

Research Ethics Framework

1. Introduction

The University Ethics Policy states that 'The University seeks to promote the highest standards of scientific, scholarly and professional integrity and to give due consideration to the ethical, social and environmental issues arising from its activities'¹. A publically available Framework for ethical review is required to comply effectively with, and should work alongside, the Concordat to Support Research Integrity², the University Ethics Policy and the Code of Good Practice in the Conduct of Research³.

At present, it is considered that the ethical review process can best be delivered through a devolved model in each College. The framework aims to provide consistent standards for the ethical review process across all Colleges and should be a benchmark for considering existing or implementing revised review processes. The Framework is complementary to existing funder and professional society guidelines and is flexible enough to recognise that implementation may vary to reflect different ethical issues and volumes of review across the range of disciplines.

2. Why is the Framework needed?

The Framework is needed to set out the University's expectations for the ethical review of research and therefore to:

- ensure the safety, rights, dignity and welfare of all research participants
- work towards sector-wide best practice and standards; realising the benefits of greater collaboration within the Russell Group and support from, e.g the Association for Research Ethics and the UK Research Integrity Office
- maintain public trust; recognising the increasing public scrutiny of research and potential reputational risks
- comply with the Concordat to Support Research Integrity and to provide a visible measure of standards for reporting to UKRI and others
- optimise the opportunities for process improvement in the University wide e-ethics system
- recognise the professional integrity of researchers, but also the requirement for ongoing development and reflection at all stages of a research career.
- recognise that research ethics are always dynamic and that there is a need to continually engage with researchers in meeting complex ethical challenges (e.g. big data, new technologies, social media) and to embed research integrity into the culture of the Institution;
- develop an increasingly facilitative process with a focus on developing ethical researchers through all stages of a project and throughout their careers.

¹ University Ethics Policy <http://www.exeter.ac.uk/cgr/researchethics/codesandpolicies/>

² Concordat to Support Research Integrity <https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf>

³ Code of Good Practice in the Conduct of Research <http://www.exeter.ac.uk/research/inspiring/about/goodpractice/>

3. Ethical principles

The University recognises the following commonly accepted ethical principles:

- Autonomy – the participant must normally be fully aware of the purpose of the research, be free to take part without coercion or penalty and be able to withdraw at any time without giving a reason and without the threat of any adverse effect.
- Beneficence – the research must be worthwhile in itself and have beneficial effects (directly for the participant or for the public good) that outweigh any risks; the methodology must be sound so that best results will be yielded.
- Non-maleficence – any possible harm must be avoided or mitigated by robust precautions.
- Confidentiality – personal data must remain unknown to all but the research team; it must be collected, stored and destroyed appropriately.
- Integrity – the researcher must be open about any actual or potential conflicts of interest and must conduct their research in a way that meets recognised standards of research integrity.

In some exceptional circumstances researchers may wish to override these principles, for example, where a participant wishes their voice to be heard and identified, where covert research or deception would be justifiable or where there is an overriding public interest. Researchers must provide justification for this approach and approval from an appropriate Research Ethics Committee (REC) must always be given.

Researchers are also expected to give consideration to the environmental, social, political, religious or economic consequences of any research undertaken as well as legal or professional obligations and any potential safety and reputational risks to participants, researchers, the College or University. RECs are not required to specifically review these aspects of research, although it is expected that committees will be able to identify concerns and direct researchers towards appropriate sources of advice and guidance.

4. When should a research project be reviewed?

All research involving humans (either living or deceased), their data or tissue, or animals (living vertebrates and invertebrates), should be ethically reviewed and receive a favourable opinion before work commences. The definition of research does not include routine audit, service evaluation, quality assurance studies, performance review, literary or artistic criticism. Decision tools such as the following from the Health Research Authority may be helpful: <http://www.hra-decisiontools.org.uk/research/> . Studies involving human remains or artefacts from ancient sites may be exempt from the review process, but care should be taken to follow local College ethical review requirements, all relevant professional standards and legal requirements. In cases where the requirement for review is unclear, researchers should seek advice from their local Ethics Officer.

This applies to all staff research projects (funded or unfunded, contract research, University consultancy and private consultancy⁴), any research leading to the award of a degree and any teaching module with a research component that involves any of the above elements.

The Ethics Policy, Research Ethics Framework and the Code of Good Practice in the Conduct of Research apply to all researchers working under the auspices of the University of Exeter.

⁴ Consultancy work must be carried out within University guidelines and private consultancy is strongly discouraged <http://www.exeter.ac.uk/research/toolkit/collaborating/industry/consultancy/>

It is accepted that researchers (and their supervisors where applicable) are responsible for and best placed to evaluate the ethical issues and the conduct of their research, but researchers should be accountable for the design, management and conduct of their research. Independent scrutiny and review can be, and should be of sufficient quality to be, useful in improving the proposed research and in ensuring that ethical standards are applied consistently.

In-depth dual-review should be avoided where possible (for example, where projects require ethical approval by a recognised research ethics committee such as an NHS REC), although Colleges are expected to log and ensure that appropriate ethical approval is in place before work can begin and that recognised ethical standards are met.

Where research involves the use of restricted, security sensitive or illegal materials, the University's policy on restricted materials <http://www.exeter.ac.uk/ig/policy/restrictedmaterials/> must be followed and the declaration form submitted by the researcher following ethical review and/or supervisor approval as relevant.

Where research is being conducted by staff or students in more than one College in the University, the research should be ethically reviewed in one of the Colleges, taking into account the location of the Principal Investigator and the expertise of the ethics committees in each College.

Where research is being conducted by staff or students from the University of Exeter in collaboration with researchers from another institution, the research should be reviewed by the relevant College research ethics committee at Exeter, although the committee can take into account reviews carried out by other Institutions, particularly if the Principal Investigator is from another Institution.

Where research is carried out outside the UK, researchers are expected to seek local ethical approval from a properly constituted and independent ethics committee and to comply with local ethical and regulatory standards. If local review is not available or appropriate then such research must be reviewed by a College committee. College ethics committees must ensure that they log and confirm that appropriate ethical approval is in place before work starts and that recognised ethical standards are met.

5. Principles for ethical review

The following principles should underlie ethical review arrangements in each College, although it is recognised that they may be addressed differently according to need.

- **Independence** – mitigating conflicts of interest and ensuring sufficient impartial scrutiny
 - Reviewers from an appropriate range of disciplines or research fields
 - Membership from outside the discipline or College as appropriate; this may vary depending on the structure of a College's ethical review process
 - Where possible, inclusion of lay members from outside the University
 - Evidence of process to recognise and address potential conflicts of interest in the review process
- **Competence** – ensuring that membership of committees/selection of reviewers informed by relevant expertise and that decision making is consistent and coherent
 - Standard Operating Procedures in place (see 'Procedures' below);
 - Application system that provides all the information needed to make a sound and competent decision
 - Evidence of appropriate time, support and training for REC members and a sustainable commitment to competent ethical review
- **Facilitation** – recognising the role of RECs in facilitating good research and support for researchers

- Administering the review process efficiently and effectively within agreed timescales
 - Balancing duties of care with enabling of research and innovation
 - Review process that recognises different levels of risk and handles them efficiently and proportionately
 - Appropriate process in place to manage expectations, concerns or difficulties at an early stage
 - Working with colleagues across the University, provide training for researchers at all stages of their careers in ethical issues and the review process
- **Openness** – RECs to be transparent and accountable, with responsibilities discharged consistently
 - Decisions clearly recorded and open to scrutiny
 - Clear process for escalation of complaints/concerns
 - Compliance with annual reporting process
 - Open discussion between committee members and with the University Ethics Committee (UEC) on broader ethical issues, concerns or complaints

6. Procedures

Each College is expected to develop a Standard Operating Procedure (SOP) for ethical review. Each SOP should include information on the following:

- Terms of reference and membership of RECs
- The application process and the provision of guidelines for researchers on completing applications
- Description of review processes which recognise differing risk levels (e.g. two-tier system of 'proportionate' and full review, or Track A and B review) whilst still maintaining the principles of review outlined above
- Schedule of committee meetings or online review (as appropriate), including normal timelines
- Definition of opinions that could be given following review and implications of those opinions for researchers
- Process for review of amended research proposals, including normal timelines
- Sources of support and resources for researchers, research integrity and ethics induction and training available for researchers, supervisors and research leaders
- End of project reporting
- Appeals and complaints procedures available to researchers, supervisors and participants – the approach to this should be consistent across the University.

Where appeals need to be escalated beyond the College, they will be considered by the University Ethics Committee. The UEC could choose to refer the matter onwards to the University Animal Welfare & Ethical Review Board if deemed appropriate. The UEC will not hear appeals against the decisions of external ethics committees which should provide their own appeals procedures. Broader ethical issues can be referred by Colleges to the UEC for advice and guidance, for example, on a controversial issue or where a common University approach would be desirable. A response should be provided by the UEC (co-ordinated by the Research Ethics and Governance team), or by the REG team directly if appropriate, within a maximum of three weeks. Where RECs consider that research raises a potential reputational risk, it should be referred to the Research Ethics and Governance Manager who will ensure that the risk is appropriately considered in accordance with the Due Diligence policy and associated review process.

It is recommended, for example by the Parliamentary Committee on Women in Science, that researchers should consider the gender implications and dimensions of their research. Ethics Committees can contribute to this by asking researchers to consider this aspect in their ethical review applications and to justify their selection of participants where exclusion criteria based on e.g. gender, ethnicity or other protected characteristics are imposed.

The use of third parties (e.g. market research organisations) to carry out data processing or other research activities must be supported by a legally-binding contract, signed by a recognised signatory in the University Legal Services team. The contract must specify the standards and processes for the research activities and any arrangements for data sharing and responsibilities for compliance with current data protection legislation.

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