The University of Leeds

Research Ethics Policy

1.0 Introduction

This policy sets out the principles underpinning ethical research conduct at the University of Leeds and the process for reviewing research proposals that require ethical approval. It will be reviewed and updated annually by the University Research Ethics Committee (UREC), subject to approval of any substantive changes by the Council.

Research at the University of Leeds is conducted according to the principles of academic excellence, community, integrity, inclusiveness and professionalism. All research must be conducted according to appropriate ethical, legal and professional frameworks, obligations and standards.

In addition, the following research must be subject to review through the appropriate research ethics committee[1] and formally approved before it is undertaken:

- research involving living human participants
- research involving the personal data of a living human participant or different pieces of information, which collected together can lead to the identification of a particular person,
- research involving human tissue[2];
- research with the potential for adverse environmental impact; *and*
- research involving animals

Research that may raise other significant ethical issues or pose a reputational risk to researchers or the institution should also be referred for advice and/ or review to the relevant University research ethics committee.

The purpose of ethical review is not to discourage controversial or high-risk research. An ethical approach to research should not imply an impediment to the pursuit of knowledge, rather, the clear recognition of, and preparation for, any risks inherent in that pursuit.

2.0 Applicability

This policy applies to **all staff and students** of the University who contribute to research involving the University (including those with visiting or honorary contracts and students on placements), whether or not their current place of work or study is within University premises. Third parties (for example staff of other institutions working with Leeds students) are expected to adhere to the University's ethical standards of research conduct and associated policies.

All **members of the University are individually responsible** for ensuring that their work is conducted in accordance with the University values and with all policies that form part of the terms and conditions of employment and study. Failure to comply with this policy may lead to the failure of assessed work; the suspension of study, research projects, and/or funding from research sponsors; or to the inability to publish. Work conducted in deliberate contravention of the decisions of an ethical review committee, or with deliberate disregard for the ethical review process, could be considered under the misconduct policy

Broadly defined, research includes all investigation undertaken in order to acquire knowledge and understanding. This would include:

- work of educational value undertaken to improve the understanding of the research process;
- scholarship such as contributions to research databases, catalogues and dictionaries;
- the generation of designs, concepts, artefacts and performances that lead to new intellectual understanding;

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[1] The appropriate body might be internal or external: paragraph 4 of this policy sets out further information about the appropriate review bodies.

[2] This is regulated by the Human Tissue Act and applies to tissue taken from living individuals and, in some circumstances, deceased individuals, as set out in Part 2, Section 14 of the HTA.

- the reuse of existing data for purposes other than those for which it was originally intended.
- the experimental use of existing knowledge to develop new materials and processes.

This definition of research would **not** normally include:

- audit and evaluation, such as the routine evaluation of teaching;
- the development of teaching materials that do not involve original research;
- purely documentary research on sources that are already in the public domain such as historical, literary, and theoretical research[3].
- routine testing and analysis of materials and processes.

3.0 Ethical standards

All research must be conducted to high ethical standards. Guidance upon the identification and management of ethical issues is attached in Annex II. Key principles include appropriate protection and respect for participants (research subjects *and* researchers); clear lines of accountability for the ethical conduct of research; and an appropriate balance between the value of the research and the rights of the individuals.

3.1 Participants' rights

The dignity of all research participants must be respected. In particular, there is an expectation that participants will have rights to:

- an appropriate and proportionate opportunity to give or refuse informed consent to participate or to withdraw from research projects without inducement or adverse consequence[4];
- appropriate confidentiality;
- security, including where possible and appropriate anonymisation and storage of their data or samples;
- safety, and safeguards appropriate to the risks posed by participation in research;
- a clear framework for raising queries, concerns or complaints.
- where relevant, the University Policy on safeguarding children, young persons and adults in vulnerable circumstances

3.2 Researchers' obligations

Individual researchers and research student supervisors are responsible for ensuring that their projects, or their students' projects, are designed and conducted ethically and are appropriately reviewed (see Annex I). More broadly, researchers have an obligation to ensure that research is conducted:

- in accordance with the University's standards of research integrity and good conduct
- in compliance with the law;
- in accordance with the relevant funders' and professional bodies' requirements;
- having obtained informed consent wherever appropriate; and
- in such a manner that the risks to participants or researchers are proportionate and managed.

Any proposal raising ethical issues as categorised in this policy and the associated guidance **must** be referred for review, and appropriate ethical approval **must** be obtained before the research involving the ethical issues is conducted. If approval is sought from another appropriate body, clear evidence of that approval **must** be obtained and retained by the researcher.

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[3] This would be particularly applicable to documentary sources that are not covered by the terms of the Data Protection Act (primarily those concerning deceased individuals or already in the public domain) and to activities such as the compilation of bibliographic material and other research that does not have a substantive interpretative element.

[4] There might be circumstances under which it is not practical to gain fully informed consent in advance, or in which capacity to consent is limited. Further information about consent is set out in paragraph 7 of the guidance appended to this policy as Annex II.

4.0 Locus of responsibility for ethical review

Research involving animals is carried out in line with Home Office requirements and guidance and is reviewed separately by the University's Animal Welfare and Ethical Review Body. Further information can be obtained by contacting the University's Home Office Liaison Officer at h.o.admin@leeds.ac.uk.

The University's framework of ethical review has been designed to complement that provided by the NHS Health Research Authority, in the case of research involving genetically modified organisms the DEFRA and Ministry of Defence Research Ethics Committee (MODREC). Research reviewed through these frameworks will not require internal review but **evidence of NHS HRA Research Ethics Approval, DEFRA review or MODREC approval must be provided.**

Certain NHS Research Ethics Committees (RECs) are flagged for research involving prisons and/or prisoners. If the research project is with Prisons or Probation Trusts an application to Her Majesty's Prison and Probation Service (HMPPS) will also be required. The HMPPS application process covers all research projects requiring access to data, staff or offenders

Research reviewed by the DEFRA includes projects involving the potential release of genetically modified organisms into the environment.

Most work funded by the Ministry of Defence or including military participants (but not veterans) must be reviewed by the MODREC.

The University will normally accept **evidence of approval by another institution** in lieu of internal review, provided it is demonstrated that comparable standards have been applied, including registered institutional review boards in the United States of America. Care should be taken with international research – legislative and cultural imperatives vary widely. Research outside the UK will often require review within the University of Leeds, as well as being compliant with relevant legal and ethical requirements in the host country. Compliance with ethical and legal requirements is the responsibility of the principal investigator.

Other research falling into the definitions set out in paragraph 1, or raising other significant ethical issues, **must** be reviewed through the University's internal framework for ethical review.

4.1 Submission of proposals to External Ethic Committees

It is University policy that only one formal ethics review should take place, subject to the guidance in section 3.

It is recommended that any application to an external ethics committee should have approval within the University before submission to the ethics committee, this can be arranged through the Secretariat Administrative team.

5.0 Further information

The appendices to this policy set out the following information: roles and responsibilities and policy notes, including key definitions; and links to further guidance and other University policies (including those related to good research conduct).

The Secretariat
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Annex I: Roles and Responsibilities

Individual researchers, whether staff or students, ultimately have responsibility for ensuring that they consider ethical issues and obtain any appropriate ethical approval. There are, however, specific *ex officio* responsibilities for elements of the review process, as set out below.

1. The Council

has overall responsibility for the framework of regulation of ethical issues arising from research. The Council will consult other University bodies and officers as appropriate.

2. The University Research Ethics Committee

has responsibility for the oversight of ethical issues arising from research; the formulation of policy in this area; and the consideration of significant or complex issues arising from particular research. The UREC is accountable to the Council.

3. The Faculty Research Ethics Committees

have responsibility, delegated from the UREC, for the operational review of ethical issues arising from research proposals; auditing and monitoring compliance; and disseminating best practice. The FRECs are directly accountable to the UREC.

4. Deans of Faculties

have responsibility for ensuring that appropriate arrangements for the review and management of ethical issues are in place within their faculty.

5. Pro-Deans and Heads of Schools

have responsibility for the operational arrangements to ensure that staff and students are able to participate in training and the ethical review process.

6. Student Supervisors and Module Leaders

have responsibility for ensuring that students are aware of the requirements for review and approval (for example as part of a research degree programme), and that students are aware of training opportunities. Module leaders must also ensure that risk assessments of projects involving fieldwork take account of any potential impact on the environment.

7. The Research Ethics Training and Development Consultative Group

has responsibility, delegated from the UREC, for ensuring that training needs within the University community are identified and can be met.

8. Organisational Development and Professional Learning and the Inter-Disciplinary Ethics Applied Centre

have responsibility for the design and delivery of research ethics training across the University, working closely with the Research Ethics Training and Development Consultative Group, the UREC, FRECs and staff and student representatives.

9. The Secretariat Ethics Administration Team

has responsibility for the administration of research ethics policy and review, including providing secretariat services to the UREC, FRECs and providing formal and informal guidance to researchers.

10. The Secretariat

has responsibility for providing formal and informal advice upon University policy and legal issues.

Annex II: Policy notes

These notes should be read in conjunction with the University's policy on research ethics. They anticipate some of the key ethical issues which may arise from research, particularly that involving human subjects, tissue or data or the risk of an adverse impact upon the physical environment. Practice on the use of the terms 'subject' and 'participant' varies. Herein, the term 'subject-participant' is employed (in order to preserve the distinction between subject- and researcher-participant) on each first occasion of use, then 'subject' thereafter.

1.0 Introduction

Researchers will need to consider a wide range of issues, many of which will be specific to the discipline or situation in question. They will also need to ensure that they abide by University policy in areas such as health and safety, intellectual property, research data management, research integrity, data protection and whistleblowing.

The first step is always for the individual researcher or supervisor to consider carefully the potential ethical implications of their work, or that of their students, and members of the University are encouraged to reflect carefully upon the broad range of conceptual, as well as practical, issues that may arise. Individuals then have a responsibility to seek the appropriate advice, available on the Research and Innovation Services website - and/ or formal review and approval of the proposed work.

Projects involving human participants or their data or the risk of significant environmental impact will require review – whether by the University or an external body (such as the Health Research Authority).

Whilst not an exhaustive list, the following points provide, in no particular order of priority, an indication of ethical issues which may require consideration:

- the balance of risk and benefit;
- the physical and psychological health and safety of subject-participants;
- obtaining informed consent to participate;
- particular arrangements for participants who may be considered vulnerable
- conflicts of interest;
- confidentiality and data protection;
- intellectual property issues;
- funding sources;
- monitoring and audit;
- proportionate and reasonable review.

For the avoidance of doubt, all relevant research proposals must be subject to appropriate review. The University already obtains consent, however, for routine data processing, including sensitive and personal data, from staff and students (see the Code of Practice on Data Protection. In addition, under the terms of the Data Protection Act and the University Code of Practice on Data Protection, the University can process data without consent 'where this is for the legitimate activities of the institution and is not to the detriment of individuals.' Therefore, as set out in paragraph 4 of the policy document, routine data collection and analysis does not require review under this policy.

2.0 Research design

In the case of original research, the project design should ensure that the project is necessary for the advancement of knowledge; that it will not duplicate work that has already been undertaken; and that it will address the question which has been posed. In the case of research conducted as part of a taught course, as an educational exercise, the project may duplicate work that has already been undertaken but must be based upon sound pedagogic principles.

3.0 The Conduct of Research

Research must be conducted with integrity. This means that in addition to the satisfactory resolution of issues surrounding consent, confidentiality and data protection, the principles of honesty and openness should be observed in both the conduct of the research and the publication of the results. Researchers, and research student supervisors, must be competent to undertake the research – for example, must have received adequate training in the methodology, techniques and equipment involved.

The University's policy statement on research integrity and good conduct is available at http://ris.leeds.ac.uk/ResearchIntegrityPolicies.

4.0 Risks and Benefits

The expectation is that the likely benefits of research, including the advancement of knowledge, will outweigh the risks involved to subject-participants. Any risks, physical, psychological, financial or of any other type, must be clearly identified; must be manageable; and must be clearly explained to subjects before consent to participate is sought.

Researchers will also need to consider the potential for reputational risk, to both individuals and institutions. Advice can be sought, in confidence, from the Secretariat Administrative Team, the appropriate Faculty Research Ethics Committee, or the University Research Ethics Committee.

4.1 Proportionate review

The likelihood and severity of the risks posed by particular projects will, of course, vary, and will be reflected in the process of review and approval.

4.1.1 Higher risk

Projects which present higher risks or more serious or complex ethical issues will require full review by a School or Faculty Research Ethics Committee or, in certain cases, by the University Research Ethics Committee.

4.1.2 Lower risk

Projects which present lower risks may be reviewed through an expedited procedure proportionate to the nature of the issues arising.

5.0 Projects reviewed through other procedures

As set out in the policy (link), certain categories of projects will be reviewed through other procedures, either internal or external, which will not require duplication through the ethical review framework. Further information is set out below.

5.1 Research involving animals

The University of Leeds has a separate procedure for the review of research proposals involving animal experimentation, which is regulated by the Home Office

(http://www.leeds.ac.uk/info/5000/about/136/values_and_responsibility).

5.2 Externally regulated research and data collection

Certain research will be subject to external regulation which the University will accept in lieu of internal review. This is currently limited to:

- research involving NHS patients, personal data or tissue (which must be reviewed by the appropriate NHS Research Ethics Committee);

- research involving adults lacking the capacity to consent (which must be reviewed by the appropriate NHS Research Ethics Committee);
- research involving the release of genetically modified organisms into the environment (which must be reviewed by DEFRA and is subject to Health and Safety oversight);
- research classified as a Clinical Trial under the Medicine for Human Use Act (2004) and research involving human tissue, as defined by the Human Tissue Act (2004) and associated Regulations (2006) [5];
- research that has been reviewed and approved by another UK Higher Education Institution or an accredited Institutional review board within the United States(provided that evidence of sufficiently robust review is confirmed by the appropriate FREC.
- Work funded by the Ministry of Defence or including military participants (but not veterans) must be reviewed by the MODREC
- If the research project is with Prisons or Probation Trusts an application to Her Majesty's Prison and Probation Service (HMPPS) will be required. The HMPPS application process covers all research projects requiring access to data, staff or offenders

The NHS does not require review by an NHS Research Ethics Committee for activities that they consider to be service evaluation, clinical audit, surveillance, usual practice in public health or where NHS staff are the only participants. Such studies *may*, however, require Health Research Authority approval and University research ethics review.

6.0 Treatment of subject-participants

All reasonable measures must be taken to protect the health, safety and psychological wellbeing of researchers and all subjects. In particular, the location and environment of the study and any equipment or procedures will be subject to review under national Health and Safety legislation and University Health and Safety regulations.

Should an adverse incident occur during the course of research, this must be reported to the appropriate person. In most cases, this will be the researcher's line manager. In the case of a critical incident, researchers should be aware of their responsibility to notify the University Secretary (or, out of hours, the Security Office) at the first opportunity. More information about critical incidents is available at: https://secretariat.leeds.ac.uk/critical-incidents.

6.1 Vulnerable subjects

The following should be considered when potential participants may be considered vulnerable.

The process of recruitment

When obtaining informed consent the researchers should consider is the participant both willing and able to understand what is being asked of them, weigh up for themselves the costs and benefits, and make a choice to take part free of actual or perceived coercion or pressure from the recruiter? Is what is being asked of them the absolute limit of burden to answer the research question and justified in pursuit of new knowledge?

In addition researchers should consider mental capacity- is an impairment or disturbance to the mind or brain of a sufficient level that means the person is unable to make a particular decision? Some people may lack capacity to make complex decisions whilst having capacity to make more straightforward decisions. Often there is a risk that a person deemed vulnerable is simply assumed to not have capacity at all, when this is often far from the case.

Researchers should be mindful of Human Rights and adhere to the following principles:

- a person must be assumed to have capacity unless established otherwise
- individuals should be helped to make their own decisions as far as practicable

[5] Both Clinical Trials and human tissue studies should be referred to the Secretariat's Research Regulatory Compliance Team for advice.

- a person is not to be treated as unable to make a decision merely because they make an unwise decision
- all decisions and actions must be in the best interests of the person lacking capacity
- all decisions and actions must be the least restrictive of the person's rights and freedom of action.

People are also vulnerable due to other reasons, such as their risk of being coerced into taking part due to a power differential in the recruiter or by the nature of some of their current or past experiences of coercion or abuse. They also may be experiencing significant life events that mean that the research they are being asked to do is likely to cause stress and distress or be overly burdensome in relation to their current circumstances.

Our current application reminds applicants to consider vulnerability and uses terms such as "child" "learning disability" and "psychiatric patient"

There is a risk that using somewhat stigmatising labels as blanket definitions of vulnerability that assumptions (which are often inaccurate) about who has capacity and who might be vulnerable are applied to an entire group rather than considering the unique set of circumstances under which each research project is conducted

UREC supports a shift to defining "vulnerable" participants in terms of the "what" not the "who".

For instance, people with serious mental illness could be perceived as "vulnerable" and lack capacity but also this needs to be balanced with their rights to be informed about studies that they may be eligible to take part in and it also gives a voice to an under- served group. There is a significant service user driven movement to include people in research for this very reason – this has been really successful for increasing research involvement for people who have cancer and for people with dementia.

Children are often perceived as unable to give consent but it depends on the research study and for low risk studies such as asking children about healthy food choices they may not require parental consent.

Alternatively, there is a real risk if there is a list of "vulnerable" participants, that people not on that list might not have the specific vulnerabilities considered: such as someone who is experiencing or has experienced abuse (this is often not known to the researcher). People who have just experienced an unexpected event (such as a road traffic accident).

Things that researchers should factor in:

- Has the researcher consulted with the key stakeholders including those with lived experience about their protocol and procedures?
- Is the person undertaking the research suitably experienced and supported to undertake the specific research?
- Quality of information given both written and verbal- including the risks of taking part and the support that's offered if required (Samaritans phone number is not really good enough in most cases)
- Who makes the initial approach and the power differential between the recruiter and potential participant?
- How much time is given between information and seeking consent?
- Does Mental Capacity need to be formally assessed and monitored?
- Can the participant speak to a third party to discuss whether to participate or not?
- Is there a robust but balances risk protocol that mitigates for some of the risks identified?
- Are the tasks required as a participant perceived as appropriate given their specific needs and are things such as flexibility of data collection, timings, comfort, access etc considered?

7.0 Informed consent

The expectation is that researchers will obtain, and record, the informed consent of participants. In order to achieve this, participants must be given clear information about the study's aims, the risks and benefits, and the nature of their involvement. Participants must be given sufficient time to reflect upon any information

that they are given, and researchers must be satisfied that this information has been understood. A subject's right to withdraw at any time, without giving a reason, must also be clearly explained and understood. In no circumstances should coercion, disproportionate payment or inducement, or the expectation of any other inappropriate advantage be used to influence consent.

There may be circumstances under which it would not be practicable to obtain participants' fully informed consent in advance – examples might include projects involving the use of covert observation or projects which depend upon the subject being unaware, at least initially, of the subject under investigation. Under such circumstances, researchers should consider carefully the justification for the methodology employed and be prepared to set out their reasoning. In any case, where it is practicable to do so, it is good practice to obtain subjects' consent to the use of their data (if necessary, retrospectively).

When using observational methodologies, researchers should be aware of whether members of the public who are not direct participants might also be observed, and whether their data might be recorded as a consequence of their interaction with a subject. Consideration should be given to whether such interaction takes place within a public or private sphere, and how data collection can be minimised and/or anonymised.

In the case of groups considered to be vulnerable, it may be necessary to obtain proxy consent from, for example, a parent or other competent adult. Such subjects will, or course, retain the right to refuse participation and to withdraw at any time.

7.1 Complaints

A clear procedure should be in place for resolving complaints from participants, set out in the information given to them before seeking their consent. Appropriate contacts would include the Principal Investigator, research supervisor or research group director. The University's Research Ethics Complaints Procedure is available at https://secretariat.leeds.ac.uk/research-ethics/university-protocols-and-policies.

8.0 Data protection

Confidentiality of subject-participants' data must be assured, including through adequate anonymisation or pseudonymisation. The storage and use of data must comply with the Data Protection Act 2018, the General Data Protection Regulation and the Human Rights Act and the University's Code of Practice on Data Protection (https://dataprotection.leeds.ac.uk/data-protectionand-personal-data).

The Data Protection Act contains eight basic principles, which state that personal data must:

- be obtained and processed fairly and lawfully and shall not be processed unless specified conditions are met;
- be obtained for a specified and lawful purpose and shall not be processed in any manner incompatible with that purpose;
- be adequate, relevant and not excessive for those purposes;
- be accurate and kept up to date;
- not be kept for longer than is necessary for that purpose;
- be processed in accordance with the data subject's rights;
- be kept safe from unauthorised access, accidental loss or destruction;
- not be transferred to a country outside the European Economic Area, unless that country has equivalent levels of protection for personal data.

The lawful basis for processing the data needs to be documented, (usually task in the public interest) and a Data Protection Impact Assessment will need to be undertaken: https://dataprotection.leeds.ac.uk

9.0 Confidentiality and disclosure

During the course of research it is possible that researchers may uncover information relating to illegal activity; to intent to engage in illegal activity; or information about topics that are sensitive or that may carry particular obligations to consider disclosure to the appropriate authorities (such as potential harm to children or vulnerable adults). The law in this area is complex and it is likely that the question of whether to

breach confidentiality in such cases, and to whom to disclose any information, would be best decided upon a case by case basis.

Advice upon individual cases is available from the University Secretary. However, there are a number of general principles which might apply in such cases:

researchers should consider whether they can seek the subject's consent to breach confidentiality;

- there may be a legal obligation to breach confidentiality, for example if a court orders disclosure;
- under any circumstances, disclosure should be restricted to those who need to know the information concerned, and should be relevant and not excessive.

10.0 Ownership of research

The ownership of research should be clearly documented, and there should be clear lines of responsibility for the conduct of the research. This includes, amongst other things, issues of intellectual property; health and safety; and the training and competence of researchers.

11.0 Monitoring of research

Research should be monitored to ensure compliance with the principles of good practice. Records should be kept for inspection by the appropriate FREC and/or the UREC, as required.

12.0 Research conducted externally

If staff or students participate in collaborative studies, it is essential that these are conducted to a standard compatible with the University's requirements. This includes studies undertaken at, or conducted in partnership with, overseas institutions – although it is recognised that careful consideration will be required of local circumstances and of any limitations these might place upon the research protocol, such as difficulties with obtaining written consent. Researchers will be expected to demonstrate that the best possible practice has been adhered to under the circumstances pertaining.

13.0 Conclusion

The advice set out above constitutes general guidance upon the type of ethical issues that researchers might encounter, and the expectations of the University and other research stakeholders about how such issues should be managed. It is not intended to be exhaustive, and further advice is available from the Secretariat Ethics Administrative team, the Secretariat, and from the FRECs and the UREC.