Annexure A

CENTRAL UNIVERSITY OF TAMIL NADU, THIRUVARUR

FORMAT OF APPLICATION FOR HUMAN ETHICS CLEARANCE

1. Title of the project
2. Name and Designation of Principal Investigator with full address.
3. Name of Guide and Address (For Students' research proposal)
4. Name and Designation of Co-Investigator(s) and Address. (if any)
5. Institution where the Research will be carried out.
6. Name of the Funding Agency and Address
7. Duration of the scheme
8. Objectives of the study
9. Brief review of the literature
10. Brief summary of the methods with the sample size (number of patients to be studied and number of controls to be enrolled)
11. Inclusion and exclusion criteria for admission of subjects in the study
12. Patient information sheet (The patient information sheet must include the following information in a simple languages which can be understand by them
    a. Aims and methods of the research
    b. Expected duration of the subject participation.
    c. The benefits that might reasonably be expected from the outcome of research to the subject or to others.
    d. Any risk to the subject associated with the study.
    e. Maintenance of confidentiality of records.
    f. Provision of free treatment for research related injury
    g. Compensation of subjects for disability or death resulting from such injury;
    h. Freedom of individual to participate and withdraw from research at any time without penalty or loss of benefits to which the subject would otherwise be entitled.
13. Informed consent and the procedure for obtaining it.

Name and Signature of the Principal Investigator

Signature of Guide (For Students' research proposal)

IMPORTANT NOTES:

- The project must be accompanied by a cover letter, patient information sheet and the informed consent form to be used in the project.

- The date of meeting will be intimated to the researcher, to be present, if necessary to offer clarifications.
- Twelve copies of the research project giving following information should be submitted to the IERB, well in advance before commencement of the meeting.
- The decisions will be minuted and the Chairperson's approval will be taken in writing.
- The decision will be communicated by the Member Secretary in writing. If revision is to be made, the revised document in required number of copies should be submitted within a stipulated period of time as specified in the communication or before the next meeting.
- Suggestions for modifications, if any, should be sent by IHERB-CUTN.
- The schedule of review by the IHERB-CUTN will be communicated to the PI.

Annexure A-1

Additional documents (or information) to be included in a research proposal (where applicable), for submission to IHERB-CUTN for review.

In addition to the items required in Section IV-B for all research proposals involving human participants, the investigator shall submit additional information, such as:

1) An explanation of how the research is relevant to the health needs of the population in which it will be conducted and how it is consistent with the research agenda of the country where it will be conducted, or, in the absence of such relevance or consistency, a justification for why it is appropriate to conduct the research in that country.

2) A copy of any instruments being used to collect data, such as questionnaires that will be administered, including translations into the local language.

3) Detailed information about how biological materials or other data from the research will be collected, preserved, transported and stored, and the conditions under which such items will be released in the future to people outside the present research project. A copy of the information that will be provided to participants about such future use and whether, and if so how, their consent will be sought before such use outside the present project would occur, and whether they will be provided with information derived from such future studies.

4) A description of the plans that have been made and any formal agreements that have been negotiated with representatives of the participant population or officials of the country where the research will occur. The description should include plans to continue to provide any drug, device, vaccine or other product being tested, or any other service, to any participants who are benefiting from such intervention at the conclusion of their participation in the research or a justification for the absence of such plans.

5) A description of the plans that have been made and any formal agreements that have been negotiated with officials of the country where the research will occur (or with any agency providing services to the members of the population from which participants will be drawn or to residents of that country) to make any drug, device, vaccine or other product being tested,

or any other service, available at an affordable cost to the population or residents once such drug, device, vaccine or other product has been approved for use by the relevant authorities or a justification for the absence of such plans.

6) Complete information on the regulatory status of any drug, vaccine or device being studied, including an adequate summary of all safety, pharmacological, pharmaceutical and toxicological data available on the product and of the clinical experience to date.

7) Where the research involves a risk of injury (such as research on an infectious agent or research involving venipuncture), a description of the means that will be used to avoid or minimize risks to the investigator and other persons conducting the research.

8) Where the research involves an infectious agent or a vaccine, a description of any risk to people who are not directly involved in the research but who might be exposed to risk through contact with participants or otherwise.

9) A description of the arrangements that have been put in place to address any needs that will arise should harm occur to the people conducting the research or to other people who might be harmed in the foreseeable future.

10) Details concerning any Data Safety and Monitoring Board (DSMB) or comparable body that will be established to oversee the research, including information on who will appoint the DSMB, to whom it will report (including the circumstances for which it will provide specified information to the Committee), and the decision rules it will use in deciding or recommending that the research should be altered or halted.