



UNIVERSITY OF  
LINCOLN

## ACADEMIC POLICY FRONT COVER SHEET

<b>Name of Policy:</b>	Research Ethics Policy
<b>Scope of Policy:</b>	The intended purpose of the policy is to support good conduct in research, in order to encourage research of the highest quality.
<b>Author:</b>	The Code is owned by the Deputy Vice Chancellor (Research and Innovation) and was drafted by the Research Governance Manager
<b>Applicable to:</b>	Staff and Students
<b>Consultation Process:</b>	University Research Ethics Committee Research Committee
<b>Approval Body:</b>	Academic Board
<b>Date of Approval:</b>	20 June 2018
<b>Date of Implementation</b> (if different from date of approval):	10 September 2018
<b>Review Date:</b>	June 2021
<b>Version:</b>	University of Lincoln Version 2.0 25 May 2018
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## Research Ethics Policy

Version 2.0

Date: 25 May 2018

The University of Lincoln's **Research Ethics Policy** is intended to support good conduct in research, 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.

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

## 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 in order 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

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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.

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](#))

## 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, a Home Office Licence must be held and research conducted elsewhere.

## 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 very 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 the 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.

#### **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 Research ethics committees**

The University Research Ethics Committee (UREC), which reports to Academic Board (AB) through the Research Committee (RC), has overall responsibility for the University's ethical review process and 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.

UREC 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.

In all cases, research (see definition), whether conducted by staff or students\* of the University, must receive acknowledgement of a Project Registration Form or 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.

\*For undergraduate/postgraduate taught students, ethics approval must be obtained in line with College/School procedures.

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

- Research requiring registration only (no formal review required);

- 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 full review but has a short lead time and is commissioned in response to a demand of pressing importance).

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. Collaborating UoL University of Lincoln researchers will not be required to submit a full ethics application to a UoL research ethics committee, but will be required to complete a project registration form.

### **8.2 External requests that have not been subject to 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 prior to any research commencing, in line with this policy and E-QMS.

### **8.3 External request with favourable ethics opinion from another institution/research ethics committee**

If research is conducted by a member of staff or student of another Higher Education Institution (HEI) within the United Kingdom and has been approved by the appropriate research ethics process within that institution, or if the research has been approved by the HRA (see 8.5), then the Chair/Deputy Chair of the relevant research ethics committee may grant approval on the basis that any ethical issues have already been given sufficient consideration.

However, if the Chair/Deputy Chair wishes, they may seek further clarification and/or require a submission for ethical approval in accordance with section 7.

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 8.3 above.

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

Where research requires a favourable opinion from an outside body, for example, from the **Health Research Authority (HRA)**, 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. 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, UREC 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 UREC.

### 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):** Academic Board 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):** The HRA protects and promotes the interests of patients and the public in health and social care research.

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

**University Research Ethics Committee (UREC):** The University Research Ethics Committee (UREC) is established to have oversight of the principles and practices of ethical research conduct across the University and of the University Human and Non-Human Research Ethics Committees.