Sheffield Hallam University

UNIVERSITY RESEARCH ETHICS COMMITTEE

RESEARCH ETHICS POLICY AND PROCEDURES

10th Edition (December 2020)

Contents

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 postgraduate) of the University should be subject to ethical scrutiny. Researchers are required to demonstrate that this scrutiny has occurred. Research supervisors have overall responsibility for ensuring that appropriate ethical scrutiny of their students' research occurs and must advise their students on the processes required.

1.2 Responsibility for undertaking the scrutiny 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's procedure not all research projects will undergo the same level of scrutiny. The University has an online system for ethics submission and review. The filter questions at the start of the submission help determine the level of review required. This is always checked to ensure that it is the appropriate level. Projects with no human participants can be approved following some basic checks.

1.3 All research by staff or students involving the Health Research Authority (HRA), Social Care, some categories of Human Tissue, and Her Majesty's Prison and Probation Service (HMPPS) is subject to HRA, social care or HMPPS governance procedures specified by the Department of Health (DoH). For this research, there is now a national Health Research Authority (HRA) portal, the Integrated Research Application Service (IRAS), which provides a more integrated service for obtaining the necessary approvals covering NHS, social care and HMPPS research. These 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 researcher can utilise the IRAS online ethics proforma and once completed, can download it, and must then submit it to the IRAS pathway of the University's ethics application system for methodological evaluation, and review. Any required changes must be undertaken before it is submitted to the IRAS 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-Malfeasance - 'doing no harm'
- Integrity
- Informed Consent
- Confidentiality/Anonymity

- Impartiality

All research must conform to the following:

2.3 Beneficence and Non-Malfeasance

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, damage to the environment 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 for face-to face research, but can be given via a tick box for online studies or even verbally at the start of recordings if this is deemed more appropriate but these records of consent should be retained;
- 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 and then they must be informed that withdrawal of their data is impossible;
- 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 in a staff project 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 HRA IRAS 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 archive data collected for one study and then use it in future studies or for open access data sharing. It is important that relevant guidelines are followed and that participants are made aware of the intention.

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 during the ethical review process. A list of further guidelines and codes of practice is available via the Research Ethics website at www.shu.ac.uk/research/ethics-integrity-and-practice or from the secretary to the University Research Ethics Committee (UREC).

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 (UREC) who oversee and quality assure the University wide online ethics review system. Training is provided for researchers to become approved research ethics reviewers. In addition, where appropriate, decisions are referred to the DoH, NHS, social care and HMPPS 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 There are three different levels of ethical review for staff, doctoral or masters by research students depending on the nature of the research. In all cases, however, the researcher still has a responsibility to consider ethical issues such as conflicts of interest and take note of any relevant codes of practice and University policy and procedures.

1. No human participants - E.g., Laboratory studies involving non- human materials, Library based studies, or secondary data analysis. These reviews are checked by the ethics administrators before approval emails are issued.
2. Low risk human participants – E.g., 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 potentially vulnerable participants. These are reviewed by one independent reviewer but can be escalated to members of UREC if required.
3. All other Human Participant studies. These are reviewed independently by three reviewers, one of whom may be a lay reviewer, one a subject specialist and one with methodology expertise.
There are also routes on the online system for:

- Recording research already granted permission by other ethics committees;
- Health Research Authority, IRAS applications

3.4 It is important to note that ethical scrutiny does not replace other procedures and advice relating to insurance cover, contract authorisation, and health and safety issues.

3.5 **Delegated Committees for Review of Student Research Projects**

Colleges are required to have a College Teaching Programme Research Ethics Lead and a College Teaching Programme Research Ethics Committee (CTPREC) which is responsible for ensuring that all undergraduate and taught masters research is appropriately scrutinised. In each College each department appoints departmental research ethics leads, one for undergraduate and one for postgraduate courses as required. The departmental ethics leads are members of the CTPREC. The CTPREC reports to the University Research Ethics Committee, who shall:

- Approve the terms of reference, membership, policies and procedures of the delegated CTPRECS;
- Act as an appeal body for these 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.

The chairs of the CTPRECS are members of UREC and their role is to:

1. Represent their College on the University Research Ethics Committee (UREC) and provide any relevant feedback from the taught courses to UREC
2. Organise and Chair the College Teaching Programme Research Ethics Committee (CTPREC)
3. Oversee the implementation and dissemination of UREC policies and procedures
4. Advise the academic staff and students in the College on matters pertaining to the ethics and integrity of research
5. Advise on the necessary procedures for reviewing student ethics applications in each Department. This includes the approval of course or programme specific Ethics Review Groups (ERGs)
6. Ensure that appropriate research ethics training is provided for students on taught courses in their College and contribute to such training when required.
7. Disseminate access to training resources for students and staff including online resources
8. Consider referrals from Ethics Review Groups for projects where the ERG has failed to reach agreement. Seek further advice from the CTPREC members or the Head of Research Ethics.
9. Prepare an annual report for UREC on research ethics on taught courses within their College as dealt with by the CTPREC.

10. Embody the Hallam Values both within and outside the organisation.
11. Promote equality, diversity and inclusion within all aspects of the delivery of the role.

3.6 **Reviewing Student Research:**

Each Department within the Colleges has a designated Departmental Undergraduate Research Ethics Lead and a Departmental Taught Masters Course Research Ethics Lead. Their role is as follows:

1. to Represent their Department on the College Teaching Programme Research Ethics Committee (CTPREC) and contribute meaningfully to activities set by the committee.
2. Dissemination of UREC policies and procedures to teaching staff in their department and monitoring of their implementation.
3. Advise the academic staff and students in their department on matters pertaining to the ethics and integrity of research in student work.
4. Manage the CTPREC approved course or programme specific Ethics Review Groups (ERGs)in their department.
5. Disseminate access to training resources for students and staff including online resources.
6. Report any issues in their department to the CTPREC at least annually.
7. Develop/sustain an ethical culture around research in the Department and encourage participation on ethics training offered by the University.
8. Embody the Hallam Values both within and outside the organisation.
9. Promote equality, diversity and inclusion within all aspects of the delivery of the role.

For review purposes, student research is classified as constituting **research projects** as students are learning to do research**.** This is made clear when students are conducting research externally. Ethics review of student work focuses on protection of participants, compliance with legal requirements, participants being properly informed about the research, consent being taken appropriately, and procedures for anonymising, storing and eventually deleting data meeting University requirements. Reviewers do not normally comment on the methodologies being employed as this element of the student work is being assessed. With staff, doctoral and masters by research students, reviewers may advise on methodologies if these are deemed to be inappropriate to the research questions being posed. Approving the latter would result in unethical use of participants time and resources for research.

Where Group research exercises such as laboratory practicals or very similar work-based learning projects are undertaken regularly within modules as part of learning, module tutors can apply for a Research Ethics Category Approval from the CTPREC to reduce their administrative burden. In the category approval the module tutor outlines the nature of the research and the ethics review process that all students will complete. If deemed satisfactory approval is given for five years and if nothing changes it can be renewed. Any significant changes to the projects must be notified. Category Approvals do not apply to dissertation/research project modules, as here all students must complete an appropriate ethics proforma.

3.7 The University Research Ethics Committee appoints Human Tissue Management Leads for research relating to the Human Tissue Act. They represent areas of the University where

human tissue research is regularly undertaken. The Human Tissue leads are members of UREC and provide the committee with an annual report.

3.8 The University Research Ethics Committee may act as a 'court of appeal' in difficult cases or where researchers do not agree with the outcome of the initial review.

3.9 **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 funded by the NHS;
- 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 Her Majesty's Prison and Probation Service guidelines and obtain ethical approval through their online review system.

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 www.legislation.gov.uk/ukpga/1986/14/contents

5. Guidance on Sources of Research Funding

1. Introduction

1.1 The University encourages its staff and students to engage with the external world, to be innovative and risk-taking, and to seek funds from a diverse range of sources. It is to be expected that, sometimes, researchers will undertake work where both the questions and the answers are controversial and challenge vested interests. On such occasions the University should be vigorous in protecting the integrity of knowledge and its own independence. However, there may be circumstances in which funding or collaboration is unethical, imprudent, or otherwise against the interests of the University as a corporate body.

1.2 It is beyond the scope of this statement to give examples of what may or may not be acceptable. What it aims to do is raise the key issues, outline some broad principles, and identify responsibilities for decision making.

2. Potential Issues

Some of the circumstances where there may be concern can be categorised as follows:

- Sponsors may put pressure on researchers to suppress or alter results which do not further, and indeed may damage, their interests. This may infringe a researcher's intellectual property rights and ultimately their employability.
- The University may decide that the practices of a potential sponsor are so inimical to its own mission and character that it should not accept funding from that source.
- The University may decide that collaboration would be so damaging to its reputation that it would not be prudent to accept funds.
- A research project may involve collaborating with institutions and organisations in other parts of the world which may not adhere to similar ethical and environmental codes. For example, they may not have equality legislation.

3. Principles

3.1 The first of the categories listed above is, perhaps, the most straightforward to deal with as such problems should be covered by the contract authorisation process and the policies on safeguarding integrity in research and the ethical conduct of research involving human participation.

3.2 The other areas are more difficult and delicate. Decisions should be based on the following broad principles.

- The expectation should be that the University will accept funds from any legal source for sound research where that funding meets the requirements of current financial and contractual policies.
- In responding to the exclusion policies of sponsors (see 2 above), the University should, where possible, seek to agree a common response and position with other UK Universities. It should also consider the balance of damage to the University and the strength of the ethical argument of the body imposing conditions.
- Any refusal to accept funds on ethical grounds (see 3 above) should only take place where there is a clear and major conflict of values.
- Any refusal to accept funds because of potential damage to reputation (see 4 above) should only take place where there is a strong possibility that the damage will be so great that it will seriously undermine a significant part of the University's activities.

3.3 With regards to collaborating with institutions and organisations in other parts of the world which may not adhere to similar ethical and environmental codes, it is suggested that collaborating organisations in such circumstances should agree to develop a plan of action that will eventually bring their policies and practices in line with the University policy. (The Nuffield Council on Bioethics, the Missenden Centre Code of Practice for Ethics and Accountability and the Guidelines on Ethical Trading produced by a consortium of trade unions, Oxfam and Marks and Spencer are useful sources of practical advice in this area).

4. Responsibilities

4.1 Research and Innovation Services office will be the repository for decisions so that it may inform University enquirers of any relevant precedent.

4.2 If a researcher has any doubt as to the acceptability of a particular source, the researcher owes a clear duty of care to the University and must seek advice from the relevant Director of Research Institute, Head of Department.

4.3 In cases where the difficulties cannot be resolved following 4.1 or 4.2, queries should be referred to the Pro Vice-Chancellor for Research and Innovation, who may seek the advice of the University Research Ethics Committee and may consult with the University Secretary and the Vice Chancellor if appropriate.