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 to 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 expedited 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 document Ethical Guidelines for Social Science Research in Health, prepared by the National Committee for Ethics in Social Science Research in Health.
CHECKLIST FOR PHASE 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; specifically describe any previous work in the same field as the present study – not more than 2 pages each)

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<th>Principal Investigator:</th>
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<td>INSTITUTION/CENTRE</td>
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| Name: | Address: |

Co-Principal Investigator(s)

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<th>(1) Name:</th>
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<td>(3) Name:</td>
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Send Correspondence to: [ ] PI; [ ] PI & Co-PI No. ( ); [ ] Only to Co-PI No. ( )

If this study involves collaboration between institutions or department, are details of inter-organisational/departmental co-operation clearly defined?

Is there a formal MoU drafted? Does it contain the following?

1. Responsibilities of the respective organisation
2. Ownership of data
3. Responsibility for addressing harm which may befall any participant during the course of the study
4. Responsibility for dissemination of findings, sharing of benefits with the participants
5. Legal liability of participating organisations
6. Monitoring the adherence to ethical norms agreed to by the team and mandated by the IEC

(B) TITLE AND DURATION OF PROPOSED STUDY:

Study Title:

Month and year of likely commencement of the study:

Duration of the study:
**C) FUNDING:**

<table>
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<th>Type of funding:</th>
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<tr>
<td>Externally funded:</td>
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<td>Internally funded:</td>
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<tr>
<td>Student/internship project</td>
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**Status of funding:**

<table>
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<tr>
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<th>[ ] Funding awarded/available;</th>
<th>[ ] Funding partially awarded/available;</th>
<th>[ ] Fund application pending</th>
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<tr>
<td></td>
<td>[ ] No funding application made;</td>
<td>[ ] No funding required</td>
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**Budget Details (show fund allocation to various heads)**

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

<table>
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<tr>
<th>Does your study require permission from regulatory authorities?</th>
<th>[ ] Yes</th>
<th>[ ] No</th>
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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:

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<th>Does your study require approval from any other institution?</th>
<th>[ ] Yes</th>
<th>[ ] No</th>
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If yes, have you obtained permission?

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<tr>
<th>Does your study require approval from any other ethics committee</th>
<th>[ ] Yes</th>
<th>[ ] No</th>
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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.

If you foresee any investigator bias, what measures have been taken to address it?

(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 |
### REQUIRED LIST OF ATTACHMENTS:

1. Full proposal (mandatory)
2. Minutes of the Scientific Committee (mandatory)
3. Letters of permission, approval (as applicable)
4. Written statement declaring any conflict of interest and resolution of the same (as applicable)
5. Copy of the MoU between collaborating institutions

### Investigators’ 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 organisation 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 approved protocol. I will not modify this certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

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CHECKLIST FOR PHASE I

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

(A) SUMMARY:
Briefly summarise the study design: 250 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)

General description of design (200 words) should contain information about sampling design, randomisation, assignment and controls

<table>
<thead>
<tr>
<th>Research Questions</th>
<th>Variables</th>
<th>Sources of data</th>
<th>Methods</th>
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(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 (300 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(300 words)
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<th><strong>(c) ELIGIBILITY:</strong></th>
<th>Is there any exclusion/inclusion criteria? Please state (50 words)</th>
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<td><strong>(d) RECRUITMENT:</strong></td>
<td>Who will be responsible for recruitment of the participants? Who will be responsible for obtaining informed consent from the participants? (50 words)</td>
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<td><strong>(F) DATA COLLECTION PROCEDURES:</strong></td>
<td>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)</td>
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<td>Please describe who will be responsible for the collection of data.</td>
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<td>How will they be recruited?</td>
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<td>What kind of training and skill enhancement will be provided by the institution to them</td>
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<td>What will be the mechanism for monitoring the quality of data collection in the field</td>
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<td><strong>(G) DATA ANALYSIS:</strong></td>
<td>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)</td>
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## Section II: 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) Withdrawal of participant from study: Describe the circumstances under which you will forego taking participant’s consent for excluding him/her from the study


### (d) 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?

iii) In case there is any change in the risk benefit analysis, please submit a progress report giving details of the changed circumstances


### (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 III: 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.

(e) Will community consent be sought? What is the procedure for obtaining this consent? How will this consent be documented?

Section IV: 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?
Section V: AUTHORSHIP AND ACKNOWLEDGEMENT
List potential authors (including investigators and others) for publication and their likely contributions

In case of collaborative studies, how will authorship be shared with the other organisations? How will the contribution of individuals/organisations be acknowledged?

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.

Investigators’ 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 organisation 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 approved protocol. I will not modify this certified protocol or any attached materials without first obtaining approval for an amendment to the previously approved protocol.

Name and Signature       Date
Name and Signature       Date
Name and Signature       Date
Name and Signature       Date
CHECKLIST FOR INTERIM 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 I 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.

This phase of review is optional. Investigators may request for IEC Responses to questions discussed at phases I of review will function as a guideline for preparing the post-fieldwork note. The detailed checklist at this stage is given to help you think through various aspects of your work.

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

i. 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?

j. 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?

k. 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?

l. 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?

m. Were any safety measures necessary for field investigators? If so, were they provided?

n. 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?

o. 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?

p. If there are any changes from the proposed plan at phase 1 IEC review, 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

q. Please state your plans for data sharing and dissemination, along with any changes from those proposed at phase I IEC review
IEC/Ver2/06

CHECKLIST FOR PHASE II

IEC approval must be sought when the draft report/papers are ready, after it is reviewed by the peer review committee before it is submitted for publication.

The purpose of the IEC review at this stage is to address the following concerns:

- Have the data been utilized optimally and in a scientifically sound manner?
- Are the results presented irrespective of whether they support or contradict the expected outcomes(s)?
- Was the research team able to meet the commitments it made to stakeholders such as participants, team members, the general public and the funding agency?
- Is the dissemination plan adequate and appropriate?

(A) INVESTIGATORS: (Attach brief CV of each investigator; specifically describe any previous work in the same field as the present study – not more than 2 pages each)

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<th>Principal Investigator:</th>
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<td>INSTITUTION/CENTRE</td>
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Name:                                                                                                          Address:

Co-Principal Investigator(s)

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Send Correspondence to:      [    ]  PI;     [   ] PI & Co-PI No. (    );     [    ] Only to Co-PI No. (    )

(B) TITLE AND DURATION OF PROPOSED STUDY:

<table>
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<tr>
<th>Study Title:</th>
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Month and year of commencement of the study:

Duration of the study:

Date of completion of the study:

(C) REVISIONS IN PLAN OF ANALYSIS SUBMITTED AT THE TIME PHASE 1 REVIEW

a. Briefly outline the revisions in the plan of analysis presented at the time of phase 1 review, if applicable. Why was this revision necessary? Does this revision have any implications for the scientific rigor of the study?

b. Does this revision alter the balance of risks and benefits of the study?

c. Was this revision occasioned by some adverse event, high non response and respondent bias? If so, what implications does this have for the study (both scientific and ethical)
d. Have any data been left out deliberately? If so, please explain why. Has this omission been recorded in the report?

(D) PRESENTATION OF FINDINGS

| a. Have all the results been reported regardless of whether or not they conform with the stated hypotheses? |
| b. What steps did you take to ensure that the presentation of data has maintained the anonymity and confidentiality of research participants and other concerned persons? |
| c. If there were any serious ethical concerns encountered during the study, have they been communicated to the IEC? Have these been documented in the report/paper? |
| d. If any ethical concerns were noted after the data analysis, have they been reported to AT-IEC? |
| e. If there are any concerns regarding current or future adverse implications for public health, human rights and law, have they been reported to AT-IEC for appropriate action? |

(E) AUTHORSHIP AND ACKNOWLEDGEMENTS

| a. In brief, list the contribution of each of the authors (1) (2) (3) (4) (5) (6) |
| b. Have all those individuals involved in the study who are eligible for authorship as per the authorship guidelines of the organisation/s and the ICMJE guidelines been given authorship? If any exceptions have been made, please provide details |
| c. Has any individual refused authorship? If so, for what reason? |
| d. Have all those individuals and organisations who contributed to the study but are not eligible for authorship been suitably acknowledged? |
(F) PLAN FOR PUBLICATION AND DISSEMINATION AND DATA ARCHIVING

a. What is the plan for dissemination of the report or other alternative forms of publication based on the research findings?

b. Is there a plan for dissemination of findings to the participants? Please elaborate

c. Is there a plan for archiving of raw data? Who will have access to the data? What is procedure for approving requests for data? Have adequate steps been taken to anonymise the data?

List of enclosures:

(1) Completed checklist
(2) The draft report/papers which should contain
   a. A section in the methodology presenting the ethical dilemmas faced at different points in the research and how these were address.
   b. Highlights of the IEC deliberations and the certification.
   c. An annexure with the tools of data collection and the informed consent documents in English and/or vernacular as applicable

Investigators’ 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.
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Intent
Guidelines for submission to the AT IEC

Format and deadline for submission to IEC - The IEC will not accept late or incomplete submissions. The submissions should include the following and in the following order:

- Covering letter
- Completed Application form for IEC
- Research proposal and full protocol. Data collection tools should be in English and the relevant language/s.
- Plan of analysis
- Information sheet and informed consent forms in English and the relevant language/s
- Decisions of the scientific review committee
- CV of the Principal Investigator

All the documents must reach the Secretariat 21 days prior to the IEC meeting. The documents must be in a single PDF file with continuous page numbering. Submissions which do not conform to these specifications will not be accepted by the Secretariat.