



## Research Ethics Policy

Leeds Trinity University expects all research carried out at the University, or in its name, to be undertaken to the highest standards of integrity and ethical conduct. This policy sets out the principles underlying ethical research at the University and should be read in conjunction with the relevant ordinances and regulations, and other policies, procedures or guidance issued by the University. It will be reviewed annually by the Research and Knowledge Exchange Committee.

### 1. Principles and application

Research at the University should be conducted in full compliance with the UK Research Integrity Office code of practice for research (<http://www.ukrio.org/publications/code-of-practice-for-research/1-0-introduction/>), in that it should be in accordance with the principles of academic excellence, community, integrity, inclusiveness and professionalism. It must be conducted with respect for participants, and in full compliance with legislative, regulatory body and funder requirements.

All researchers must complete the university's research ethics self-assessment form and submit this to the Chair of their School or Institute's Research Ethics Committee before commencing any programme of research. For the avoidance of doubt, research is defined as *"a process of investigation leading to new insights, effectively shared. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction"* (Research Excellence Framework (2011) *Assessment framework and guidance on Submissions*).

If completion of the self-assessment form indicates that full ethical review is required, then an ethics application must be submitted to a School or Institute Research Ethics Committee.

No research project (or stage of a research project) may be conducted unless, and until, the project (or that stage) has been granted ethical approval by a Leeds Trinity (School/Institute or University) Research Ethics committee or other appropriate external body (see below) or the completion of the University's research ethics self-assessment document directs that ethical approval is not required.

In addition, the following research must be reviewed by the appropriate School or Institute Research Ethics committee:

- a. Research involving human participants, their personal data, tissues or body fluids.
- b. Research that has the potential to have an adverse environmental impact
- c. Research that poses a reputation risk to the University or its researchers

Routine audit or evaluation of University business (e.g. evaluation of teaching) is excluded from this policy unless this is to be published externally, constitutes scholarship, increases knowledge and understanding of education and educational processes or is to be utilised in the creation of impact for any University activity.

This policy applies to everybody carrying out research under the auspices of the University, whether on its premises or elsewhere. This includes, but not limited to, all staff (including honorary and visiting staff) and all registered students (whether undergraduate or postgraduate). It is the responsibility of the principal investigator, research supervisor (postgraduate research) or project supervisor (undergraduates) to ensure that all researchers (including external collaborators) are aware of and fully comply with this policy. Heads of Schools or Institutes have a responsibility to ensure compliance with this policy within their School or Institute.

This policy is linked to and operates in conjunction with conditions of employment for the relevant Staff groups and other related University policies and procedures including, but not limited to, those for academic and research misconduct, the code of practice for research degree candidates and the taught student academic and professional misconduct policy and procedure. Failure to abide by this policy may lead to the matter being considered under the University's disciplinary procedures.

## **2. Ethical review by other Bodies**

Research undertaken by Leeds Trinity researchers at other Institutions or Organisations within the UK should comply with this policy and also follow the guidelines of appropriate professional bodies. However, to avoid duplication, the University will accept ethical approval by that Institution or Organisation provided the appropriate School or Institute Research Ethics Committee is informed (supported by evidence).

Where required by law (e.g. Human Tissue Act) or where the research involves the NHS (e.g., but not limited to, patients, their data, records, tissue or body fluids), confirmation should be sought from the relevant NHS body as to whether or not the research needs to be reviewed by an National Research Ethics Service (NRES) Research Ethics Committee.

Research undertaken outside of the UK must be approved by a Leeds Trinity Research Ethics Committee as well as being compliant with the legal and ethical requirements of the host country.

The University is not licenced to undertake studies using research animals regulated by Animal (Scientific Procedures) Act 1986. Any such studies should be undertaken at Institutions which hold the appropriate licences and be reviewed by that Institutions Animal Welfare and Ethical Review Body. The relevant School or Institute Research Ethics Committee should be notified that such studies are being undertaken and be provided with details of the requisite personal and project licences.

## **3. University Research Ethics Sub-committee**

The remit of this committee is to:

- Oversee the development and execution of policy and procedures relating to research ethics and conduct.
- Consider approval of the ethical dimensions of research proposals from staff and postgraduate research students which exceed the remit of School or Institute Ethics Committees.

- Consider appeals against School or Institute Ethics Committees' decisions on research proposals from staff and postgraduate research students.
- Log the outcomes, and monitor the progress of, cases across the University, in accordance with institutional policy.
- Provide a forum for convenors of School or Institute Ethics Committees to facilitate consistency of practice.
- Conduct an annual audit of the work of School or Institute Ethics Committees.
- Provide the Research and Knowledge Exchange Committee with regular summary reports on its activities and recommendations for changes to policies and procedures.
- Make an annual report to the Research and Knowledge Exchange Committee.

#### **4. School or Institute Research Ethics Committees**

Each School or Institute (or grouping of Schools/Institutes) is required to establish a Research Ethics Committee. It is the responsibility of the Head of School/Institute to ensure that their School or Institute has a properly constituted ethics committee.

School or Institute research ethics committees will have responsibility for:

- Providing ethical review of all appropriate student and staff research proposals in their School or Institute. In the case of undergraduate student projects or project modules, this may be via block approval of groups of projects.
- Establishing procedures to ensure that research conducted by staff or students complies with this policy.
- Maintaining records of ethical permissions for research conducted by staff or students which has approved by other ethical review bodies or organisations.
- Collation and retention of completed research ethics self-assessment documents.
- Disseminating good practice.
- Auditing a minimum of 10% of approved projects per annum.
- Providing an annual report (in June) to the University Research Ethics Sub-committee on its research ethics activities, outcomes and any issues of concern and a report every three years providing information about the main ethical issues addressed by their committee, their procedures and how these have operated.
- Retaining all documentation relating to the business of the committee including all research ethics applications for a period of 10 years (to be held by School/Institute REC Chair).

The committee should have formal terms of reference. Membership should comprise of a Chair and at least 4 other members including one member from outside of the School or Institute. School or Institute should ensure that any applicants for project approval by the ethics committee, and in the case of students, their supervisors, should not take part in decisions on their applications. If a member of the Committee is not able to attend the meeting, he or she may submit written observations on any issue under consideration. Where agreement cannot be reached, decisions are by a majority and, in the case of equal votes, the Chair shall have the casting vote.

In considering proposals, the committee may:

- Approve new proposals or authorise significant deviations from any approved proposals
- Reject a research proposal, in whole or part
- Revoke approval of research if dissatisfied with the conduct of the research
- Refer matters to the University Research Ethics Sub-committee as appropriate

- Seek advice from the University Research Ethics Sub-committee or its Chair before coming to a decision
- Refer students or staff under the University's research misconduct or disciplinary procedures

The committee should give reasons for its decisions. It may also call for reports on the conduct of research during the project and on completion.

In exceptional circumstances when, for good reason, issues need rapid consideration or it is a minor amendment to an approved proposal, the Chair may act after consultation with no fewer than two members of the Committee. The Committee shall be informed promptly of decisions made on this basis.

Research that raises significant or complex ethical issues or poses significant reputation risk to the University should be referred to the University Research Ethics Sub-committee. Where proposals are referred to this committee for advice, it will require a written statement of the issues, supported by relevant documentation and a summary of the reasons for doubt or disagreement. The University Research Ethics Sub-committee may also hear appeals against School or Institute Research Ethics Committee decisions but only after School/Institute level processes and remedies have been exhausted. The Committee will not hear appeals against the decisions of external ethics committees, which should provide their own appeals procedures.

## **5. Complaints**

Investigations of allegations of misconduct or unethical conduct on the part of staff or students will follow the University protocol for investigating and resolving allegations of misconduct in academic research and student academic and professional misconduct policy and procedures respectively.

Leeds Trinity University Research Ethics Committee  
December 2015

## Research Ethics Policy Notes

The following document should be read in conjunction with the University's Research Ethics policy

### Introduction:

Before beginning a programme of research, researchers need to consider the potential ethical issues that may arise, which may be either be specific to the discipline or situation in question, conceptual as well as practical. They also need to ensure that they abide by related university policies including, but not limited to Health and Safety, data protection and research integrity.

The following checklist, in no particular order of priority, highlights some of the areas for consideration, particularly for research involving human subjects, tissue or data, where there is risk to Society, animals or the environment, or where the research may pose reputational risk to the University or its researchers. It should be read alongside guidance provided by relevant professional bodies or learned societies.

For undergraduate final year projects, particularly those where block permission for groups of projects or a final year project module is sought, additional School or Institute specific guidance will be made available by School or Institute Research Ethics Committees

### Regulations and guidance:

- Adherence to the University research ethics policy and other related policies
- Ethical review by other external bodies where dictated by statute
- Adherence to the University policies on academic conduct and research integrity
- Adherence to statutory requirements
- Adherence to discipline-specific codes and guidance or those of other outside bodies

### Research involving human participants:

- Fully informed, voluntary consent with the unconditional right of withdrawal of participation and/or of data
- Financial incentives or participants expenses
- Support for and protection of individuals (including consideration of gender or cultural needs)
- Additional protections for minors or vulnerable adults
- Physical and psychological health and safety of participants
- Management and reporting of adverse events
- Appropriate policy and practice concerning confidentiality, anonymity or acknowledgement of research participants
- Anonymity and security of research data
- Retention, future use or disposal of data and samples in line with consent
- Clear complaints procedure
- Procedure for disclosure of information to legal or other authorities (e.g. illegal activity, potential harm to minors or vulnerable adults etc.)

### Other considerations:

- Research design
- Ownership of research
- Risk versus benefit
- Risk to people, society, environment or animals

- Reputational risk to individuals (including the researchers), the University or other organisations
- Intellectual property issues
- Publication of research results/dissemination of results
- Funding sources, financial and confidentiality agreements with funders or sponsors
- Conflicts of interest
- Monitoring and audit
- Support and training for junior researchers and other staff