

Where a study is to be carried out in a host organisation (e.g. school, university, work-place, etc.) a letter is required from the host organisation granting the researcher permission to undertake the research.

The consent forms should meet four criteria - be brief (but have complete basic information); be readable (and understandable) to most people; be in a format that helps people comprehend and remember the information; serve as a script for face-to-face discussions with potential participants.

To allow the participants to obtain additional information (or to report concerns) with respect to ethical aspects of this study, the contact details of the researcher and the research supervisor must be provided on the informed consent form.

GUIDELINES FOR DRAWING UP AN INFORMED CONSENT DOCUMENT

The Informed Consent document must be in the form of a letter to the participant, containing information on the items listed below and concluding with a declaration allowing for the name of the participant, signature and date:

- The project title understandable by the lay person.
- A statement of the projects aims, in terms understandable by the lay person,
- The names, affiliations and contact details of the investigator/s, with qualifications where appropriate,
- Contact details for HSSREC Research Office (Ms P Ximba, Tel: 031 260 3587, Email: ximbap@ukzn.ac.za)
- State degree, School and University at which the research will be undertaken
- Name, contact address or telephone number of an independent person whom potential subjects may contact for further information, usually the project supervisor, team leader or school director,
- A brief explanation of how the subject was identified,
- A clear explanation of what is required of the subjects who agree to participate, including descriptions of any procedures they will undergo and any tasks they will perform, together with an indication of any possible discomfort or any possible hazards involved.
- The estimated total time of involvement and the number of occasions or duration of time over which this involvement is spread should be stated.
- Potential benefits to be derived from participating in the study should be stated,
- An indication of payments or reimbursements of financial expenses incurred by subjects,
- A statement on the use of any written, audio or video recordings made,
- An indication of how and when the gathered data will be disposed of,
- A statement assuring confidentiality or anonymity as appropriate,
- A statement that a decision not to participate will not result in any form of disadvantage,
- A statement that participation is voluntary and that subjects are free to withdraw from the study at any stage and for any reason.

EXAMPLE OF DECLARATION

.....(full names of participant) hereby confirm that I understand the contents of this document and the nature of the research project, and I consent to participating in the research project.

I understand that I am at liberty to withdraw from the project at any time, should I so desire.

I consent / do not consent to this interview being recorded (if applicable).

SIGNATURE OF PARTICIPANT

DATE

.....
NOTE: Potential subjects should be given time to read, understand and question the information given before giving consent. This should include time out of the presence of the investigator and time to consult friends and/or family.

Common mistakes:

- Researchers do not introduce themselves, do not write in the first person;
- Full specification of the purpose of the study / its auspices not provided;
- No clear description of the research procedures that are to be used is given;
- No clear statement of the time that a participant will take to complete the requirements of the study;
- No explanation to the potential participant of how or why he / she has been selected;
- No clear, 'up front' statement that participation in the study is entirely voluntary; that a choice not to participate will have no negative consequences. Should the participant choose to participate, he / she may decline to answer questions and may withdraw from the study at any time;
- If the participants are from a workplace or similar institutional setting (i.e. a university) a lack of clear reassurance that they do not risk job loss or other institutional sanctions;
- The wording of the Participant Information Sheet is unnecessarily technical / sophisticated;
- The specific guarantee of confidentiality / anonymity is not provided.
- Inadequate measures to protect the identity of participants (names, addresses, student numbers, etc. should not be recorded on the research instrument together with participants' answers). A coding system must be employed.
- Anonymous return of completed questionnaires is not provided for.
- The effects of coercion are not fully allowed for (e.g. lecturers asking students that they teach, and whose work they mark, to participate in a research study).
- If the participation in a research procedure is likely to awaken feelings of past trauma, not making arrangements for a helping person to be available to counsel the participant.
- If the questionnaire is not available for submission with the application (e.g. the questionnaire will be finalised only after a pilot study has taken place, the researcher gives no indication of the type of questions that he / she is likely to use).

UNIVERSITY OF KWAZULU-NATAL

GUIDELINES FOR COMPLETING THE HUMAN AND SOCIAL SCIENCES RESEARCH ETHICS APPLICATION FORM (including all applications for Degree purposes)

THE RESEARCH PROPOSAL

Research Methodology/Experimental procedure:

Clearly outline the methods to be used. Comment specifically on:

- Nature of data to be collected;
- Method of collection and processing of data; and
- Storage and analysis and disposal of data.

Preventing/Minimising Stress and/or Harm

Should your project include special/vulnerable participants (such as children, persons who are intellectually or mentally impaired- the application form has other examples), indicate how the autonomy of these participants will be protected and how social stigmatization and/or secondary victimization of participants will be prevented (see question 3.1 of application form)

Also indicate how potential stress/ harm will be minimized in the following instances (see question 3.2 of the application form):

- if participants are required to engage in activity that might diminish their self-respect or cause them to experience shame, embarrassment, or regret;
- If participants are exposed to questions which may be experienced as stressful or upsetting, or to procedures which may have harmful side effects; or
- If stimuli, tasks or procedures are used which may be experienced as stressful, noxious or unpleasant.

Statistical Planning:

If applicable, please give details - outline statistical considerations such as randomisation, size of groups, exclusions etc.

If this is not applicable, specify why statistical consultation was not obtained and motivate the design adopted.

INFORMED CONSENT:

Informed Consent is not valid unless the participant understands the information. It is the responsibility of the investigator to ensure comprehension.

A translation into the home language of the participant must be provided. A translation of the information leaflet into the home language of the participants must be provided in addition to the English version.

CONFLICT OF INTEREST DECLARATION

It is an ethical rule that investigators should have no undisclosed conflict of interest with their study collaborators, sponsors or participants. Conflicts can arise, for example, when a commercial or other sponsor may not wish research results detrimental to their corporate image / interest to be disclosed, especially when the investigator is being remunerated by the sponsor for the research in question; when research participants are being rewarded for their participation in the research; or when an investigator has a vested interest in, or is an employee / shareholder / director in the sponsor's corporate entity. Investigators should note that the duty to disclose a conflict of interest to the ethics review committee begins at the stage of application for ethical approval and continues until the research in question is complete and the research results are submitted to the sponsor / published (if applicable).

If the investigator(s) has / have / foresees any such conflict of interest, these details must be provided in the Research Ethics Application Form.

Updated 20 September 2013