

Research Ethics Policy

1 Introduction

1.1 Background

The University is committed to maintaining the highest ethical standards and principles in the conduct of its research. The Research Ethics Policy sets out the principles underpinning the ethical conduct of research and defines the process and principles for the objective and rigorous ethical review of research which falls within its scope.

The Research Ethics Policy **must** be read in conjunction with the [Research Code of Conduct](#), which sets out the University's commitment to research integrity.

Researchers are expected to familiarise themselves with the Research Ethics Policy and observe the principles and procedures to embed good ethics practice in all aspects of their work before commencement of and during the conduct of the research.

This Research Ethics Policy has been drawn up to conform with the principles laid out in other relevant policies, guidelines and codes of conduct, including funding bodies such as the ESRC and the Wellcome Trust, and the Universities UK's Concordat to Support Research Integrity.

1.2 Definitions

The "Policy" refers to the Research Ethics Policy

The "Committee" refers to the University Ethics and Integrity Committee.

The "Sub-Committee" refers to one of the six Research Ethics Committees.

For consistency, definitions and meanings of other key words in the Research Ethics Policy (such as Principal Investigator, student, research and researchers) shall have the same meaning and definition as those found in the University Research Code of Conduct.

'Researcher' or 'You' indicates an individual involved in research, including, but not limited to:

- staff in any of the University's job families (teaching and research, technical and experimental, management and administration, and community and operational), including Honorary Staff and Emeritus Professors;
- staff visiting from other institutions undertaking or supervising research at or for the University;
- undergraduate and postgraduate students (both taught and research), whether registered here or on temporary placement.

This term also covers those involved in fundraising providing consultancy, innovation, commercial and analytical services and those involved in the setting up and running of University spin-out companies.

‘Research’ is defined according to the internationally accepted OECD Frascati Manual as "Creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications" [sic]. This includes, but is not limited to, funded and unfunded research projects, consulting within and outside the University, and exploitation and knowledge transfer activities. This Code applies to all research and consultancy activity undertaken by University staff and students in collaboration with other organisations, such as collaborative research projects, and to individuals from other organisations who are undertaking or supervising research at or for the University.

‘Principal Investigator’ or ‘PI’ refers to the lead investigator – generally the main holder of the research funding or leader of a project or, for multi-institution projects, the University of Leicester lead investigator.

‘Supervisor’ covers any person or persons who are responsible for oversight of other researchers.

‘Head of Department’ refers to the Head of the academic unit to which a researcher belongs, which can include Schools, Departments, Research Centres and other academic divisions within the University.

‘Student’ covers any person who has registered on a programme of study with the University, which can include undergraduate, postgraduate taught and postgraduate research programmes. This also includes students from elsewhere visiting as part of an exchange or similar programme.

A ‘Research Student’ is a student who is registered on a research-based programme of study, such as an MPhil, professional doctorate or PhD.

‘Research Funder’ covers any organisation or person which provides research funding to the University, and can include research councils, public sector organisations, charities, non-governmental organisations, commercial and business organisations and government agencies whether located within the UK or elsewhere.

‘Research Funding’ covers all forms of external funding in support of research and enterprise activities including research grants and contracts, philanthropic donations, consultancy and industrial research contracts and grants in kind providing access to external expertise, facilities, equipment, etc.

2 Scope

2.1 Application and observance

The Policy applies to all researchers, supervisors and students conducting research under the auspices of the University.

Researchers, supervisors and students must familiarise themselves with this Policy before commencing research.

2.2 Scope of University ethical review

University ethical review is required for:

- (a) Research involving human participants, human tissue, material or remains, personal data; and
- (b) Any other types of research that might not involve humans but still raises ethical issues or concerns. For example, the research or results of the research may pose a risk of damage to the environment, or cause political or social tensions or sensitivities or may impact on cultural heritage.

Animal research ethics is regulated by the [University's Policy Statement on Research Involving the Use of Animals](#) and applicable statute and is not covered by this Policy.

Legislation or Government bodies may require ethical review to be conducted by a specific ethics committee. For example, the Human Tissue Act, the Mental Capacity Act, or the Medicines for Human Use [Clinical Trials] Regulations 2004, as amended), the Department of Health's Research Governance Framework for Health and Social Care or research funded by the Ministry of Defence. In these cases, ethics review by, for example, the NHS Research Ethics Committee takes precedence over the University ethics system. Researchers should avoid duplication of ethics review.

3 Principles underpinning the ethical conduct at all stages of research

Researchers must abide with the following principles at all stages of the research lifecycle. This includes the planning stage, applying for funding, the conduct and later stages of the project, such as dissemination and impact activities.

- (a) Researchers must respect the rights, interests, dignity of participants and related persons in research.
- (b) Research must be undertaken in accordance with any relevant common law or legislation.
- (c) Full informed consent should normally be obtained from participants to enable participants to take part voluntarily. Consent should be given freely without force or coercion.
- (d) Researchers have an obligation to protect research participants wherever possible from significant harm consequent upon the research.
- (e) The confidentiality of information supplied by research participants and any agreement to

grant anonymity to respondents should be respected.

- (f) Care must be taken with collecting, handling and storing sensitive, classified and/or personal data. Such data should be kept securely and protected from unauthorised access. Particular care should be taken to ensure that human data cannot be linked back to individuals unless by authorised persons. It is essential that all sensitive, classified and /or personal data are disposed of appropriately in line with legal and funder requirements.
- (g) Both the design of research and its conduct should ensure integrity, quality and provide benefits that outweigh potential risk or harm.
- (h) Research shall be undertaken subject to the principle of academic independence. Where any conflicts of interest or partiality arise, these must be clearly stated prior to ethical approval being obtained.
- (i) The same high ethical standards shall apply wherever in the world the research is being undertaken.
- (j) The principal investigator and the research team shall be responsible for determining what ethical issues emerge from the proposed project and for obtaining ethical approval of the project.
- (k) All research involving human participants is subject to ethical approval.
- (l) Research that does not involve humans but raises ethical issues or concerns is also subject to ethical approval
- (m) Researchers are responsible for ensuring the project is undertaken as approved by the University research ethics approval process and in compliance with any legal or organisational requirements.
- (n) Any major divergence from the approved project must be subject to further ethical approval and the researcher is responsible for acquiring further ethics approval before continuing with the research.

4 Training and Resources

The Committee will ensure that researchers are provided with adequate and regular training in research ethics as is appropriate for their level of expertise or study and subject discipline.

Researchers and students must undertake appropriate training or experience in the ethical implications of research and on all aspects of this Policy.

If you are in doubt about the scope of applicability of this Policy, or about the appropriate ethical review, you should seek advice from a member of the Committee or a Sub-Committee or a departmental ethics advisor.

5 Complaints Procedure

The University takes ethics and ethical standards very seriously. Any complaint of misconduct in research concerning a University member of staff or student or regarding the University's ethical review process must be made to the Chair of the Research and Enterprise Committee for an initial assessment of the nature and severity of the complaint.

The misconduct policy, definitions and procedure for investigating an allegation of misconduct are found in the [Research Code of Conduct](#).

6 Other University policies and guidance

From time to time, the Committee may issue policy or guidance for staff and students on such issues as: informed consent, internet research, recruiting online recruiting vulnerable participants, and recognition of another institution's ethics approval.

Any policy approved by the Committee will be uploaded on the [University ethics webpages](#) and circulated appropriately.

7 External Codes

Researchers must adhere to any regulations laid down by their professional body and any legal requirements relating to their research, such as Acts of Parliament or statutory regulations.

Reference should, in addition, be made to different funder and professional ethical codes in relation to different subject areas where this is appropriate. A list of relevant codes of ethics is appended as Annex 2.

8 Oversight and Monitoring

8.1 Oversight

The Policy is subject to oversight by the Committee, which reports to the Research and Enterprise Committee.

8.2 Reporting

Each Sub-Committee will submit a written annual report to the Committee for review.

The annual report will contain summary data on the projects reviewed (number, discipline/ type, outcome of review process); information on any strengths, issues or trends identified; and a random sample of approved applications and, in some cases, disputed applications as well.

The Committee reports to the Research and Enterprise Committee and will routinely submit minutes of its meetings. In addition, it will submit an annual report drawing on the reports from the Sub-Committees.

The Committee will also submit reports to the University Audit Committee as appropriate.

8.3 Monitoring

The Committee will ensure a system of monitoring of projects is in place and shall report to the Research and Enterprise Committee on its findings and recommendations.

9 Ethical Funding Policy

It is University policy not to accept donations or funding that it judges to be illegally obtained or to risk adversely affecting its reputation or compromising its academic freedom or integrity. Researchers should contact the Research and Enterprise Division for guidance on acceptance of funding and the Philanthropy, Alumni and Community Engagement (PACE) office for guidance on donations.

Research Ethics Review System

1 Process for the ethical review of research

1.1 Background

The Committee is responsible for overseeing and monitoring the ethical review process. Ethical review of research project applications is carried out by six Research Ethics Committees (“the Sub-Committees”), which are responsible for the operation of the ethical review system.

1.2 Online Form

All applications for ethical review of research must be completed and submitted via the [Ethics Online Review System](#). The relevant Sub-Committee will review each research proposal submitted by the Principal Investigators as follows:

1.3 Initial Review

Upon receipt of an application, the relevant Sub-Committee shall assess the likelihood and magnitude of risks, and consider the risk of harm. For staff-led and postgraduate research projects, this process will be carried out by two reviewers from the Sub-Committee. For undergraduate student projects and taught postgraduate student projects, this review will be undertaken by an authorising supervisor.

Where the actual or potential risk of harm to participants and others affected by the staff-led and postgraduate researcher proposed research is minimal, the reviewers shall carry out a light-touch review.

Should there not be sufficient information for a decision on the level of risk to be made, the application will be returned to the applicant and a request made for more detail to be supplied.

For levels above minimal risk the application will be escalated.

1.4 Escalation

For undergraduate student projects and taught postgraduate student projects, the authorising supervisor will assess the risks in the application. The authorising supervisor will escalate to the Departmental Ethics Officer any applications that are above minimal risk or where it is unclear whether or not they meet the criteria for minimal risk.

All projects which involve more than minimal risk will be subject to an ethics review by a Sub-Committee. Where this is the case, the initial reviewers or authorising supervisor will escalate the application for review by the appropriate Sub-Committee.

For undergraduate student projects and taught postgraduate student projects, the application will be escalated to the Departmental Ethics Officer in the first instance. The Departmental Ethics Officer will confirm whether or not the application involves more than minimal risk. If considered more than minimal risk, the application will be escalated to be considered by the appropriate Sub-Committee.

1.5 Minimal risk criteria

The Economic and Social Research Council provides a list of criteria where light touch review is generally not considered as appropriate (i.e. the [research application potentially requires a full ethics review](#)).

1.6 Feedback

Where a proposal does not meet the expected ethical standards or changes are required, the Sub-Committee will give feedback on what needs to be done. The decision made for each proposal, and the grounds on which it was made, should be recorded and provided to the researchers.

1.7 Generic Approval

In some instances, it may be appropriate for a Sub-Committee to review and approve 'one research ethics protocol' for commonly occurring situations (e.g., research undertaken by undergraduate students with children in mainstream school settings). In such instances of generic approval, the applicant researcher should confirm compliance with the established protocol when research is being conducted and that this is appropriate for the research project.

1.8 Ethics Review for collaborative research

Where a joint research project with another institution is proposed, the lead principal investigator at Leicester shall submit an application to seek ethical approval.

In cases where the co-applicant is at Leicester (and the lead principal investigator is at another institution), the Leicester co-applicant shall submit an application to seek ethical approval, ensuring that the ethics approval from the other institution is attached with the ethics application (if it is made available).

In addition, it should be noted that compliance with ethical principles which may be regarded as appropriate in the jurisdiction where the research is being undertaken is not a substitute for ethical approval from the University of Leicester.

1.9 Referral to University Ethics Committee

When an issue of principle arises, the Sub-Committee may refer the application to the Committee for guidance and will continue with the ethics review by the Sub-Committee once guidance is provided.

1.10 Retrospective ethics applications

In accordance with the University Research Code of Conduct and this Policy, research involving human participants should not begin until proper ethical review has taken place and approval given. Retrospective ethical reviews are therefore not permitted.

2 Principles underpinning the ethics review system

- (a) The primary role of the Committee and Sub-Committee is to ensure good ethical practice and protect the dignity, rights and welfare of research participants and researchers.
- (b) The Committee and Sub-Committee will act in a way that is independent, competent and timely.
- (c) The Committee and the Sub-Committee will act within their Terms of Reference.
- (d) The Sub-Committee will review research proposals in terms of their ethical probity and any discipline-specific ethical issues which may arise.
- (e) The Sub-Committee will consider ethical issues arising from the design, outputs and proposed conduct of the research.
- (f) The Sub-Committee will be sensitive to the context in which a research study will be conducted
- (g) The Sub-Committee will act independently, free from bias and undue influence from the University, from the applicant researcher and from the personal or financial interests of their members.
- (h) The Sub-Committee members must declare any conflict of interest which they may have in relation to an application or matter under consideration and withdraw from the proceedings.
- (i) The Sub-Committee will record each decision in writing using the online system.

3 Information in the ethics application

The application used by researchers to apply for an ethics review is found on the online system. The Ethics Sub-Committee expects that the applicant will, as a minimum, address the following criteria:

- Aims of the research
- Scientific/academic background of the research
- Study design
- Participants – who (inclusion and exclusion criteria), how many, how potential participants are identified and recruited, vulnerable groups
- Methods of data collection
- Methods of data analysis
- Methods of data storage
- Response to any conditions of use set by secondary data providers
- Principal investigator's summary of potential ethical issues and how they will be addressed
- Benefits to research participants or third parties
- Risks to participants or third parties
- Risks to researchers

Procedures for informed consent – information provided and methods of documenting initial and continuing consent

- Expected outcomes, impacts and benefits of research
- Dissemination (and feedback to participants where appropriate)
- Measures taken to ensure confidentiality, privacy and data protection.

4 The University Ethics Committee and Sub-Committees

4.1 Membership

The Committee and Sub-Committees will be formed in accordance with principles of equality and non-discrimination. The Committee and Sub-Committees should also be multi-disciplinary, including at least one lay member and led by a Chair. The Chair of the Committee is appointed by the President and Vice Chancellor of the University and the Chairs and members of the Sub-Committee are appointed by the Heads of Colleges in consultation with Heads of Department. The appointment of these posts shall be for three years in the first instance, with the possibility of renewable for another three-year-term if deemed appropriate.

4.2 Review

Each Sub-Committee will consider applications on a regular basis. It is expected that an initial review of the ethics application by the two reviewers or authorising supervisor (in case of undergraduate student projects) will happen within three weeks of a complete and valid application via the online system.

A final decision is expected to be given no later than 60 days from date of submission of a complete and valid application, unless there are special circumstances warranting a longer time for a decision.

4.3 Quorate

The Committee must be quorate before making a decision on any application which has more than minimal risk -- i.e. as a minimum, the majority of the number of members of the Committee must have reviewed and commented on the application.

For projects that involve more than minimal risk, the Sub-Committee will endeavour to seek the opinion of the lay member before making a decision, to ensure independence of judgement.

4.4 Meetings

Although most decisions will be made via virtual communication, the Sub-Committee may convene a face to face meeting to discuss an application, review ethics review progress, may also ask the applicant to attend in order to clarify an application and other matters falling within the remit of the Sub-Committee. The Sub-Committee should meet at least once a year to conduct an annual review.

4.5 Expert advice

Where appropriate, the Sub-Committee may seek further advice through an expert opinion.

4.6 Decisions

The Sub-Committee may make one of the following determinations:

- a) to request changes or revisions
- b) to approve the project without amendment,
- c) to approve the project conditional upon amendment
- d) to reject

4.7 Appeal

The Committee may consider an appeal following a decision by one of the Sub-Committees to reject an application.

5 Significant amendments

Following ethics approval and the commencement of the project, any significant change to the question, design, methodology or conduct over the course of the research project should be submitted as an amendment to the original application for re-approval by the Sub-Committee via the online system.

A change to the question, design, methodology or conduct of the project is significant where it could have a potential impact on the welfare, dignity and rights of the participants or researcher. Examples of significant changes include proposing:

- a different method to recruit participants
- a different method to obtain consent
- a new lead researcher or
- a different place to conduct the research.

6 Extraordinary cases

In very exceptional circumstances, where a case raises an issue of acute difficulty for the Sub-Committee, the Committee has the power to review an application instead of the Sub-Committee. In reviewing the application, the Committee shall abide with the procedures described above.

7 Review of the Research Ethics Policy

The Committee is responsible for regularly reviewing and updating this Policy to ensure it takes into account current guidelines and relevant legislation.

The Committee will oversee light-touch reviews annually to include minor revisions and updating of references. Where the need for more major revisions to all or part of the Policy is identified, for example to reflect changes to legislation or changes to funder regulations, the Committee will be responsible for revising the Code and requesting approval from the Research and Enterprise Committee.

This version: June 2016

Light touch revision: May 2019

Major review: 2019/2020

Annex 1: Ethics Codes

This list is merely illustrative and not exhaustive:

[ESRC Framework for Research Ethics](#)

[Code of Ethics and Conduct Guidance: Ethics Committee of the British Psychological Society](#)

[Code of Ethics: British Society of Criminology](#)