An Ethics Protocol for Human Subjects Research

RATIONALE:

The excesses of covert and non-consensual medical research on human subjects in the 20th century attracted public outrage and opposition. While social science research does not cause such criminal harm to human subjects, there has been ethical reflection on implications of professional practice, for instance, on subject anonymity. Environmental social sciences, along with conservation biology and environmental science now constitute a wider interdisciplinary field of ethical reflection and caution. Research subjects are often rural forest dwellers or urban slum dwellers, whose share a common risk of displacement for conservation or gentrification. Even the affluent urban consumer, farmer, bureaucrat, policy maker or enforcer may be a subject of environmental research, whose need for anonymity and assurance against any potential harm needs to be equally respected.

There are conventional and contemporary research ethics that require attention. That research is the pursuit of objective truth, and the objective researcher is obliged to consider the consequences of such truth on respondents and their communities is a conventional notion. A more contemporary complication of ethics entails the questioning of this traditional model of experts unearthing truths. Gender, race and class scholarship has replaced the faith in neutral observation with sensitivity to social difference and inequality.

The conventional ethics framework may constitute professional adherence to procedure, and risk an assumption that procedure automatically ensures and exhausts ethics. But while the insistence that an academic and action institution needs to morally mature by reflecting on politics of research, be it researcher positionality or subject's complex experience of consequences, is important, procedural ethics constitutes necessary and minimum first step. Even as students follow procedure, they can be encouraged to reflect more deeply on their interactions with subjects at every stage of research.

Research is now an area of governance. Serious consideration needs to be afforded to human subjects review committees or ethics committees. Before a researcher begins fieldwork, the committee conducts an ethical review of the proposal. The committee negotiates dilemmas of accountability and independence. However bureaucratic procedures and elaborate whetting can stifle innovative research methodologies. Research methodologies are, even when well designed, are a legitimate matter for evaluation and comment by ethics committees. It is also ethically problematic to involve subjects in poorly designed studies. People usually participate in studies with a belief in the social usefulness of results. Badly designed studies belie this contract, with implications of wasting participant time and misleading them.

Ethical safeguards are crucial if research concerns vulnerable populations. At ATREE, vulnerable sections like forest dwelling *adivasis* and slum-dwelling *dalits* constitute research subjects. Research poses serious and potential displacement prospects for them. In recruiting, and interacting with, research subjects or participants, ensuring globally agreed upon fundamental ethical principles, namely, beneficence (minimizing inconvenience, risk and harm and maximizing benefits), and informed consent (prior and voluntary consent.

ETHICAL PRINCIPLES AND RELATED PROTOCOLS[1]

A. Informed consent of Human Subjects

Informed Consent is a process through which researchers provide information to participants of 18 years and over, regarding the details of a research study prior to their participation in the research study. The participants are informed of: the purpose of the research study, how their privacy will be protected, as well as information about any risks, benefits, or compensation. The participants will also be informed of contact details of the research organization (ATREE) and the researcher in case of grievances. Consent forms document that the informed consent process took place. While in the Indian context, a

[1] This document draws heavily upon *Ethical guidelines.* 2003. Social research association. Scotland. UK*;* the ethics sections of the website of the Economic and social research council; and Ali and Kelly. 'Ethics and social research', in Seale Clive (eds). 2012. *Researching Society and Culture*, Sage.

signed consent is not always possible, in such a case, oral consent is sufficient to indicate that the participant understands and agrees to participate in the research study.

No human subjects may be involved in a study without obtaining consent of the participant.

Protocols

1. A statement of how informed consent will be ensured must be provided as part of the IRB application. Information given to the participant typically includes
    - An explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed.
    - A description of any reasonably foreseeable risks or discomforts to the subject.
    - A description of any benefits to the subject or to others which may reasonably be expected from the research. If none, so state.
    - A description of the extent, if any, to which confidentiality of records identifying the subject will be maintained. This can extend to the community under certain circumstances where the risk extends to the community.
    - For research involving more than a minimal risk, statement as to whether there is any compensation and whether medical treatments are available if injury occurs. If so, specify the extent and nature of the compensation and treatment.
    - An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related grievance to the subject.
2. A statement that explains how it will be ensured that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time during the interviews without penalty or loss of benefits to which the subject is otherwise entitled.
3. In case the research involves minors, in addition to all of the above, consent must be taken from the minor as well as the parent or the guardian of the minor.
4. A statement explaining, what steps will be taken, in the event of hiring field associates outside of the research area, to impart training in these protocols.

B. Data sharing/Stewardship

Data collected during the process of research should be done carefully and with full informed consent of the participants. Any information that links back to the participant (e.g., names, addresses, geographical coordinates etc.) must always be protected. The participants may be informed about the process of data managed by ATREE.
Research subjects and participants must be assured that their identities will be kept confidential in reports and publications. Without their consent no information that identifies them must be made available to agencies and individuals other than the institution conducting the research.

Protocols

1. Clearly indicate the person(s) responsible for managing the data on various platforms: computer, photographs, written documents, etc.
2. Clearly explain how data privacy will be ensured. E.g. it may be necessary to keep two separate databases: one database with any identifiable info that contained a participant id, and one database with the non-identifiable data.
3. Explain how data will be shared with the PIs, researchers and PhD scholars involved in a particular study. E.g. ATREE's Academy will maintain an archive of the data which can be shared with others interested in using the data only with the permission from the PIs.
4. Data containing sensitive information must be informed to the Academy before archiving the data in addition to de-identifying the participant or the community.
5. Any data generated using technologies such as cameras, drones, microphones, which may violate privacy of a person, harm a person or is of no relevance to the research must be deleted or be under clear chain of custody, where a paper trail that records the sequence of custody, control, transfer and use of the imagery/data is maintained during and after the research.
6. Final outcomes (analysis and results) resulting from the use of data can be shared with the original participants.

C. Conflict of interest

A conflict of interest may be present when the researcher's private interests may have the potential to compromise or bias professional judgment and objectivity about the research study. A disclosure of the same will be made to the PIs and donors.
Conflict of interest may arise in form of academic conflict of interest or financial conflict of interest.

1. Academic conflict of interest may arise due to conflict of conscience, which occurs when personal beliefs or value system of the researcher influences the researcher's objectivity.
2. Financial conflict of interest may arise when some type of financial payment, such as a consulting fee, equity in a company, or other benefits can influence an individual to prefer one outcome to another. Financial conflict of interest can arise when the research and the donors may prefer one outcome to the other e.g. Oil companies funding research for climate change. Any such conflicts of interest must be clearly acknowledged in paper/reports or Informed Consent documents shared with participants.

D. Balancing Benefits and Risks to Participants

Research must benefit participants and researchers should be realistic in their benefit assessment and communication. Risks and intrusions for participants must be minimised and justified by expected benefits. At some level all research is intrusive. Researchers are not an entitled lot, and scientific pursuit of knowledge is no automatic justification for studying communities and groups and superseding the rights and values of participant subjects. Care and sensitivity needs to be exercised in not intruding upon the private and personal spaces of subjects.

Collecting excessive information on subjects, amounts to overburdening them. Further, data obtained for one agreed purpose must not be used for another and subjects have the right to object to such 'misuse'. Harm need not necessarily befall subjects, but they can feel aggrieved and annoyed without actively being harmed. A subject is a thinking agent and has dignity and should not be treated merely as an object for measurement and prediction. Subject inconvenience and grief can arise for many reasons and in many ways that are

tough to anticipate, but the researcher is in some ways absolved of responsibility by seeking prior informed consent.

Protocols

1. Overenthusiastic or opportunistic gathering of more data than necessary must be avoided. For in-depth interviews, set saturation levels, researchers must be sensitive to non-verbal and bodily cues of discomfort.
2. Data i.e. subject identity must be anonymised in field and archival research.
3. A clear data stewardship plan and chain of custody in case of highly sensitive data must be put in place (e.g. password protected files, with tracking of who the password is shared with).
4. Data must not be used for reasons other than, for which they were collected without informing subjects ahead of time.
5. An appropriately deferential (but not artificially patronizing demeanor) must be used while interacting with subjects.
6. Formal interactions with participants must be scheduled in ways that do not disrupt daily chores and activities.