

## Operating Guidelines for the Governance and Oversight of Research Ethics

### Research Ethics Governance, RECs, and Operations

These Operational Guidelines for research ethics governance set down the terms of reference for the Research Ethics Committees (RECs), provide reference to the application methods for ethics approval and guidelines for specific research fields.

The development and maintenance of appropriate policies and procedures regarding research ethics governance is essential to ensure the University undertakes high quality and ethically sound research that stands up to the standards set by evolving and new legislation. Numerous research awarding bodies now require assurances at both application and award stage that projects have, where necessary, been approved by an institution's ethics committee and that research ethics governance structures and policies are in place. The University of Limerick is committed to achieving the highest academic and ethical standards in all its research activities. Thus ULREG will seek to follow best practice in terms of research ethics governance with its members participating in National and International Research Ethics bodies.

### Oversight Structure

ULREG operates under delegated authority from Academic Council. The reporting responsibilities relevant to ULREG as well as its remit are described in fig. 1.

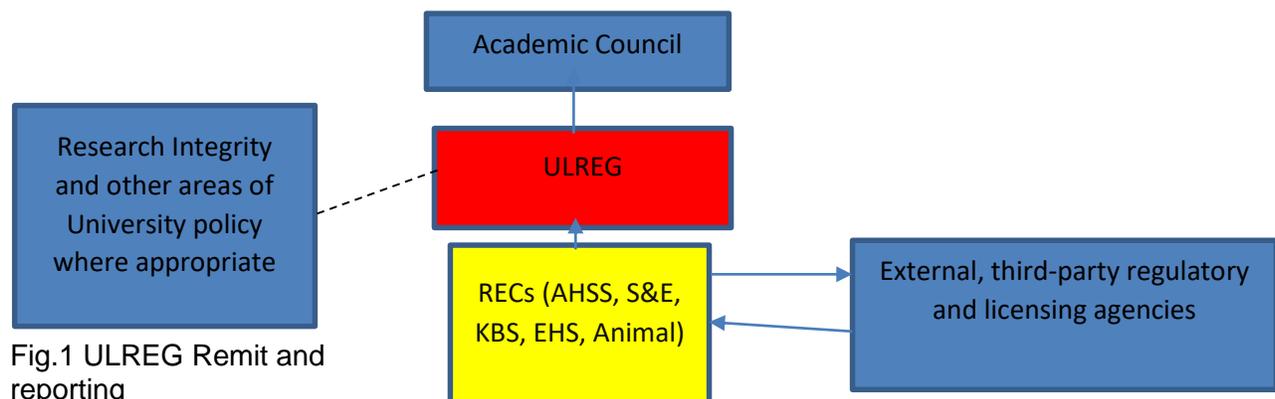


Fig.1 ULREG Remit and reporting

### Meetings of ULREG

Meeting agendas will be prepared and provided in advance to members, along with appropriate briefing materials.

Reports of the RECs will constitute a standing item on each meeting agenda for ratification, and the Chair of the relevant REC (or their alternate in their absence) will speak to their respective REC's report.

All matters arising will be addressed with completed items being noted, and incomplete items becoming matters arising for the subsequent meeting.

Draft meeting minutes will be prepared and circulated to the Committee members and alternates in a timely manner.

Decisions made will be recorded in the meeting minutes with the action that need to be taken and the person responsible for the action.

The Chair and Research and Enterprise Office will coordinate sub-committee meetings and extraordinary meetings of the committee as required. Meeting dates for the academic year will be notified to committee members ahead of the beginning of the session.

### **Membership and Induction**

Members of ULREG will be listed on the University website.

ULREG members shall be offered induction and training on an on-going basis as appropriate by the Dean of Graduate School.

### **Research Ethics Committees (RECs)**

The University of Limerick Research Ethics Governance Committee (ULREG) is reported to by five standing Research Ethics Committees: one each from the University's four faculties, and a separate Animal REC. The constitution of these RECs is set out below.

Research projects requiring ethical approval should be submitted to the most appropriate REC of the research discipline concerned, normally the Faculty REC related to the applicant's "home" faculty; where clarification is required, applicants should liaise with their faculty REC Chair and/or the Chair of ULREG as appropriate.

The RECs have the authority to consider proposed research projects and to provide research ethics approval/disapproval. Ethical approval is deemed to have been given on communication of the REC's decision to approve to the applicant; the decision is ratified by ULREG at its next appropriate sitting.

Principal Investigators and Supervisors have the responsibility for ensuring ethics applications are submitted as required under these procedures and assuring the quality of such submission by signing completed ethics application forms prior to their submission to the relevant REC.

The RECs are responsible for the implementation of policy and procedures related to research ethics and as such, they report to ULREG. The RECs have the authority to consider the ethics of proposed research projects and to provide research ethics approval/disapproval. In undertaking this role, the RECs aim to ensure that research is conducted according to best practice for ethics standards in research. In keeping with this, the RECs aim to safeguard the health, welfare, dignity and rights of human participants, animals and researchers in order to minimise risk to participants, researchers, third parties, and to the University itself. The RECs are deemed to facilitate, not hinder, valuable research and to protect researchers from unjustified criticism and/or legal action.

The RECs are deemed to include the Faculty Research Ethics Committees and the Animal Research Ethics Committee.

### **Animal Research Ethics Committee**

The remit of the Animal Research Ethics Committee (Animal REC) is as set out below and shall provide a thorough, expert, robust and independent ethics assessment of scientific work involving animals by UL personnel. In this regard, the Animal REC will be guided by the requirements as set out by relevant external third-party licensing and regulatory bodies (such as the HPRA, formerly the Irish Medicines Board) and will ensure that research conducted by UL researchers is in line with the ethos of the University. Notwithstanding its independent role, the Animal REC

will also provide advice and guidance to UL personnel on animal ethics issues and on the legislative requirements of animal licensing at national level.

ULREG pledges its full support to the RECs in discharging the authorities and responsibilities contained in this operational guidelines.

### **Terms of Reference of the RECs**

Evaluation of Ethics Applications for Research Projects:

- Adjudicate on whether research projects are deemed ethical;
- Liaise with external third-party regulatory and licensing bodies if required on applications relating to University research approved by external ethics committees (for example HSE Ethics Committees);
- Co-opt internal and/or external experts to the REC as deemed necessary for specific situations for defined periods;
- Comment to ULREG on procedures and policy;
- Forward applications to ULREG that are deemed outside the expertise of REC.

Development of Policy and Procedures:

- To develop policy and procedures for HSE related research in conjunction with ULREG;
- To develop policy and procedures for specific area related to research within the Faculty in conjunction with ULREG;
- To develop procedures for the efficient operation of REC.

Implementation of Policies and Procedures:

- To promote a University Research Integrity Policy;
- To adjudicate ethics issues of applications;
- To adhere to guidelines of good practice in research ethics within the University;
- To facilitate an appeal of the committee's decision to ULREG;
- To facilitate any quality audit as defined by ULREG/ University.

Evaluation of Policies and Procedures:

- To provide feedback to ULREG on operational structures for the development of research ethics approval within the University;
- To provide feedback to ULREG as required on the development of other policy and guidelines documents related to research ethics governance;
- To provide feedback to ULREG on the decision making process within each REC on:
  - The application of the ethics principles in the decision making;
  - The process, volume and speed of decision making;
  - The feedback to applicants;
  - The review of research completion reports on approved applications.

Reporting:

- Each REC will make a written report on its activities to ULREG using the appropriate template.
- Each REC will report details relating to appeals on decisions, any queries/clarifications of note, and any applications outside the expertise of the REC committee.
- In cases of applications requiring particular legal interpretation, they will be reported in the first instance by the appropriate REC chair to the Chair of ULREG, who will then

liaise with the Corporate Secretary's office with a view to reporting any advice to the REC chair for action where appropriate.

## **Composition of the RECs**

### Faculty RECs

Each Dean of Faculty will appoint the members and alternates to their relevant Faculty REC as follows:

- A Chairperson with experience in the subject area;
- Up to four members from within/outside the University who are competent in the specialist area, to include a member who is trained in or has practical experience in the area of research ethics.

### Animal REC

The ULREG Committee will appoint the members and alternates to the Animal REC as follows:

- A Chairperson with experience in the subject area;
- Up to four members from within/outside the University who are competent in the specialist area, to include a member who is trained in or has practical experience in the area of research ethics.

In both Faculty and Animal RECs, the Chair's alternate will as Vice-Chair in the Chair's absence. REC Vice-Chairs should normally be appointed from a different faculty to that of the Chair. Chair's and/or Vice-Chairs are expected to attend ULREG meetings to speak to their submitted REC reports

One or more of the members of the Faculty RECs and Animal REC must be trained in ethics and all REC members shall be offered induction and continuing training as appropriate.

The Chairperson of the Faculty RECs and Animal REC will be appointed for a term of 3 years, with 1 extension of term only to be normally facilitated.

Internal and/or external experts may be co-opted to a REC as deemed necessary for specific situations for defined periods. Co-options are with the majority approval of the members of the REC present at the meeting at which the proposal is made.

## **Meetings of RECs**

Each REC will convene a meeting every month with a summer suspension if warranted; additional meetings may be scheduled as required.

REC members are expected to attend the meetings.

A quorum shall consist of half of the REC membership, including at least one of the Chair or Vice-Chair. However, it is assumed that where alternates are appointed, the full membership should sit in all but exceptional cases.

Non-members may be invited to attend meetings as deemed necessary for specific situations. Invitations are with the majority approval of the members of the REC present at the meeting at which the proposal is made.

Meeting agendas will be prepared and provided in advance to members, along with appropriate briefing materials.

All matters arising will be addressed with completed items being noted, and incomplete items becoming matter arising for the subsequent meeting

Draft meeting minutes will be prepared and circulated to the REC members and alternates in a timely manner

Decisions made will be recorded on the meeting minutes with the action that need to be taken, and the person responsible for the action.

Applications deemed to be outside the expertise of a REC or requiring a specific legal position will be passed to ULREG; where appropriate, ULREG may convene a sub-committee to consider such applications, or escalate issues around potential legal implications to the Corporate Secretary's office.

### **ULREG Sub-committees**

In cases where the implementation of policy and procedures related to a specific topic of research ethics is required, a sub-committee of ULREG will be established by the Chair and will report to ULREG. Such committees will be formed for a specific purpose. Sub-committees of ULREG will also be established as and when required to consider appeals against REC approval decisions, and applications referred to ULREG by RECs for special consideration.

### **External third-party regulatory research ethics committees**

Research applications that have been approved by external third-party regulatory research ethics committees (such as that of the HSE or similar body) must be noted by the relevant REC of the Principal-Investigator/Supervisor.

Approval letters should be copied to the recording secretary of the REC, with the successful applications being noted as approved on the University of Limerick Research Ethics Governance Committee Report Form with the Faculty acronym being replaced by HSE.

### **Principles for Research Ethics**

Principles for Research Ethics are outlined in the document, "Guidelines in Support of Research Ethics Procedures."

### **Procedures for Research Ethics Applications**

The University of Limerick 'Procedures for Research Ethics Approval' provides comprehensive information on making a Research Ethics application. These Procedures along with additional REC guidelines and ethics application forms are available at [www.ul.ie/researchethics](http://www.ul.ie/researchethics).

### **Insurance Cover for Research**

Confirmation of insurance cover is a requirement for all research ethics applications submitted to a REC for consideration. A Principal Investigator/Supervisor must ensure the necessary insurance cover is in place as part of their application. Details of the University's insurance cover and the University's 'Guidelines on Insurance Cover for Research' are available at [www.ul.ie/insurance](http://www.ul.ie/insurance).

### **Processing of Research Ethics Applications**

The decisions of the REC are guided by the following set of generic ethics principles:

- Respect for the dignity, worth and self-determination of all participants;
- Responsibility to the research participant and to society;
- The conducting of research which is within the competence of the researcher;
- Whether the research has non-human ethical implications.

In addition, the REC may also take into account any codes of practice or guidelines which apply to the discipline. The decision making process of the REC is governed by the following factors:

- Transparency and accountability of ethics decision making;
- Awareness of the limitations of the competence of the REC;
- Obligation to accumulate and disseminate a knowledge-base of ethics issues and procedures to inform future ethics decision making.

The REC may approve such applications where, in its own judgement, the ethics issues that arise in the research and decision making process have been addressed adequately.

Where it is considered appropriate, a REC may invite Principal Investigators/Supervisors to attend a REC meeting and participate in discussions about their proposal. RECs should also accommodate reasonable requests from Principal Investigators/Supervisors to participate in discussions about their proposal. Principal Investigators/Supervisors may not be present when the REC is making its decision.

In the event that the Principal Investigator/Supervisor for a research project is also a Chairperson of the relevant REC, sign-off approval for ethics regarding the research project should be undertaken by the Vice-Chair of the REC.

It is desirable to adopt a consistent approach to granting or declining approval of a proposal. It is recommended that the following terminology be used in communicating the decision of the REC to an applicant:

1. **Approved**, the applicant may conduct the research as outlined in the research proposal submitted to the REC;
2. **Provisionally approved**, subject to recommended revisions to the proposal or answers to questions posed to the applicant. The revisions and/or answers must be resubmitted to the REC and/or for Chair's Action before receiving final approval. No research may be conducted prior to receiving final approval;
3. **Approval declined**, detailed reasons for declining approval should be forwarded to the applicant, with or without an invitation to resubmit a substantially altered proposal for reconsideration.

The REC decision will normally be communicated to the applicant in writing within two weeks of the meeting at which the decision was taken.

All decisions should be recorded on the University of Limerick Research Ethics Governance Committee Report Form, and reported to ULREG.

### **REC Chairperson Approval**

In the context of an application viewed by a REC and given the designation "provisionally approved", the relevant REC Chairperson can independently consider whether the changes recommended by the REC have been applied to the REC Application and give final approval to the application. This decision will be reported by the Chairperson at the following meeting of the

REC. This should then be recorded on the University of Limerick Research Ethics Governance Committee Report Form.

### **Appeal of a Research Ethics Application Decision**

In the event that an applicant is dissatisfied with the outcome of a research ethics application, an appeal of a REC decision may be referred to the University of Limerick Research & Ethics Governance (ULREG) Committee, which will convene an appeals sub-committee to consider the case. The procedure for the appeal to ULREG is as follows:

- An appeal of a decision made by a REC should be made in writing to the Chairperson of ULREG and copied to the recording secretary, outlining the grounds of the appeal, within 10 working days of the decision being relayed to the applicant.
- The appeal will be heard at a specially-convened meeting of the ULREG appeals sub-committee, convened by the ULREG chair
- The decision of the sub-committee will be relayed to the REC Chairperson, and the applicant, within 5 working days of the meeting;
- The decision of ULREG through its sub-committee is final.

### **External Ethical Approval by commensurate organisations**

ULREG and RECs will respect the approval decisions of commensurate organisations (universities, public sector organisations, research institutes) with robust research ethics procedures where the PI of a collaborative research project is not based at UL but UL staff, students, or property are in use. Commensurability of institution will be confirmed by ULREG. Such approvals should be lodged with the relevant REC and recorded as noted.

In the case of research that is deemed high risk by an REC, the REC may require additional information from the PI and in the event of serious concerns being raised about the ethical standards of the project, the REC may refer to ULREG, which would make a determination as to the ratification of such an approval.

### **Records Management and Retention**

RECs should adhere to the University's Records Management and Retention Policy, its Data Protection Policy, its Data Protection Compliance Regulations, and all other relevant policies, procedures, legislation, and regulations with regard to its retention of application forms, reports, and decisions. As a general rule, applicants should state on their submissions if they intend to retain data collected through their research beyond a period of seven years.

All documentation and communications of ULREG and the RECs must be dated, filed and archived appropriately. The REC Chairperson for each REC Committee will be responsible for the archiving of all relevant documentation. Documents must be stored in a secure place where there is adequate protection against fire. Electronic records and backups of all documents must be maintained on password protected computers. A statement is required defining the access and retrieval procedure (including authorised persons) for the various documents, files and archives, this can be found on the individual ethics sites of the Faculties and the Graduate School.

Documents to be filed and archived include, but are not limited to:

- All material submitted by an applicant;

- All correspondences by REC members with applicants or concerned parties regarding applications, decision and follow-up;
- Copies of decisions & any advice and/or requirements issued to applicants;
- The agenda of all ULREG and REC meetings;
- The minutes of all ULREG and REC meetings which should include members present, 3<sup>rd</sup> parties present, time, date & place of meeting;
- Annual reports of ULREG to the Academic Council of the University;
- Risk assessment procedures;
- Research completion forms were applicable.

**Retention of ethics application forms**

The retention time for ethics application forms by the RECs is as per the University's Records Management & Retention Policy.

**Training**

An annual ethics training program is available to all staff, via the Graduate School's generic and transferable skills program.

## REC Reporting Format

The following table is the report template for REC meetings. The Template forms the basis of the REC's report to ULREG, and should be forwarded to the ULREG recording secretary together by soft copy following the REC meeting.

The decisions can be noted with a tick in the appropriate box:

- A - Approved
- PA - Provisional approval
- D - Declined

**Comments** should be made in regard to the ethical reasons for approval (if needed) provisional approval or declining the application.

### Application numbers

'Application Number' be recorded in the following format –  
**'year\_month\_project no.\_Faculty'**

e.g. for an Arts Humanities & Social Science Faculty application in December 2012 the first application will be coded:

'2012\_12\_001\_AHSS'.

The second on the list '2012\_12\_002\_AHS', etc.

For an Education & Health Sciences Faculty application in August 2011 the first application will be coded:

'2011\_08\_001\_EHS'.

The second on the list '2011\_08\_002\_EHS', etc.

For a Kemmy Business School application in March 2014 the first application will be coded:

'2014\_03\_001\_KBS'.

The second on the list '2014\_03\_002\_KBS', etc.

For a Science and Engineering Faculty application in October 2015 the first application will be coded:

'2015\_10\_001\_S+E'.

The second on the list '2015\_10\_002\_S+E', etc.

Approvals from the Animal REC will be noted with an AREC acronym, HSE approvals will be noted with a HSE acronym.

University of Limerick Research Ethics Governance Committee Report Form

REC Type:  
(Faculty/Animal or  
Specialist)

Faculty name

Date: dd-mm-yy

Quorum:

name

Signature

name

Signature

Chair

Member

Non UL rep

Member

Recording  
Secretary

Member

Member

Member

Member

Member

Member

Member

Application Number	Project Name	Principal Investigator	Primary Supervisor	Decision			End Date	Comment
				A	PA	D		

