

THE UNIVERSITY OF SHEFFIELD

ETHICS POLICY GOVERNING RESEARCH INVOLVING HUMAN PARTICIPANTS PERSONAL DATA AND HUMAN TISSUE: GENERAL PRINCIPLES AND STATEMENTS

1 FUNDAMENTAL PRINCIPLES OF RESEARCH ETHICS

The founding motto of the University of Sheffield is 'To discover the causes of things'. The University's mission is to uphold the ideals of discovery, to encourage and support research into new ways of acquiring, investigating and developing knowledge for the good of society, and to ensure that all research is conducted in accordance with ethical principles.

The paramount principle governing all University of Sheffield research involving human participants, personal data and human tissue is respect for the participants' dignity, rights, safety and well-being.

1.1 Participants' rights

Participants have a right, as a principle of research ethics, to:

- be fully informed about how and why their data will be collected and used as part of a research project, and by whom;
- consent to participate, withdraw from, or refuse to take part in research projects;
- confidentiality: personal information or identifiable data should not be disclosed without participants' consent;
- security of their data: data and samples collected should be kept secure and anonymised where appropriate;
- safety: participants should not be exposed to unnecessary or disproportionate levels of risk, and;
- request erasure of their data if and when it is no longer required for research purposes.

1.2 Researchers' obligations

Researchers have an obligation to ensure that their research is conducted with:

- honesty;
- integrity;
- minimal possible risk to participants and to themselves; and
- respect for other people, their values and their cultures.

Guidance on the interpretation and application of these principles is detailed in this Policy document.

These principles of research ethics are recognised in international and regional treaties, as well as national laws. Breach of these principles may, in some instances, be a civil or criminal offence. The principles and requirements outlined in this Policy reflect the principles of research ethics but do not displace a researcher's obligation to comply with any relevant legal and regulatory requirements.

Ethical research conduct does not require the avoidance of potentially high-risk research. An ethical approach to research involves, rather, proper recognition of, and preparation for, risks,

and their responsible management. Ethical research is therefore a matter of being risk aware, not risk averse.

Finally, if research ethics are to be more than merely formulaic and procedural they must be meaningful and relevant to - and accepted by - researchers. To this end, this Policy specifies an ethics review procedure that is devolved to academic departments in the first instance, and which depends on ethically aware, self-reflective researchers taking responsibility for operationalising the principles and requirements embodied in the Policy.

2 INTRODUCING RESEARCH ETHICS

The University's definition of research is taken from the Research Excellence Framework 2014: **'a process of investigation leading to new insights, effectively shared'**. This applies to all research undertaken by, or on behalf of, the University, across the full range of academic disciplines, from the arts and humanities to the natural sciences (whether funded or not), and also encompassing administrative research (undertaken within, or on behalf of, professional services departments or academic faculties/departments), and research undertaken by or within University research centres/institutes, advisory/consultancy services and subsidiary companies. This definition includes:

- work of educational value designed to improve understanding of the research process;
- work of relevance to commerce and industry;
- work of relevance to the public and voluntary sectors;
- scholarship supporting the intellectual infrastructure of subjects and disciplines (such as dictionaries, scholarly editions, catalogues, and contributions to research databases);
- the invention, design and generation of ideas, images, performances and artefacts, where these lead to new or substantially improved understanding; and
- the experimental use of existing knowledge to develop, design and construct new or substantially improved materials, devices, products and processes.

This definition of research excludes:

- the routine testing and analysis of materials, components and processes - e.g. for the maintenance of national standards - as distinct from the development of new analytical techniques;
- routine audit and evaluation, within the established management procedures of organisations; and
- the development of teaching materials that do not embody original research.

The University of Sheffield's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, applies only to research involving human participants, personal data and human tissue. What is understood by these terms is discussed in Research Ethics Policy Note no. 1. It does not cover broader ethics or integrity issues that may apply to any type of research (e.g. ethical issues surrounding the source of funding for research), or ethical issues surrounding the use of animals in research.

3 RESEARCH ETHICS AT THE UNIVERSITY OF SHEFFIELD

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue recognises that the responsibility for maintaining ethical conduct lies, in the first instance, with researchers themselves. If researchers do not take responsibility for the ethical conduct of their own research, defensible research ethics will be an unrealisable goal. To this end, responsibility for operating the University's Ethics Review Procedure, informed by the Policy, is devolved to academic departments and funding units.

Within this devolved framework, the University recognises that diversity enriches and strengthens its research culture and performance. Diversity means that research activities involving human participants, personal data and human tissue may differ widely from one department or funding unit to another. Thus the ethical issues relating to human participation in research may also differ considerably from one academic department or funding unit to another.

This means that the formal ethical review of research proposals involving human participants, personal data or human tissue is best carried out within departments, within the broad parameters provided by this Policy and the Research Ethics Approval Procedure.

The key principle underlying the Research Ethics Approval Procedure is that researchers should reflect on the ethical issues that are raised by their research and be able to justify, in ethical terms, the practices and procedures that they intend to adopt during their research. Matters of research ethics are often not 'black and white', and there is no 'one size fits all approach'. This Policy therefore aims to set a clear framework and guiding principles to assist researchers in addressing the ethical issues that may arise in the course of their research.

4 RESEARCH GOVERNANCE AND RESPONSIBILITIES

Heads of departments and funding units are responsible for the conduct of the research that is undertaken in their departments. They are therefore responsible for ensuring that departmental researchers have access to appropriate ethics review procedures for research activities that involve human participants, personal data or human tissue, in line with the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue. They are also responsible for ensuring that all research-active staff and students are familiar with the content of the Policy and that appropriate training and guidance is made available. In particular, it is compulsory for all staff to undertake the University's Information Security training, and this training is also recommended for students who undertake research involving personal data. As in all other matters, individual researchers are expected to follow the leadership of their Head of Department.

In everyday research practice, however, the first responsibility for considering, respecting and safeguarding the dignity, rights, safety and well-being of human participants involved in research lies with the lead researcher (e.g. the principal investigator or supervisor). However, this practical principle does not absolve more junior, or more senior, staff, or students, from personal responsibility in this respect, or from their responsibility to disclose any failure to meet the principles of conduct required by the Policy.

All researchers at the University of Sheffield, whether staff members or students, are responsible to a range of stakeholders for their conduct during, and delivery of, their research activities involving human participants. These are:

- the human participants involved (as defined by this Policy);
- society in general;
- the University of Sheffield;
- fellow researchers, whether colleagues or students;
- colleagues who undertake research support activities;
- their department or funding unit;
- the research funder; and
- their academic profession or discipline.

The University Research Ethics Committee (UREC) is responsible to the University's Senate for:

- reviewing the Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue every 5 years and reporting its findings to the University's Senate;
- offering guidance within the University on the interpretation of the Policy;
- resolving disputed or uncertain ethics approval decisions;
- auditing and accrediting the ethics review arrangements in place within departments and funding units on at least a 5 yearly basis, and monitoring the ethics review arrangements within departments and funding units;
- in the event of concerns arising about whether a research proposal or ongoing research activity complies with the Policy, suspending the approval process, or the research activity in question, pending further investigation;
- actively promoting awareness and knowledge of the Policy, and research ethics more generally, within the University via training events and other activities;
- keeping abreast of externally-driven developments, policies and regulations concerning research ethics, and ensuring that the University meets all necessary requirements;
- providing advice on any ethical matters relating to research that are referred to it from within the University.

5 SCOPE AND APPLICABILITY OF THE RESEARCH ETHICS POLICY

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue applies to:

- all University staff and registered students who conduct, or contribute to, research activities involving human participants, personal data or human tissue, whether these take place within or outside University premises and facilities, or are part of a work placement undertaken in fulfilment of a University degree award; and
- all individuals who, although they are not members of the University, conduct, or contribute to, research activities involving human participants, personal data or human tissue that take place within University premises and facilities.

This specifically includes research undertaken by non-academic departments of the University of Sheffield, and administrative research undertaken within academic departments or faculties. For further definition and discussion of these activities and the procedures for their ethical review, see Research Ethics Policy Note no. 7, 'Administrative research within the University'.

The University of Sheffield's Policy is designed to complement the National Health Service (NHS) ethics review system. The University's Ethics Review Procedure does not, therefore, duplicate the functions, or overlap with the remit, of the NHS ethics review system. For further detail about ethics review via the NHS ethics review system, and information about which University research requires NHS, rather than University, ethics approval, see Research Ethics Policy Note no. 5.

Other external bodies, such as some public-sector social care providers or the armed forces, also have their own research ethics policies and review procedures. In the case of social care research, see Research Policy Note no. 5. In all other cases, contact the Secretary of the University Research Ethics Committee for guidance.

Research funding bodies may have their own research ethics policies and/or requirements, which must be met as a condition for receiving research funding. However, this does not obviate the need for observance of the University's Policy and its associated procedures; in such cases, the external policies and requirements are an *extra* layer of research ethics governance, not an alternative to the University's Policy.

Similarly, external research collaborators may be required to follow the ethics policies and procedures of their own organisations. However, the University's Policy and procedures must still be followed in any collaborative research that involves University of Sheffield staff or students. In some cases, an external organisation's ethics review procedure may be deemed sufficiently robust that additional ethical approval via the University of Sheffield's procedure is not required – see section 4 of the Research Ethics Approval Procedure for more details ('Alternative Ethics Review Procedure').

The final external stakeholders to be considered are professional bodies and learned societies, which may also have their own research ethics policies, guidelines and requirements. While learned societies' research ethics guidelines are useful resources that may offer supplementary guidance, the University's Policy must, in the first instance, take precedence for University staff members and with respect to research conducted on University premises. External bodies that have professional licensing or registration responsibilities are, however, a different matter and their external principles have a different weight. Although it is unlikely that professional ethical codes will conflict with the University's Policy, in the event of a perceived conflict of this kind, the member of staff concerned should contact the Secretary of the University Research Ethics Committee for guidance.

6 THE OBJECTIVES OF THE ETHICS POLICY GOVERNING RESEARCH INVOLVING HUMAN PARTICIPANTS, PERSONAL DATA AND HUMAN TISSUE

The Policy is intended to:

- protect the dignity, rights, safety and well-being of human participants;
- codify the University's position on research ethics for research involving human participants, personal data and human tissue;
- demonstrate a commitment to high quality, transparent and accountable research ethics throughout the University, from senior management policy-making to the practicalities of individual staff and student research projects;
- warrant and inform the operation of the University's Ethics Review Procedure within departments and funding units;

- provide guidance on research ethics involving human participants, personal data and human tissue for all staff and students;
- encourage an organisational research culture based upon defensible standards of research practice;
- reduce risks to the University, departments and funding units, and individual researchers;
- strengthen the eligibility and quality of University research funding applications; and, not least,
- enhance the University's reputation with the general public and wider society, within the academic professions, and with funding bodies and external auditors.

7 GOOD RESEARCH PRACTICE

Observing recognised research ethics principles is basic to good research practice in general. The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue should, therefore, be read alongside:

- the University's Good Research & Innovation Practices (GRIP) Policy; and
- the University's Research Misconduct Toolkit.

Upholding ethical standards in the conduct of research means accepting and respecting principles of integrity, honesty and openness. Conducting research with integrity means embracing intellectual honesty and accepting personal responsibility for one's own actions.

Prior to, during, and following the completion of research activities, researchers are expected to consider the ethical implications of their research and, depending on its nature, the cultural, economic, psychological, physiological, political, religious, spiritual and social consequences of it for the human participants involved.

Researchers should always consider their research from the perspective(s) of the participants and any other people who may possibly be affected by it.

8 SAFETY AND WELL-BEING

Finally, issues of safety and well-being are at the heart of research ethics. Researchers have a responsibility to protect all participants, as well as they can, from avoidable harm arising from their research. Researchers also have a responsibility to consider their own safety and that of any co-researchers or collaborators.

As a general rule, people participating in research should not be exposed to risks that are greater than, or additional to, those they encounter in their normal lifestyles. If it is expected that harm, unusual discomfort or other negative consequences might occur in prospective participants' future lives as a result of participation in a research project, the researcher should highlight this during the ethics approval process, and discuss the matter fully with participants during negotiations about informed consent.

However, it should also be noted that it may not be possible for researchers to identify every eventuality that may arise in the course of a research project, and that this Policy is not designed to cover all possible situations. Unexpected incidents affecting the safety or well-being of those involved, and/or presenting a potential reputational risk to the University, may

arise even in a project that has been well-considered and thoroughly ethically reviewed. Should such an incident arise, the researcher should take appropriate steps to manage the immediate situation in line with the University's Health and Safety procedures. At the earliest opportunity they should make their supervisor or line manager aware of the situation. Where there are potential implications relating to research ethics (e.g. if the terms of ethics approval have been breached), the UREC's Secretary should be contacted for advice.

Further detailed discussion of informed consent, and safety and well-being, can be found in Research Ethics Policy Notes nos. 2 and 3.