3. 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. Further advice is available from the appropriate Ethics Board.

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 secondary data that raises ethical concerns.
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.

The University provides a self-assessment checklist to help researchers decide whether ethical approval is needed.

Researchers should note that, prior to progressing to ethical review, they must consider the need for a DPIA (Data Protection Impact Assessment) and, if a third-party supplier (including a supplier of software or of a service to the research) is involved, an SCDA (Supplier Cyber and Data Assessment). See the DPIA guidance and SCDA guidance for further information. A Data Protection Checklist for Researchers is also available, which guides researchers through their obligations under data protection legislation when planning to use personal information/data in a research project.

3.1 How to Obtain Ethical Approval

First the researcher must decide whether ethical approval is needed (see checklist above). 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 research students (PGRs) and staff must complete the University's online Research Ethics and Governance training course (see Section 7) before submitting an ethics application.** This is in addition to the mandatory online training in Research Integrity, that must be completed by all PGRs and research staff (see Section 7). Further guidance on the appropriate application process to be followed is available on the Ethics Board webpages. Applications submitted to our internal Ethics Boards should be submitted via the Worktribe Ethics process.

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 (also known as a 'Favourable Opinion') or rejected (also known as an 'Unfavourable Opinion').

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 & Strategy team or the Ethics Advisory Group or seek external advice, for example from the UK Research Integrity Office.

Some Schools and disciplines have a 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 additional review processes. This applies to research involving animals (see 3.6 below) and may apply to 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). Research involving UK local authorities (including employees, service users, analysis of data already held by the local authority; or involving school staff, pupils etc) may also require external ethical approval (see 3.9 below). If a project is led by researchers from another UK 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.

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 Ethics Advisory Group. On an annual basis, each ethical review board or committee is required to provide (i) a report to the Ethics Advisory Group 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 Ethics Advisory Group.

3.3 Research Involving Health Services

Some research requires ethical review by law, in which case it must be reviewed by the NHS Research Ethics Service (RES). This is a UK-wide service supported in Scotland by the Health Research Authority (HRA) 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 a NHS REC can be found here, by contacting Clinical Research Governance (email researchgovernance@abdn.ac.uk) 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 (or their Data)

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, students or relatives of the researchers) or when the research involves vulnerable participants (such as children or adults at risk). Where appropriate, a safeguarding plan should be put into place (see 4.1.2).

Researchers may also require ethical approval for the use of secondary data in their research, particularly if this involves personal data or access to sensitive data not already in the public domain. Secondary data also includes data obtained from websites or social media that can be attributed to an individual. Further advice is available in the University's Ethics Checklist.

3.5 Research Involving Audio or Visual Data Collection

Research involving the collection, preservation and use of audio or visual material must conform to relevant ethical and technical practice, including data protection legislation. It is recommended that University of Aberdeen approved audio and visual software is used wherever possible e.g MS Teams is recommended for recording online interviews. Further information on MS Teams is available on the Toolkit page. If cameras and audio recording devices will be used these should be password protected wherever possible. It is also recommended that the data is transferred from the device as soon as possible onto the University's research data storage, and recordings are then deleted from the audio/visual device. Participant Information Sheets should clearly inform participants of any audio/visual data collection and ask for their consent to record.

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 the performance of regulated procedures on protected 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.

Research involving animals that does not fall under Home Office Regulation must be submitted for ethical approval via the appropriate University ethical approval process, as described in section 3.1 above).

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 Utilisation to the Convention on Biological Diversity is a 2010 supplementary agreement to the 1992 Convention on Biological Diversity. Its aim is the fair and equitable sharing of benefits arising out of the utilisation of genetic resources, as well as associated traditional knowledge. From 12 October 2014, anyone who wishes to access genetic resources and/or the traditional knowledge associated with resources in participating countries will be required to comply with these regulations.

If research involves the utilisation of non-human genetic resources (or their derivatives, e.g. proteins, lipids, enzymes) from a participating country that exercises its sovereign rights (i.e. has established measures relating to access and benefit-sharing), the research must undergo a separate approval process. See the Nagoya Protocol webpage for further details, including a checklist which guides you in deciding whether your planned research is in scope of the Nagoya Protocol. Please contact your Research Development Executive for further guidance on whether your research is in scope. Your research may also need to go through the standard ethical approval process described in 3.1 above.

Please note that even if the provider country is not a Party to the Nagoya Protocol and the material is out of scope, the country might have their own access and benefit-sharing regulations. Their National Focal Point (NFP) should be consulted before genetic resources are accessed.

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, including student projects where the student is registered at the University, formal ethical approval should be obtained from the University. This University approval is in addition to obtaining local ethical approval in the country where the research is taking place, as per the requirements of that country. If the project (or a distinct work package within a project) is led by external researchers, it may be appropriate to obtain ethical approval via the processes in place at their institution.

It is the responsibility of the Principal Investigator to ensure that ethical approval has been obtained for all work packages, either via the University of Aberdeen process or at the external institution, where appropriate. In these circumstances, researchers should seek further guidance from the Research Policy & Strategy team.

In cases where a potential conflict of interest or uncertainty on the home country's procedure 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. Further information on obtaining ethical approval from local authorities is available here.

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.

Researchers who require to travel to undertake research activity must abide by the requirements of the University's Travel Policy.

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) e.g. for public engagement activity, Athena SWAN preparations/submissions, data gathering in support of service evaluations or teaching evaluations, market research, this activity will **not** require to be submitted for ethical review. Data protection requirements still apply, however, to any use of personal, sensitive or confidential information. The Data Protection policy should be consulted and the Information Governance Team (dpa@abdn.ac.uk)

can be contacted for any questions about legal or regulatory requirements, including UK GDPR compliance.

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 the Research Policy and Strategy team, the Dean for Academic Research Partnerships & Research Governance, the Ethics Advisory Group or the Vice-Principal for Research.

3.12 Appeals Procedure

It is recognised that research ethics applicants may wish to appeal against the decision made by one of the University's internal ethics boards to award an 'Unfavourable Opinion' to an ethics application. Unfavourable opinions may be awarded where the research project is considered to be in contravention of the University's research governance framework and associated policies and procedures on ethical conduct in research (including board level guidance, etc).

Applicants should, in the first instance, seek informal resolution by discussing the matter with the Chair of the appropriate ethics board. Where such discussion fails to resolve the issue, an appeal may be submitted to the University's Ethics Advisory Group.

The Research Ethics Applications (Worktribe Ethics) – Policy and Procedure on Appeals provides further guidance on the process to be followed. Appeals may only be submitted where it is believed:

- The University's review procedures were not followed, and the failure would cause reasonable doubt as to whether the ethics board would have reached the same decision had these irregularities not occurred;
- The board making the decision did not have the authority to do so;
- The board making the decision did not act impartially i.e. there is demonstrable evidence of prejudice, bias or inadequate review.

For appeals relating to decisions made by the Ethics Review Board (animal welfare) or the clinical research ethics approval process, further guidance should be sought from the appropriate board.

For appeals relating to decisions made by a School ethics review process (UG and PGT ethics applications), further advice should be sought from the appropriate School.