

## Research Ethics Policy

Version 4.0

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The University of Lincoln's **Research Ethics Policy** is intended to support good conduct in research and research related activities, in order to encourage research of the highest quality. It provides general principles and standards for good ethical practice in research, for the individual researcher (staff member or student) and the institution as a whole.

The University of Lincoln seeks to:

- foster a culture within the University that embraces the principles set down in this policy and relevant legislation to protect the rights, dignity and welfare of those involved in research (whether they are participants, third parties, animals (or other living organism) or staff and students);
- provide ethical guidance that communicates regulatory requirements and best practice, and offer ongoing support and training to researchers to maintain high ethical standards; and
- maintain a review process that subjects research to a level of scrutiny in proportion to the risk of harm or adverse effect.

This policy is applicable to all staff and students and should be read in conjunction with the University's **Code of Practice for Research**, which reflects the principles and commitments outlined in the **Concordat to Support Research Integrity**.

Good research ethics applies to all researchers (see section 11) who conduct research for the University of Lincoln – regardless of whether the research is funded or unfunded, who it is funded by and where the research is conducted including research related consultancy.

Student research must always be overseen by an identified academic, who takes responsibility for ensuring that the University's Research Ethics Policy, Code of Practice for Research and all other relevant legislation, policies and procedures are followed.

Researchers should consider to:

- Replace any activity in order to mitigate against any risks of harm to themselves or others.
- Reduce the scale of the activity to the minimum necessary to meet the study objectives
- Refine the activity to reduce risks

## 1 Ethical principles for research with human participants and personal data

The University of Lincoln is committed to ensuring that its research activities involving human participants and personal data are conducted in a way which:

- respects the dignity, rights and welfare of all participants in research;
- minimises risk to participants, researchers and third parties;
- appropriately manages personal data; and
- aims to maximise the public benefit of research.

The University requires that all those carrying out such research engage with the University's commitment to conduct research to high ethical standards; understand the reasons for, and participate fully in, the ethical review process (whether under the University's procedures or those of authorised bodies such as the Health Research Authority); and fulfil their moral and legal responsibilities in respect of the rights and welfare of participants.

The principle of **respect**:

- Acknowledges the dignity and autonomy (when possible) of individuals, and requires that people with diminished autonomy be provided with special protection;
- Ensures that certain participant populations including (but not limited to) children, prisoners, the mentally disabled and people with severe illnesses are appropriately protected;
- Requires that participants (and third parties – which may include family members, carers, or the wider community) are fully informed about the purpose and intended possible uses of the research, what their participation involves and details of any risks (unless the ethics committee explicitly approves otherwise because, for example, the research involves the deception of participants in the research project);
- Ensures that participants freely and voluntarily provide their consent to participate in such research and can choose to withdraw without adverse consequences (or, for those with diminished autonomy, consent is sought from an appropriate representative);
- Requires researchers to observe the confidentiality of information provided by participants and, where appropriate, respect their anonymity.

The principle of **beneficence**:

- Requires that any risk of adverse effect on people, either directly or indirectly as a result of participation in the research project, is outweighed by the benefits.

The principle of **non-maleficence**:

- Makes it necessary to examine carefully (through risk assessment) the design of the study and its risks and benefits including, in some cases, identifying alternative ways of obtaining the benefits sought from the research.

The principle of **justice**:

- Requires that we treat participants fairly. Participants should be carefully and equitably chosen to ensure that certain individuals or classes of individuals – such as prisoners, elderly people, or financially impoverished people – are not systematically selected or excluded, unless there are academically or ethically valid reasons for doing so;
- Requires that unless there is careful justification for an exception, research should also not involve persons from groups that are unlikely to benefit from subsequent applications of the research.

Each of these principles carries strong moral force, and difficult ethical dilemmas arise when they conflict. A careful and thoughtful application of the principles will not always achieve clear resolution of ethical problems. However, it is important to understand and apply the principles, because doing so helps to ensure that people who agree to be research participants will be treated in a respectful and ethical manner.

## 2 Ethical principles for research with non-human related research

The University of Lincoln is committed to ensuring that its research activities involving domestic and non-domestic animals; animal-based cells, tissue or DNA; plants, fungi and plant based samples; unicellular organisms; and environmental sampling follow ethical and legal guidelines, and that such research is subject to internal ethical review.

The following principles apply specifically to research with non-human organisms at the University:

### 2.1 Replacement, Reduction and Refinement (3R's) will be sought wherever possible.

University staff and students are required to show a respect for all life.

- **Replacement** refers to technologies or approaches which directly replace or avoid the use of animals in experiments where they would otherwise have been used.
  - **Full replacement** avoids the use of any research animals. It includes the use of human volunteers, tissues and cells, mathematical and computer models and established cell lines.
  - **Partial replacement** includes the use of some animals that, based on current scientific thinking, are not considered capable of experiencing suffering. This includes invertebrates<sup>1</sup> such as *Drosophila*, nematode worms and social amoebae, and immature forms of vertebrates<sup>2</sup>. Partial replacement also includes the use of primary cells (and tissues) taken from animals killed solely for this purpose (i.e. not having been used in a scientific procedure that causes suffering).
- **Reduction** refers to methods that minimise the number of animals used per experiment or study consistent with the scientific aims. It is essential for reduction that studies with animals are appropriately designed and analysed to ensure robust and reproducible findings.

Reduction also includes methods which allow the information gathered per animal in an experiment to be maximised to reduce the use of additional animals. Examples of this include the use of some imaging modalities which allow longitudinal measurements in the same animal to be taken (rather than for example culling cohorts of animals at specific time points), or micro sampling of blood, where small volumes enable repeat sampling in the same animal. In these scenarios, it is important to ensure that reducing the number of animals used is balanced against any additional suffering that might be caused by their repeated use.

Sharing data and resources (e.g. animals, tissues and equipment) between research groups and organisation's can also contribute to reduction.

- **Refinement** refers to methods that minimise the pain, suffering, distress, or lasting harm that may be experienced by research animals, and which improve their welfare. Refinement applies to all aspects of animal use, from their housing and husbandry to the scientific procedures performed on them.

Examples of refinement include ensuring the animals are provided with housing that allows the expression of species-specific behaviours, using appropriate anaesthesia and analgesia to minimise pain, and training animals to cooperate with procedures to minimise any distress.

Evidence suggests that pain and suffering can alter an animal's behaviour, physiology and immunology. Such changes can lead to variation in experimental results that impairs both the reliability and repeatability of studies.

Source: National Centre for the Replacement, Refinement & Reduction of Animals in Research ([NC3Rs](#))

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<sup>1</sup> Note cephalopods such as octopuses and squid are protected in the UK by the [Animals \(Scientific Procedures\) Act 1986](#).

<sup>2</sup> Under the UK's [Animals \(Scientific Procedures\) Act 1986](#) embryonic and foetal forms of mammals, birds and reptiles are protected during the last third of their gestation or incubation period, fish and amphibians once they can feed independently and cephalopods at the point they hatch. Embryonic and foetal forms are protected from an earlier stage of development if they are going to live beyond the stage described above and the procedure is likely to cause them pain, suffering, distress or lasting harm after they have developed to that stage.

## 2.2 A Home Office licence:

- In the UK the Animals (Scientific Procedures) Act 1986 – ASPA – regulates experimentation that is likely to cause distress to any living vertebrate other than human and any living cephalopod. Any such vertebrate in its foetal, larval or embryonic form is a protected animal only from the stage of its development when:
  - (a) In the case of a mammal, bird or reptile, two-thirds of the gestation or incubation period for the relevant species has elapsed; and
  - (b) In any other case, it becomes capable of independent feeding.Any living cephalopod in its embryonic form is not a protected animal.
- In the event of uncertainty about whether a Home Office Licence is required, Home Office inspectors can advise on whether a licence is needed.

Note: The University does not hold a Home Office Licence for research that falls with the remit of ASPA regulations. Researchers must ensure that where their research falls within the remit of ASPA, a Home Office Licence is obtained, and research conducted elsewhere. A favourable ethical opinion should also be sought in accordance with the host institutions policy and processes.

## 2.3 Husbandry of all non-human animals:

- Must show compliance with species' specific welfare standards:

This arises from the special circumstances of the University as owner of farming, companion animal and equine enterprises.
- The public nature of any educational establishment means that confusion must not arise between husbandry practices and experimental procedures.

The University will respond to any concern about the **welfare** of the non-human animals in its care.

Further guidance on animal testing and research may be found on relevant [NC3Rs](#) and [Home Office](#) websites.

## 3 Responsibilities

Researchers have an ethical obligation to refrain from tampering with data. Thus, research data and data analyses should not be fabricated, altered nor discarded. In addition, researchers have a responsibility to exercise reasonable care in processing data to ensure no errors affect the results.

Researchers are required to declare any conflicts of interest and should be aware of the potential influence of personal or commercial interests on their work and take all practical measures to ensure that information is presented without distortion.

Nothing that is said in this policy will absolve the responsibility of the researcher to act in accordance with the best interests of the participants, and researchers should undertake research legally and in accordance with any relevant professional codes of conduct.

Appropriate risk assessment for any research activity must be undertaken in line with the University's health & safety policy and processes. For student research (in line with H&S office guidance) it is the responsibility of the supervising academic to ensure that an appropriate risk assessment exists before any research activity commences.

When accessing specialist research facilities at the University of Lincoln, researchers will be required to adhere to any specific building/equipment Standard Operating Procedures (SOPs) and risk assessments.

## 4 University staff and students as participants in research

The University of Lincoln extends to its staff and students the same protection as to all other participants.

Staff and students may be invited to participate in research carried out in the University but their participation must be entirely voluntary, they may withdraw and their participation or decision not to participate will not affect their employment or academic assessment in any way.

It is normally acceptable for students to be invited to take part in teaching exercises, one of the main aims of which is to train them to make their own observations.

## **5 Training and mentoring**

The University will encourage ethical research conduct among staff and students through the provision of training to equip them with the skills to recognise potential risks and by raising awareness of the University's policy and procedures and the responsibilities of researchers in helping the University meet its obligations under the relevant legislation.

## **6 University Research Integrity Ethics Committee (URIEC) and Research ethics sub-committees**

The University Research Integrity Ethics Committee (URIEC), which reports to the Research and Knowledge Exchange Committee and Academic Board (AB), has oversight of Research Integrity and ethical standards across the University to ensure research and research related activity is conducted to the highest standards. URIEC makes recommendations to Academic Board on changes to this policy, its remit as set out in the University's policies and procedures and the composition of its membership and that of its subcommittees.

URIEC will regularly review the effectiveness of the ethical review process, including the composition of its review committees.

Research ethics committees (sub-committees of UREC) shall appoint a combination of members who are independent of the University or who are no longer involved in research, and also those who are still active in the research areas submitted to the committee for review, that reflects the interests of researchers, participants and third parties.

Research ethics committees shall operate in line with the Ethics - Quality Management System (E-QMS).

## **7 Ethical review**

The University is committed to providing a competent, rigorous and externally moderated process of ethical review that is proportionate to the potential risk and, where a high risk is identified, assesses that risk against the benefits.

Research (see definition) and research related activities, whether conducted by staff or students of the University, must receive a favourable opinion (approval) obtained from a University ethical review committee and/or external research ethics committee, as required (see below), prior to the commencement of the research including any recruitment and/or data collection.

Ethical review of research shall fall into one of three categories:

- Research requiring proportionate review (where the actual or potential risk of harm to participants (or others affected by the proposed research) is minimal);
- Research requiring full review (where research involves more than minimal risk);
- Research requiring expedited review (in exceptional circumstances an expedited review may be appropriate where a research project requires review but has a short lead time and is commissioned in response to a demand of pressing importance).

Researchers are no longer required to complete a Project Registration Form (PRF) where there are no ethical risks. A list of study types that would typically not require an ethics application may be found in Appendix One.

It is the responsibility of the researcher (academic supervisor(s) for students) to ensure that ethical permissions are sought where required.

Ethical reviews shall be conducted in line with E-QMS.

## **8 Approval of research conducted by external bodies**

Where the University is approached by external bodies (organisations or individuals) who wish to conduct research involving the University's staff, students, facilities and/or data, or any other thing owned or controlled by the University, we shall facilitate such research where this is properly conducted, does not act to the detriment of the University or its staff and acts to the public good or to the advancement of knowledge.

Where appropriate, arrangements should be in place in accordance with section 2.5 of the University's Code of Practice for Research.

### **8.1 Researchers as collaborators on external projects**

Where a researcher is a collaborator on an external project, an ethics application should be submitted to the lead institution's own ethics committee. The university does not need to undertake an ethics review where the collaborating body has an ethics process deemed equivalent to ours (e.g. other UK HEI, NHS ethics and HEIs in some other countries). Collaborating UoL researchers will not be required to submit an ethics application but should retain a copy of the lead institution's favourable ethical opinion for their records. If the lead institution is in a country without rigorous ethics processes, then the collaborating UoL researcher(s) should submit an ethics application in accordance with section 7. Further advice may be sought from the Research Governance Team.

### **8.2 Researchers as collaborators on external project [recruiting via the University – including recruiting staff and students]**

Where an external researcher wishes to recruit staff and students at the University, permission must be sought from the relevant Head of School or designated nominee. The Head of School must be provided with evidence of a favourable ethical opinion and any recruitment material.

If the Head of School wishes, they may seek further clarification and/or require a submission for ethical approval in accordance with section 7.

### **8.3 External requests for ethical review**

External bodies will be required to identify an internal collaborator who will be responsible for submitting an application to a UoL research ethics committee in line with section 7.

External requests with no internal collaborator should be sent to [ethics@lincoln.ac.uk](mailto:ethics@lincoln.ac.uk) in the first instance.

Consideration of external requests should be handled in line with the E-QMS.

### **8.4 Staff or students**

Where a member of staff or student transfers research from another institution, then this shall be processed in accordance 8.1 and/or 8.2 above.

### **8.5 NHS/HSC research**

Where research requires a favourable opinion from an outside body, for example, from an NHS / HSC ethics committee (via IRAS), the research application shall be submitted for a favourable opinion to such bodies (an internal ethics application will not be required). This will take place once it has been approved through university procedures for confirming sponsorship in line with the Clinical Governance Quality Management System (CG-QMS).

An external favourable ethical opinion will need to be satisfactorily documented before such research begins.

## **9 Status and sanctions**

The University regards any breach of this policy as suspected misconduct and will be handled in accordance with 10.3.

In appropriate circumstances, URIEC has the power under the policies and procedures to withhold, suspend or withdraw a favourable opinion of research, whether as part of disciplinary proceedings or otherwise.

## **10 Appeals and complaints**

### **10.1 Appeals**

Staff or students may appeal the decision of a university research ethics committee to withhold, suspend or withdraw a favourable opinion of research by contacting the Chair of URIEC.

### **10.2 Complaints**

Suspected breaches of this policy should be reported to the Chair of UREC.

### 10.3 Misconduct

Suspected misconduct in research should be considered and reported as set out in the University's Code of Practice for Research.

## 11 Definition of terms

**Academic Board (AB):** is responsible for general issues relating to the research, scholarship, teaching and courses of the University, including criteria for the admission of students; the appointment and removal of internal and external examiners; policies and procedures for assessment and examination of the academic performance of students; the content of courses; the procedures for the award of qualifications and honorary academic titles; and the procedures for the expulsion of students for academic reasons.

**Animals (Scientific Procedures) Act 1986 – ASPA:** regulates experimentation that is likely to cause distress to non-human animals.

**External bodies:** Organisations or individuals who wish to conduct research involving the University's staff, students, facilities and/or data, or any other thing owned or controlled by the University.

**Favourable opinion:** Formal confirmation that a research ethics committee has reviewed and reached an opinion that the research may be conducted.

**Health Research Authority (HRA):** protects and promotes the interests of patients and the public in health and social care research.

**Research:** is defined as any form of disciplined enquiry that aims to contribute to a body of knowledge or theory.

A more comprehensive definition may be found in the [Frascati Manual 2015](#).

**Researcher(s):** Any person(s) who conducts research, including but not limited to: an employee; an independent contractor or consultant; a student; a visiting or emeritus member of staff; or a member of staff on a joint clinical or honorary contract.

**Research & Knowledge Exchange Committee (RKEC):** is a sub-committee of Academic Board with specific monitoring responsibilities and oversight of both research and knowledge exchange, in relation to the strategic plan, Key Performance Indicators (KPI) and strategic objectives.

**University Research Integrity and Ethics Committee (URIEC):** has oversight of Research Integrity and ethical standards across the University to ensure research and research related activity is conducted to the highest standards.

## Appendix One

### Studies typically not requiring ethical review

- Chemistry / Pharmacy / Physics (not using human participants or human tissue)
- Collaborator on project with other (HEI/NHS) ethics
- Computing / Mathematical / Modelling / Equation-based (not using human participants)
- Creative practice (not involving interactions with human participants)
- Engineering or mechanical-based (not using human participants)
- Exhibition / Performance / Curation (no contact with audience)
- Library / Desk based research
- NCFM Food Microbiology
- NCFM Product development not involving human sensory evaluation
- NCFM Research using commercially available food products
- Programming (not using human participants)
- Review of data held publicly (if collecting data from social media any ethics application is required)
- Review of published literature
- Robotics (not using human participants)
- Systematic review