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The Deccan Merchants Co-op. Bank Ltd.

Authorised Signatory

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of _____ ***2021*** **Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Manipal Centre For Clinical Research., located at ***Manipal*** ("**Institution**") and having its address at ***Mezzanine floor of OLD KMC library building, near KMC Dean office, Kasturba Hospital, MAHE, Manipal – 576 104*** which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr Tom Devasia as clinical practitioner in the field of ***Cardiology*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: [*name, number*] (hereafter the "Trial Drug") in accordance with a protocol entitled, "***A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease, CTQJ230A12301"*** and its potential subsequent amendments (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

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

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by Novartis.

all, as amended from time to time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments, unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Trial is to be performed has been obtained, if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 5.3 (d) provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective from 12-November-2020, when the agreement was executed via email by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

4.2 The following provisions shall survive the termination or expiry of this Agreement: Section 11 (Intellectual Property), Section 13 (Publication), Section 14 (Confidentiality)

and Section 15 (Data Privacy), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not shall make payments for new Trial Subjects.

During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drug in sufficient quantity to conduct the Trial. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

(c) not permit Trial Drug to be used for any purpose other than the conduct of the Trial in compliance with the Protocol;

(d) shall not make the Trial Drug available to any third party other than as specified in the

(e) keep full and accurate records of who dispenses the Trial Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor entrusted with the oversight of the Trial ("Novartis Monitor") at any scheduled monitoring visit;

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

(g) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Trial Drugs to Novartis.

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the qualification of each prospective Trial Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Trial Subject's suitability for participation in the Trial, and abide by Novartis's decision as to whether or not to enrol that Trial Subject;

(c) ensure that, before their participation in the Trial, the Trial Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Trial that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Trial; and (ii) the collection, processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF") in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Trial Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with; and

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (1 Subjects per month) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

Novartis will review the Trial Subjects recruitment on an on-going basis to ensure that the enrolment continues at an acceptable rate. Novartis is empowered to discontinue the Trial at Institution medical facilities in case of no or poor enrolment.

In a multicentre trial, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrolment of Trial Subjects prior to enrolment of the targeted number of Trial Subjects. Institution and Principal Investigator undertake to cease such enrolment upon request of Novartis and further undertake not to seek any compensation thereof.

5.5 **Recordkeeping**

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely fashion:

(a) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Trial Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and

disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial; and obtain Novartis approval prior to disposing of any Records that would not be owned by the patient under Applicable Laws. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

(f) Make available all Records to Novartis, its nominee or Health Authorities promptly upon request for monitoring and/or auditing purposes;

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Trial; and

(b) Make the hospital notes and Case Report Forms for each Trial Subject available for source data verification or auditing purposes by representatives of Novartis and the officers of any competent regulatory authority.

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

The Institution and the Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol. Each such notice shall be given whether or not notification was initially given by telephone. This Section shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet reflecting its transmission to Novartis.

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Trial Subject or which could result in a re-assessment of the risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such

immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per current ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the Protocol) in accordance with the trial Protocol, applicable trial procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

These reporting obligations shall survive expiration or earlier termination of the Agreement.

During the Trial Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

After completion of the Trial and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Trial procedures.

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annexure 1) and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto (but in any case within ten (10) days after the Indemnitee shall have received notice thereof);

(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis. The Institution confirms that the Principal Investigator has appropriate medical liability insurance.

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

6 & 7 floor, Inspire BKC, G Block,

BKC Main Road,

Bandra Kurla Complex , Bandra (East),

Mumbai – 400051

GST NO: 27AAACN5094N1ZY

PAN No: AAACN5094N

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

9. EQUIPMENT

9.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution, the Investigator and/or the designated Trial Staff: The Equipment shall only be used for the conduct of the Trial in accordance with the Protocol, Novartis instructions and until the Trial is completed or discontinued.

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall remain in the same condition during the Trial, with the exception of ordinary depreciation.

9.3 During the term of the Trial, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

9.4 Following completion of the Trial or upon discontinuation of the Trial for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

10. TERMINATION

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution accordingly. Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations (as set out in Annex 3), or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis all documents, Trial results and material used, generated or referred to in the course of the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution and/or Principal Investigator by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Trial or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion to any of its Affiliate or such third parties with no further payment or other obligation to the Institution and/or Principal Investigator. The Institution and/or Principal Investigator shall have no rights whatsoever therein

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1 shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

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

13. PUBLICATION

13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary or confidential information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.2 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement.

13.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Trial are made available to Novartis, whichever is later.

13.4 If the Trial is a multi-centre trial, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Trial and by Novartis.

13.5 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.6 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.7 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.8 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

14. CONFIDENTIALITY

14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Trial (collectively "**Information**") shall be treated as confidential. The Institution agrees not to disclose to any third parties or to use any Information for any purpose other than the performance of the Trial. The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

14.3 The confidentiality obligations set out above shall not apply to:

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said Information, its collection or creation did not occur during or in connection with the Trial;

(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning any Trial Subjects) shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for obtaining appropriate consent to the extent it is required by the Applicable Laws.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual competent authorities or Applicable Laws, for example to report serious adverse events and comply with drug safety laws and regulations.

15.5 Retention of data. Personal data will be kept only for the period necessary to fulfil the purposes of the collection unless a longer retention period is required or permitted by Applicable Laws.

16. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement.

17. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

18. SUBCONTRACTING

The Institution shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution of its obligations hereunder.

Whenever a subcontractor is appointed and approved by Novartis, the Principal Investigator shall be responsible for the oversight of the subcontractor's personnel as part of the Trial Staff.

19. SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the Parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

22. DEBARMENT OF INSTITUTION/PRINCIPAL INVESTIGATOR OR OTHER RESTRICTIONS FROM THE COMPETENT AUTHORITIES

(a) **Debarment**. The Institution and the Principal Investigator certify that they are not debarred or more generally under a prohibition under the relevant Applicable Laws to perform their activities. They certify that they will not use in any capacity the services of any person debarred (or otherwise under a prohibition to perform their activity) with respect to services to be performed under this Agreement. During the term of this Agreement and for three (3) years after its termination, the Institution and the Principal Investigator will notify Novartis promptly if this certification needs to be amended in light of new information. Principal Investigator also certifies that he/she does not have a revoked or suspended medical license or applicable certification.

(b) **Investigations, Inquiries, Warnings or Enforcement Actions Related to Conduct of Clinical Research**. The Institution and the Principal Investigator certify that they are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Competent Authority Action**") related to its conduct of clinical research that has not been disclosed to Novartis. The Institution and the Principal Investigator will notify Novartis promptly if it receives notice of or becomes the subject of any Competent Authority Action regarding its compliance with ethical, scientific, or regulatory standards for the conduct of clinical research, if the Competent Authority Action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

23. CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

23.1 The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified

will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

23.2 As the case may be, the Institution and the Principal Investigator shall ensure that the Principal Investigator and all Sub-Investigators involved in the Trial provide Novartis or its designee with the appropriate financial disclosures required by the U.S. Food and Drug Administration under 21 CFR Part 54, on such forms as Novartis or its designee may supply or approve. During the term of this Agreement and one (1) year following its expiration or earlier termination, the Institution and the Principal Investigator agree to assist the Sponsor or its designee in obtaining updated forms.

24. TRANSPARENCY/DISCLOSURE

24.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Trial; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

24.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services. In addition, disclosures of transfers of value in accordance with national pharmaceutical industry association codes to which Novartis is a party shall also apply.

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy. This term is mandatory for clinical studies that have sites in China as they have to be registered in the "Drug Clinical Trial Registry", and this registration includes investigator's personal data. Please inform clinicaltrial.cn@novartis.com if this term could not be included due to Local Regulations on Data Privacy so that individual consent request could be administered.

The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws or pharmaceutical industry codes applicable to Novartis. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Trial Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Trial Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

25. AUDITS AND INSPECTIONS

(a) Audit by Novartis and Records. The Institution shall grant access to its premises periodically as frequently as required for the proper performance and oversight of the Trial site in order to proceed with any and all monitoring activities required for the Trial. In addition, the Institution shall permit Novartis and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the Institution and the Principal Investigator in the course of conducting the Trial and to inspect the facilities at which the Trial is conducted to verify compliance with this Agreement, the Protocol, Applicable Laws and the accuracy of information provided in connection with the Trial. The Institution shall ensure that the Principal Investigator and other relevant staff is available for Novartis and its agents during an audit in order to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Novartis or its agents, the Institution and the Principal Investigator shall immediately correct any errors or omissions in such records and reports.

(b) Cooperation during Audit by Novartis. The Institution shall cooperate, and shall cause the Principal Investigator and the staff to cooperate, with Novartis and its contractors and agents in the event of any internal audits, upon reasonable notice and during normal business hours. The Institution shall furthermore make available to Novartis and its contractors and agents (for examination and duplication) all documentation, data and information relating to the Trial. Trial Subject medical records will be made available where appropriate for the purpose of source document verification procedures as part of the audit. The Institution also shall make the Principal Investigator and staff available to Novartis and its contractors and agents to explain and discuss such documentation, data and information. For the avoidance of doubt audits shall be supported at no cost by the Principal Investigator and investigational staff.

(c) Inspection by Competent Authority. The Institution and the Principal Investigator acknowledge that the Trial is subject to inspections by regulatory agencies worldwide, and that such inspections may also occur after completion of the Trial. In the event the Institution or the Principal Investigator receives notice that the Institution shall be the subject of an investigation or audit by any competent authority or Ethics Committee, as applicable, in relation to the Trial, it shall notify Novartis immediately within twenty four (24) hours the latest and shall obtain approval for Novartis or its agents to be present at the inspection or otherwise keep Novartis timely and constantly informed of the progress. In the event the Institution or the Principal Investigator does not receive prior notice of said inspection, it shall notify Novartis as soon as practicable after receiving knowledge of said inspection. Institution shall provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response. The Institution will promptly forward to Novartis copies of any inspection findings that the Institution receives from a competent authority or Ethics Committee, as applicable, in relation to the Trial. The Institution will provide Novartis with an opportunity to prospectively review any Institution responses to competent authority inspections in regard to the Trial.

(d) The Institution, the Principal Investigator and the staff shall cooperate with the relevant competent authorities or Ethics Committee, as applicable and comply with the legitimate requirements of an inspection. This also includes the making available (for examination and duplication) of documentation, data and information relating to the Trial. Subject medical records shall be made available where required for source document verification procedures as part of the inspection. The Institution also shall make the Principal Investigator and other staff available to the relevant competent authority to explain and discuss such documentation, data and information.

26. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The Parties hereby submit to the exclusive jurisdiction of Mumbai, India, without restricting any right of appeal.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in relation with trial procedures.

IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE Pvt Ltd.

By: _____

Name: MURUGANANTHAN K.

Title: Country Monitoring Head

Date: 09 Feb 2021

MANIPAL CENTRE FOR CLINICAL RESEARCH

By: _____

Name: Dr. Satish Rao

Title: Director, MCCR

Date: 15/03/2021

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr Tom Devasia

Title: Professor and HOD, Department of Cardiology

Date: 12/3/21

Annex1: Payment (and Equipment) Schedule

STUDY NUMBER: CTQJ230A12301

STUDY NAME: A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease

Investigator's Name: Dr Tom Devasia

Institute Name: Manipal Centre For Clinical Research

Payee Name: Manipal Academy of Higher Education

Pan Card Number: AAETM8695B

GSTIN: 29AAETM8695B1Z4

Committed Number of Study Subjects: 8

List of Equipments provided to Institution / Principal Investigator:

- Thermohygrometer- To be retrieved post DBL

Payment Terms:

1. Payment shall be made directly by Novartis
2. One time, non-refundable Administrative charges of INR 50,000/- will be provided by sponsor post CTA execution for site infrastructure and for study start up activities performed by the Study team.
3. Study Coordinator fees of INR 8,000/- will be paid monthly starting from FPFV till study closeout.
4. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be any and all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial;
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved;
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will not receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.
- Sponsor shall reimburse INR 500/- for patient's travel cost per protocol visit for which institution/PI shall provide original invoice along with the supporting receipts.
- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol, but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.

- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.
- Add provision of equipment terms E.g. leasing, Novartis own equipment lent or other ad hoc solution
- Prior to close-out, Sponsor shall provide INR 75,000/- as per EC SOP for Archival of study documents for 15 years.

The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Study Budget:

Epoch	Screening	CV Treatment Optimization				Treatment							
Visit	Screening Visit	M -3 to -1	M -2 to -1	M -1 D-30	M -1 D-1 Treatment Optimization failure	Baseline	M1	M2	M3	M4	M5	M6	M9
Investigator Grant	12000	3000	3000	3000	3000	12000	7000	7000	9000	7000	7000	8000	7000
Institutional Overhead (30%)	3600	900	900	900	900	3600	2100	2100	2700	2100	2100	2400	2100
Total Per Patient Visit	15600	3900	3900	3900	3900	15600	9100	9100	11700	9100	9100	10400	9100

M12	M15	M18	M21	M24	M27 TC	M30	M33 TC	M36	M39 TC	M42	M45 TC	M48	Study Completion Visit	Follow-Up TC
10000	7000	10000	7000	10000	4000	8000	4000	10000	4000	8000	4000	10000	12000	4000
3000	2100	3000	2100	3000	1200	2400	1200	3000	1200	2400	1200	3000	3600	1200
13000	9100	13000	9100	13000	5200	10400	5200	13000	5200	10400	5200	13000	15600	5200
Total Financial Break up for a completed patient													Rs 2,60,000/- per subject (For 28 patient visits)	

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.

You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

- □ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..
- □ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.
- □ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.
- □ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date:

Name: Dr. Tom Devasia

Principal Investigator

ANNEX 3

Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act, 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti-Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:

(i) securing any improper advantage; or

(ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state-owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records, and accounts, which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties;

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that –

(i) transactions are executed in accordance with management's general or specific authorization;

(ii) transactions are recorded as necessary

(I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and

(II) to maintain accountability for assets;

(iii) access to assets is permitted only in accordance with management's general or specific authorization; and

(iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

ANNEX 4: NOVARTIS PROFESSIONAL PRACTICES POLICY