

LEEDS BECKETT UNIVERSITY

RESEARCH ETHICS POLICY

August 2014

Approved July 2012

www.leedsbeckett.ac.uk



Contents

A1	INTRODUCTION	1
A1.1	Overview and Summary	1
A1.2	Origins of Research Ethics Committees.....	1
A1.3	Rationale for Ethical Approval within the University	1
A1.4	Alignment with University Strategic Plan.....	2
A1.5	Implementation / Application of this Policy	2
A2	RESEARCH ETHICS POLICY AND PRINCIPLES	3
A2.1	Research Ethics Policy.....	3
A2.2	Statutory, Professional, Regulatory or Other Body Requirements	3
A2.3	Information to Staff and Students	3
A2.4	Research Ethics Principles.....	4
A3	ETHICAL PRINCIPLES DEFINED.....	6
A3.1	Definitions.....	6
A3.2	Requirement for Ethical Approval	6
A3.3	Ethical issues related to the Conduct of a Research Project	6
A3.4	Ethical issues relating to Dissemination of Results.....	7
A3.5	Appeals	7
A3.6	University level approval	8
A3.7	Composition and responsibilities of Research Ethics Committees in the University.....	8
A3.7.1	Responsibilities	8
A3.7.2	Members of Research Ethics Committees	8
A3.8	Non-Compliance / Provisions for Raising Concerns.....	9
A3.8.1	Non-Compliance	9
A3.8.2	Raising Concerns	9
A3.8.3	Good Faith.....	9

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 nine 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 Statutory, Professional 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.

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 Vision, Values and Themes set out in the *Quality, Relevance and Sustainability*, the University's Strategic Plan for 2010-2015. In particular, research ethics underpins most of the work under Strategic Theme 3 (Research and Enterprise) and is central to Themes 1 (Learning and Teaching), 2 (Employability and Skills) and 4 (Development and Diversity). 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 Implementation / Application of this Policy

This revised Research Ethics Policy document, effective from 1st August 2012, 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, faculty 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, faculty and local level.

The University recognises the importance of independent (including lay) contributions to decisions on ethical approval and ethical policy at faculty and university level. Faculty and University Research Ethics Committees have external membership in their Constitutions.

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, group or school level in a faculty.

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 Faculty. Faculties will be responsible for identifying appropriate learned societies with ethical guidelines and the University Research Ethics Sub-Committee will review and approve societies on Faculty lists.
- 4 Research projects with human participants should aim to avoid or minimise social harm 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, faculty 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 will be expected that simple, low-risk research projects that comply with appropriate learned society ethical guidelines will be approved by supervisors (for undergraduate and master's level research projects) and Local Research Ethics Co-ordinators (for MPhil/PhD and staff research projects).

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 Faculty 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 under the provisions relating to the Code of Good Practice and Regulations relating to Misconduct in Academic Research.

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 Faculty Research Ethics Committee. The applicant and person(s) responsible for considering the application have the right to attend

the meeting and speak to the issue. The decision of the Faculty Research Ethics Committee is final and the matter is concluded at this point.

Where an application for ethical approval is not approved by the Faculty Research Ethics Committee, the researcher has the opportunity to appeal to the University Research Ethics Sub-Committee. The applicant and a representative of the Faculty 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.

The decisions of all parties relating to undergraduate or taught postgraduate research projects is final with no right of appeal at any stage.

A3.6 University level approval

The Faculty 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 Research Ethics Committees in the University

A3.7.1 Responsibilities

The composition and responsibilities of Research Ethics Committees at both Faculty and University level will be set out in detail in their Terms of Reference and Constitution.

The chief responsibilities of these committees for research ethics are:

- policy development
- development and communication of good practice
- debate and developmental work relating to research ethics issues
- determination of specific ethical issues
- developmental opportunities for Local Research Ethics Co-ordinators and members of Research Ethics Committees, including lay and/or external members;
- approval of research proposals
- oversight of research ethics approval processes
- Audit of compliance with this policy and associated procedures across the faculty/ university

A3.7.2 Members of Research Ethics Committees

Responsibility for developmental work with members of Research Ethics Committees and Local Research Ethics Co-ordinators, together with research ethics training, is a shared responsibility at university and faculty level.

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:

- *Plagiarism, Cheating and Other Forms of Unfair Practice*
- *Policy, Regulations and Procedures relating to Professional Suitability or Professional Misconduct*
- *Code of Good Practice and Regulations relating to Misconduct in Academic Research*
- 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.