

General Guidance on Procedures for Research Ethics Approval

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1. RESEARCH ETHICS POLICY AND RESOURCES

1.1 This guidance should be read in conjunction with:

- The University's Research Ethics Code of Practice
- Specific guidance issued by the Faculty Research Ethics Committees (FREC) to which an application for an ethics review has been made.

1.2 The Code of Practice and associated procedures, guidance and training materials can be found on the University's research ethics webpages which is open to all staff:

<https://www.lancaster.ac.uk/research/research-services/research-integrity-ethics-and-governance/research-ethics/>

2. RESPONSIBILITIES FOR ETHICAL APPROVAL, REVIEW AND MONITORING

2.1 The University's Research Ethics and Integrity Committee (UREIC) is responsible for formulating and implementing research ethics strategy across the University and for assuring the ethics standards of the University's research projects and awards.

2.2 Research ethics reviews and approvals of specific research activities are conducted by the FRECs which are sub-committees of UREIC. The appropriate FREC guidance should be used by applicants.

2.3 To accommodate specialised or controlled areas of research and to avoid unnecessary multiple reviews, the University will refer to or recognise the process and decisions of other ethics review bodies as appropriate. The FRECs will always, for example, refer projects engaging NHS patients to the appropriate NHS mechanism; others will be assessed on a case-by-case basis and a recommendation given to UREIC which will formally approve this. A register is kept of recognised bodies. Where a review is made by a recognised body, a copy of the application and decision letter (with any conditions) must be presented to the FREC for monitoring purposes. If you have obtained Sponsorship from Lancaster University this will be presented on your behalf.

2.4 Ethics review and approval is separate and distinct from the approval of the research activity itself.

3. OVERVIEW OF THE PROCEDURES FOR CONSIDERING THE ETHICAL DIMENSIONS OF A RESEARCH PROJECT

3.1 All researchers engaging in research associated with the University should consider the ethical dimensions of their work as part and parcel of good research practice and project design. It is the responsibility of researchers to be familiar with, and conform to, the University's Research Ethics Code of Practice.

3.2 Ethics approval must be obtained before any research activities commence which have an ethics dimension. This will be in the form of a letter which will specify one of the following:

- i) approved as submitted (with guidance on the baseline for the decision as appropriate)
- ii) approved subject to requested revisions or specified conditions
- iii) rejected based on the principles of the Research Ethics Code of Practice

3.3 It is good practice to incorporate ethics into the research design and so should be a consideration at this stage.

- 3.4 The ethical dimensions of a research project may change during the course of a project. It is important for researchers to monitor developments for ethical implications and to seek approval, or approval of changes when changes affect ethical dimensions significantly. Examples include changes that affect the need to seek approval or that affect the nature of participation or the category of risk.
- 3.5 All researchers are expected to abide by the decision of the FRECs. Research projects may be monitored and may be called in for review at any time by the FREC or the appropriate University body. Research projects cannot continue if the FREC withdraws or suspends ethics approval.
- 3.6 If the research involves any of the following elements, then it is likely to have an ethics dimension for which approval must be obtained:
- i) Involvement of human participants - actively or passively
 - ii) The use of human tissue
 - iii) Potential adverse impacts on the environment
 - iv) Health and safety risks, including to the researcher(s)
 - v) Potential reputational risk to the University

There are special arrangements for research involving animals. These should be referred to University's Animal Welfare and Ethical Review Body.

- 3.7 Where there is an ethics dimension and it does not fall under the scope of the University's Animal Welfare and Ethical Review Body, an application for research ethics approval must be made to the appropriate FREC using the designated forms. Where none of the above elements apply, this should be positively confirmed. For funded research, the University's ACP system incorporates a governance checklist for this purpose. Unfunded or internally funded research is covered by the FRECs' ethical review application forms. PhD and MRes student research are also covered by the FRECs' ethics review application forms.
- 3.8 Where a referral to another research ethics approval body is intended, researchers should check whether the UREIC has already recognised this body and it is included on the register of recognised bodies (see 2.3) and seek prior advice if it has not. Other bodies will be screened by the Chair of the FREC and recognised in principle or not; where it has been recognised, it will be logged in a format that is fully accessible to Chairs of FRECs and the Chair and Deputy Chair of UREIC. The FREC may impose additional requirements to accommodate any University-specific issues, including internal referral on, for example, risk to reputation and fit with the University's values.
- 3.9 The forms require the researcher to supply information about the project which is set out in such a way that the FRECs can review the project in relation to the guiding principles set out in the University's Research Ethics Code of Practice.
- 3.10 In many cases, research ethics approval is sought because the proposal involves human participants, in these cases additional material must be submitted with the ethics approval form, usually participant information material and participant consent forms.
- 3.11 FRECs may establish mechanisms for expedited review. This is a 'fast track' route to ethics review and approval while maintaining the Committee's usual standards of care and consideration which may be necessary and appropriate in some circumstances. However, it is the responsibility of the researcher to seek ethical approval early enough to allow time for review through the normal channels and therefore fast track approval should only be required in exceptional circumstances which may include:
- minimal risk;
 - a requirement to co-ordinate data collection with other researchers or existing activities.

- 3.12 FRECs will make available a calendar of meeting dates with deadlines for submitting paperwork where appropriate.

4. APPEALS AGAINST DECISIONS MADE BY FRECs

- 4.1 FRECs will have a formal appeal mechanism. It is encouraged and expected that all informal avenues will be exhausted through the Chair or Deputy Chair of the FREC concerned, or the Chair of UREIC if those people are conflicted. If all are conflicted, the appeal should be addressed to the Head of Governance Services.
- 4.2 Appeals will be made in writing, with relevant supporting evidence. The person receiving the appeal or complaint will set up procedures for the matter to be investigated and, as appropriate, reconsidered. Appeals will be included in FRECs' reports to UREIC.

5. ADVERSE EVENTS AND NEAR MISSES IN RESEARCH ACTIVITY

- 5.1 An adverse event in this context is an unexpected event in the course of research activity that results in research participants being caused physical or psychological harm, unintentional release of information, breach of regulations or law, harm to the environment or any other event which may damage the reputation of the University. Participants are classified as members of the public irrespective of their employment status or enrolment for study at the University. Adverse events may occur for any number of reasons beyond the control of researchers, as well as through errors or mistakes made in the course of the research activity.
- 5.2 A 'near miss' is an unexpected event which did not result in an adverse event, but had the potential to do so, i.e. a fortunate break in the chain of events prevented it.
- 5.3 All adverse events in research activity or near misses are to be reported to the Head of Department and a copy sent to the secretary of the FREC which approved the project. Adverse events should be reported as soon as possible and no later than the timescales stipulated in 5.7. Unless a funder or external regulatory body has mandated a specific format or process, in which case this is normally set out in the research protocol or the regulatory boards SOPs and policies, the University's dedicated form will be used for this. In some circumstances a research project may need to be suspended or discontinued (see table, below). The Chair of the FREC which approved the project will make an assessment of the event and actions undertaken or proposed, and, drawing on advice and support from appropriate academic colleagues and professional services, may direct further action be taken. This report to UREIC is in addition to any other report which is required (e.g. according to Departmental or University safety, health and wellbeing policies).
- 5.4 Where an investigation is deemed to be warranted, the Chair of the relevant FREC will consult with the Chair of UREIC to determine the nature and composition of the investigatory team. The Chair of the FREC or UREIC may seek legal advice and may need to liaise with colleagues in Professional Services in case there are legal or financial consequences. Copies of investigation reports will always be sent to Heads of Department, UREIC and, where applicable, the relevant committee.
- 5.5 All activities at the University are subject to the requirements of the Health and Safety at Work Act 1974 and associated regulations. The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 apply to events which arise out of, or in connection with, (the University's) work activities.
- 5.6 Where the University is the sponsor of a study which comes under the UK Policy Framework for Health and Social Care Research, this will formally be the Pro-Vice-Chancellor for Research and Enterprise. He or she will normally delegate this responsibility to the Head of Research Quality and Policy. The adverse event will be reviewed and directed to the relevant body and logged dependent on severity.

- 5.7 The timelines for reporting and the reporting lines for an adverse event vary based on severity (speed) and seriousness (impact). In some circumstances a research project may need to be suspended or discontinued. This is set out in the table below.

Table 1: healthcare research

Serious adverse event/reaction or unexpected serious adverse reaction	Any adverse event, adverse reaction or unexpected adverse reaction, respectively, that: (a) results in death; (b) is life-threatening; (c) requires hospitalisation; (d) results in persistent or significant disability or incapacity.	Must be reported immediately and within 24 hours to the Chair and Secretary of the FREC which approved the study in the first place. The study should be suspended immediately and not re-started until an investigation is completed.
Unexpected adverse reaction	An adverse reaction, the nature and severity of which is not consistent with the information about the product in question.	All cases should be reported to the Secretary of the FREC which approved the study within 48 hours of notification. If two or more cases occur the cases should be investigated. If more than 4 cases occur the trial should be halted until investigation is completed.
Adverse reaction	Any untoward and unintended response in a subject to an investigational product which is related to any dose administered to that subject.	All cases should be reported to the Secretary of the FREC which approved the study within 48 hours of notification. If two or more cases occur the cases should be investigated. If more than 4 cases occur the trial should be halted until investigation is completed.
Adverse event/experience	Any untoward medical occurrence in a subject, including occurrences which are not necessarily caused by or related to the product, e.g. vomiting, diarrhoea or fainting.	Should be recorded in the study records. If two of more adverse events are reported these should be reported to the Secretary of the FREC which approved the study within 48 hours of notification. If more than 4 cases occur the trial should be halted until an investigation is completed.
Near-miss	An event which may in other circumstances have caused harm, for example, failure of equipment, administration of an incorrect dose (even in the absence of an adverse reaction).	Reported to the Secretary of the FREC which approved the study within 48 hours of notification

Table 2: non-healthcare research

Adverse event	This includes research participants being caused physical or psychological harm, unintentional release of information, breach of regulations or law, harm to the environment or any other event which may damage the reputation of the University.	Must be reported immediately and within 24 hours to the Chair and Secretary of the FREC which approved the study in the first place. The study should be suspended immediately and not re-started without the permission of the Chair which may be subject to the completion of a formal investigation.
Near miss	An unplanned event which did not result in an adverse event but had the potential to do so.	Should be recorded in the study records and reported to the Secretary of the FREC which approved the study within 48 hours of notification.