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 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 1
Prior to forwarding a proposal to funding agencies for financial support

Objectives

This is for the first time in the life span of the project that researchers would interact with IEC for ethical review. Researchers are expected to address broadly the ethical issues involved in the proposed research.

The specific objectives of an ethical review at this stage are:
1. To facilitate researchers to articulate ethical issues involved in the area of enquiry, especially if it is a new area.
2. To understand the nature of ethical issues involved,
3. To ensure protection and prevention of harm not only to participants but also to researchers

(A).Administrative

Title:	
Principal Investigator	
Institution/Centre:	
Name:	Address:
Team Members:	
Duration:	
Field- work location:	
Collaborators (if any):	
Proposed funding agency:	

(B). About the research project

a. A note on the reasons for undertaking the research.
b. A note on the ethical concerns that you anticipate during the course of the entire study.
c. In case of short duration projects (less than 3 months), a statement on the phases for ethical reviews needs to be presented.
REQUIRED LIST OF ATTACHMENTS: Project proposal Proposed Budget

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 the 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**

Name and Signature **Date**

CHECKLIST FOR PHASE II
AT THE STAGE OF FINALISATION OF METHODOLOGY AND BEFORE LAUNCHING FIELD WORK

Objectives
This is the most critical phase for researchers, as it requires attending to ethical issues in a comprehensive and exhaustive manner. Not attending to ethical issues satisfactorily will have serious implications for research participants and thus the responsibility lies with both the research team and members of IEC to brainstorm the ethical issues involved and design an ethically sound methodology.

The specific objectives of an ethical review at this stage are:
1. To assess whether the study design and methodology laid down attends adequately and sensitively to the ethical issues involved,
2. To assess whether adequate measures are proposed to protect rights of research participants,
3. To assess whether the processes planned to sensitise the research team to ethical issues are adequate and feasible,
4. To assess whether adequate measures are proposed to protect rights of researchers and especially field based staff.

Section I: Administrative

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)*

Principal Investigator:	
INSTITUTION/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. ( )
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:

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?
Does your study require approval from any other ethics committee [ ] 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.
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**

Attachments:
1.
2.
3.
4.
5.
6.

Section II : 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

Research Questions	Variables	Sources of data	Methods

(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) rationale 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)
(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? How will this be reinforced throughout the study? (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 III: 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) 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 measures/ approaches you will take to maintain confidentiality (iv) what are the likely consequences to the subject/participant in the event of violation of confidentiality.
(d) 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.
(e) BENEFITS: Describe benefits to the subject/participant in participating in the study. Also describe the benefits, if any, to the society.

(f) 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:
[ ] 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 & why) Note: Signed written consent is a norm. If not possible, exceptions need to be justified by researcher.
(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 (where applicable), (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. (11) contact details for the research team/PI. (12) contact details for the IEC in case the participant wants to raise any concerns about the study.
(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 engagement be conducted? What is the process involved? How will this engagement be documented?

Section V: 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?

Section VI: 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

Name and Signature	Date

CHECKLIST FOR PHASE III
After completing the field work

Objectives
By this time/phase the research team would already have brainstormed on most of the ethical issues and dilemmas specific to the project. The mechanisms/strategies designed to resolve the issues would have been put to use during the field-work. Upon completion of the field-work then is the time for assessment of the strategies conceptualized. It is also the time to document experiences as learning lessons and also an opportunity for the historical documentation of practicing ethical research.

Specific objectives of an ethical review at this stage are:
1. To examine the adequacy of the discourse and debates on various ethical issues and concerns generated during field work.
2. To assess the appropriateness and applicability of the strategies in the field.
3. To review if things have gone wrong as regards any of the ethical aspects and to examine if there is any need to take corrective measures
4. To keep the IEC informed about the adequacy of strategies to address ethical issues during earlier phases.
5. To document ethical practices and problems faced while doing so for the benefit of others and for one's own learning.

(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)*

Principal Investigator:	
INSTITUTION/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 commencement of the study:
Duration of the study:
Date of completion of the study:

C: ETHICAL ISSUES ENCOUNTERED IN PROTECTION OF RIGHTS OF PARTICIPANTS
a. What was ~~Please document~~ your experience in seeking informed consent from research participants? Was it written or verbal? If verbal, please mention the reason and whether permission was taken from IEC for verbal consent. Did you take assent from minors? Did you have to take post-interview/intervention 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. What were the steps taken by you for maintaining participants' privacy, anonymity and confidentiality?

D: EXPERIENCE OF ANTICIPATED/UNANTICIPATED RISKS OR HARMS
a. What was the average time taken to complete interviews with individual research participants?
b. Were there circumstances or events which posed significant risks or resulted in harm to the participants?
c. 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?

d. 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?

E: 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. 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?
h. If there are any changes from the proposed plan at phase II of 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
i. Please state your plans for data sharing and dissemination, along with any changes from those proposed at phase II of IEC review

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
Name and Signature	Date
Name and Signature	Date

CHECKLIST FOR PHASE IV
Prior to publishing the research report

Objectives
This is the phase after the draft research/project report is completed and before the report is formally presented to external peers for review. By this time in the life span of the project, the team of researchers would have had adequate opportunities to discuss and understand the ethical research practices and issues specific to the subject matter under study.

Specific objectives of preparing for ethical review at this stage are as follows:
1. To review whether the data obtained has been utilized optimally, non-selectively with no biases and in a scientifically sound manner.
2. To review/assess whether the results are presented irrespective of whether they support or contradict the expected outcomes(s).
3. To assess whether the research team have been able to meet the commitments made vis-à-vis concerned stakeholders, such as, research participants, team members, general public, funding agency.
4. To review/assess whether the dissemination plan is adequate and appropriate to reach out to the concerned stakeholders.

(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)*

Principal Investigator:	
INSTITUTION/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 commencement of the study:
Duration of the study:
Date of completion of the study:

(C) REVISIONS IN PLAN OF ANALYSIS

a. Briefly outline the revisions in the plan of analysis presented at the time of previous IEC 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)

(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. Has there been any change in your plan for dissemination of findings to the participants? If yes, please elaborate.
c. What is the plan for archiving of raw data? Who will have access to the data? How long will the data be stored? What is procedure for approving requests for data? What are the steps you have taken to anonymise the data?

(G) Optional questions

Please state potential areas/topics for further work based on the findings from the present research study. For example, documenting or writing based on the experiences obtained during the field-work, or training of field investigators. (These may mostly be outside the commitments made in the formal/official project proposal). Please specify areas/topics, purpose/s, possible modes of documenting (writing, manuals, handbooks, audio-visual material etc.), and type of resources required (human power and skills, time, finances etc.).

Do you plan to work on these? How? In case the existing team does not have adequate resources, the Institution should consider this as part of its responsibility and accordingly resources could be allocated to take this up in consultation with the team.

Please state potential areas for further work that could be undertaken either by research, advocacy, action or service-intervention. (This is primarily to identify areas, which could be pursued by the Institution beyond the project tenure and which could also to be shared with peers from outside the Institution. Such areas for further exploration could be given space in CEHAT's Annual Reports and could also be placed on CEHAT's website.).

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.

- 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.
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