Institution Staff with the privacy notice below in a manner which is enforceable under applicable laws and regulations. The privacy notice below describes how Sponsor and its affiliates process Personal Information. Any changes to the privacy notice will be agreed in writing with Sponsor.
- b. Personal Information related to Institution Staff (such as name, hospital or clinic address and phone number, curriculum vitae) may be processed by and transferred to Johnson & Johnson's affiliates for purposes of drug monitoring, implementation, documentation and control of clinical trials, as well as for contacting Institution Staff and their respective agencies around the world in case of other future studies or investigations in which they may be involved. The Parties also agree to use Personal Information provided by Principal Investigator and Institution for managing internal studies and ensuring that contact information is contained in a faithful and complete way in other systems.

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Privacy Notice – Principal Investigator and Institution Staff

Personal Information Collection

Sponsor, its affiliates and agents processing personal information on behalf of Sponsor, collect and process personal information about you. This information may come directly from you, from the Institution that you are affiliated with for purposes of this clinical research, or from public or third-party information sources.

The types of Personal Information that Sponsor collects depends on the role you have with Sponsor and/or its affiliates, as well as applicable laws, and may include the following categories of information:

- Name;
- Contact information (e.g. address, telephone number, e-mail address);
- Age and/or date of birth;
- Government identification number (if applicable);
- Training and qualifications, including information that you have a valid, active medical or professional license, as applicable, and are not debarred by a competent health authority;
- Organizational or institutional affiliations;
- Professional programs and activities in which you may have participated;
- Financial information relating to compensation and reimbursement payments for clinical trial activities;
- Engagement or interaction with Sponsor or its affiliates, or their products and services;
- Information obtained via surveys and other direct interactions with you.

How Sponsor Uses and Discloses Personal Information

Personal Information about you will be processed for the following purposes to meet Sponsor's and/or its affiliates' obligations under applicable laws and regulations, and as necessary to fulfill the Clinical Trial Agreement:

- To assess if you are suitable for acting as Principal Investigator or Institution Staff in relation to the clinical trial;
- To provide training, and access to tools and other resources that may be required for the execution of the Clinical Trial Agreement;
- To manage the clinical trial, including to monitor and audit clinical trial activities;
- To prepare and submit regulatory filings, correspondence, and communications to government authorities concerning the clinical trial;
- To conduct safety reporting and pharmacovigilance activities relating to the clinical trial;
- To publish results of the clinical trial as defined in the Clinical Trial Agreement;
- To disclose payments and other transfers of value to the Institution, Principal Investigator or other Institution Staff in order to comply with transparency reporting laws, including but not limited to the US Physician Payments Sunshine Act and implementing regulations, as well as industry codes of practice or standards to which Sponsor and/or Sponsor's affiliates are subject or
- As otherwise required under applicable laws or necessary to fulfill the Clinical Trial Agreement.

Personal information about you will be processed for the following purposes based on Sponsor's and its affiliates' legitimate interest under applicable laws:

- To consider, from time to time, potential sites and investigators for future clinical trials; and
- To conduct surveys, manage internal studies, improve processes and practices related to the

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execution of clinical trials and other activities related to medical research.

To accomplish the abovementioned purposes, Personal Information is made available to:

- Other affiliates of the Johnson & Johnson Family of Companies and their respective agents. A list of the affiliates is available at <http://www.investor.jnj.com/sec.cfm> (see exhibit 21 - Subsidiaries);
- Government authorities and ethics committees in jurisdictions around the world;
- Agents, such as contract research organizations or other third-party service providers, processing Personal Information on behalf of Sponsor.

Cross Border Transfer

Your Personal Information may be stored and processed in any country where Sponsor and its affiliates have facilities or agents, including the United States, which may provide for different data protection rules than in your country. Notwithstanding the above, Sponsor and its affiliates of the Johnson & Johnson group of companies and respective agents will apply adequate privacy safeguards to protect your Personal Information as required in your country of residence. Personal Information may also be disclosed as required by individual regulatory agencies or applicable laws, such as to report serious adverse events.

Data Subject Rights

If you would like to review, correct, update, restrict, or delete Personal Information that Sponsor may have in its systems, or if you would like to request to receive an electronic copy of your Personal Information for purposes of transmitting it to another company (to the extent these rights are provided to you by applicable laws), you may contact Sponsor as specified in the Contacting Sponsor Section below. Sponsor will respond to the request in accordance with applicable laws. Please note, however, that certain Personal Information may be exempt from requests pursuant to applicable data protection laws, or other laws and regulations.

Retention Period

Sponsor will retain your Personal Information for as long as needed or permitted considering the purpose(s) for which it was obtained. The following criteria are used to determine the proper retention period: (i) the length of time Sponsor has an ongoing relationship with you; (ii) whether there is a legal obligation to which Sponsor or its affiliates are subject; and (iii) whether retention is advisable in light of Sponsor's legal position (such as in regard to applicable statutes of limitations, litigation, or regulatory investigations).

Contacting Sponsor

The Sponsor can be contacted as specified below:

Janssen can be contacted via the Site Manager. In case the site manager has not been identified, please use the contact information as defined in the Notice Section of the agreement with the clinical site for the clinical study/trial. Consult with the Principal Investigator as necessary.

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Exhibit E

JOHNSON & JOHNSON'S POLICY ON EMPLOYMENT OF YOUNG PERSONS

Institution and Principal Investigator shall comply with Johnson & Johnson's Policy on Employment of Young People as follows:

This policy applies to the employment by Institution of persons under the age of 18 ("Young Persons") in the Institution/Study Site or providing any services to the Sponsor.

- a) Age, Health & Safety: No person under the age of 16 shall be employed. No person between the ages of 16 and 18 shall be employed unless such employment is in compliance with the health, safety and moral provisions of the International Labour Organization Convention 138 Concerning Minimum Age.
- b) Hours: No Young Person shall be required to work more than 48 hours of regularly scheduled time and 12 hours of overtime per week, nor more than six days per week.
- c) Law & Regulations: No Young Person shall be employed unless such employment is in compliance with all applicable laws and regulations concerning age, hours, compensation, health and safety.

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Exhibit F

CODE OF CONDUCT – CONFLICT OF INTEREST

The Institution and its personnel and Principal Investigator shall prevent conflict of interest and avoid circumstances pertain thereto.

Any circumstance that could cast doubt or the appearance of doubt on any employee of the Sponsor to act with total objectivity with regard to the interests of the Sponsor is considered a potential conflict of interest.

The Institution and Principal Investigator should not:

- a) Offer gifts, gratuities, entertainment, travel or hospitality to employees or relatives of the Sponsor's employees. Dinners and luncheons, which provide a continuity of business discussions, are allowed as time saving expediency. Gifts of inconsequential value, such as calendars, pens, note pads, appointment books, may be given in circumstances where such minor gifts are customary.
- b) Seek to profit or gain advantage over other Institution and Investigators from confidential information or business opportunities made known to them as a result of their relationship with the Sponsor. This includes, but is not limited to, product volumes, new products, and other personal business ventures. Institution and Principal Investigator shall not solicit from any Sponsor's employee, without a need to know, confidential information of any kind with respect to strategies, decisions, pricing, proceedings or other activities of the Sponsor.
- c) Give fees, commissions or other compensation to any Sponsor's employee or members of their family.
- d) Deliberately hide the fact that Institution is owned, controlled or represented by an employee or relative of an employee of the Sponsor. Director, officer, partner, employee, agent or consultant of the Institution, with or without compensation, who is an employee or relative of the Sponsor's employee, shall not be considered for qualification unless such circumstance had been previously disclosed and formally cleared.

In appropriate cases, after full written disclosure of the facts, an exception to the foregoing standards may be authorized by the Head – Global Clinical Operations, Asia Pacific, if it is determined that no material conflict of interest exist.

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Exhibit G

Additional Study Services

"[Intentionally left blank]."