Guidelines for Ethical Evaluation of Research

General Guidelines

1. Clearance by the Ethics Committee is necessary when the research, by faculty, students, or others at CDS involves human subjects. The Human Subject is defined as a living individual about who research investigators gain identifiable private information through active intervention (changing their environment, activities etc) or through interaction (communication and other kinds of interpersonal contact of the research investigator with the subject).Private information refers to information about behaviour, practices etc that happens outside recording and observation, and is provided by the human subject for specific purposes, and meant for limited circulation only. Identifiable information is of the sort that may help identify the human source of the information.

2. All human groups and individuals who researchers may be interested in as research subjects are considered 'human subjects', but research among vulnerable groups like women, members of marginalized social, political, and cultural communities, differently-abled people is especially sensitive.

3. The well-being and the rights of human subjects precede the interests of the researcher and should not be violated under any circumstance. In other words, respect for human subjects and concern for their well-being should be understood as a primary duty of the research investigator. Specifically, this is the duty to protect (a) the dignity, (2) integrity, (3) self-determination, (4) privacy, and (5) confidentiality of identifiable private information of human subjects involved in the research. The responsibility of all five aspects, especially confidentiality, rests with the researcher and not the human subjects. Research proposals on vulnerable groups must specify how the research will benefit the vulnerable groups and not cause harm.

4. Such responsibility for protection rests with the research investigator irrespective of whatever specific social, cultural, moral, or national values they may adhere to.

5. Every research proposal must contain a statement of ethical issues involved including (a) vulnerable human subjects involved (b) ways of securing their informed consent (c) ways of securing their privacy and confidentiality and (d) ways of ensuring no harm.

6. Failure to comply with ethical standards will delay permissions for the research. Research cannot commence until full compliance is obtained.

7. Instances of research in which the use of deception is unavoidable are not automatically rejected. They must be evaluated by the Ethics Committee to check that (a) the risk to vulnerable populations are kept minimal[1] (b) the violation of research subjects' rights are remedied (c) the research is impossible without deception and (d) participants can be offered information on the data collected after the research and also the right to erase it after the research.

8. The given submission form must be fully filled up by the student in consultation with the supervisor and forwarded to the Ethics Committee through the supervisor. Faculty researchers may directly submit the form. The Ethics Committee should examine submissions and determine if they may be cleared or not. The Ethics Committee can offer suggestions for improvement of the submissions. The ethical protocol of the study must be finalised only after these suggestions are taken into account. The minimum quorum for examining submissions in the Ethics Committee must be three. In case of a lack of consensus about the submission, external members of the Ethics Committee may be consulted and their decision can be final.

Specific instructions

(a) **Vulnerable human subjects**: in the research proposal, social groups must be assessed for vulnerability using local as well as global criterion. Vulnerable subjects are socially, politically, or culturally-marginal groups who are likely to suffer wrongs, incur losses or additional harm.

(b) **Informed consent**: The research subject's consent to participate in research must be (a) voluntary and (b) based on adequate information. The information shared with the research subject must include enough details about the (a) aims and purpose of the research (b) methods used (c) the researcher's institutional affiliations (d) any conflict of interest (e) potential risks or discomfort, if necessary.

[1] "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

(b1) The research subject must be informed of their right to withdraw consent or refuse participation at any stage without penalty.

(b2) The above information must be delivered to the research subject in ways accessible to them, for example, in their languages of choice.

(b3) Consent should be sought preferably in written form. Non-written consent should be recorded and witnessed. The template of the consent form provided may be used or suitably modified for use.

(b4) If a potential research subject is minor or incapable of giving informed consent, informed consent should be sought from a legally authorised representative. However if the potential research subject dissents, that should be respected.

(b5) The consent form should include (1) details about the study and the researcher (i.e. introduction of self and affiliation) (2) aims, scope and objective of the study) (3) study location and sample participants and criteria of selecting human subjects/participants (4) the interaction with participant (5) risks and benefits (6) confidentiality assurance measures (7) assurance of voluntary participation, and (8) type of consent (i.e. verbal or written).

(c) **Privacy and confidentiality**: All personal identifiers of research subjects should be changed before research findings are discussed. This must be especially the case in telephonic surveys as well.

(c1) Research subjects should receive written assurance that measures will be taken to protect their privacy and confidentiality, that data will be password-protected, and all signed consent forms, filled interview schedules etc. will be accessible only to the researcher/research team.