

Medical School Ethics and Research Governance requirements for research involving human participants, their personal data or tissue

This briefing aims to summarize the key requirements in relation to the University's Ethics Policy, research governance requirements and the Medical School's process with regard to research involving human participants, their personal data or tissue. Most of the research within the Medical School that involves human participants, their tissue or their data will require either NHS (for research involving NHS patients) or University ethics approval. This document primarily relates to University ethics processes.

The University defines research as 'investigation undertaken in order to gain knowledge and understanding, including work of educational value designed to improve understanding of the research process'. Staff and students need to be aware that this is a much broader definition than that taken by the NHS and is the definition used by the Research Excellence Framework (REF). **Ethical approval is required for all research involving human participants, their personal data or human tissue whether conducted by staff or students (at any level), including visiting researchers and students.**

Achieving excellence in the Faculty's and University activities relies on a number of attributes including curiosity, intellectual rigour, integrity, honesty, and reflection. These values are fundamental to the reputation and standing of the institution and its departments and faculties within. In the same way, delivering excellent Research and Innovation requires integrity through transparent good practices. As the University's Good Research and Innovation Principles (GRIP) Policy explains, at stake is the 'credibility, reputation and value of the University's research and the reputation of individual researchers'. Research practice with integrity includes 'respecting the values of society, including not causing harm and considering the public interest'. All researchers should be familiar with the University GRIP policy which can be accessed via: http://www.sheffield.ac.uk/polopoly_fs/1.546079!/file/GRIPPolicySenateapproved.pdf

This guidance is based on the University policy as well as on good practice guidelines outlined at the end of this document.

If the intent of the activities are research (according to the University's definition of research), research ethics approval is required in accordance with the University Research Ethics policy. The context of the research (whether it is an undergraduate project, postgraduate dissertation or data gathering using questionnaires), duration or size of the project does not matter; what is important is the intent. If the intent fits with the University definition of research then you need to apply for ethics approval PRIOR to commencing any data collection activities.

How can I obtain ethics approval from the UOS?

The Medical School operates via the UOS on-line ethics application system which can be accessed via 'My services' within MUSE or via: <https://ethics.ris.shef.ac.uk/>. All staff and students should use this on-line application process.

Staff and Post-graduate Research (PGR) students

Two academic and one lay reviewer will review applications made by staff and PGR students. The Medical School does not hold ethics review panels (unless there is a particularly contentious application) and aims to review applications within 10 days.

Undergraduate and Post-graduate Taught (PGT) students

All students, including undergraduates, are required to find an appropriate member of staff to supervise any research they intend to undertake. It is expected that the student will consider the ethics and governance requirements and complete the appropriate processes in conjunction with the supervisor. For low-risk applications the supervisor **is the sole reviewer of the application**. If the project is deemed to be high risk (vulnerable participants, sensitive topics, any safety concerns) then the application will be

received by the ethics administrators who will assign two academic reviewers (one of whom can be the supervisor). The University Research Ethics Committee (UREC) has produced 'A Brief Student Guide to Research Ethics' which we encourage all students to read. This and other guidance on how to complete an ethics application can be accessed via: <http://www.sheffield.ac.uk/ris/other/gov-ethics/index>

Special notes:

Generic approval for student projects

For research projects that are similar in nature generic research ethics review can be requested. In this case a member of staff (course director, supervisor) would be required to complete the application process. The application would then be considered by 3 Medical School ethics reviewer panel members.

Service Evaluation

A difference between the NHS ethics requirements and the University Ethics Policy is that NHS ethics approval is not required for projects which it deems to be service evaluation or audit. With the University Ethics Policy if the intent of the project is to evaluate a service or to conduct an audit but there is no intent to present it as research (see University definition), then the project will not require ethics approval.

However, if the service evaluation is being presented as research for the purposes of a degree award, or is a student or staff research project (no matter how large or small), or is being disseminated beyond the service being evaluated i.e. in a research publication, then the University would consider this to be research even if the NHS does not, and the work would require ethics approval. In such circumstances University Ethics Approval should be sought.

Cell lines/Tissue microarrays/Biological samples

Established cell lines, tissue arrays and samples obtained from biorepositories will have received prior approval and usually do not require additional UoS ethical approval. The removal, storage and use of human tissue (including the development of primary cell lines) falls under the Human Tissue Act (www.hta.gov.uk) and requires ethical approval from a recognized research ethics committee i.e. the NHS. It is the responsibility of the lead researcher to ensure that appropriate ethics approval is in place.

Anonymised datasets

There is no need for ethical approval if using anonymized datasets that are publicly available. However the Ethics Policy states that ethics approval is required for databases that are not publically available.

UoS guidance on Research Governance

In addition to ethics, the project may also require research governance. Any study involving patients at Sheffield Teaching Hospitals NHS Foundation Trust (or equivalent) must obtain research governance approval from the Trust (<http://www.sheffieldclinicalresearch.org>). Non-NHS projects may require research governance approval when the research relates to healthcare research or is a human intervention study.

The definition of 'Healthcare Research' according to the Department of Health (March 2016) is: 'research concerned with the protection and promotion of public health; research undertaken in or by a UK Health Department, its non-Departmental public bodies or health and social care providers; and clinical and non-clinical research, research undertaken by NHS, social care or (in Northern Ireland) HSC staff using the resources of health and social care providers and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services'.

The key element of the above definition to consider is whether the research will have a direct impact on the quality of health and social care services. If it does then you will probably need research governance. You will also need research governance if you are conducting a human intervention study.

All healthcare research projects need to be sponsored either by the University of Sheffield, an NHS trust or an appropriate institution to protect participants, the data and the researchers. This process is managed by ensuring that all healthcare research projects are registered on URMS, so that there is a clear identifying reference against which the necessary information can be recorded. The healthcare research governance requirements are overseen by the Health and Human Interventional Studies Research Governance Sub-Committee.

For more information to determine whether your project requires research governance and from whom, please visit the following links:

The University of Sheffield Research Governance procedure: <http://www.sheffield.ac.uk/ris/other/gov-ethics/governance/rgp>

Sheffield Joint Clinical Research Office:

<http://www.sheffieldclinicalresearch.org>

If you have further questions or require university research governance please contact Lindsay Unwin, l.unwin@sheffield.ac.uk.

Research Ethics Approval Policies and Tools

University Research Ethics: <https://ethics.ris.shef.ac.uk/>.

<http://www.sheffield.ac.uk/ris/ethicsandintegrity>

Do I need NHS REC approval rather than University Ethics approval? <http://hra-decisiontools.org.uk/ethics/>

Useful Policies or guidance

1. *University of Sheffield Good Research and Innovation Practices*
<http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy>
2. <http://www.sheffield.ac.uk/ris/other/gov-ethics/governance/rgp>
3. *British Medical Journal Policy on Research Ethics approval* <http://www.bmj.com/about-bmj/resources-authors/forms-policies-and-checklists/ethics-approval-research>
4. *Department of Health policy*
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213753/dh_133993.pdf

Contacts:

If you have questions or suggestions about this document please contact: e.a.williams@sheffield.ac.uk or p.vivekananda-schmidt@sheffield.ac.uk

If you have queries or questions or require advice you can contact any one of these persons on the list below:

Medical School Ethics Office: medschoolethics@sheffield.ac.uk.

Principal Ethics contact for the Medical School: Liz Williams, e.a.williams@sheffield.ac.uk.

Special note for course leaders/administrators of MBChB, PGT, PGR, UG, SSC projects

For all projects, the supervisors need to ensure that the following questions can be answered. To aid in the administration of student projects, it may be helpful for these questions to be added to the project description or “Call for projects proformas”.

Please refer to the University of Sheffield Research Ethics and Governance policy (<http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy>) before answering these questions.

1. Does your project require ethics approval? Yes/No
2. If yes, (1) have you obtained approval, (2) are you in the process of obtaining approval; please tell us from where?
3. Does your project require research governance? (Is it a healthcare project or human intervention study? Yes/No
If yes, who is the sponsor?
4. If your project is on URMS please give URMS number to avoid duplication.