

LEEDS BECKETT UNIVERSITY

RESEARCH ETHICS POLICY

2017/18

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A1 INTRODUCTION

A1.1 Overview and Summary

The provisions are divided into three main parts:

Section A1: Introduction

This section describes the history of and the purpose of ethical approval within the University and emphasizes the centrality of 'ethics' to all our research processes, for staff and students. The approval process safeguards the status of the University, by ensuring the proper treatment of human participants and researchers at all levels.

Section A2: Policy and Principles

This section details the policy requirements, intentions and influences. It sets out the requirements for compliance by all researchers and emphasises the protection from victimisation for anyone who raises concerns about any aspect of non-compliance. Importantly, it lists the principled concerns that guide the involvement of human participants in research projects.

Section A3: Ethical Principles Defined

This section defines key terms in use. It indicates in detail the intended applications for the policy and explains all the options, including appeals, monitoring, development, representation and provisions for raising concerns.

A1.2 Origins of Research Ethics Committees

Consideration of ethical issues has long been a feature of medical research. The often cited Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, issued in 1964, is the policy-statement of the World Medical Association. It has been amended many times since its issue, most recently in 2013.

Although the Declaration was written for physicians, many of the underpinning principles have general application, for example; regard for human dignity; care for human and animal welfare, consideration of risk, and informed consent of human subjects in research projects. Since then many Professional, Statutory and Regulatory and other bodies, for example, Research Councils, have adopted either Codes of Practice or Guidelines for research ethics.

A1.3 Rationale for Ethical Approval within the University

As the importance of ethical scrutiny of research projects has grown, the value of having similar bodies in other institutions was recognised, and now all UK universities have ethical approval systems. In Leeds Beckett University, Research Ethics Committees at University and Faculty level were established in 2002, with the Faculty Research Ethics Committees being replaced by School review groups in 2016 following changes to the University's academic structures.

The purpose of ethical approval within the University is positive and threefold:

- It reflects the University's commitment to good ethical practice, as a principle in itself and as a means of maintaining public confidence in the work of staff and students of the University.
- The provisions for ethical approval assist researchers, supervisors and students doing research to identify appropriate issues and to address these in the structuring of research proposals. Appropriate ethical development in the University across subject boundaries is a necessary concomitant of this continuing good practice.
- The approval process itself acts as a safeguard to researchers, supervisors and students who can be confident of the ethical propriety of their project once it has been approved. The University's Insurance and Indemnity Policy requires that all research projects receive ethical approval prior to any data collection being carried out (this does not preclude the need for certain projects to be referred individually for confirmation of cover).

A1.4 Alignment with University Strategic Plan

This Policy is fully aligned with the University's Strategic Planning Framework 2016-21.. In particular, research ethics is underpinned by the key themes of 'An Excellent Education and Experience' and 'Leading Research and Academic Enterprise'. The Policy contributes to the promotion and maintenance of scholarly ethics throughout the curriculum; and in particular to setting standards for an ethical culture of respect and dignity throughout the research process, conducted both within the University and through research projects in which staff and students engage with the wider community.

A1.5 Alignment with UK legislation and Sector Guidance

This Policy has been benchmarked against and is aligned with:

- The Concordat to support research integrity:
<http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/the-concordat-to-support-research-integrity.pdf>
- The UK Research Integrity Office (UKRIO) – Code of Practice for Research:
<http://ukrio.org/publications/code-of-practice-for-research/>
- Research Councils UK (RCUK) Policy & Guidance on Governance of Good Research Conduct: <http://www.rcuk.ac.uk/Publications/researchers/grc/>

All research taking place under the auspices of the University must also adhere to the 'Prevent Duty' guidance for Higher Education Institutions (England and Wales) and the procedures for students and staff working on sensitive or extremism-related research as set out in the University's Research Ethics Procedures.

A1.6 Implementation / Application of this Policy

This revised Research Ethics Policy document, effective from 1st August 2017, replaces all previous versions.

A2 RESEARCH ETHICS POLICY AND PRINCIPLES

A2.1 Research Ethics Policy

The University recognises the importance of maintaining public confidence in the ethical quality of approved research conducted by staff and students of the University.

The University requires that all research carried out at all levels within the University is conducted according to high ethical standards.

The University requires that all research undertaken by staff or students complies with the legal requirements of the UK, and/or the country of location of the research project.

All research requires either ethical approval or an assessment to be undertaken to confirm that ethical approval is not required. Researchers and supervisors overseeing the research projects of students have a responsibility to consider whether their student's research needs ethical approval or whether their student's research will involve matters excluded from the approval process.

The University has research ethics approval procedures in operation at supervisor, local¹, School and University level; and all research projects with human participants conducted by staff or students of the University require approval at the relevant level.

A2.2 Statutory, Professional, Regulatory or Other Body Requirements

The University recognises that statutory, professional, regulatory or other bodies may have requirements which also need to be met before a research proposal may be approved.

A2.3 Information to Staff and Students

The University will ensure that staff and students are fully informed of the relevant research ethics requirements of the University.

The University recognises the importance of ongoing staff and student development in the field of research ethics, and will promote and facilitate this at University, School and local level.

The University recognises the importance of independent (including lay) contributions to decisions on ethical approval and ethical policy at School and University level. The University Research Ethics Committee has external membership in its Constitution.

The University undertakes to conduct appropriate monitoring of approved research projects to ensure compliance with the project as approved, and/or to ensure revised approval for developing projects.

¹ Local level refers to approval by Local Research Ethics Co-ordinators, which may be at course or subject group level in a School.

The University undertakes to protect from any subsequent victimisation or reprisal any member of University staff or any student who has honest and reasonable suspicion that serious breaches of research ethics approval have taken place; even if the suspicion is subsequently found to be mistaken or unfounded.

A2.4 Research Ethics Principles

The main principles are:

- 1 Research should be designed, reviewed and undertaken to ensure integrity, value and quality.
- 2 The results of research should benefit society either directly or by generally improving human knowledge and understanding.
- 3 Researchers must ensure their proposed research projects follow the ethical guidelines of an appropriate learned society recognised by their School. Schools will be responsible for identifying appropriate learned societies with ethical guidelines and the University Research Ethics Sub-Committee will review and approve societies on School lists.
- 4 Research projects with human participants should aim to avoid or minimise harm in general to groups and individuals. Risk assessment appropriate to each research project will be undertaken.
- 5 Participants should be fully informed about the purpose, methods, and intended possible use of the research. Where there are exceptions to this, the purpose and rationale of such research projects will be fully considered, as appropriate, before approval is given.
- 6 Research participants must participate in a voluntary way, free from coercion.
- 7 The interests of research participants should be considered at all stages of the research projects. In particular the following should be observed, where appropriate to the project and in line with learned society practice:
 - Participants should be no worse off as a result of their participation in the project;
 - Provisions for withdrawal from the project should be in place;
 - The interests of children, vulnerable adults and other vulnerable groups should be given specific consideration;
 - Participants should not be subjected to undue intrusion, distress, indignity, physical discomfort, personal embarrassment or other harm.
- 8 The confidentiality of information supplied by participants must be respected, except where the requirements of professional and learned society practice determine. Any limits to confidentiality must be explained to participants.

- 9 Issues of anonymity and anonymisation of results should be fully considered, and where personal disclosure or identification is likely, this must be discussed with the participants and their specific consent to this obtained.
- 10 Researchers should ensure that the research methodology is appropriate. Research designs should be such as to maximise a project's utility and relevance for the benefit of society.
- 11 Research outcomes should be disseminated in a manner which makes them accessible.
- 12 The independence of the research outcomes must be ensured. External sources of funding and any potential conflict of interest must be declared during the approval process.
- 13 The research culture will be characterised by respect for all groups in society, in line with the University's Equality Policy and national legislation on Equality, Diversity and Human Rights.
- 14 The health and safety of both researcher and participants/subjects will be carefully considered in the design and execution of research projects.

A3 ETHICAL PRINCIPLES DEFINED

A3.1 Definitions

These definitions and applicability apply to all research projects within the University and are adapted from the Ethics Policy and Principles of King's College London (www.kcl.ac.uk/innovation/research/support/ethics/about/index.aspx).

Research is a form of disciplined enquiry which aims to contribute to a body of knowledge or theory. This does not normally extend to general coursework assignments, but does apply to final year undergraduate dissertations or projects.

Research ethics are the moral principles guiding the planning and conduct of research, the publication of outcomes, and post-project care and/or disposal of records or materials.

Research with human participants should be taken in its broadest possible sense and includes questionnaires, observations and the use of materials derived from human participants as well as invasive or intrusive procedures. If the study meets the definition of research and does not involve human participants, but raises any ethical issues with potential social or environmental implications, ethical approval may be needed.

The re-use of already collected data may require ethical approval due to its sensitive nature or if individuals can be identified from it.

A3.2 Requirement for Ethical Approval

Any research project undertaken by staff or students of the University which involves human participants must receive ethical approval before it takes place. This may be given at supervisor, local, School or University level, depending on the nature of the research proposal. It is the responsibility of the researcher to seek guidance on research ethics from their supervisor or the Local Research Ethics Co-ordinator.

It is expected that simple, low-risk research projects not involving participants or their data will be approved by research supervisors and all other projects will be approved at local, School or University level.

Detailed guidance on ethical approval is found in the Research Ethics Procedures document.

A3.3 Ethical issues related to the Conduct of a Research Project

While it is important that ethical considerations are taken into account at the inception of a research project, it is also important that ethical considerations inform it throughout, up to and including the publication/dissemination of the research project.

All research must comply with the Data Protection Act. All funded, contractual or collaborative research must comply with the specified requirements for data storage. All researchers (and for student research projects, the research supervisor) must take full responsibility for ensuring appropriate storage and security for all study information, including research data and consent forms. Students and staff must keep appropriately secure data records for the life of research projects. For taught course students the life of a project includes completion of all forms of assessment, including re-submission. Any researcher that wishes to retain data beyond the life of a research project (e.g. for future research use) must gain ethical approval, with the appropriate consents, to do this and must store the data in a form that complies with the Data Protection Act.

It is the researcher's responsibility to abide by the terms of the ethical approval given. If the need for further ethical approval becomes apparent as the project develops, it is the responsibility of the researcher to apply for that further approval.

The School may monitor the progress of the research project to ensure compliance with the terms of approval.

Failure to comply with the terms of ethical approval for a research project, or failure to seek further approval if required, may lead to action for staff under the University's Policy & Procedures for Investigating Allegations of Misconduct in Research or for students under the University's Academic regulations relating to Academic Integrity. .

A3.4 Ethical issues relating to Dissemination of Results

Researchers also need to ensure that dissemination and/or publication follows good ethical practice. Researchers should seek advice locally and follow appropriate learned society guidelines.

Researchers have a responsibility to take account of all relevant evidence and present it without omission, misrepresentation or deception. Data and information must not knowingly be fabricated or manipulated in a way which might lead to distortion.

Work of other scholars or colleagues must be acknowledged. Professional standards need to be observed in: attribution of authorship; acknowledgement of sources; correctness of references.

Fair attribution of authorship in a collaborative research project should be observed, with seniority of position not creating an automatic right to co-authorship. Honorary authorship is unacceptable. The order of authors should recognise their respective contributions to the work.

A3.5 Appeals

If at any stage the application for ethical approval is likely to be rejected, this will normally be referred back to the applicant with the deficiencies of the application identified, and giving the applicant the opportunity of a further submission.

Where an application for ethical approval is not approved at supervisor or local level, the researcher has the opportunity to appeal to the relevant School research ethics review group or School Academic Committee. The applicant and person(s) responsible for considering the application have the right to attend the meeting and speak to the issue..

Where an application for ethical approval is not approved by the School research ethics review group, the researcher has the opportunity to appeal to the University Research Ethics Sub-Committee. The applicant and a representative of the School have the right to attend the meeting and speak to the issue. The decision of the University Research Ethics Sub-Committee is final and the matter is concluded at this point.

The decisions of the University Research Ethics Sub-Committee on matters referred to it are final and there is no appeal mechanism.

A3.6 University level approval

The School should forward to the University Research Ethics Sub-Committee any proposals on which it cannot agree the ethical propriety of the proposed research; or which pose complex institution-wide ethical issues.

A3.7 Composition and responsibilities of the Research Ethics Sub-Committee

A3.7.1 Responsibilities

The composition and responsibilities of the University Research Ethics Sub-Committee are set out in detail in the Terms of Reference and Constitution.

It is responsible to the Research & Enterprise Committee for overseeing the development and implementation of the University's Policy & Procedures relating to research ethics. And specifically to:

- oversee and monitor the implementation of, and compliance with, the University's Policy & Procedures for Research Ethics;
- advise the Research & Enterprise Committee on the development of institutional policies and guidelines relating to ethical issues in research arising from teaching, research and other related institutional activities;
- monitor the external research ethics environment and ensure that the University responds to all external requirements;
- advise the Research & Enterprise Committee of the training & development needs of University Staff in relation to research ethics;

A3.7.2 School research ethics review groups

These groups are normally led by the School Research Ethics Co-ordinator and include all subject Local Research Ethics Co-ordinators in the School. The groups have delegated authority from the University Research Ethics Sub-committee to make decisions on projects where the Local Research Ethics Co-ordinator cannot make a decision, but the project does not require a full University review. The operationalisation of these groups is driven by requirements of the School for research ethics and is not prescribed.

A3.8 Non-Compliance / Provisions for Raising Concerns

A3.8.1 Non-Compliance

The University expects that all research carried out in its name complies with the requirements and expectations of this policy and associated procedures. Where a research study or researcher is suspected to be in breach of this Policy and / or associated procedures, the University may take action at a local level to resolve this. Where the circumstances invoke other policies of the University these may also be applied. This may include the following University regulations, policies and procedures:

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- *Academic Integrity Code of Practice*
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- *Policy & Procedures for Investigating Allegations of Misconduct in Research*
- *Fitness to Practise Policy*
- Staff or student disciplinary procedures

A3.8.2 Raising Concerns

In the interests of openness, good practice and the reputation of the University, members of staff and students of the University, and members of the public, are entitled to raise concerns about the correct ethical practices in research, and particularly in relation to compliance with research ethics.

A3.8.3 Good Faith

It is expected that all concerns will be raised in good faith. Where this is the case, the person raising the concern(s) will be protected from reprisal or victimisation even if the concern is shown to be unfounded.

Where a complaint or concern raised is vexatious or malicious, the member of staff or student complaining may face disciplinary proceedings.