3 How to Obtain Ethical Review - Responsibility of the Deans of Research

It is expected that each broad research area will manage its own local ethical review processes, taking account of all internal and external requirements. Researchers seeking ethical approval of a research proposal should follow the local ethical review processes in place for their research area.

Each ethical review board or committee must have in place clear and formal policies for ethical review and for carrying out ethical review on all research proposals, to whatever extent required, before research can commence. Further information on local ethical review processes within each board or committee, and how to obtain ethical review for your research is available via the following webpages:

- Arts and Social Sciences Ethics
- Life Sciences and Medicine Ethics
- Physical Sciences and Engineering Ethics

It is the responsibility of the Schools to ensure that staff and research students are aware of the institutional research ethics and governance arrangements, including the need to consider the ethical implications of their research and to seek ethical review where required. It is the responsibility of researchers to have an awareness of the ethical frameworks and requirements which apply to their area of research and to ensure compliance.

The University does not normally delegate its institutional responsibility for ethical matters to external bodies. However, for some types of research, separate ethical approval arrangements are in place which means that it may not be necessary for the University to repeat an ethical review process. Areas of research where this might be applicable include, for example, research involving NHS patients. If a researcher is in doubt, advice should be sought from the Deans of Research or the Chair of ethics committees or review boards, or from the Research Policy Committee.

Each ethical review board or committee is required to provide an update to the first meeting of the academic year of the Research Policy Committee and on activities relating to research ethics at School level, reporting on any significant issues that have arisen.

3.4. Determining Whether You Need Ethical Approval

Where there is no explicit legislative or regulatory requirement for ethical approval in place, there are a number of questions which should be taken into account when considering whether formal ethical approval is required.

The checklist below helps to identify whether or not a full application for ethical approval must be submitted, and can be used in conjunction with appropriate School or disciplinary ethical review guidelines.

The majority of questions listed applies to all disciplines and all forms of research, and particularly to those which involve human participants. They apply to survey based research, interviews, focus groups and to observation techniques.

If a researcher answers “yes” to any of the questions listed then ethical approval must be sought for their research proposal. The list of questions is not exhaustive, and local guidance within Schools may require ethical approval even if the answer to all of the questions is “no”. If in doubt, please consult with your School Ethics Officer or member of your local ethics committee or review board.

1. Is the study externally funded? If yes, please state which funding agency and: whether the funding agency requires proof of ethical approval
2. Does the study involve children (under 18 years old)?
3. Does the study involve clinical populations (i.e. have participants been identified as a result of their status as a patient)?
4. Does the project involve vulnerable adults such as individuals with mental health problems or learning disabilities, or prisoners or young offenders up to the age of 21?
5. Have arrangements been made for ensuring informed consent and does the study involve participants who are unable to give informed consent?
6. Does the study involve any clinical procedure?
7. Are drugs, placebos or other substances to be administered to participants, or will the study involve invasive or potentially harmful procedures of any kind?
8. Could the study induce psychological stress or anxiety, or cause harm or negative consequences beyond the risks encountered in normal life?
9. Is pain or more than mild discomfort for subjects likely to result from the study?
10. Does the project involve the collection of material that could be considered of a sensitive personal, medical or psychological nature?
11. Does the project involve use of human remains?
12. Does the project involve the use of animals and procedures not covered by the Animal Scientific Procedures Act 1986?
13. Is your research activity likely to involve people involved in illegal activities?
14. Does the project use covert research techniques?
15. Will the subjects of the study include staff or students of the University?
16. Does the study involve potential clients of your department/place of work?
17. Are there any ethical concerns relating to research data management? For example, are there potentially ethical issues relating to the collection, use, storage, access and retention of data in the proposed research?
18. Does the project involve interaction with groups, materials, data that one subject to the Counter-terrorism and Security Act 2015?

3.5. NHS North of Scotland Research Ethics Service

Some of the University's research will fall under the remit of the North of Scotland Research Ethics Service (NoSRES) or other equivalent regional NHS ethics services. As required under the Framework established by the Secretary of State, NoSRES considers all research projects involving NHS patients or premises, including projects falling within these categories undertaken by students. NoSRES is part of the Health Research Authority (HRA) which has overall responsibility for allocating NHS ethical approvals within the UK. NoSRES may review projects which fall outside their remit, such as those involving community-based studies, or healthy volunteers which might not strictly need its approval. Where a research project involves using a medicinal product or a regulatory device, researchers should follow the Universities policies and Standard Operating Procedure to comply with our statutory obligations. (for further information see Clinical Governance)

3.6. Research Involving the Use of Animals

All research undertaken by the University which involves the use of animals must be fully compliant, with the Animal (Scientific Procedures) Act 1986 (Amended 2012). The Act was amended after transposition of the European Directive 2010/63/EU on 1 January 2013, following its approval by the UK Parliament. Research involving animals is governed by the Advisory Group to the Establishment Licence Holder and the Animal Welfare and Ethical Review Body (AWERB). The AWERB has responsibility for implementing a central ethical review process for the robust review of all proposed research involving animals prior to any application being submitted to the Home Office. Detailed information on the AWERB and the applicable ethical review process is included in the University's Code of Practice for Research Involving the Use of Animals and can be obtained from the Life Science and Medicine College Admin Officer.

The University is committed to avoiding the use of animals in research unless absolutely necessary. It is fully committed to the widespread promotion and implementation of the 3Rs in all research involving the use of animals. The 3Rs are:

- **Reduction** - the development of methods which facilitate reducing the number of animals used in research, by improving experimental design or by sharing data.

- **Refinement** - improvements to scientific procedures and husbandry which minimise actual or potential pain, suffering, distress or lasting harm and/or improve animal welfare in situations where the use of animals is unavoidable.
• Replacement – methods that avoid or replace the use of animals defined as 'protected' under the Animals (Scientific Procedures) Act 1986 in an area where they would otherwise have been used.

3.7. Research utilising genetic resources - Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity came into force in the UK on 12 October 2014. It is a supplementary agreement to the Convention on Biological Diversity (CBD). It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol applies to genetic resources (plants, animals, microorganisms) physically acquired after 12 October 2014 that are covered by the CBD, and to the benefits arising from their utilization. The Nagoya Protocol also covers traditional knowledge (TK) associated with genetic resources that are covered by the CBD and the benefits arising from its utilization.

Access is governed by legislation of the provider country, and is a UK statutory requirement. The Access and Benefit-sharing Clearing-house (ABSCH) available at https://absch.cbd.int/ is a platform for exchanging information on ABS and a key tool for facilitating the implementation of the Nagoya Protocol. Sector specific guidance is being developed and will be available in due course.

3.8. Undertaking Research outside the University or the UK

Some research projects involve work external to the University and/or the UK. Where research involving human participants is being undertaken at another institution or outside the UK, it should undergo formal ethical approval via the processes in place at the host institution/organisation. Once it has received ethical approval, formal evidence of that approval will normally be accepted as sufficient to meet the University’s own requirements. Where the University is not satisfied that the review process provided by the host institution/organization meets our own standards, further institutional review may be required.

The primary responsibility for securing relevant ethical approval lies with the institution that employs the researcher, therefore it is imperative that the University is satisfied that appropriate ethical review has been undertaken.

The University respects the traditions and cultures with which it has dealings. Where there is conflict between local customs and the ethical principles and values set out by the University this should be brought to the attention of the relevant Chair of the ethics committee or review board in the first instance, and also the Research Policy Committee.

3.9. Whistleblowing

Staff, students and lay members of the University are expected to report actual or potential infringements of research ethics and unacceptable research conduct. Section 4 of this handbook and the University’s Policy and Procedure on Public Interest Disclosure (Whistleblowing Policy) set out clear procedures for reporting concerns. It details how allegations will be investigated. The Research Policy Committee should also be kept informed; it has overarching responsibility for ensuring that all alleged ethical breaches are investigated.

3.10. Prevent

The Counter Terrorism & Security Act 2015 and the UK Government’s associated Prevent strategy require universities and public bodies to ‘have due regard to the need to prevent people from being drawn into terrorism’ and places responsibility on them to ensure that measures are taken to meet these responsibilities.

The University has issued detailed guidance to researchers working in areas that are subject to counter terrorism legislation and Prevent measures (Prevent and Counter Terrorism Guidance).