

# **Research Ethics Guidelines for Staff and Students**

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# Key Terms

**Research:** It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research. It includes research that is published, disseminated or made publicly available in the form of assessable research outputs, and confidential reports (Research Excellence Framework – Definition).

**Researchers:** Any people who conduct research, including but not limited to: as an employee; as an independent contractor or consultant; as a research student; as a visiting or emeritus member of staff; or as a member of staff on a joint clinical or honorary contract - UK Research Integrity Office Code of practice for research (2009).

**Research Ethics:** Research Ethics refers to the moral principles guiding research, from its inception through to completion and publication of results and beyond (ESRC guidelines).

# **Introduction**

The University expects that all activity undertaken by its staff and students will be carried out to a high ethical standard. These guidelines are a living document which set out the University's approach, aims and methods in relation to research conducted at undergraduate/postgraduate and staff level. Alongside the University Ethics Guidelines those conducting research are expected to comply with all relevant policies and guidelines, with particular attention to the University Good Research Practice guidelines. All researchers are also expected to follow their discipline specific codes and standards (and keep an awareness of these).

### Responsibility

Ultimate responsibility for applying these guidelines lies with individual researchers, whether students or staff. The University Ethics Sub-Committee oversees the guidelines and has an advisory role.

Members of staff with responsibility for undergraduate, postgraduate or doctoral research projects (as well as staff research), are responsible for ensuring that those conducting research are fully aware of these guidelines, and have taken, or will take, appropriate action to ensure that ethical principles are upheld. Researchers should be aware that failing to comply with the University Ethics Guidelines could result in University disciplinary action.

Please ensure that you are aware of, and up to date with all University liability and insurance information before starting your research. For further information please discuss any matters regarding this with your School Ethics Representative.

#### **Compliance with Legislation**

These guidelines should be used in conjunction with current legislation, notably the Data Protection Act 1998, Equality Act 2010 and a requirement to hold a Disclosure and Barring Service certificate prior to seeking ethical approval, if required.

# Ethical Principles

There are **four key ethical principles** that the University expects all involved in research should adhere to whenever applicable:

- Research should be designed, reviewed and undertaken to ensure integrity and quality.
- The autonomy of individuals should be respected.
- Harm to individuals must be avoided.
- People should be treated fairly and with respect.

### 1. To Ensure Research Integrity and Quality

- 1.1 Research is carried out with integrity when researchers genuinely strive to achieve the objectives of sound research by ensuring valid methodology, objective research processes and well-grounded findings. Research that lacks integrity is ethically unacceptable.
- 1.2 The objectivity and impartiality of research can be threatened if it is in any way dependent on a sponsor, institution or participants who have particular interests or values. Researchers should therefore ensure that the objectives of all parties are clearly articulated at the outset, and that the research is set up in such a way that it is independent of any special interests.
- 1.3 To avoid conflict of interests, researchers should maintain a professional relationship with their participants at all times.

#### 2. Respect the Autonomy of all Participants

#### 2.1 Autonomy

It is the responsibility of researchers to respect the autonomy of everyone involved in the research: this includes fellow researchers, participants and those who may not be actively involved but about whom data is used. To respect autonomy, researchers should obtain informed consent and avoid practices and methodologies that involve deceit, coercion, dishonesty, invasion of privacy, breaking confidentiality and using data for purposes not clearly explained to participants.

#### 2.2 Informed Consent

Informed consent entails giving as much information as possible about the research so that the prospective participants can make an informed decision on their possible involvement. Typically this information should be provided in written form and signed off by the research subjects.

- 2.2.1 Research should be based on the freely given informed consent of those in the study.
- 2.2.2 It is the responsibility of the researcher to explain as fully as possible, and in terms meaningful to the participants the aims and the nature of the research. Therefore confirming who is undertaking the research, who is funding it, its likely duration, the possible consequences of the research, how the results are to be disseminated and all the likely disclosures of personal data.
- 2.2.3 The power imbalance between researcher and researched should be addressed. Care should be taken to ensure that the latter are not pressurised into participation. Research participants should be made aware of their right to refuse participation whenever, for whatever reason, without giving an explanation. It should also be recognised that research may involve a lengthy data-gathering period and that it may be necessary to regard consent as being subject to renegotiations over time.
- 2.2.4 If there is a likelihood of data being shared with or divulged to other researchers, the potential uses of the data should be discussed with the participants. Their written agreement to such use should be obtained through the consent form or a collection notice.
- 2.2.5 The Data Protection Act 1998 provides for various exemptions with respect to the processing of data obtained in research studies. Further processing of personal data may be undertaken if it is compatible with the original purposes for which it was obtained, and personal data may be kept indefinitely. If researchers wish to use data in subsequent research projects that are not directly related to the initial study, ethical approval should be sought.
- 2.2.6 In cases where research participants are children under 18 years of age or are considered part of another vulnerable group (such as older, disabled or sick people or people with learning difficulties, or whose understanding is impaired in some way) every effort should be made to gain their informed consent. However, if they are unable to give fully informed consent, it may be necessary to use a proxy in order to gain consent. In this case great care must be taken not to intrude upon the privacy of the vulnerable participants. The researcher should consult relevant professionals, parents/guardians and relatives, as appropriate, and undergo a Disclosure and Barring Service check before working with these groups (if required). Researchers should attempt to obtain the informed consent of children and their parents (and, in relation to school children, those in loco parentis).
- 2.2.7 In regard to multi/inter-disciplinary or international research; if the original research data is going to be used in a different way than was originally agreed to (by the participant) then the researcher will need to gain further consent.

# 2.3 Confidentiality and Anonymity

- 2.3.1 The anonymity and privacy of research participants should be respected and personal information relating to participants should be kept confidential and secure. Researchers must comply with the provision of the Data Protection Act 1998, and should consider whether it is proper or appropriate to record certain kinds of sensitive information.
- 2.3.2 The researcher should anonymise data in such a way that it would not be possible to identify the individuals from that data, or any other data held.
- 2.3.3 The researcher should explain how research participants will be afforded anonymity and confidentiality. Participants should have the option of rejecting the use of data-gathering devices such as dictaphones or video cameras.
- 2.3.4 While the researcher should take every practicable measure to ensure the confidentiality and anonymity of research participants, s/he should also take care not to give unrealistic assurances or guarantees of confidentiality. Research participants with easily identifiable characteristics or positions within an organisation should be reminded that it may be difficult to disguise their identity. Therefore researchers also should take into account the need to annoymise environmental factors and personal characteristics which could identify participants.

# 3. Avoid Harm

- 3.1 A primary responsibility of researchers is to conduct research in such a way that it minimises harm or risk to subjects. This consideration should be an over-riding factor at all stages in a research project. Harmful effects may also occur some time after cessation of the research process and publication of results and this. The possible consequences of each stage should be assessed and every step taken to ensure the safety of, and prevent the adverse effects on researchers, participants, individuals about whom data is used, More widely, researchers should keep in mind the effect on others in the community (in which the research occurs) and those who could be affected by the results of the research.
- 3.2 Harm includes physical, psychological damage and stress to individuals or groups. This could include the invasion of privacy, deception, damage to self-esteem or to the social fabric of their community. Researchers should be particularly aware of those who could be considered more than a minimal risk, such as those within vulnerable groups.

Harm may also include damage to the reputation of the University, the research discipline and future research. These can be caused by a project that is ill-conceived, deceptive, carelessly executed or irresponsibly used. Therefore researchers should make sure that their research adheres to the University's values and principles when conducting research.

3.3 If the objectives of a piece of research cannot be achieved without minimal risk of harm, researchers should consider abandoning the project. They should only apply for approval to continue if they can provide an overwhelming justification for doing so. Should approval be granted, they must ensure that every effort is made

to reduce the risk and must make clear to all who may be involved in the project or affected by it that the risk exists.

# 4. Treat Everyone Fairly and With Respect

4.1 Meet the Needs of Everyone

Researchers have a responsibility to ensure that the needs of everyone who may be affected by the research are met as far as possible.

Needs include sufficient information, guidance, equipment, support and other resources to:

- Participate fully in the research process
- Deal with any effects of the execution and cessation of the research and the dissemination of its findings.

Communities as well as individuals may have needs arising from the execution and consequences of research.

4.2 Give Equal Consideration to the Interests of Everyone

Care should be taken to ensure that the values and attitudes of researchers do not result in the interests of some people being given unequal consideration. It is easy, for example, to regard the interests of people peripheral to the research activity as of no concern to the researcher. However if people may be affected by the research, however minimally, then steps should be taken to protect their interests.

To treat people with respect researchers have a responsibility to treat all those involved in a research project with consideration, and to work co-operatively with them. Researchers must remember that participants have volunteered and steps should therefore be taken to accommodate their needs and requests where possible.

For example, when collecting data on sex and gender, avoid using the category 'other (please specify)', and consider using instead the option 'not listed (please specify)' which is more inclusive and avoids 'othering' participants.

# 5. The Ethical Approval Process

Proposals for new research involving human and animal participants will be subject to the University's ethical review process. All research must be approved before work commences.

Researchers (including undergraduate/postgraduate and staff) should be aware of the University guidelines noted in section 6 prior to submitting any application.

Researchers should follow the three-tier ethical review process (which can be found on the SimmSpace and Staffnet ethics pages).

Once a research proposal has been approved via the University ethical review process and the research commences, the day-to-day responsibility for reviewing and monitoring the ethical aspects of the project rests with its researcher. For undergraduate, postgraduate and MPhil/PhD research the Supervisor/Director of Studies should oversee ethical aspects of the project and act in an advisory capacity.

# 6. University Policies, Codes of Practice and Guidelines

Copies of relevant University policies, codes of practice and guidelines can be found on SimmSpace and Staffnet ethics pages:

- Ethical application system (Three Tiers)
- St Mary's Ethics Process Flowchart
- Ethical Guidelines for Conducting Research with Children and Young People
- FAQs and commonly made mistakes

and on the external website:

- <u>St Mary's Code of Practice for Research</u>
- Procedures for Dealing with Allegations of Misconduct in Research
- Research Data Policy TBA

# 7. Helpful Organisations and Bodies

**Professional Bodies** 

- British Psychological Society
- The Law Society
- The Bar Council
- The Biochemical Society
- The General Medical Council

# **Relevant Legislation**

- Freedom of Information Act 2000: <u>www.legislation.gov.uk/ukpga/2000/36/contents</u>
- Health and Social Care Act 2008: <u>www.legislation.gov.uk/ukpga/2008/14/contents</u>
- Human Rights Act 1998: <u>www.legislation.gov.uk/ukpga/1998/42/contents</u>
- Human Tissue Act 2004: <u>www.legislation.gov.uk/ukpga/2004/30/contents</u>
- Data Protection Act 1998: <u>www.legislation.gov.uk/ukpga/1998/29/contents</u>
- The Medicines for Human Use (Clinical Trials) Regulations 2004: <u>www.legislation.gov.uk/uksi/2004/1031/contents/made</u>
- Mental Capacity Act 2005 <u>www.legislation.gov.uk/ukpga/2005/9/contents</u>
- Safeguarding Vulnerable Groups Act 2006: <u>www.legislation.gov.uk/ukpga/2006/47/contents</u>
- Equality Act 2010: <u>http://www.legislation.gov.uk/ukpga/2010/15/contents</u>

# **Research Councils**

- Arts and Humanities Research Council
- Biotechnology and Biological Sciences Research Council
- Engineering and Physical Sciences Research Council
- Economic and Social Research Council
- Medical Research Council
- Natural Environment Research Council
- Science and Technology Facilities Council
- Research Councils UK (RCUK)

# Other

- NHS National Research Ethics Framework: <u>http://www.nres.nhs.uk/</u>
- Social Research Association: <u>http://the-sra.org.uk/research-ethics/ethics-guidelines/</u>
- UK Research Integrity Office (UKRIO): <u>http://ukrio.org/publications/code-of-practice-for-research/</u>
- Universal Ethical Code for Scientists <u>https://www.gov.uk/government/publications/universal-ethical-code-for-scientists</u>
- UK Data Archive: <u>www.data-archive.ac.uk</u>
- Secure Data Service (SDS): https://www.ukdataservice.ac.uk/
- Disclosure and Barring Service: <u>https://www.gov.uk/government/organisations/disclosure-and-barring-service</u>