



UNIVERSITY RESEARCH ETHICS COMMITTEE

RESEARCH ETHICS POLICY AND PROCEDURES

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1. Coverage

- 1.1 This policy and associated procedures apply to all research undertaken under the auspices of the University. Any research undertaken by staff or students (undergraduate or post graduate) of the University which involves direct contact with human participants, whether clinical, biomedical or social research, or the secondary use of human and animal materials or specimens, or where there may be any other ethical issues, should be subject to ethical review. Researchers are required to demonstrate that this review has occurred. Research supervisors have overall responsibility for ensuring that appropriate ethical scrutiny of their students' research occurs and must advise on the processes required.
- 1.2 Responsibility for undertaking the review will depend on the nature of the research. While demonstrating that ethical scrutiny of research projects has occurred is the responsibility of supervisors or principal investigators, under the University self-regulation policy not all research projects will need to be formally approved by a committee. Very low risk projects can be self-assessed using the university checklist. However, for all low risk research with human participants a copy of the self-assessment checklist must be lodged with the faculty research ethics administrator.
- 1.3 All research by staff or students involving the National Health Service (NHS), Social Care, some categories of human tissue, and the national offender management Service (NOMS) is subject to NHS, Social Care or NOMS governance procedures specified by the Department of Health (DoH). For this research, there is now a national Health Research Authority (NRES) portal, the Integrated Research Application Service (IRAS), which provides a more integrated service for obtaining the necessary approvals covering NHS, Social Care and NOMS research. All systems require that the scientific quality of research proposals is evaluated before ethical approval is requested. The University has delegated authority to conduct this Independent Scientific Review (ISR) for research being undertaken in this region. The system requires a detailed research protocol, which must be submitted to the relevant University Faculty Research Ethics Committee for methodological evaluation and any required changes must be undertaken before it is submitted to the NRES system. The research quality evaluation is a requirement of the DoH Research Governance Framework.

2 Guiding Principles

- 2.1 Research undertaken by staff and students must confirm to all legal requirements. This will include compliance with relevant data protection legislation, appropriate screening of researchers working with vulnerable groups and strict adherence to standard operating procedures and licensing requirements for any animal, biomedical or other research associated with the collection and analysis of human tissue.
- 2.2 Research should be undertaken in accordance with commonly agreed standards of good practice such as are laid down in the Declaration of Helsinki, The Economic and Social Research Council (ESRC) Research Ethics Framework, by the Medical Research Council (MRC) and Research Councils UK (RCUK). These fundamental and widely accepted principles may broadly be categorised as:
- Beneficence - 'doing positive good'
 - Non-Maleficence - 'doing no harm'
 - Integrity
 - Informed Consent

- Confidentiality/Anonymity
- Impartiality

All research must conform to the following:

2.3 **Beneficence and Non-Maleficance**

Terms such as risk, harm and hazards include emotional and mental distress, and possible damage to financial and social standing as well as to physical harm and threats to national or international security.

- The importance of the objective should be in proportion to the inherent risk to the participant. Concern for the interests of the participant must always prevail over the interests of science and society;
- The research should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the participants or to others;
- Research should not be undertaken where the hazards involved are not believed to be predictable;
- Adequate facilities and procedures should be in place to deal with any potential hazards;
- Due concern should be given to minimising risks to the environment.

2.4 **Integrity**

- The research should be scientifically sound and the purpose should be to contribute to knowledge;
- The research should be undertaken and/or supervised by those who are appropriately qualified and experienced; researchers and their supervisors must be accountable for the research they undertake;
- The University requires research supervisors to take reasonable steps to ensure the research integrity of their students' research, e.g. listen to interview tapes, check lab books, or examine data sets.

2.5 **Informed Consent**

- Each potential participant must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort it may entail;
- Any documentation given to potential participants should be comprehensible and there should be an opportunity for them to raise any issues of concern;
- Consent should normally be in writing and records of consent should be maintained;
- Potential participants must be informed that they are free to withdraw consent to participation at any time during the study and up to a specified date after the data has been collected unless data collection is anonymous;
- There should be a procedure for making complaints and participants should be made aware of this;
- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, students must be assured that any decision not to participate will not prejudice in any way their academic progress;
- Any inducement offered to participants should be declared and should be in accordance with appropriate guidelines;
- Consent must be obtained from a legal guardian in the case of minors or for any others who do not have the legal competence to give informed consent, in the latter case

research ethics review must be undertaken by the NHS National Research Ethics System.

2.6 Confidentiality/Anonymity

- All research should conform to data protection legislation;
- Details that would allow individuals to be identified should not be published, or made available, to anybody not involved in the research unless explicit consent is given by the individuals concerned, or such information is already in the public domain;
- All reasonable steps should be taken to ensure that confidential details are secure;
- Great care must be taken where there is an intention to use data collected for one study to be archived for use in future studies or for open access data sharing. It is important that relevant guidelines are followed.

2.7 Independence and impartiality

Researchers should be honest with respect to the conduct of their research from inception to publication. Conflicts of interests are not necessarily unethical but should be declared and dealt with appropriately. The MRC suggest that researchers ask themselves, "Would I feel comfortable if others learnt about my secondary interest in this matter or perceived that I had one?" The recommendation is that if the answer is no, disclosure is required.

2.8 This guidance is only intended to be an introduction to the issues and an indication of the matters that will be considered by University Research Ethics Committees. A list of further guidelines and codes of practice is available via the Research Ethics website at <http://www.shu.ac.uk/research/ethics/> or from the Secretary to the University Research Ethics Committee. In addition, Faculties should make researchers aware of guidance that relates to particular disciplines and professions via their websites.

3. Authority

3.1 The ultimate responsibility for the care of human participants rests with the researcher. However, in discharging its duty the University has established a University Research Ethics Committee and empowered Faculties to establish their own Research Ethics Committees (delegated committees). In addition, where appropriate, decisions are referred to the DoH, NHS, Social Care and NOMS Governance procedures.

3.2 The researcher or supervisor, in the case of student research, has the responsibility for deciding what authorisation, if any, should be sought. If researchers are in doubt as to what is appropriate they should seek advice. However, it is possible to give a general indication, as follows:

3.3 Self-Regulation

There are a number of straightforward procedures where it may not be necessary for researchers to seek Research Ethics Committee approval. However, in these cases the researcher still has a responsibility to consider ethical issues and take note of any relevant codes of practice. Procedures which may come under this category include:

- Library studies, secondary data analysis, questionnaires and interview schedules where there are no major issues relating to confidentiality or sensitive information or controversial subject matter and which do not involve vulnerable participants;
- Research already granted permission by other ethics committees;
- Group research exercises such as laboratory practicals or work-based learning projects where category approval has previously been given by the Faculty Research Ethics Committee.

For all low risk research with human participants a copy of the self-assessment checklist (SHUREC1) must be lodged with the faculty research ethics administrator for auditing purposes.

3.4 However, where there is any doubt about any ethical issues relating to the project, it should be referred to the most appropriate delegated committee. Also researchers should seek advice from more experienced colleagues, within or outside the University.

3.5 It is important to note that consideration by an ethics committee does not replace other procedures and advice relating to insurance cover, contract authorisation and health and safety issues.

3.6 **Delegated Committees**

Faculties are required to have a Faculty Research Ethics Committee which is responsible for ensuring that all research is appropriately scrutinised. The University Research Ethics Committee appoints a Human Tissue Management Sub-committee for research relating to the Human Tissue Act.

It is the responsibility of these delegated committees to develop their own terms of reference and procedural guidelines for approval by the University Research Ethics Committee. Faculty Research Ethics Committees may be sub-committees of the Faculty Research and Innovation Committees. If this is the case, reporting relationships should be administered accordingly.

The University Research Ethics Committee shall:

- Approve the terms of reference, membership, policies and procedures of the delegated committees;
- Act as an appeal body for delegated committees;
- Monitor the activities of delegated committees through the receipt of annual reports, minutes of all meetings and other reports as appropriate;
- Issue clear instructions and guidelines to the delegated committees on the standards of support and record keeping required.

3.7 In the first instance, all projects requiring ethics committee approval should be submitted to the delegated Faculty Research Ethics Committee. The University Research Ethics Committee may act as a 'court of appeal' in difficult cases.

3.8 **External Research Ethics Committees for Research Involving Human Participants**

In some cases approval must be obtained under NHS and Social Care Governance procedures specified by the DoH. This applies to any research project that involves:

- NHS patients or social services clients or their relatives; people recruited as participants by virtue of current or past contact with the NHS or Social Services including those being treated under contract with private sector providers;
- Access to records of previous or former NHS patients or Social Services clients;
- Individuals who because of mental incapacity cannot give informed consent themselves;
- Clinical trials.

Research involving offenders must follow either the National Offender Management Service guidelines or gain approval from the Youth Justice Board or the Ministry of Justice depending on the nature of the study and the commissioner.

3.9 It is essential that the delegated committees maintain a record of any application to any external ethical committee and the related decision.

4. Research involving animals

The University does not possess an animal house. The use of animals is tightly governed and monitored by law and by the Home Office, specifically under the Animals (Scientific Procedures) Act 1986 and its accompanying codes of practice and processes. Researchers using animals should operate in accordance with these. Details can be found at <http://www.legislation.gov.uk/ukpga/1986/14/contents>