Annexure 1

List of ethical guidelines which will be referred to by the Multi-institutional Ethics Committee

a. Guidelines for Social Science Research in Health drafted by the National Committee for Ethics in Social Science Research in Health, 2000
b. Ethical guidelines for Biomedical Research on Human Participants drafted by the Indian Council of Medical Research, 2006
c. Ethical Principles for Medical Research Involving Human Subjects, World Medical Association Helsinki Declaration, last amended in 2004
d. Ethical Principles and Guidelines for the protection of human subjects of research (The Belmont Report), 1979

Annexure 2

Confidentiality / Conflict of Interest Agreement Form

In recognition of the fact, that I…..*member's name, and his/her affiliation*……..herein referred to as the "Undersigned", has been appointed as a member of the *Multi-institutional Ethics Committee* and has been asked to assess research studies involving human subjects in order to ensure that they are conducted in a humane and ethical manner, with the highest standards of care according to the applied national, local regulations, institutional policies and guidelines;

Whereas, the appointment of the undersigned as a member of the ... *Multi-institutional Ethics Committee* is based on individual merits and not as an advocate or representative of a home province/territory/ community nor as the delegate of any organization or private interest;

Whereas, the fundamental duty of an IEC/IRB member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits of the submissions under review;

Whereas, the *Multi-institutional Ethics Committee* must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The undersigned, as a member of the *Multi-institutional Ethics Committee* is expected to meet the same high standards of ethical behavior to carry out its mandate.

This Agreement thus encompasses any information deemed Confidential or Proprietary provided to the Undersigned in conjunction with the duties as a member of the *Multi-institutional Ethics Committee*. Any written information provided to the Undersigned that is of a Confidential, Proprietary, or Privileged nature shall be identified accordingly.

As such, the Undersigned agrees to hold all Confidential or Proprietary trade secrets ("information") in trust or confidence and agrees that it shall be used only for contemplated purposes, shall not be used for any other purpose or disclosed to any third party. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the IEC/IRB.

The Undersigned agrees not to disclose or utilize, directly or indirectly, any Confidential or Proprietary information belonging to a third party in fulfilling this agreement. Furthermore, the Undersigned confirms that his/her performance of this agreement is consistent with the institute's policies and any contractual obligations they may have to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist but has faith in the IEC/IRB and its Chairperson to manage the conflict issues so that the ultimate outcome is the protection of human subjects.
It is the policy of the *Multi-institutional Ethics Committee* that no member may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the IEC/IRB.

The Undersigned will immediately disclose to the Chairperson of the ...*INSTITUTE*.... IEC/IRB any actual or potential conflict of interest that he/she may have in relation to any particular proposal submitted for review by the Committee, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an IEC/IRB member has a potential conflict, the investigator may request that the member be excluded from the review of the protocol. The request must

be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the EC member(s) in question.

The Committee may elect to investigate the applicant's claim of the potential conflict. When a member has a conflict of interest, the member should notify the Chairperson and may not participate in the IEC/IRB review or approval except to provide information requested by the Committee.

Examples of conflict of interest cases may be any of the following:

- A member is involved in a potentially competing research program.
- Access to funding or intellectual information may provide an unfair competitive advantage.

A member's personal biases may interfere with his or her impartial judgment

Agreement on Confidentiality and Conflict of Interest

Please sign and date this Agreement, if the Undersigned agrees with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the Multi-institutional Ethics Committee. A copy will be given to you for your records.

In the course of my activities as a member of the IEC/IRB, I may be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information; subject to applicable legislation, including the Access to Information Act, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Committee's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Committee duties) to the Chairperson upon termination of my functions as a Committee member.
Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I, ……., have read and accept the aforementioned terms and conditions as explained in this Agreement

_____
Undersigned Signature

_____
Date

_____
Chairperson (*Multi-institutional Ethics Committee)*

_____
Date

Annexure 3

Application Forms

Multi-Institutional Ethics Committee
APPLICATION FOR ETHICS REVIEW

General guidelines to researchers

1. ***All proposals must be complete***, based on the checklist given for each stage of review. Please include a covering note listing all the items on the checklist, so that you are assured that the checklist is complete. Please present the material in the suggested order, to help the IEC follow a standard procedure. Please ensure that you have inserted page numbers to make it easy for the IEC refer to various sections during its discussion. It is your responsibility to ensure that the submission is complete. Sending proposals in bits and pieces can cause confusion and can also result in errors. For this reason, incomplete proposals will not be sent for review.
2. ***The Peer Review Committee must have scrutinised*** and approved the proposal, at all the appropriate stages, before it is sent for IEC review. Please send a copy of all documents that have been sent for IEC review to the relevant **PRC** member.
3. ***All revised proposals must include*** the original proposal, the IEC's comments and requests at the time of the first review, your response to the IEC, and an indication of where these responses are included (refer to page numbers). If you have any doubts about the IEC's comments, please clarify them with IEC members during the review itself.
4. ***In general, proposals will be considered only at scheduled IEC meetings*** (the schedule is available on the website). Short-term projects needing expedited review will be considered at special meetings. The criteria for emergency/interim review are given at the end of this document.
5. ***Completed submissions should reach the IEC Secretariat*** at least three weeks before the IEC meeting at which they will be discussed, in order to allow the Secretariat to scrutinise them and also to give sufficient time to IEC members to read the proposal properly. Please append any material that is to be translated (such as research protocols and consent forms) to the documents sent to the IEC.
6. ***All correspondence regarding review is between the researcher designated for that project and the IEC Secretariat*** and will not include other researchers or individual IEC members.
7. ***Revisions should not be made once a proposal has been submitted*** for IEC review. Any revisions, including in the proposal itself, the sampling method, the interview schedule and the information sheet and consent forms, should be made ***after*** the IEC reviews it, and should be based on the IEC's suggestions. Sending revised submissions increases the work of the Secretariat and can result in the wrong proposal being sent for review. The IEC cannot conduct an effective review if it must take post-submission revisions into consideration at the meeting itself, and will have to postpone discussion of the proposal.
8. ***For each proposal one researcher is expected to be available*** to clarify the IEC's queries during the meeting. This researcher is expected to be responsible for the proposal; it is not acceptable to indicate that the question is best answered by another researcher. If for unavoidable reasons the researcher is not available for the IEC meeting s/he will be permitted to present responses over the telephone. This, however, may be done only in exceptional circumstances.

9. ***Proposals will be reviewed at the IEC meeting***; minor revisions may be approved by circulation among the members appointed for a particular proposal. Major revisions will be discussed at the next IEC meeting.
10. ***Researchers will receive the formal decision on their proposals*** approximately one week after the meeting.

What your submission should contain

Checklists have been developed for each stage of research. These checklists have been developed by the IEC in order to systematize the ethics review process, by ensuring that all the necessary documents are presented in a standardised manner. Specific requirements in the checklist help you identify potential ethical problems in your work and look for ways to address them. You can get a better understanding of ethical principles in research by going through the guidelines listed in Annexure 1 accompanying the Standard Operating Procedures

CHECKLIST FOR PHASE I

Section I:ADMINISTRATIVE

You are expected to give a broad assessment of the ethical issues involved in the proposed research. The objectives of an ethics review at this stage are:

- **To help researchers articulate the ethical issues** involved in the area of enquiry, especially if it is a new area.
- **To understand the nature of the ethical issues** involved
- **To ensure that the ethical issues are not so great** that the research must be abandoned.

Application No. _____

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

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

Principal Investigator:	
CENTRE	
Name:	Address:
Co-Principal Investigator(s)	
(1) Name:	Address:
(2) Name:	Address:
(3) Name:	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:
Duration of the study:

(C) FUNDING:

Type of funding: **Externally funded:** **(name of sponsor)** **Internally funded:** **Student/internship project**
Status of funding:
[ ] Funding awarded/available; [ ] Funding partially awarded/available; [ ] Fund application pending [ ] No funding application made; [ ] No funding required
Budget Details (show fund allocation to various heads)

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

Does your study require permission from regulatory authorities? [ ] Yes [ ] No
If yes, specify the following:
(i) From Government department(s)/bodies: [ ] Yes [ ] No If yes, specify details: (a) Dept./Bodies Whether permission obtained: [ ] Yes [ ] No
If yes, have you obtained permission:
Does your study require approval from any other institution? [ ] Yes [ ] No If yes, have you obtained permission?

(E) 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), participants, collaborating institutions and outcome of

the study.
(F) OUTCOME OF THE SCIENTIFIC REVIEW
State in brief the comments of the Scientific Review Committee: (please attach minutes, if finalised)
Is prior approval by the Institutional Ethics Committee a prerequisite for receiving funding?
For short term projects (less than three months), please specify the stages of review being requested

Section 2: STUDY DESIGN, SUBJECT/PARTICIPANT SELECTION AND DATA COLLECTION PROCEDURES

(A) SUMMARY:

Briefly summarise the study design: 50 words.

(B) STUDY PURPOSE:

Give specific hypothesis, aim/goal, research questions 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)

[ ] **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 any vulnerable persons or groups, such as person incompetent to give informed consent, students, prisoners, inmates of a closed institution, inpatients, displaced persons, persons engaging in activities recognised as illegal, survivors of violence, lower level staff of an institution (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 vulnerable persons, as defined above (v) how will they be identified (vi) whether persons other than those finally included in the sample will be enumerated, briefly interviewed or screened**(200 words)
(c) ELIGIBILITY: Is there any exclusion/inclusion criteria? Please state (50 words)
(d) RECRUITMENT: Who will be responsible for recruitment of the participants? Who will be responsible for obtaining informed consent from the participants? (50 words)

(F) DATA COLLECTION PROCEDURES:

Explain, in sequence, the conduct of study and all data collection procedures. Please include information on (a) sampling (b) (c) interviews, discussions, observations, (d) follow up, (e) specific locations where they will be performed and (f) by whom. (g) number of sessions for data collection planned for each participant (h) duration of each session (i) Specify if any information is going to be tape-recorded, video-graphed. (j) Specify if it involves obtaining of any personal information, biological samples, medical examination or tests. (200 words)
Please describe who will be responsible for the collection of data. How will they be recruited. What kind of training and skill enhancement will be provided by the institution to them What will be the mechanism for monitoring the quality of data collection in the field

(G) DATA ANALYSIS:

Plan of data analysis – including by whom and how.Please specify whether any markers of identification will be retained. If so, in what form will these markers be presented (name of location, name of persons, name of institutions, description of sites and events, profiles of individuals and groups, etc). Please mention the main categories to be used for analysis (caste, gender, class, etc). (150 words)

Section 3: RISKS, BENEFITS, PRIVACY AND CONFIDENTIALITY

(A) RISKS:

(a) Do you anticipate any risks to any participant (physical, psychological, social and economic)?
(b) MINIMISATION: What steps are you taking to mitigate these risks? How do you balance the potential risks against the possible benefits?
(c) DATA AND SAFETY MONITORING:
i) Do you anticipate any harm which is likely to affect the participants? If so, what the frequency and severity of this harm? How do you intend to monitor the situation? What is your plan for withdrawing or curtailing the study due to harm that may come to participants? **ii) Does the project require appointment of a standing advisory sub-committee for ongoing ethical guidance?**
(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 4: 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.

Section 5: PUBLICATION AND DISSEMINATION OF RESULTS/FINDINGS

How do you plan to share your research findings with the participants, with the community, with society at large?
How will you be disseminating the results/findings to the participants or participating communities?

REQUIRED LIST OF ATTACHMENTS:

1. Full proposal, with protocols/instruments for data collection and budget in detail.
2. The letter of introduction/information sheet (in English and the local language)
3. The informed consent form (in English and the local language)
4. The plan of analysis linking each item in the methodology and section in the schedules with the various objectives of the research.

[The attachments as mentioned in the application form above]
1.
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 Multi-institutional Ethics Committee certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

Name and Signature **Date.**

CHECKLIST FOR PERIODIC/ANNUAL REVIEW

This stage of review is meant to:

- **Assess** the strategies to address the ethical concerns in the research that had been identified at the phase II review;
- **Report** on any unanticipated ethical problems that arose in the field, and to decide on whether corrective measures are needed, and
- **Document** the lessons learned, for future researchers.

Section I: ETHICAL ISSUES ENCOUNTERED IN PROTECTION OF RIGHTS OF PARTICIPANTS

a. Please document your experiences in seeking informed consent from research participants. Was it written or verbal? Did you have to get assent or consent from minors? Did you have to take post-interview consent? What differences did you note across the different categories of the study population (for example rural and urban or tribal and non-tribal)?

b. Did you have to go through gatekeepers (such as community leaders, husbands or other elders, medical professionals) to get participants' informed consent? Did you face any ethical problems while seeking consent and how did you address them?

c. Please document what you did to ensure voluntary participation. Did you feel that there was any element of coercion when seeking participation?

d. Please document how you maintained participants' privacy, anonymity and confidentiality.

SECTION II: EXPERIENCE OF ANTICIPATED/UNANTICIPATED RISKS OR HARMS

e. What was the average time taken to complete interviews with individual research participants?
f. Were there circumstances or events which posed significant risks or resulted in harm to the participants?
g. Did the communities and research participants indicate the need for health-related information and health care? How did you respond to these needs? Did you provide any assistance to the community that went beyond the purview of the project activities and commitments made to participants?
h. Was any member of the research team experience exposed to any risk or did s/he experience any harm? If so, what was the nature of that risk/harm? What did the team do in order to deal with the situation?

SECTION III: PROFESSIONAL COMPETENCE, ETHICS AND CONDUCT OF STUDY

a. Do you think field investigators and new recruits received adequate and appropriate training, both on methodology and on research ethics?? Did they receive the necessary feedback, infrastructural facilities, monetary compensation, emotional support and debriefing?

b. Were there any instances of data fabrication or other research fraud by field investigators or the core research team? If so, how did you address this?
c. Did the different values of researchers and research participants result in any conflict? How did you address them? Did this affect the quality of data? Did this affect the team's morale?
d. Did you feel the need to consult IEC members or other experts to discuss ethical dilemmas in the course of your research? What were these and how did you address them?
e. Were any safety measures necessary for field investigators? If so, were they provided?
f. Did field investigators feel the need to develop additional skills or acquire information in order to do their fieldwork ethically? If so, what did you do to meet their needs?
g. The IEC members will also speak separately to team members, including field investigators, to ask whether they have any grievances related to the research.

- *Did ethical issues arise which were not discussed and resolved* during ethics review or discussions in the field? If you were given a chance to do the study again, what would you do to address the ethical issues involved?
- *Please present your plan of analysis* and/or chapter scheme of the research report, with the rationale for the manner in which data will be used. If you feel that the plan of analysis or chapter scheme will not use all the data obtained, please explain why.
- *Please state your plans for data sharing* and dissemination, along with any changes from those proposed at phase 1 of IEC review.

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 Multi-institutional Ethics Committee certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

Name and Signature **Date.**