

Ethical standards for research involving human participants

Code of practice

1. Introduction

- 1.1 The integrity of any research depends not only on its scientific rigour, but also on its ethical adequacy. Ethical issues are many and varied, and may be quite complex. Research involving human participants is undertaken by many different disciplines and conducted in a broad range of settings and institutions. While some issues are specific to professional groups, all research should be guided by a set of fundamental ethical principles to ensure the protection of human participants.
- 1.2 Underpinning the standards are the ethical imperatives of DO NO HARM (nonmaleficence) and DO GOOD (beneficence). Consideration of risks versus benefits need to be weighed up by researchers. In medical research physically invasive procedures are easily defined, but what constitutes risk in social research is sometimes less clear cut. Questionnaires, observation and interviews can all be potentially intrusive and provoke anxiety in participants, or worse, involve psychological risk. It is important to think through carefully the likely impact on participants of any data collection methods. Certain groups are particularly vulnerable and may succumb to pressure, for example students, children or people with learning disability. Some participants are unable to give informed consent and are therefore less able to protect themselves, for example people with dementia. Research activities may be so unintrusive that individual consent is not warranted, such as in the case of some community-based studies.
- 1.3 The following standards have been developed to guide staff and students undertaking research involving human participants. They are intended to cover general principles, but they may not address all situations and the researcher should seek further advice from their School's Research Ethics Officer, the University Research Ethics Committee and their profession's code of practice for research ethics as appropriate.

2. No research should cause harm, and preferably it should benefit participants

- 2.1 A judgement needs to be made as to whether a particular intervention is likely to affect the well-being of participants and any potential risks to participants which might arise in the course of the research should be identified.
- 2.2 Procedures must be justified, explaining why alternative approaches involving less risk cannot be used.
- 2.3 The potential benefits of the research to participants, the scientific community and/or society must be clearly stated.
- 2.4 Any cultural, religious, gender or other differences in a research population should be sensitively and appropriately handled by researchers at all stages.

3. Potential participants normally have the right to receive clearly communicated information from the researcher in advance

- 3.1 Most research procedures should be explained on an information sheet written in simple language that is easily comprehensible by the potential research participant.
- 3.2 The information sheet should set out: the purpose of the investigation; the procedures; the risks (including psychological distress); the benefits, or absence of them, to the individual or to others in the future or to society; a statement that individuals may decline to participate and also will be free to withdraw at any time without giving a reason; and an invitation to ask questions.
- 3.3 The information sheet should also provide contact details of the School's Research Ethics Officer so that participants may report any procedures that seem to violate their welfare.
- 3.4 Participants should be given plenty of time to study the information sheet, and consult relevant parties.
- 3.5 The information sheet and the consent form (see Appendix) should form part of the application for ethics approval.

4. Participants should be free from coercion of any kind and should not be pressured to participate in a study

- 4.1 Promises of compensation and care for damage, injury or loss of income should not be considered inducements.
- 4.2 Inducements, such as special services or financial payments (other than reimbursement for travel expenses or in some cases time), and the creation of inappropriate motivation should usually be avoided.
- 4.3 Risks involved in participation should be acceptable to participants, even in the absence of inducement.
- 4.4 Reimbursement of participants' expenses, for example for journeys, is not payment in the sense of reward, and can be provided.
- 4.5 Participants must be free to withdraw from the study at any time.

5. Participants in a research study have the right to give their informed consent before participating

- 5.1 Participants should understand the purpose and nature of the study, what participation in the study requires, and what benefits are intended to result from the study (see section 6 for special guidance on vulnerable participants and section 7 for exceptional circumstances).
- 5.2 Voluntary informed consent, in writing, should usually be obtained from any participant who is able to give such consent (see Appendix).
- 5.3 It is the researcher's responsibility to seek ongoing consent during the course of a study.
- 5.4 Consent may be implied by the completion and return of many social survey questionnaires, removing the need for written consent.

- 5.5 Individual consent may be unnecessary for some research activities, such as community research, which may be quite unintrusive, for example studies involving observation of public behaviour.
- 6. Where third parties are affected by the research, informal consent should be obtained**
- 6.1 When third parties, for example spouses, teachers or health care professionals, are directly involved in the care, education or treatment of the potential participants, consent should also be obtained from them.
- 6.2 Informal consent should involve sharing of information about the project.
- 6.3 If the proposed research is likely to interfere with the treatment or care being provided by a third party, it is necessary that they be fully informed and sign a consent to participate.
- 6.4 In certain situations, the affiliation of participants to particular organisations or special groups such as educational institutions, business organisations, or hospitals, may necessitate the granting of permission to conduct the research project and any relevant policies or guidelines should be followed.
- 7. The consent of vulnerable participants or their representatives' assent should be actively sought by researchers**
- 7.1 If the involvement of children in a research study is justified, then parents or other legal guardians have the right to be informed and to give their assent for inclusion of the child in the study.
- 7.2 In the case of educational research, any special school policies or procedures should be followed.
- 7.3 To the extent that it is feasible, which will vary with age, the willing consent of participants who are children should also be sought. Generally, children over age 16 may be assumed to be capable of giving informed consent, but this will vary depending on the nature of research and special guidance may need to be sought.
- 7.4 In cases where people are unable to comprehend the implications of research, for example people with dementia, assent to participate may have to come from a representative, such as a legal guardian or immediate relative.
- 7.5 Witnessed consent is required for vulnerable participants who have intellectual or cultural difficulties in speech or understanding, but who are deemed capable of giving consent.
- 7.6 The quality of the consent of participants who are in a potentially dependent relationship with the researcher (e.g. students, employees and patients) requires careful consideration, as willingness to volunteer may be unduly influenced by the expectation of advantageous benefits.
- 8. Honesty should be central to the relationship between researcher, participant and institutional representatives**
- 8.1 The deception of participants should be avoided.
- 8.2 The use of one-way mirrors for observation in any investigation must be clearly justified.

8.3 If deception is necessary, the reasons should be explained to participants after the study.

9. Participants' confidentiality and anonymity should be maintained

9.1 Researchers should take precautions to protect confidentiality of participants and data.

9.2 The identity of the participant, or any information which may identify the participant, may not be revealed without the participant's adequate prior consent in writing.

9.3 Researchers and other collaborators should deal with all data obtained through their project in such a manner as not to compromise the personal dignity of the participant or to infringe upon the participant's right to privacy.

9.4 All information obtained in the course of a research project should be considered privileged information and should under no circumstances be publicly disclosed in a fashion that would identify any individual or organisation (except if subpoenaed by a court).

9.5 When personal identifiers are used in a study, researchers should explain why this is necessary and how confidentiality would be protected.

9.6 Procedures for protecting the confidentiality of participants should be followed and include:

- securing individual confidentiality statements from all research personnel;
- coding data with numbers instead of names to protect the identity of participants;
- using codes for identification of participants when transcribing audiotapes, and destroying the tapes on completion of transcription;
- storing data with any identifying information in a locked file to which only one or two persons have access;
- using pseudonyms for participants, agencies and geographical settings in the publishing of reports;
- disposing of information that can reveal the identity of participants or places carefully (e.g. burning or shredding rather than disposal in wastebaskets).

10. The collection and storage of research data by researchers must comply with the Data Protection Act 1998

10.1 Researchers should follow the University's Data Protection Policy and Guidelines.

10.2 Researchers should be aware of the risks to anonymity, privacy and confidentiality posed by all kinds of personal information storage and processing, including computer and paper files, e-mail records, audio and videotapes, or any other information which directly identifies an individual.

10.3 Participants must be informed of the kinds of personal information which will be collected, what will be done with it, and to whom it will be disclosed. 'Consent to process' may need to be obtained where information collected from individuals is to be used later for research purposes.

10.4 Measures to prevent accidental breaches of confidentiality should be taken (see section 9), and in cases where confidentiality is threatened, relevant records should be destroyed.

10.5 Provisions for data security at the end of a project must be made. Where the researcher leaves the University, this responsibility should usually rest with the relevant School.

11. Researchers have a duty to disseminate their research findings to all appropriate parties

- 11.1 Participants and relevant stakeholders should be offered access to a summary of the research findings.
- 11.2 Reports to the public should be clear and understandable, and accurately reflect the significance of the study.

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Consent form guidelines

The following issues should be addressed in a consent form:

- Title of the study
- Purpose of the study
- Why participant was selected
- Description of procedures, purpose, length of time required and how participants will be involved
- Discomforts, inconveniences expected
- Risks, if any
- Benefits, if any
- Withholding standard care/treatment or an alternative, if any
- Compensation to be expected, if any
- How confidentiality, anonymity and privacy will be maintained
- Right of participant to refuse to participate or withdraw at any time for any reason
- Sources for information and assurances that researcher will provide further and ongoing information (e.g. name and contact phone number of the researcher)
- Signature of the researcher and the participant or the participant's representative
- Signature of the witnesses where appropriate.