Appendix 2
Sree Chitra Tirunal Institute for Medical Sciences and Technology
Thiruvananthapuram, Kerala
INSTITUTIONAL ETHICS COMMITTEE
APPLICATION FOR ETHICS REVIEW

Section I: ADMINISTRATIVE

Application No. _____

Date of Receipt: (dd) (mm) (yy)

(A) INVESTIGATORS: *(Attach brief CV of each investigator – not more than 2 pages each)*

Principal Investigator:
Name: Degree: Address:
Co-Principal Investigator(s)
(1) Name: Degree: Address:
(2) Name: Degree: Address:
(3) Name: Degree: Address:
Send Correspondence to: [ ] PI; [ ] PI & Co-PI No. ( ); [ ] Only to Co-PI No. ( )

(B) TITLE AND DURATION OF PROPOSED STUDY:

Study Title:
Month and year of likely commencement of the study (study can start only after IEC Approval):
Duration of the study:

(C) FUNDING:

Type of funding:
[ ] Contract/Grant [ ] Subcontract [ ] Gift/donation of drugs/devices [ ] Student Project [ ] Other (specify)
Source of funding: *(If multiple sources, give information on primary source)*
[ ] Government: *specify: ( ) Central ( ) State ( ) local* **[ ] SCTIMST** **[ ] Private Foundation:** *specify: ( ) Indian ( ) Foreign* **[ ] Industry:** *specify: ( ) Private ( ) Public ( ) Other* **[ ] Other** **[ ] No funding required**
If multiple sources of funding, give information on secondary source(s):
Status of funding:

[ ] Funding awarded/available; [ ] Funding partially awarded/available; [ ] Fund application pending [ ] No funding application made; [ ] No funding required Processing Charges paid if any: Specify Details
Name, address and tel/fax/email of (primary) sponsor with the name of contact person
Budget Details for the whole study including all components and sites(show fund allocation to various heads)
Are the study participants protected by insurance coverage? [ ] Yes [ ] No If yes, specify the amount and conditions of coverage

(D) DRUG, DEVICES AND BIOLOGICS:

Does your study involve testing of drug(s), device(s) and/or biologics? [ ] Yes [ ] No
If yes,
Are they already approved by the regulatory authorities and available in the market or are they new ones? [ ] Already approved [ ] New one
Who has prepared and/or is manufacturing the drug(s), device(s) and biologics under investigation?
Who holds the patent or IND/IDE of the drug(s), Device(s) and biologics under investigation?
What are the reasonable possibilities of the availability after the study of the investigational drug(s), device(s) and biologics for the study participants/subjects if it is found to be effective?

(E) PERMISSIONS: *(Attach copy of relevant permission letters)*

Does your study require permission from regulatory authorities? [ ] Yes [ ] No
If yes, specify the following:
(i) From Drug Controller: [ ] Yes [ ] No. Whether permission obtained: [ ] Yes [ ] No
(ii) From the ICMR: [ ] Yes [ ] No. Whether permission obtained: [ ] Yes [ ] No
(iii) From other Government department(s): [ ] Yes [ ] No If yes, specify departments: (a) Dept. Whether permission obtained: [ ] Yes [ ] No (b) Dept. Whether permission obtained: [ ] Yes [ ] No
Does your study require you to send human biological material outside India? [ ] Yes [ ] No
If yes, have you:

(i) Obtained permission of the Director, SCTIMST? [ ] Yes [ ] No
(ii) Has SCTIMST and the foreign party signed agreement/MoU for that? [ ] Yes [ ] No. *(if yes, attach a copy of the agreement/MoU)*
If study will be conducted fully or partially outside the SCTIMST, please describe the need for permission from institution(s), health centre(s), local government/administrative bodies, etc.

Budget details for the portion of the study that is conducted outside SCTIMST (show fund allocation to various heads)

Are the study participants protected by insurance coverage? [ ] Yes [ ] No
If yes specify the amount and conditions of coverage

(F) STATEMENT ON CONFLICT OF INTERESTS, IF ANY:

Describe briefly, if any, the financial and other interests of any of the investigators and/or close relative(s), with the sponsor(s) and outcome of the study.

Section II: STUDY DESIGN, SUBJECT/PARTICIPANT SELECTION AND DATA COLLECTION PROCEDURES

Note: As far as possible, complete items A to G given below using non-technical, lay language. Give full form or definition of all *abbreviations and acronyms*. The word limit prescribed is recommendatory, but as far as possible, the total length of items A to E should not exceed five pages or 1500 words.

(A) SUMMARY:

Briefly summarise the study design: 50 words.

(B) STUDY PURPOSE:

Give specific hypothesis, aim/goal and objectives: 200 words

(C) STUDY BACKGROUND:

Give summary of literature review and rationale for the proposed study: 300 words

(D) DESIGN (check all applicable)

[ ] **Phase – I**, [ ] **Phase – II**, [ ] **Phase – III**, [ ] **Phase – IV**; [ ] **Randomised** [ ] **Blinded**, [ ] **Multi-Centre**. **If Multi-Ce**ntre, is SCTIMST the coordinating centre? [ ] Yes, [ ] No [ ] **Epidemiological,** [ ] **Social Sciences,** [ ] **Survey,** [ ] **Focus Groups**, [ ] **In-depth interviews** [ ] **Case Studies**, [ ] **Observations**, [ ] **Any other (specify)** _____
Any general description of design, if needed. (50 words)

(E) SUBJECT/PARTICIPANT SELECTION

(a) TYPE: Explain who will be the subjects/participants and rationale for selecting them (specific explanation if participants will include Minor, Pregnant woman, Neonate, Person incompetent to give informed consent, Prisoner, Normal/Healthy volunteer, Student, Staff of the institute). (100 words)
(b) NUMBER: Explain about subject/participant selection (please respond to each item)**: (i) total number, (ii) rational for having that number or sample size, (iii) sampling method, if any, (iv) what proportion of them will be women, (v) from where they will be recruited and (vi) whether screening of larger number will be required.** (200 words)

(c) ELIGIBILITY: Explain Inclusion and Exclusion criteria, with specific explanation if the gender, class, caste, ethnicity, race, will be used as Inclusion and/or Exclusion criteria (50 words)
(d) RECRUITMENT: Explain who will do the recruitment of the subjects/participants and how. (50 words)

(F) DATA COLLECTION PROCEDURES:

Explain, in sequence, the conduct of study and all data collection procedures. Please include information on (a) medical/surgical procedures, tests, (b) treatment, (c) interviews, discussions, observations, (d) follow up, (e) specific locations where they will be performed and (f) by whom. Specify if procedure involves banking of biological samples, HIV testing, genetic testing. (200 words)

(G) DATA ANALYSIS:

Plan of data analysis – including by whom and how. Please mention whether data will be analysed to understand gender, caste, class, ethnicity, race differentials. (150 words)

Section III: RISKS, BENEFITS, PRIVACY AND CONFIDENTIALITY

(A) RISKS:

(a) RISKS, DISCOMFORT AND SIDE EFFECTS: Describe all possible risks and discomfort for subject/participant due to use of intervention and/or interaction procedures/data collection methods proposed. Describe expected degree and frequency of such risk, discomfort, side effect of drug etc.

(b) MINIMISATION: Describe steps you have taken or propose to take to minimise such risk, discomfort or for early recognition of side effects and their management.
(c) DATA AND SAFETY MONIORING:
i) Describe how you define adverse events in your study, how and to whom you propose to report them, and what rules you will use for stopping the study due to adverse events. Describe Data and Safety Monitoring Plan of your project. **ii) Does the project require appointment of an Internal *Data Safety Monitoring Board* (DSMB)? If Yes, suggest 5 or 6 names and addresses of the proposed DSMB members for the IEC approval.**
(d) PRIVACY AND CONFIDENTIALITY: Describe (i) how you propose to provide privacy to subjects/participants while conducting study, (ii) what level of confidentiality you propose to promise, (iii) what are the likely consequences to the subject/participant in the event of violation of confidentiality.
(e) IDENTIFIERS: Describe (i) the types of identifiable information on subject/participant you intend to collect, (ii) how do you propose to mask/remove identifiers, (iii) how do you propose to ensure safe keeping and storage of identifiable data.
(f) BENEFITS: Describe benefits to the subject/participant in participating in the study. Also describe the benefits, if any, to the society.
(g) RISK/BENEFIT: Analyse the extent to which the benefits of the study out-weigh the risk to the subjects/participants.

Section IV: INFORMED CONSENT PROCESS

(a) TYPE: (Check all applicable)
[ ] Signed witnessed consent; [ ] Signed non-witnessed consent; [ ] Witnessed Thumb Impression [ ] Non-witnessed thumb impression; [ ] Verbal consent; [ ] No consent will be obtained [ ] Consent from Surrogate will be obtained (If so, specify from whom)
(b) PROCESS: Describe (i) How, Where, When and By Whom the Informed Consent will be obtained. (ii) how much time the subject/participant will be given to consider participation and decide, (iii) describe additional plans/needs for informed consent in case the study involves special population such as minors, pregnant mothers, neonates, prisoners, etc. (iv) Describe how you will assess that information is correctly understood by the participant.
(c) INFORMATION CONTENT: Please attach Informed Consent form in English and translated local language(s). The IC form must contain the following information: (1) a statement that consent is for a study/research/experiment, (2) an explanation of the purpose of research and nature of procedure, (3) all foreseeable risks/discomforts to participants due to research, (4) any benefits to be expected, (5) alternative procedures or courses of treatment in case subject does not want to participate, (6) the extent of confidentiality protection provided, (7) explanation on provision of compensation for injury caused to participant during the study, (8) whom to contact to know more about the study and participants' rights, (9) a statement that participation is voluntary, (10) A statement that participant can withdraw consent and from the study at any time without any facing any penalty.
(d) COST AND PAYMENT: Describe the cost for participating in the study to the subject/participant. Describe plan to reimburse or compensate participant – if yes, the amount of payment proposed.

LIST OF ATTACHMENTS:

1. **Full proposal, with protocols/instruments for data collection and budget in detail.**
2. **Copy of the agreement signed by the Institute and the sponsor of the study (if applicable)**

[The attachments as mentioned in the application form above]

2.
3.
4.
5.
6.

Principal Investigator's Certification:

- I certify that the information provided in this application is complete and correct.
- I accept ultimate responsibility for the conduct of this study, the ethical performance of the project, and the protection of the rights and welfare of the human subjects who are directly or indirectly involved in this project.
- I will comply with all policies and guidelines of the SCTIMST and affiliated/collaborating institutions where this study will be conducted, as well as with all applicable laws regarding the research.
- I will ensure that personnel performing this study are qualified, appropriately trained and will adhere to the provisions of the IEC-SCTIMST approved protocol. I will not modify this IEC-SCTIMST certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

Name and Signature **Date.**

Declaration

I / we hereby certify that I am / we are fully involved in the conception & design of this study and assume full responsibility for the ethical and scientific conduct of this study.

Designation	Name	Signature	Date
PI			
Co PI			
Co Investigators			