Research Ethics and Research Governance at Lancaster: Procedures

1. Introduction

A code of practice for ethical research at Lancaster, including measures relating to research malpractice, was approved by Senate in May 2006 and implemented in August 2006. The code of practice and procedures are now revised in light of developments since their implementation and recent publications.

The original code of practice was developed by drawing on good practice from a range of institutions, and papers and guidelines produced by The Association of Research Ethics Committees. Lancaster’s code of practice is compatible with the ESRC Research Ethics Framework published in 2005 which makes it clear that breaches of good ethical practice could result in the suspension of the project concerned and other ESRC-funded projects at the same university, or even potentially a halt to the consideration of further applications from that institution. Recent publications by UKRIO (Procedure for the Investigation of Misconduct in Research) and Research Councils UK (Code of Conduct) have been taken into account in the updated Lancaster code of practice and procedures.

This paper offers a structure and set of processes that should enable Lancaster to ensure good ethical research practice.

2. Lancaster’s committee structure relevant to ethical research

The Senate has the ultimate responsibility for the conduct of research at Lancaster, which it exercises through the Research Committee and its sub-committee, the University Research Ethics Committee (see Appendices 1 and 2).
The University Research Ethics Committee (UREC) terms of reference are laid out in Appendix 2, including:

(a) the committee has a standing item at every meeting whereby any of its members can draw attention to a research ethics issue that is potentially troubling or contentious for the institution;

(b) the committee takes on an overview role involving the receipt of reports from faculty committees as an important component;

(c) it assesses selected projects and their progress.

The faculty ethics committees, or the faculty research committee where there is no ethics committee, in turn agree procedures to manage the research ethics within their faculty, in the context of the code of practice and these procedures and report to the University Research Ethics Committee. These committees should make a direct input into the University Research Ethics Committee about issues of policy or practice that require institutional guidance. The faculty research committees in turn receive reports and recommendations from departmental/faculty ethics committees where they exist. Neither faculty nor the departmental committees, however, make institutional research ethics policy.

It is also intended that the projects of students registered for research degrees should be treated for the purpose of ethical review in the same way as staff research (see section 4.3). This includes the requirement, with the research supervisor in the lead, to ensure that student research for projects and dissertations are undertaken in accordance with the university’s code of practice.

The university’s departments and equivalent units have responsibility for the delivery of the learning, teaching and assessment of the degree schemes so designated. Thus, departments should assume responsibility for all activity in undergraduate and taught postgraduate courses that require ethical review. Departments are likely to develop a range of practices appropriate to the academic level involved, and these should be clearly articulated and reported to UREC through faculty committees.

3. **Ethical research training**

Some ethics training exists as part of academic provision, and externally funded courses have been delivered and attended by Lancaster staff. The University will provide training for postgraduate students and early career researchers, and all staff will have the option to attend this training.
4. **Ethical review**

4.1 **General**

In setting out a process for ethical review, the university confirms that the primary responsibility for the ethical conduct of research resides with the individual researcher and particularly with the principal investigator or research supervisor. However, the individual researcher is in turn working within the context of a university framework that should be supportive and effective, and with colleagues who share the responsibility, including the head of department or equivalent, the Research Support Office, the faculty’s dean (and associate dean for research) and the faculty committee structure, and ultimately the Pro-Vice-Chancellor for Research.

A balance has to be struck between making appropriate provision to manage the university’s risk, while not burdening the research with unreasonable delays or overly officious bureaucracy, and the procedures set out in this document seek to attain that balance.

4.2 **Ethical review: externally funded research grant proposals**

All externally funded research grant proposals should be costed and approved through pFACT (Project Financial Appraisal and Costing Tool) before submission. An ethics questionnaire is completed within pFACT as part of this process.

A [stage 1 self-assessment form](#) is also completed, providing a signed commitment from the principal applicant that they will conform to the code of practice and identifying whether there are any potential areas of ethical concern. Where the research involves human participants or other potential areas of ethical concern are identified, the project must either be reviewed by an appropriate ethics committee (University Research Ethics Committee or a recognised external committee) or the principal investigator must provide additional information to explain why they consider the project to have low ethical risk. The preferred procedure is that the principal investigator should discuss the project with colleagues who are likely to be involved with the research and, if contentious issues are already identified, with the head of department. Where such additional discussions have taken place, e.g. with the head of department, the discussions should be recorded and the record held by all the parties involved.

The stage 1 self-assessment form is counter-signed by the Head of Department and the original submitted to the Research Support Office. If the Head of Department has any concerns regarding the proposed research they should seek further advice from the faculty’s dean. Where the research involves human participants or other potential risk factors have been identified, signed stage 1 self-assessment forms submitted to the Research Support Office will be subject to review by members of the University Research Ethics Committee.
At any stage in the approval process, any of the postholders mentioned above may consult the Pro-Vice-Chancellor for Research, who will *inter alia* consider whether the project in question should be referred to the University Research Ethics Committee.

Where areas of ethical concern are identified requiring further review, a [stage 2 ethical review form](#) must be completed unless the project is being reviewed by a recognised external committee. If a stage 2 form is required the principal applicant should liaise with the appropriate Research Support Officer to arrange for the proposal to be reviewed by the University Research Ethics Committee.

Where a project is classified as requiring further review, but will be considered by an external ethics committee, details will be reported to the University Research Ethics Committee. In these cases the University Research Ethics Committee is also willing to review the project in an advisory capacity, at the principal investigator’s request, before it is submitted to the external committee.

Projects will usually be reviewed at scheduled meetings of the University Research Ethics Committee, and the principal investigator will be invited to attend the meeting to address any questions raised by the committee. Where a project needs to be reviewed with particular urgency, if possible, a sub-group of the University Research Ethics Committee will be used to consider the application. Review by the University Research Ethics Committee will include the following considerations:

- the balance between the benefits of the project and the strength of the objections to it, including the nature of the project i.e. the project itself or its wider context, including the funding source;
- the level of risk to the reputation of the university, including both in the conduct of the research and the impact of its dissemination;
- the potential to modify the research, by (a) protecting or enhancing its benefits; or (b) reducing or eliminating the objections to it; or (c) managing the potential hazards arising from it;
- observance of the tenets of academic freedom;

leading to one of the following outcomes:

- the project can proceed as planned;
- the project can proceed with minor modifications;
- the project can proceed on agreed conditions that are documented and signed off by the relevant parties;
- the project is referred for further discussion or investigation, or if appropriate to informal or formal arbitration;
- approval for the project is refused.
4.3 Ethical review: research not requiring external funding

Much of the discussion about managing the ethics of research centres around the procurement of external funding. In all such cases the options set out above can ensure that ethical issues are appropriately dealt with. However, colleagues may be working on an individual project that does not need external funding for the research to proceed, or be collaborating with external persons or bodies in a relationship that does not involve the funding of the research at Lancaster over and above the proportion of contractual time already allowed.

In such cases, the individual scholar or researcher is de jure also a principal investigator and should follow the precepts of the university’s code of practice on ethical research and research ethics, including access to advice and support (see above). In addition, mentoring or appraisal processes, as well as applications for or reports on the use of sabbatical leave, should be extended by heads of department and other appropriate officers, in consultation with the researcher, in order that any ethical implications of the research in question can be considered.

Academic staff will be asked to confirm annually that they have read the code of practice recently, and that all their research adheres to the code of practice.

4.4 Ethical review: student projects

As stated in section 2, the projects of students registered for research degrees should be treated for the purpose of ethical review in the same way as staff research, therefore the process described in section 4.2 will apply. It is expected that research students will complete the ethics questionnaire (available from the Research Support Office or http://www.lancs.ac.uk/depts/research/lancaster/ethics.htm) and stage 1 self-assessment form in conjunction with their research supervisor. Whilst preliminary review of student research projects may take place at department or faculty committees, this does not replace the need to complete the questionnaire and stage 1 self-assessment form, and any project that is identified as having significant ethical risk must be referred to the University Research Ethics Committee for review.

Taught student projects are reviewed according to department/faculty procedures (see section 2). Depending upon the nature of the work to be undertaken, there may be specific research ethics issues that need to be considered (for example if the project involves human subjects in any way). It may be necessary to complete a research ethics form and the student should consult their dissertation/research supervisor for details of the required process.
5. **Sponsorship under Research Governance Framework for Health and Social Care**

Requests for Lancaster to act as sponsor under the Research Governance Framework for Health and Social Care will be considered by the Chair of the University Research Ethics Committee or reviewed at University Research Ethics Committee meetings (depending on the timescales involved). Where the research project does not require approval by an external ethics committee the request for sponsorship will always be considered by the University Research Ethics Committee or a sub-group of the University Research Ethics Committee (not the Chair alone). Applicants should consult the Research Support Office at the earliest opportunity to avoid delays to their research programme. Once the University has agreed to act as sponsor, a letter will be provided detailing the responsibilities of the applicant and the conditions under which the University agrees to act as sponsor.

6. **Human Tissue Act**

6.1 **General**

The University does not hold a licence under the Human Tissue Act. This means that any research at Lancaster involving human tissue must be approved by a recognised Research Ethics Committee (only NHS committees are currently recognised under the Act) and tissue cannot be stored for future projects.

6.2 **Generic Ethical approval for Tissue Banks**

As of 30 October 2006, licensed tissue banks were able to apply for generic ethical approval for research using tissue that they supply. This means that straightforward projects can be carried out using tissue supplied by an ethically approved tissue bank without the need for ethical approval from an NHS REC for the individual project. Before providing samples these tissue banks will expect to see approval from the University Research Ethics Committee.

6.3 **Sample storage**

Samples must be returned to the tissue bank or destroyed once the project has been completed. However, samples may be retained at the end of the project if it is necessary for scientific audit purposes, but they should be stored solely for that purpose (if the University subsequently applied for ethical approval for a project using the same samples it would be seen as an attempt to circumvent the Act).
7. **Appeals and complaints relating to these procedures and decisions of UREC**

Appeals, for example against decisions of the University Research Ethics Committee, or complaints about the operation of the above procedures, should be made in the first instance to the Research Support Manager. (Whistleblowing procedures under Statutes 22 and Ordinance 8 are however treated separately.)

The Research Support Manager will seek clarification about the nature of the appeal or complaint and will refer it either to the chairperson of the University Research Ethics Committee or, if that is inappropriate, to the University Secretary. The person receiving the appeal or complaint will set up procedures for the matter to be investigated and, as appropriate, reconsidered.

8. **Misconduct in research**

8.1 **Institutional context**

The university is committed to ethical behaviour by all its members, both in relation to other members of the university, to other scholars, and to external parties including international research groups and research journals. If an individual researcher fails to meet the obligations set out in the university’s code of practice, or an allegation of misconduct is made, the procedure outlined below will be followed.

8.2 **Whistleblowing**

A separate procedure is in place to cover whistleblowing, in particular, there are safeguards for employees of the university who make disclosures or complaints (Statute 22 and Ordinance 8 available from the Research Support Office or [http://www.lancs.ac.uk/depts/research/lancaster/ethics.htm](http://www.lancs.ac.uk/depts/research/lancaster/ethics.htm)).

8.3 **Procedure**

The procedure will follow the principles of the UK Research Integrity Office *Procedure for the Investigation of Misconduct in Research* (Appendix 3). Complaints and disclosures will be dealt with as quickly and efficiently as possible (without detriment to the process).

8.3.1 **Initial contact**

Any person, whether a member of the university, a representative of a relevant external party, or other third party who has reasonable grounds for believing misconduct has taken place, who wishes to make a disclosure or complaint in relation to an alleged or suspected offence as defined in the university’s code of practice, shall in the first instance be referred to the Pro-Vice-Chancellor (Research), or, in the absence of the Pro-Vice-Chancellor (Research), the University Secretary.
The Pro-Vice-Chancellor (Research), shall review the nature of the allegations and where they concern situations that require immediate action to prevent further risk of harm to staff, participants or other persons, suffering to animals or negative environmental consequences, take immediate appropriate action to ensure any such potential or actual danger/illegal activity/risk is prevented or eliminated (making it clear that these actions do not indicate that the allegation is considered to be true). In the light of informal and confidential soundings as he or she deems fitting, including with the member(s) of staff concerned, the Pro-Vice-Chancellor (Research) shall decide, in discussion with the Director of Human Resources and the Research Support Manager if appropriate:

(a) to dismiss the disclosure or complaint, recording in writing the reasons for doing so (for example the allegations are mistaken, frivolous, vexatious or malicious); or
(b) that the situation is not serious in nature and may be resolved by informal discussion, education and training, and/or arbitration and/or dispute resolution without the requirement for a formal investigation; or
(c) to refer the disclosure or complaint to an investigatory panel (see 8.3.2 below); or
(d) to ask the Vice-Chancellor, in the light of the seriousness of the disclosure or complaint, to initiate the procedures under serious disciplinary matters (Statute 20, Part III, 14ff).

8.3.2 Investigatory panel

If the Pro-Vice-Chancellor (Research) decides to set up an investigatory panel, he or she shall invite three members of the University Research Ethics Committee, who are not involved with the person or his/her/their work about whom the complaint or disclosure has been made, to constitute such a panel. The panel members shall between them decide who is to take the chair of the panel. The proceedings of the panel shall be strictly confidential, a written report of them shall be made, and the business shall be conducted as expeditiously as possible.

The panel shall invite the person concerned to attend in person, and shall inform him of her in advance about the substance of the disclosure or complaint. Written statements shall be presented to the panel, who shall have the right to invite relevant persons to attend and give evidence if appropriate.

The person about whom the complaint or disclosure has been made may be accompanied by a friend, whether such person be legally qualified or not, and may submit a written statement in advance of the hearing. He/she shall be given a full and fair hearing, and has a right to call witnesses and question them.
Once the hearing has been concluded, whether at a single session or at one or more hearings, the panel shall consider all the evidence presented to it and may:

(a) dismiss the complaint or disclosure, giving reasons in writing for so doing;
(b) advise the head of department in writing, with a copy to the Director of Human Resources, that it has established a prima facie case that warrants initiation of the disciplinary procedures.

The head of department, in considering (ii), shall have access to the written report by the panel.

If a relevant external body or individual has made the initial complaint or disclosure, the representative of such a body or that person shall be notified in writing of the outcome on a strictly confidential basis i.e. the information may not in turn be transmitted to other parties.

8.3.3 Disciplinary procedures

The disciplinary procedures referred to in 8.3.2 (ii) shall be those set out in Statute 20, Parts III and V that apply to those members of the university referred to in Statute 20 (3).

Any matters concerning non-academic members of staff shall be dealt with, after investigation as set out above, under the disciplinary procedures approved by the Council for non-academic staff.

8.3.4 Changes to Disciplinary procedures

Any changes made to the procedures under 8.3.3 that postdate the approval of the present document shall be substituted for the procedures set out above.

Bibliography

ESRC, *Research Ethics Framework* (undated)


Appendix 1:
Remit of University Research Ethics Committee

UNIVERSITY RESEARCH ETHICS COMMITTEE
(a sub-committee of the Research Committee)

Terms of reference

To consider all ethical issues arising in relation to the conduct of research in the university, and/or by members of the university, including:

(i) research on people or animals, referred to it by researchers or officers, and to make recommendations;
(ii) guidelines about the use of and access to information of a personal or confidential nature gained as a result of research activity and to monitor their implementation;
(iii) issues of privacy, confidentiality and ethical behaviour between researchers and human participants, and to make recommendations;
(iv) guidance compiled by regional, national and international bodies (e.g. European Parliament Committee on Research; the hospital trusts in the North West); and the university’s guidance to researchers in the context of this body of external information;
(v) where necessary, the suitability of funding sources, and to offer guidance;
(vi) the implications of research which inadvertently provides information about illegal activities or where the contractor offering the research wishes to impose unreasonable constraints, that are manifestly unworkable or ethically objectionable, and to offer guidance;
(vii) issues related to the ethical responsibilities of the university’s researchers, both staff and students, including regulatory and non-regulatory aspects likely to arise from their research, and to draw up guidelines and disseminate them;
(viii) to assess projects requiring review;
(ix) to receive reports on work in progress where appropriate;
(x) to receive reports from faculties where appropriate.
Appendix 2:
Membership of the University Research Ethics Committee

Pro-Vice-Chancellor for Research
University Secretary
Director of the Graduate School
Associate Dean for Research, Arts and Social Sciences
Associate Dean for Research, Management School
Associate Dean for Research, School of Health and Medicine
Associate Dean for Research, Science and Technology
Two additional members from the Faculty of Science and Technology
Two additional members from the Faculty of Arts and Social Sciences
Two additional members from the School of Health and Medicine
Two additional members from the Management School
Director of the Centre for Bioethics and Medical Law
Four lay members including at least one person directly connected with the NHS
Student member
Appendix 3:
UKRIO, *Procedure for the Investigation of Misconduct in Research: Principles*

The full document can be downloaded from: