Ethics Principles for Research Involving Human Participants

The Open University
Human Research Ethics Committee
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**Principle 1: Compliance with protocol**

Research with humans conducted by Open University employees and their agents and assignees should be aware of the range of research ethics and in particular comply with an explicit protocol* defining how valid consent to participate is sought, gained and recorded, how data are collected, stored and accessed, and how participants are informed of their rights within the study.

A favourable opinion on the protocol should be gained from the Open University Human Research Ethics Committee (HREC) before data collection commences, and from other bodies such as the Open University Student Research Project Panel and UK National Health Service Research Ethics Committee(s) as appropriate. The only exception to this requirement shall be where any reasonable judgement would suggest that no harm could possibly arise to any person, living or dead, in connection with the proposed research.

*In these Principles, the term ‘protocol’ refers to a filed document which specifies the procedures for recruiting participants and gathering and managing data, with which all research staff agree to comply.
Principle 2: Valid consent

Potential participants should always be informed in advance and in understandable terms of any potential benefits, risks, inconvenience or obligations associated with the research that might reasonably be expected to influence their willingness to participate.

Consent should always be gained in a consistent manner, as specified in the research project’s ethics protocol. This should normally involve the use of an information sheet about the research and what participation will involve, and a signed consent form. Sufficient time shall be allowed for a potential participant to consider their decision between the giving of the information sheet and the gaining of consent.

Except in exceptional circumstances, where the nature of the research design requires it, no research shall be conducted without the opt-in valid consent of participants. In the case of children (individuals under 16 years of age) no research shall be conducted without a specified means of gaining their valid consent (or, in the case of young children, their assent) and the valid consent of their parents or guardians, or persons who are legally responsible or appointed to give consent on their behalf.

Where participants are involved in longer-term data collection, the use of procedures for the renewal of consent at appropriate times should be considered.

No inducement to participate should be offered prior to seeking consent, either in the form of payments or of gifts. Reasonable recompense for inconvenience and time contributed to the research and reimbursement of travelling expenses can be offered.

Participants should be informed clearly that they have a right to withdraw their consent at any time up to a specified date, that any data that they have provided will be destroyed if they so request up to a specified date, and that there will be no adverse consequences for participants if they choose to withdraw or request data destruction. However, it must be clear that withdrawal after a specified date may not be possible as it would unduly affect the study.
Principle 3: Openness and integrity

Researchers should be open and honest about the purpose and content of their research and behave in a professional manner at all times.

Researchers should comply with the University’s principles for integrity in the general conduct of research.

Where an essential element of the research design would be compromised by full disclosure to participants prior to their involvement, such withholding of information should be specified in the project protocol and explicit procedures stated to obviate any potential harm arising from such withholding.

Deception or covert collection of data should only take place where it is essential to achieve the research results required, where the research objective has strong scientific merit and where there is an appropriate risk management and harm alleviation strategy.

Participants should be given opportunities to access the outcomes of research in which they have participated and debriefed if appropriate after they have provided data.

Principle 4: Maximising benefit and protection from harm

Researchers should make every effort to maximise the benefits of research while minimising the risks of any harm, either physical or psychological, arising for any participant, researcher, institution, funding body or other person or community.

Every project should include a risk analysis and, where significant risks are identified, should specify a risk management and harm alleviation strategy in the protocol.

Researchers should comply with the requirements of the UK Data Protection Act 1998, the Freedom of Information Act 2000 and any other relevant legal frameworks governing the management of personal information in the UK or in any other country where the research may be conducted.

Where research involves children or other vulnerable groups, an appropriate level of disclosure should be obtained from the Criminal Records Bureau for all researchers in contact with participants.

Where harm does nevertheless arise in the course of research, researchers should take remedial steps.

Participants should be given information as to whom they may contact in the event of any issues arising in the course of the research that cannot be resolved with members of the project team.
**Principle 5: Confidentiality**

Except where explicit written consent is given to reveal identities, researchers should respect and preserve the confidentiality* of participants’ identities and data. The procedures by which this is to be achieved should be specified in the protocol.

*Note that the duty of confidentiality is not absolute in law and may be overridden by more compelling duties such as the duty to protect individuals from harm or in the public interest – such as in research involving public officials. Where a significant risk of such issues arising is identified in the risk assessment, specific procedures to be followed should be specified in the protocol.

**Principle 6: Professional codes of practice and ethics**

Where the subject of a research project falls within the domain of a professional body with a published code of practice and ethical guidelines, researchers should explicitly state their intention to comply with the code and guidelines in the project protocol.

Research within the UK NHS should always be conducted in compliance with an ethical protocol approved by an appropriate NHS Research Ethics Committee.

Human Research Ethics Committee (HREC)

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