

Code of Practice for Ethical Standards in Research involving Human Participants

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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 particular 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 ethical standards is the ethical imperative of *DO NO HARM* (nonmaleficence). Risks and benefits need to be weighed up by researchers, bearing in mind that risk is related to scientific rigour and the quality of research. 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.
- 1.3 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 of the researcher, 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.
- 1.4 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 Department'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

- 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 have the right to receive clearly communicated information from the researcher in advance enabling them to provide informed consent**
- 3.1 Most research procedures should be explained on an information sheet (see the Appendix at the end of this document) 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); any benefits, , to the individual or to others in the future or to society; a statement that individuals may decline to participate, that participation is voluntary and informed about the withdrawal procedure; and an invitation to ask questions.
- 3.3 The information sheet should also provide contact details of the Department'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. This is closely related to section 4.4
- 3.5 The information sheet and a consent form (see Appendix for guidelines on consent forms) 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 Incentives, 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 Where there are significant ethical issues involved in a study, potential participants should be approached in writing and given sufficient information and time to allow full and proper consideration of their willingness to participate
- 4.5 Reimbursement of participants' expenses, for example for journeys, is not payment in the sense of reward, and can be provided.
- 4.6 Participants must be aware of the withdrawal procedure

5. Participants in a research study must provide their informed consent

- 5.1** Participants should understand the purpose and nature of the study, what participation in the study requires and how the results or findings will be used. (see section 6 for special guidance on vulnerable participants and section 7 for exceptional circumstances).
- 5.2** Voluntary informed consent, should usually be obtained from any participant who is able to give such consent (see Appendix for guidelines on the construction of an informed consent statement). If deception is required for the study, and has been approved ethically, then there also needs to be an appropriate debriefing document for the participants.
- 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 questionnaires (on and offline), removing the need for written consent.
- 5.5** Individual consent may be unnecessary for some research activities such as community research which may not be intrusive, for example studies involving observation of public behaviour.

6. Where third parties are affected by the research, informed 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** Informed 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 in the form of a gatekeeper letter 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 under 16 in a research study is justified, then parents or other legal guardians have the right to be informed and to give or withhold their assent for inclusion of the child in the study.
- 7.2** In the case of educational research, any special policies or procedures should be followed in place at the School or other establishment.

- 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, colleagues 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 through an oral debriefing meeting and a written debriefing document that explains the nature of the research (aligned with the principles in section 5) and why deception was necessary to fulfil the objectives..
- 9. Participants' confidentiality and anonymity should be maintained**
- 9.1** Researchers should protect the 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 without their consent (except if subpoenaed by a court).
- 9.5** **No** personal identifiers should be used in a study, and where this is necessary researchers should explain this and how confidentiality and anonymity would be protected at all stages in the research. The ethical approval process should pay particular attention to this aspect.

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 recordings, and destroying the recordings on completion of transcription;
- storing data with any identifying information in a secure location or, if it is computer data, is password protected to which only the researcher(s) 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.

10. The collection and storage of research data by researchers must comply with the Data Protection Act 1998 and the General Data Protection Regulation (Regulation (EU) 2016/679) (GDPR)

10.1 Researchers should follow the University's Data Protection Policy and Guidelines. The University Data Protection Policy and Student Privacy Notice set out the rules for adherence to the requirements of data protection laws and are available at: <http://www.bolton.ac.uk/studentinformation-policyzone/Home.aspx>

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 that directly identifies an individual.

10.3 Participants must be informed of the kinds of personal information that 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 Department.

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.



APPENDIX

Guidelines For Informed Consent

Potential recruits to your research must be given sufficient information to allow them to decide whether or not they want to take part.

Participation Information Sheet

Where research involves face to face interviews, focus groups, direct observation or similar methods of data collection, participants should normally be given or allowed to read or have read to them a participant information sheet and may be asked to sign a **consent form**. Details of what should normally be included in each are given below. A participant information sheet should be written in simple, non-technical terms and be easily understood by a lay person. While it is always important to ensure that adequate information is given, the way in which the information is presented will need to be adapted to the individual circumstances of the study.

Similarly, clear evidence must be obtained that the participant has given **informed consent** to take part in the study. This will normally be in the form of a signed **consent form**, although other evidence may be acceptable.

Where participants are asked to complete and return a questionnaire, the questionnaire should be accompanied by a covering letter but no consent form is needed since consent is implied by returning the questionnaire. The covering letter, however, should include the information given below.

The information sheet should normally contain the following information:

Study title

The title should be simple and self-explanatory to a lay person.

Identification, affiliation and contact details

You should provide your name and explain that you are conducting the research as a student or member of staff at the University of Bolton and give your Department name. You should also state the organisation that is funding the research if appropriate (e.g. Economic and Social Research Council, Nuffield Foundation Tesco, etc).

Invitation paragraph

This should explain that the individual is being asked to take part in a research study. The following is an example of how this may be phrased:

'You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully.'

What is the purpose of the study?

The background and the aim of the study should be given here. You should say how long the study will run and outline the overall design of the study.

Why have I been chosen?

You should explain how the individual was chosen to take part in the study and how many other people will be asked to participate.

Do I have to take part?

You should explain that taking part in the research is entirely voluntary and that they can withdraw at any stage. For example, you could say: -

'It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason'.

What will happen to me if I take part?

You should explain your methods of data collection, including what the individual will be asked to do and how much time will be involved.

What are the possible disadvantages and risks of taking part? (where appropriate)

You should describe any disadvantages or 'costs' involved in taking part in the study, including the time involved.

What are the possible benefits of taking part?

You should outline any direct benefits for the individual and any other beneficial outcomes of the study, including furthering our understanding of the topic.

Will what I say in this study be kept confidential?

You should explain that all information collected about the individual will be kept strictly confidential and describe how confidentiality, privacy and anonymity will be ensured in the collection, storage and publication of research material. Data generated by the study must be retained in accordance with the University's policy on Data Protection. You should include a statement that the data generated in the course of the research must be kept securely in paper or electronic form for a period of five years after the completion of a research project.

What will happen to the results of the research study?

You should tell the individual what will happen to the results of the research. Will they be used in your dissertation or thesis? For what degree? Will they be published?

Will I be debriefed at the end of the research?

It is considered to be good practice for researchers to debrief participants at the conclusion of the research and to offer them (access to) copies of any reports or other publications arising from their participation should they so wish.

Who has reviewed the study?

You may state that the research has been approved by the University Research Ethics Committee, University of Bolton.

Criminal Records Check (if applicable)

A statement declaring that each researcher who may have access to children aged under 16 or to vulnerable adults has undergone a satisfactory criminal records check.

Contact for Further Information

You should give the individual contact details for further information (Name, Address, Email and Telephone). These should normally be your details if you are a member of staff or those of your supervisor if you are an undergraduate, taught postgraduate or postgraduate research student.

You should add that if they have any concerns about the way in which the study has been conducted, they should contact the Departmental Research Ethics Officer (for staff) or your supervisor (for students) in the first instance.

Thank you

Remember to thank the individual for taking time to read the information sheet.

Date

The information sheet should be dated.

Consent Form

The consent section (or separate form) should then contain clear statements of the following type:

- I have read and understand the study information sheet and I know what is expected of me as a participant
- I agree to take part in this research
- I agree to be recorded (with the form of 'recording' specified)
- I understand the withdrawal procedure

Finally, the participant and researcher(s) should sign and date the consent form.

