Research Ethics for Research involving Human Participants

Code of Practice

March 2000
Updated March 2016
1. Introduction

The University adheres to the principles of research ethics as laid out by the ESRC (2015) guidelines and which comprise the following:

- Research participants should take part voluntarily, free from any coercion or undue influence, and their rights, dignity and (when possible) autonomy should be respected and appropriately protected.

- Research should be worthwhile and provide value that outweighs any risk or harm.

- Researchers should aim to maximise the benefit of the research and minimise potential risk of harm to participants and researchers. All potential risk and harm should be mitigated by robust precautions.

- Research staff and participants should be given appropriate information about the purpose, methods and intended uses of the research, what their participation in the research entails and what risks and benefits, if any, are involved.

- Individual research participant and group preferences regarding anonymity should be respected and participant requirements concerning the confidential nature of information and personal data should be respected.

- Research should be designed, reviewed and undertaken to ensure recognised standards of integrity are met, and quality and transparency are assured.

- The independence of research should be clear, and any conflicts of interest or partiality should be explicit.

The University requires that the integrity of any research depends not only on its rigour but also on its ethical adequacy. The University expects that research should contribute to knowledge development. 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 and their personal data. Good ethical research practice is the responsibility of the researcher and or the research team and or the supervisory team. The underpinning principle of research conducted in or through Oxford Brookes University is to do no harm to research participants. The University supports a breadth of research and approaches and acknowledges that this range of research may result in an array of ethical issues.

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 Faculty’s Research Ethics Officer, the University Research Ethics Committee and the relevant professional code of practice for research ethics as appropriate.

This code of practice acknowledges key regulatory frameworks such as:

Data Protection Act 1998
Equalities Act 2010
Freedom of Information Act 2000
Human Rights Act 1998
Human Tissue Act 2004
The Mental Capacity Act 2005
Research Governance Framework for Health and Social Care: second edition 2005
Safeguarding/DBS requirements
Safeguarding Vulnerable Groups Act 2006
Legislation relating to Children including The United Nations Convention on the Rights of the Child
2. **No research should cause harm**

   No research undertaken should cause harm to participants, researchers or other persons directly or indirectly involved in the research

   a. A judgement needs to be made as to whether a particular research practice 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.

   b. Research approaches must be justified, explaining why alternative approaches cannot be used, for example in cases of potentially intrusive research.

   c. The potential benefits of the research to participants, the wider community and/or society must be clearly stated.

   d. Any cultural, religious, gender or other differences in a research population should be sensitively and appropriately handled by researchers at all stages. Relevant subject specific requirements and norms of research practice should be sought out and adhered to.

3. **Honesty**

   Honesty in the planning, conducting, analysing and reporting of research is required. Honesty should be central to the relationship between researcher, participant and institutional representatives

   a. The deception of participants should be avoided. If necessary deception must be justified by the researchers and the reasons should be explained to participants after the study.

   b. Covert research may be appropriate within certain contexts and within certain subject areas but must be justified. However the ‘do no harm’ principle must be adhered to.

   c. Any conflicts of interest must be declared to the University, research participants and in any dissemination of findings.

4. **Coercion**

   Participants should be free from coercion and should not be pressured to participate in a study

   a. Incentives for participation should be commensurate with the tasks involved.

   b. Compensation for loss of income should not be considered inducements. Reimbursement of participants’ expenses, for example travel, can be provided.

   c. Risks involved in participation should be acceptable to participants, even in the absence of inducement.

   d. Participants must be free to withdraw from the study at any time, without any repercussions to the participant.

5. **Confidentiality and anonymity**

   Participants’ confidentiality and anonymity should be maintained as a core principle

   a. Researchers should adhere to the University’s Code of Practice for Academic Integrity, including procedures for investigating allegations of misconduct in research ([www.brookes.ac.uk/research/policies-and-codes-of-practice](http://www.brookes.ac.uk/research/policies-and-codes-of-practice)).

   b. Researchers and other collaborators should deal with all data obtained through their project in such a manner so as not to compromise the personal dignity of the participant or compromise the participant’s right to privacy, through all the collection, storage, analysis and disposal stages of the research.
c. 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 when required by law, or with the express consent of the participant.

d. When personal identifiers are used in a study, researchers should explain why this is necessary and how confidentiality would be protected. In cases where participants’ anonymity may be at risk, the participants will be informed at the outset of the research.

6. Consent

Participants in a research study are usually required to give their informed consent before participating

6.1 Informed consent

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

a. Informed consent, should usually be recorded from any participant who is able to give such consent, either by implied consent (see point c below) or explicitly.

b. It is the researcher’s responsibility to seek ongoing consent during the course of a study, as appropriate.

c. Consent may be implied by the completion and return of survey questionnaires, removing the need for written consent.

d. Individual consent is not always required for some types of research activities, for example studies involving observation of public behaviour in public spaces.

6.2 Third party consent

Where third parties are affected by the research, consent should be obtained

a. When third parties, for example spouses, teachers or health care professionals, are directly affected by the research and are involved in the care, education or treatment of the potential participants, consent should also be obtained from them.

6.3 Gatekeeper consent

a. Certain situations may necessitate the granting of permission by educational institutions, business organisations, or hospitals, to conduct the research. Where this is required permission should be sought prior to the start of the research and any relevant policies or guidelines should be followed.

6.4 Vulnerable participant consent

The consent of vulnerable participants or their representatives’ consent should be sought by researchers

a. In cases where people are unable to comprehend the implications of research, assent to participate may come from a representative, such as a legal guardian, immediate relative or carer with the appropriate authority to do so.

b. Consent witnessed by an appropriate person is required for vulnerable participants who have intellectual difficulties or linguistic differences limiting speech or understanding, but who are deemed capable of giving consent.
6.5 Research involving children and their consent

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. Adherence to the UNICEF guidelines for Ethical Research Involving Children should be followed (http://childethics.com/)

a. If children are involved in a research study, then parents or other legal guardians must be informed and may be required to give their consent for inclusion of the child in the study.

b. In the case of research within an educational setting such as a school, specific school policies or procedures should be followed.

7. Dependent relationships

Where relationships may be characterised by inequalities of power or status, the impact of this relationship on all parties needs to be considered

a. Research involving participants who are in a potentially dependent relationship with the researcher (e.g. students, employees and patients) requires careful consideration, justification and mitigation where possible.

8. Data protection

The processing of research information containing personal data must comply with the Data Protection Act 1998 principles listed below

a. The University is registered as a data controller with the Information Commissioners Office (ICO). There are eight good practice guidelines which must be adhered to when processing personal data:

1. Personal data shall be processed fairly and lawfully.

2. Personal data shall be obtained only for one or more specified and lawful purposes.

3. Personal data shall be adequate, relevant and not excessive.

4. Personal data shall be accurate and, where necessary, kept up to date.

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary.

6. Personal data shall be processed in accordance with the rights of data subjects under this Act.

7. Appropriate technical and organisational measures shall be taken to protect personal data.

8. Personal data shall not be transferred to a country or territory outside the European Economic Area without adequate protections.

b. Additional care must be taken when processing sensitive personal data which may contain the following information:

i. racial or ethnic origin

ii. political opinions

iii. religious beliefs or other beliefs of a similar nature

iv. membership of a trade union
v. physical or mental health or condition
vi. sexual life
vii. commission or alleged commission of any offence
viii. any proceedings for any offence committed or alleged to have been committed.
c. In the event that personal data have been lost, stolen or compromised in any way, the incident must be reported at the first opportunity to information compliance officer via info.sec@brookes.ac.uk.

Further information on data protection is available: www.legislation.gov.uk/ukpga/1998/29/contents

9. Digital, Electronic and Social Media Data

This refers to research involving the use of online surveys, questionnaires, use of social media (e.g. Facebook, on-line groups, chat rooms, Skype etc.) for recruitment, data collection or research within this area. Continuing technological advances can introduce additional and non-obvious complexities in adhering to ethical principles

a. Members of the University who carry out research using these methods should ensure that they are familiar with current debates on the ethics of internet-mediated research.
b. Gaining informed consent, negotiating access, assessing the boundaries between the private and the public and ensuring the security of data transmissions may be problematic, however the ethical principles referred to in this document apply as much for these forms of research as they do for all other forms of research.
c. Adequate controls must be put in place to preserve the anonymity and/or protect the privacy of participants, appropriate to the technology used and the type of data which is to be collected.
d. Researchers are reminded to read the terms and conditions of any such service that they use to ensure that the service is fit for purpose. UK Legislation such as The Regulation of Investigatory Powers Act (RIPA) may require lawful disclosure of communication data. In such circumstances this must be escalated to the Information Compliance Officer via info.sec@brookes.ac.uk.
e. The type of consent obtained (e.g. documented using a separate form, in hard or soft copy, evidenced via other “implied” means) should be proportional to the risk of the research to participants.
f. The distinction between public and private domains should be considered from the point of view of the participant and not defined simply in terms of ability of the researcher to access the site, material or participant. Care must be taken in both consent and data management processes to respect individuals and their privacy.
g. Further useful guidance can be obtained from: The British Psychological Society www.bps.org.uk and the Association of Internet Research (AoIR) http://aoir.org/ethics.

10. Research involving sensitive and or illegal subjects

The University is committed to providing an environment in which students and staff are able to engage in debate and research across all subject areas within legal boundaries

a. Oxford Brookes University acknowledges the need to be vigilant in identifying and managing, where possible, research involving sensitive subjects such as but not limited to terrorism, abuse and illegal substances. In relation to terrorism the University aims to prevent individuals from being drawn into terrorism in so far as is possible.
b. The researcher should be aware that researching certain subject areas carries with it the potential for an individual being flagged by the security or other public protection services and this flagging can be irreversible.
c. For information on security sensitive material and activity please refer to the University’s guidelines (document not yet approved – August 2016).

11. Research in public contexts and with groups

**Awareness should be demonstrated when research is conducted in public spaces and or with groups**

a. In certain research contexts obtaining consent from each individual maybe impractical or unfeasible or indeed detrimental to the research being undertaken. In such instances the groups should, where possible, be informed that the research is taking place and no individual identifying detail should be included in any subsequent research report. Sensitivity should be shown to local group cultural norms to avoid the perception of the invasion of privacy despite being situated in a public space.

b. In participatory research care should be taken to ensure that participants within a group are made aware that they are being observed for research purposes.

12. Personal safety and responsibilities of the researcher

**The researcher and or research team and or supervisory team shall ensure that the research to be undertaken creates no more risk to the researcher than that of normal every day life**

a. Where it is considered that the risks are more than those in every day life a justification for those risks and suitable mitigation of the risks should be provided.

b. Where the research involves the use of specialised equipment the researcher, research team and/or supervisory team will ensure that there is adequate knowledge and training in the safe operation of that equipment.

c. The researcher and/or research team and/or supervisory team shall be responsible for ensuring that appropriate insurances are in place through communicating to the University any overseas travel plans for research purposes in addition to the nature of their research.

13. Communication with participants

**Potential participants should receive clearly communicated information from the researcher in advance**

a. Most research should be explained on an information sheet written in clear language that is easily understood by the potential research participant.

b. 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 without giving a reason; the level of feedback to be offered; the time required and an invitation to ask questions.

c. The information sheet should also provide contact details of the Faculty’s Research Ethics Officer or Chair of UREC so that participants may report any concerns about the conduct of the study.

d. Participants should be given, under normal circumstances, a minimum of 48 hours to study the information sheet, and consult relevant parties where necessary.

e. The information sheet and the consent materials (see Appendices for templates) should form part of the application for ethics approval.
14. Dissemination of research findings

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

a. Participants and relevant stakeholders will usually be offered access to a summary of the research findings where appropriate.

b. Reports to the public should be clear and understandable and accurately reflect the outcome of the study.

c. Research outputs should wherever possible be disseminated widely and openly to maximise their value.

Approved by the University Research Ethics Committee on: 9 March 2016
Approved by the University Research and Knowledge Exchange Committee on: 24 May 2016
Approved by Academic Board on: 13 July 2016
Appendix 1 – Participant information sheet template

The participant information sheet, covering letter or leaflet should be printed on Oxford Brookes headed paper or with the Oxford Brookes logo (where appropriate), with full contact details and should normally contain the following information:

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

**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 whether or not to take part, 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 invited to participate?**
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. 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'.

If your study involves the recruitment of students or pupils you must explain that by choosing to either take part or not take part in the study will have no impact on their marks, assessments or future studies.

**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 (subject to legal limitations) 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 Academic Integrity. 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 ten years after the completion of a research project.
Explain how the data will be stored securely in the field before being transferred back to Oxford Brookes University. If it is stored on a laptop, it should be encrypted, otherwise it may be stored in Google Drive, for which the University has a security agreement.

If it is a condition of your research funding that the research data must be shared and stored in a repository, you must explain how the data will be stored (for example with the UK Data Service or the UK Data Archive) and explain it will be anonymised.

**What should I do if I want to take part?**
Explain exactly how the participant should 'opt in' for the study.

**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? How can they obtain a copy of the published research?

**Who is organising and funding the research?**
You should explain that you are conducting the research as a student or member of staff at Oxford Brookes University. Give your department name as well as the Faculty name. You should also state the organisation that is funding the research (e.g. Economic and Social Research Council, Nuffield Foundation, Tesco, etc) if appropriate.

**Who has reviewed the study?**
You may state that the research has been approved by the University Research Ethics Committee, Oxford Brookes University.

**Contact for Further Information**
You should give the individual a contact point for further information. This can be your name or that of your supervisor. You should add that if they have any concerns about the way in which the study has been conducted, they should contact the Chair of the University Research Ethics Committee on ethics@brookes.ac.uk.

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

**Date**
The information sheet should be dated.
CONSENT FORM

Full title of Project:

Name, position and contact address of Researcher:

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.  
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason.
3. I agree to take part in the above study.
4. I understand that the focus group will be audio-recorded

**Note for research team / supervisory team:**
The following statements should be included if appropriate. If not, please delete from the consent form:

Please initial box

5. I agree to the interview / focus group / consultation being audio recorded
6. I agree to the interview / focus group / consultation being video recorded
7. I agree to the use of anonymised quotes in publications
8. I agree that my data gathered in this study may be stored (after it has been anonymised) in a specialist data centre and may be used for future research.

_________________________  ____________  _______________________
Name of Participant        Date         Signature

_________________________  ____________  _______________________
Name of Researcher         Date         Signature