

3. HOW TO OBTAIN ETHICAL REVIEW

Research can bring great benefit, but can also harm the interests or well-being of individuals or groups. When there is a possibility of such harm, ethical questions arise, and the researcher will need to seek ethical approval for the research via an ethical review process. The purpose of the review is to make sure that risks are managed appropriately and that the interests of anyone affected by the research are given suitable protection. It is also to ensure that data is gathered, processed, stored and archived in an appropriate way. If ethical approval is needed, the researcher cannot begin the research until it has been granted. The researcher must obtain further ethical approval if a project changes significantly.

In some cases ethical approval is a legislative or regulatory requirement, or is required by funding bodies. (Note that as well as obtaining ethical approval, the researcher may need to satisfy separate legal requirements.) Otherwise, researchers usually need to seek ethical approval for research if any of the following hold (the list is not exhaustive):

1. The project involves human participants, human remains or personal data.
2. The project involves animals.
3. The project involves genetic resources (plants, animals, microorganisms).
4. There is a possibility of harm to researchers, or to the University as an institution.
5. There is a possibility of harm to others not involved in the research.
6. There is a potential for conflict of interest.
7. There is a possibility of damage to the environment.

Some of the University ethics boards and committees (see 3.2 below) provide a self-assessment checklist to help researchers decide whether ethical approval is needed.

Research staff should note that, prior to progressing to ethical review, they must consider the need for both a DPIA (Data Protection Impact Assessment) and an ISRA (Information Sharing Risk Assessment). See the [Research Data Management Policy](#) and [Guidance](#) for further information.

3.1 How to Obtain Ethical Approval

First the researcher must decide whether ethical approval is needed. If so, they must apply to the University ethical review board or committee that covers their area of research, following the process laid out by that board or committee (see 3.2 below). **All postgraduate students and staff must complete the University's online Research Ethics and Governance training course (see section 7) before submitting an ethics application.** The ethics application process involves completing an application form and submitting it along with supporting documentation. The application is reviewed by one or more board or committee members, who consider the ethical implications of the research. The application can be accepted or rejected at this stage, but it is common for the reviewers to ask for changes to be made to a project or ask for more information. The researcher must then submit a revised application addressing the reviewers' comments. The revised application is reviewed – often, but not always, by the same reviewers – and the process continues until the application is either accepted or rejected.

Particularly simple applications are sometimes reviewed in just a few days, but ethical review often takes several weeks and maybe longer. Researchers should take account of this when they are planning their research. If difficult ethical questions arise from a particular application, the reviewers may seek advice from others on their board or committee, or from other University ethics boards or

committees. If necessary, the reviewers may consult the Research Policy Committee or the Vice-Principal for Research or seek external advice, for example from the UK Research Integrity Office.

Some Schools and disciplines have a slightly different process for research carried out by undergraduate or taught postgraduate students: for instance, the project might be reviewed by the course co-ordinator instead of by a University ethics board or committee.

Some types of research require separate or extra review processes. This applies to research involving animals (see 3.6 below) and research involving genetic resources (see 3.7 below). Research involving NHS patients must be reviewed by the NHS Research Ethics Service (see 3.3 below). If a project is led by researchers from another University or similar institution and the other institution has given ethical approval for the research, the project usually does not need separate approval from the University (see 3.9 below).

Much University research is carried out in different countries or different cultures. The University respects the traditions and cultures with which it has dealings. Where there is conflict between local customs or laws and the ethical principles and values set out by the University then this should be brought to the attention of the relevant ethics board or committee.

3.2 University Ethical Review Boards and Committees

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.

In addition to our institutional processes around [Clinical Research Governance](#) and our procedures governing the use of animals in research, the University currently has six ethical review boards and committees: one for physical sciences and engineering, one for biological sciences, one for arts, social sciences and business, one for life sciences and medicine, one for psychology and one for the Rowett Institute. Most of the members are academic staff from the relevant Schools, but some are professional staff or lay members from outside the University. Each board and committee have in place clear and formal policies for ethical review. Further information on the boards and committees, their membership and their policies can be found [here](#).

Information about the ethical review process for each board and committee can be found [here](#). This webpage contains all the application forms and other documents needed to apply for ethical approval.

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.

Oversight of the operation of each ethical review board or committee is undertaken by the Research Policy Committee. On an annual basis, each ethical review board or committee is required to provide (i) a report to the Research Policy Committee on activities relating to ethics within their research area, reporting on any significant issues that have arisen; and (ii) a copy of their remit for review and approval by the Research Policy Committee.

3.3 Research Involving Health Services

Some research requires ethical review by law, in which case it must be reviewed by the Research Ethics Service (RES). This is a UK-wide service supported in Scotland by the Health Research Authority (HRS) and NHS Research Scotland. RES reviews research that is primarily concerned with participants recruited by virtue of their being patients in the NHS, or their relatives. However, it also includes *some* research involving adults in care or who lack capacity to consent, ionising radiation, tissue samples or DNA analysis, medicinal products or medical devices, or information on the register of the Human Fertilisation and Embryology Authority. Detailed guidance on whether or not research must be reviewed

by RES can be found [here](#) or from the local (North of Scotland) ethics committee (NosRES), email gramnosres@nhs.scot, phone 01224 558474. These studies will all require sponsorship. If NHS premises, equipment or staff are to be involved, then NHS R&D permission will be required. Guidance on obtaining sponsorship for clinical research can be found [here](#). Applications are made online using the [Integrated Research Application System \(IRAS\)](#).

3.4 Research Involving Human Participants

Where it is necessary to conduct research involving humans (including their tissue, organs or data) the University will conform to the highest standards of research ethics and governance and to relevant legislation, and will carry out its research with the utmost care and respect for human welfare and rights. This applies to all forms of research involving human participants, from clinical research to social science. This includes research involving interviews, surveys, focus groups and observation of participants. A central notion is the principle of free and informed consent: participants must be given clear and complete information about the research, including any associated risks of taking part and the proposed uses of the research. For example, consent must be sought for any samples or data which might be used for future research. They must be put under no pressure to take part. They must have the right to withdraw from the research at any time. If the methodology involves deception or the withholding of information then the researcher should make arrangements for a suitable debriefing session after the research is completed.

Clinical research involving human participants must have [sponsorship](#). Approval from other regulatory bodies, such as the Human Fertilisation and Embryology Authority or the Gene Therapy Advisory Committee in the UK, should also be sought where necessary.

Researchers must take particular care where there is an existing relationship between the researchers and the participants (e.g., if participants are colleagues or students of the researchers) or when the research involves vulnerable participants (such as children).

The [Safeguarding Policy](#) (and [Safeguarding Code of Practice](#)) sets out the University's duty to safeguard all children and vulnerable (protected) adults at risk including visitors attending University events; potential students met off-campus; students, staff and volunteers who are part of the University; or anyone who comes into contact with University staff, representatives or students in the course of their work or through participation in University research activity. The policy sets out the University structures, guidance and procedures for identifying potential risk, abuse, harm or neglect, and for reporting concerns, internally and where required, beyond the University. When preparing an application for ethical approval and/or applying for research funding, researchers must also consider the safeguarding requirements of the funding organisation or particular institution.

The policy is aligned with the requirements of the [UK Research and Innovation Preventing Harm \(Safeguarding\) in Research and Innovation Policy](#), which makes a commitment to 'promoting safe research and innovation environments which are free from sexual exploitation, abuse, and harassment, bullying, psychological abuse and physical violence for all individuals that are employed on, participate in or otherwise come into contact with research activities.'

The Safeguarding Policy supports and complements a number of related University policies e.g. the [Staffing Policy against Discrimination, Harassment and Bullying in the Workplace](#), the [Equality, Diversity and Inclusion Policy](#), the policy on [Reporting of Gender-Based and Sexual Violence](#), policies and guidance under its 'Prevent duty' (Counter-Terrorism and Security Act 2015) and the [Protection of Vulnerable Groups \(PVG\) Policy](#).

Researchers should ensure the confidentiality of personal information relating to the participants in research, and that the research fulfils any legal requirements such as those of the [Data Protection Act 2018](#) and UK General Data Protection Regulations (GDPR).

3.5 Research Involving Oral Data Collection

Research involving the collection, preservation and use of sound and video oral material must conform to relevant ethical and technical practice, including data protection legislation.

3.6 Research Involving the Use of Animals

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.

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 following transposition of European Directive 2010/63/EU on 1 January 2013 following its approval by the UK Parliament). Research involving animals is governed institutionally by the Advisory Group to the Establishment Licence Holder and the Ethical Review Committee (ERC). The ERC is responsible for carrying out robust ethical review on all research proposals which are submitted to the Home Office as part of a project licence and/or major amendment application.

Detailed information on the ERC 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 School Offices within Biological Sciences and Medicine, Medical Sciences and Nutrition.

3.7 Research Utilising Genetic Resources – the Nagoya Protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (CBD) applies to research involving genetic resources (from plants, animals, microorganisms – but not from humans). The Nagoya Protocol also covers traditional knowledge associated with genetic resources that are covered by the CBD and the benefits arising from its utilization. Research of this kind must undergo a separate approval process, but it may also need to go through the standard ethical approval process described in 3.1 above. See the [Nagoya Protocol webpage](#) for further details.

3.8 Prevent Duty

[The Counter Terrorism & Security Act 2015](#) ('the Prevent duty legislation') and the UK Government's [Revised Prevent Duty Guidance](#) 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 the Prevent duty legislation. Researchers who are downloading, storing or handling terrorism-related material need to make sure they follow the correct procedures to ensure compliance with the Prevent duty legislation.

3.9 Undertaking Research Outside the University or the UK

Many research projects involve researchers from outside the University or involve work external to the University and/or the UK. If the project is led by researchers from the University, formal ethical approval should be obtained from the University. If the project is led by external researchers, it may be appropriate to obtain ethical approval via the processes in place at their institution. In cases where a potential conflict of interest exists, confirmation that the external review process meets with the University's requirements should then be sought from the appropriate ethics board or committee. Normally this will be given, but if the University is not satisfied that the review process provided by the host institution/organisation meets our own standards, further review may be required.

Researchers who wish to conduct research involving local authorities (e.g. to undertake research within primary or secondary schools) must ensure that their external applications for ethical approval receive appropriate internal University review **prior** to submission to the local authority. Researchers should check the review process that has been established within their School; this may require completed applications to be submitted to either the School Ethics Officer, Principal Investigator, Line Manager or Research Supervisor to ensure that the application has been completed to a high standard, hence more likely to receive local authority approval at first submission.

In addition, where research projects are supported by external funding, note that there may be additional requirements for ethical approval that must also be complied with. The terms and conditions of external funders should be carefully reviewed to ensure compliance. For example, it is mandatory for studies in receipt of MRC funding to have **both** UK and respective country ethical approvals.

3.10 Data Gathering for University Business (non-research purposes)

It is understood that the University undertakes many types of data processing and analysis of personal information. Where the purpose of this data gathering is for normal University business (non-research purposes), this activity will not require to be submitted for ethical review. Data protection requirements still apply, however, to any use of personal information. The [Data Protection policy](#) should be consulted and the Data Protection Team (dpa@abdn.ac.uk) can be contacted for any questions about legal or regulatory requirements.

3.11 Help and Information

In addition to the weblinks listed above, researchers may also wish to contact the School Ethics Officer (or other person in the researcher's School with responsibility with dealing with ethics). Next, the Chair or Convener of the relevant ethics board or committee. The Chair or Convener can seek advice if necessary from members of their own or another ethics committee or board, then if necessary from Research and Governance, the Dean for Cultural Strategy & Research Governance, the Research Policy Committee or the Vice-Principal for Research.