Research Ethics for Research involving Human Participants

Code of Practice
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.

- Research should be sensitive to and respectful of indigenous values and cultures.

- Research should be for the benefit of the participants' community while recognizing that it will likely also yield benefits to the global population.

- Research and the dissemination of data in publications should take place with active intellectual participation of indigenous investigators and other Indigenous stakeholders where relevant.

- Research should promote respect for individuals and communities, fairness, equity, and reciprocity.

- 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 upheld.

- 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. In certain circumstances research data may be accessed to review regulatory compliance. 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 2018
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
Governance arrangements for Research Ethics Committees
Global Code of Conduct for Research in Resource Poor Settings 2019

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, or artefacts or sites held as important to those communities 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, and culturally appropriate where relevant.

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).

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. 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.

c. 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 should be given sufficient time to read and question information regarding the study before usually giving their informed consent prior to participation.

6.1 Informed consent

Participants should understand the purpose and nature of the study, what participation in the study requires, what benefits are intended to result from the study, any relevant risks and what will happen to the data collected. Consent cannot be inferred from inaction.

a. Informed consent should usually be recorded from any participant who is able to give explicit consent, clearly indicating what they have consented to.

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

c. Consent requires clear affirmative action, such as a written statement, electronic means or an oral statement. Participants should take deliberate and specific action to agree to participate in a study.

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 for example but not limited to educational institutions, business organisations, or non-government organisations (NGOs), 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 including local cultural norms.

b. In addition to Oxford Brookes research ethics approval, it may be necessary to seek approval from other bodies, for example, but not limited to, The Health Research Authority and/or National or local Research Ethics Committees.

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, consent 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 child participants should also be sought. Generally, young people over the age of 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 a parent(s) or other legal guardian(s) 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 or gatekeeper of the research project (for example but not limited to 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 2018 principles listed below

a. The University is registered as a data controller with the Information Commissioner's Office (ICO). There are seven key principles which should be adhered to when processing personal data.

   Personal data shall be:

   1. processed lawfully, fairly and in a transparent manner in relation to individuals
('lawfulness, fairness and transparency')

2. collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall not be considered to be incompatible with the initial purposes ('purpose limitation')

3. adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation')

4. accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to the purposes for which they are processed, are erased or rectified without delay ('accuracy')

5. kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes subject to implementation of the appropriate technical and organisational measures in order to safeguard the rights and freedoms of individuals ('storage limitation')

6. processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality')

7. The controller shall be responsible for, and be able to demonstrate compliance with, paragraph 1 ('accountability')

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

i. data revealing racial or ethnic origin

ii. data revealing political opinions

iii. data revealing religious beliefs or other beliefs of a similar nature

iv. data revealing membership of a trade union

v. genetic data

vi. biometric data (where used for identification purposes)

vii. data concerning health

viii. data concerning a person's sex life

ix. data concerning a person's sexual orientation

Note: This does not include personal data about criminal allegations, proceedings or convictions, as separate rules apply.

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 the IT Services Information Security team via info.sec@brookes.ac.uk.

Further information on data protection and privacy for researchers is available from the following sources:

i. Data Protection Act 2018
9. **Digital, Electronic and Social Media Data**

This refers to research involving the use of online surveys, questionnaires, visual data, 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, or evidenced via other 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 sources such as but not limited to: The British Psychological Society [www.bps.org.uk](http://www.bps.org.uk) and the Association of Internet Research (AoIR) [http://aoir.org/ethics](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 specific information on security sensitive material and research activity please refer to the University’s guidelines.
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 may be 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 invasion of privacy or disrespect 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. **Research in Resource Poor Settings**

*Researchers should demonstrate consideration when working in resource poor locations.*

a. Local researchers should be included wherever possible and practical and consideration given for compensation for local research support

b. Careful explicit consideration will be given to any research which is prohibited in resource poor countries prior to any university approval.

c. Local expertise and advice will be followed to mitigate against the any stigmatisation howsoever caused during research in resource poor settings.

d. Researchers should familiarise themselves with regulations around bribery and corruption, adhering to the University’s [Code of Conduct for Staff](#).

13. **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 everyday life*

a. Where it is considered that the risks are more than those in everyday 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.

d. Please refer to the University guidance for [Working Alone Safely](#).

14. **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, this information may be presented in other ways where relevant.
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 before providing consent.

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

15. 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, other dissemination outputs are encouraged, depending on the research setting.

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.

d. Consideration should be given in how any benefits arising from the research might be shared with stakeholders in resource poor settings.
The participant information sheet, covering letter or leaflet should be printed on Brookes headed paper, (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 in this research study. If you do decide to take part you will be given this information sheet along with a privacy notice that will explain how your data will be collected and used, and be asked to give your consent. 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. If the study involves the recruitment of participants from an organisation/company/service, that it will have no impact on their current/future employment or use of the service.

**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. Explain if interviews or focus groups are to be audio or visually recorded, with the participants' permission.

**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. [This must mirror the information given
Research data must be kept securely at all times, especially when collected in the field before being transferred back to Oxford Brookes University. Laptops and other devices should be password protected whilst data files must be encrypted. Data may be stored in Google Drive, for which the University has a security agreement.

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. [For staff and Doctoral students only]. Should the study be externally funded and the funder's retention period is longer this should be explained. [For Taught Masters and Undergraduate students data should usually be kept until the student graduates, unless the supervisory team consider there is an advantage to storing it for longer].

If it is a condition of your research funding that the research data must be deposited into a recognised 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; who they should contact, and if there is a deadline for participation.

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 published as an output or used as a conference paper / presentation? Will they be used in your dissertation or thesis? For what degree? A copy of the findings of the study should be offered to each participant.

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 / Directorate. You should also state the organisation that is funding the research (e.g. Economic and Social Research Council, Nuffield Foundation, commercial company, etc.) if appropriate.

Who has reviewed the study?
You should 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.

Version Number
Each time the information sheet is updated, change the version numbering in the footer below to ensure accurate recording of the most up to date information sheet.
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 understand that if I withdraw from the study my data can be withdrawn up to the point of analysis.

Note for research team / supervisory team:

The following statements should be included if appropriate. If not, please delete from the consent form:

4. I understand that the research group/interview/focus group will be audio-recorded.

Yes No

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 visual material in publications.

8. I agree to the use of anonymised quotes in publications.

9. 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.

Note for research team / supervisory team:

The below must be included in all Consent Forms:

10. I agree to take part in the above study.

Name of Participant Date Signature

Name of Researcher Date Signature

Appendix 3 Privacy Notice for Research Participants
Privacy Notice for Research Participants

This Privacy Notice provides information on how Oxford Brookes University (Oxford Brookes) collects and uses participant’s personal information when you take part in one of our research projects. Please refer to the research Participant Information Sheet for further details about the study and what information will be collected about you and how it will be used.

Oxford Brookes is the Data Controller of any data that you supply for this research. This means that we are responsible for looking after your information and using it lawfully. We will make the decisions on how your data is used and for what reasons.

Why do we need your data?

<Insert research purpose here>

Oxford Brookes’ legal basis for collecting this data is:

<Insert appropriate reason for processing>

Your consent is an ethical requirement.

Oxford Brookes University’s legal basis for processing your Personal Data (or information) is as set out in Art 6 UK GDPR.

Special Category Data:

Oxford Brookes may ask you for sensitive data such as: racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, data concerning health or sexual life, genetic/biometric data. This is defined by law as Special Category Data. If Oxford Brookes requests this data it can only be used because one of the following processing exemptions applies as set out in Art 9 UK GDPR:

<Insert the reason for the Special Category Data Collection or deleted section if not being collected>

What type of personal data will Oxford Brookes use?

<Insert all types of data being gathered for the study>

Who will Oxford Brookes share your data with?

<Insert any research partner institutions or collaborators which will have access to the data here>

<Insert any third party processors that host or have access to the data>

Will Oxford Brookes transfer my data outside of the UK?

<Yes (State where data will be transferred to)/ No>

What rights do I have regarding my data that Oxford Brookes holds?

- You have the right to be informed about what data will be collected and how this will be used
- You have the right of access to your data
- You have the right to correct data if it is wrong
- You have the right to ask for your data to be deleted
- You have the right to restrict use of the data we hold about you
- You have the right to data portability
• You have the right to object to Oxford Brookes using your data
• You have rights in relation to using your data in automated decision making and profiling.

Your rights will depend on the legal ground used to process your data

**Where did Oxford Brookes source my data from?**

<Insert where the data is coming from >

**Are there any consequences of not providing the requested data?**

There are no consequences of not providing data for this research. It is purely voluntary. If you like to withdraw part way through the research, the Participant Information Sheet includes this information. It may be that some of the data that you have provided has already been used in the research. If you would like more information about this, you should feel free to contact the research team.

**Will there be any automated decision making using my data?**

There will be no use of automated decision making in scope of UK Data Protection and Privacy legislation.

**How long will Oxford Brookes keep your data?**

<Insert data how long the data will be retained. For example: In line with Oxford Brookes policies data generated in the course of research must be kept securely in paper or electronic form for a period of ten years in accordance with the research funder or University policy.>

**Who can I contact if I have concerns?**

In the event of any questions about the research study, please contact the research team in the first instance. Their contact details are listed on the Participant Information Sheet. If you have any concerns about the way in which the study has been conducted, please contact the Chair of the University Research Ethics Committee at ethics@brookes.ac.uk. For further details about information use contact the Information Security Management team on info.sec@brookes.ac.uk or the Data Protection Officer at brookesdpo@brookes.ac.uk. You can also contact the Information Commissioner’s Office via their website ico.org.uk.