

General Guidelines for the Ethics Review Processes

This guideline must be read in conjunction with the Guidelines for Completing the Human and Social Sciences Research Ethics Application Form (2014).

Introduction

All research protocols, irrespective of the level (undergraduate, postgraduate, post-doctoral, staff research) are reviewed, using a standard pre-determined set of criteria.

Studies are categorised as either:

1. Green: No Risk (no human participant involvement)
2. Orange: Minimal or Low Risk
3. Red: Increase over Minimal Risk or High Risk

Expedited reviews are conducted on protocols in the Green and Orange categories.

Any research protocol classified as Red is subject to a Full Committee Review. Studies classified as Red include the following but are not limited to:

- Children (depends on the nature of the enquiry), teenagers (under 18 years of age),
- pregnant women,
- women living in unequal relationships,
- people living in poor socio-economic conditions,
- people living with HIV,
- prisoners, and
- mentally compromised individuals.

The **Ethics Review process** includes the following:

1. Scientific Validity

- 1.1. Coherence between the topic, aim, objectives and critical research questions
- 1.2. Appropriate sample selection for both qualitative and quantitative research
- 1.3. Recruitment for each aspect of data collection
- 1.4. Submission of the research instruments: questionnaires, interview schedules, data capturing sheets, etc.
- 1.5. Research methods must suit the questions being asked

2. Data Management

- 2.1. Data management is explained clearly (storage and eventual disposal).
- 2.2. Confidentiality and privacy is maintained.

3. Gatekeeper Permission

Gatekeeper permission refers to access into an institution/organisation. This access can either be physical or informational. All Institutions/ organisations have the right to be aware of and be given the right to grant or decline permission to a researcher to conduct research in their domains.

Research being conducted in public settings do not usually need gatekeeper permissions, but be aware that some 'public' spaces, e.g. malls, concerts, etc. are actually private spaces where management permission is required to conduct research.

Gatekeepers can only provide access permission and do not provide consent for the study. Consent is only obtained from the individual participants, care givers, guardians, etc.

The gatekeeper permission letter must ideally be presented as an official document bearing either a school/company/clinic stamp or letterhead. An electronic communication is accepted provided that a corresponding e-mail address is attached.

4. Consent

The Consent process consists of three parts:

- 4.1. The **Information Sheet** (that covers the aims of the study, data collection instrument, duration of data collection, risks/benefits of the study, HSSREC contact details, PI/supervisor and student contact details).
- 4.2. The **Declaration of Consent** (where the participant confirms that he/she understands the research process, his/her rights, including the right to refuse participation and/or withdraw from the study without any negative consequences).
 - 4.2.1. The PI should also request for permission to audio-record/video record an interview. The PI simply inserts a sentence: *I hereby consent / do not consent to record this interview.*
- 4.3. **Signatures** of participants, date, etc.
 - 4.3.1. Parental consent must be considered, where applicable. For children under 18 years, learner assent must also be included, where necessary.
- 4.4 Use and adapt standard Informed Consent templates wherever possible.

Consent forms submitted to ethics review should **not** be signed. The PI can only recruit participants *after* the study has been approved. Any signed form is seen as a violation of this approval process.

The Information Sheet and Declaration of Consent should be separate unless the primary investigator intends handing out a copy of the signed Declaration Form to the participant.

5. Minimal Risk or High Risk Studies

All studies dealing with minimal or high risk must demonstrate the following:

- 5.1. How will confidentiality and privacy be maintained?
- 5.2. How will the psychosocial needs of the participants be addressed?
- 5.3. What referral patterns/mechanisms are in place?
- 5.4. Is there a cost factor involved (referrals, consultation, etc.)?
- 5.5. What will be done to actively minimize potential risks?

This information must be included in the Information Sheet.

6. Other Considerations in the Ethics Process

- 6.1. How will the study findings be appropriately disseminated among the research participants? This is an ethical obligation to maximize benefit.
- 6.2. Is there post intervention access to control groups in experimental studies (where an intervention has yielded positive results)?
- 6.3. What is the social value of the proposed study?