



**UNIVERSITY *of* LIMERICK**

**O L L S C O I L L U I M N I G H**

## **Procedures for Research Ethics Approval**

## **1. INTRODUCTION**

- 1.1. All researchers engaging in research that involves human participants (including data collected on an anonymous basis) or other areas set out in the checklist attached as Appendix 1 to these procedures, must obtain ethical approval in writing from their Faculty Research Ethics Committee (REC) prior to commencing the research. Researchers engaging in research that involves animals must obtain ethical approval in writing from the Animal Research Ethics Committee (AREC) prior to commencing the research. Guidelines and all ethics application forms are available at [www.ul.ie/researchethics](http://www.ul.ie/researchethics). It should be noted that references to RECs in the remainder of these Procedures are deemed to include the AREC.
- 1.2 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 and in accordance with ethical standards in research. In addition, 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. It should be noted that RECs are deemed to facilitate, not hinder, valuable research and to protect researchers from unjustified criticism and/or legal action.
- 1.3 The requirement to seek ethical approval applies to research to be conducted on or off the University of Limerick campus. Research must be conducted in line with the conditions, if any, of such approval.
- 1.4 A research project that requires ethical approval must not commence until such time as written approval has been secured.
- 1.5 As provided for in the University's Research Ethics & Governance Committee Operational Guidelines, specialist research ethics committees may be constituted to implement the ethics process for a specific topic of research deemed outside the scope of the RECs. These procedures will apply in the event of the establishment of a specialist research ethics committee.
- 1.6 Chairpersons and members of each of the RECs and their contact details are available at [www.ul.ie/researchethics](http://www.ul.ie/researchethics). Information on more detailed guidelines that may be developed by some or all of the RECs is also provided on this website.

## **2. RESEARCH ETHICS PRINCIPLES FOR RESEACHERS**

- 2.1 A high standard of research ethics principles are essential for all researchers. These principles aim to protect the dignity, rights, safety and well-being of all actual or potential research participants. A summary of these research ethics principles are set out below.
- 2.2 Respect for the dignity, worth and self-determination of all participants, in particular:
  - Having sensitivity to the dynamics of perceived authority or influence over participants;
  - Preserving participants' privacy and confidentiality;

- Obtaining informed consent before participation;
  - Protecting participants' rights to self-determination by allowing and facilitating withdrawal from the research process.
- 2.3 Responsibility for the care of research participants and to wider society:
- Considering all research from the participants' standpoint;
  - Considering the range of stakeholders who may be affected by the research;
  - Identifying and minimising risks to physical, psychological and social wellbeing;
  - Providing detailed debriefing to participants as to the outcomes and consequences of the research.
- 2.4 Competence of the Researcher:
- Demonstrate the capacity to carry out the research, or to avail of appropriate supervision to support the development of this capacity;
  - Demonstrate that the research is sound methodologically;
  - Demonstrate the capacity to identify ethics issues and to avoid them arising where possible, through appropriate research design;
  - Demonstrate the skill/ training to deal with sensitivities that may arise in the course of the research, or to put in place appropriate supports for participants.
- 2.5 Where relevant, additional guidelines pertaining to research with animals, child protection, military/weaponry research must be adhered to at all times.

### 3. PRINCIPAL INVESTIGATORS/SUPERVISORS

- 3.1 Principal Investigators/Supervisors have the responsibility for ensuring ethics applications are submitted as required and assuring the quality of such submissions by signing completed ethics application forms prior to their submission to the relevant REC.
- 3.2 **Principal Investigator:** A Principal Investigator is an employee of the University who has primary responsibility for the design, implementation, completion and management of a research project.
- 3.3 **Supervisor:** A Supervisor is an employee of the University who is assigned to a postgraduate research candidate at the time of their commencement of a postgraduate research project. The supervisor has responsibilities relating to the postgraduate's academic and research activities as described in Section 5 of the University of Limerick's Handbook of Academic Regulations and Procedures (Research Postgraduate Academic Regulations).
- 3.4 For the purposes of this document, an employee of the University is deemed to include individuals appointed on an adjunct basis in recognition of their professional achievements.

## **4. PROJECTS THAT REQUIRE/DO NOT REQUIRE ETHICAL APPROVAL**

4.1 All research to be undertaken involving human participants (including data collected on an anonymous basis), animals and certain other types of research, as indicated in the REC Application Form Checklist attached as Appendix 1 to these Procedures, require ethical approval by a REC.

### **4.2 Research Projects Not Requiring Ethical Approval**

4.2.1 Research projects that do not require ethical approval are those where the answer “NO” applies to **all** questions listed in the REC Application Form Checklist (Appendix 1) **and** does not involve human participants.

4.2.2 Principal Investigators/Supervisors must ensure that the research project is adequately covered by the University’s insurance. In this regard, Principal Investigators/Supervisors should review the University’s Guidelines on Insurance Cover for Research, available at [www.ul.ie/insurance](http://www.ul.ie/insurance).

### **4.3 Teaching Research Methodology as part of a Module of Study**

4.3.1 The provision of research methodology modules plays a key role in training students about how to plan and undertake good research and are provided by the Faculties at undergraduate and postgraduate level. Ethical clearance is not required for research-based, pedagogical exercises (e.g. surveys/questionnaires/ interviews/ observations of public behaviour etc.) that form part of the assessment of students on a research methodology module, once the following are observed:

- (i) Research-based exercises shall not involve the collection of sensitive personal data (e.g. sexual orientation, mental health issues, religious beliefs etc.)
- (ii) Research-based exercises shall be undertaken with fellow classmates only.

### **4.4 Other Categories of Data Collection Not Requiring Ethical Approval**

4.4.1 Ethics approval is not required in the following cases: the undertaking of Quality Reviews; Performance Reviews; Reflective Practice; Standard Professional Practice; Educational tests. University employees should be cognisant at all times of University Policies & Procedures in these areas.

### **4.5 Research Projects - Expedited Ethical Approval Process**

4.5.1 Where a research project involves human participants (including data collected on an anonymous basis) but where “NO” applies to all questions listed in the REC Application Form’s Checklist (Appendix 1), the Principal Investigator/Supervisor may submit an expedited ethics application form (where applicable) to the relevant REC. Research must not commence prior to receipt of written approval from the REC.

## **4.6 Research Projects - Full Ethical Approval Process**

4.6.1 Where a research project results in “YES” applying to one or more of the questions listed in the REC Application Form Checklist (Appendix 1) then the Principal Investigator/Supervisor must submit a full ethics application form to the relevant REC. Research must not commence prior to receipt of written approval from the REC.

## **4.7 Ethics Approval where Research Element is built into a Taught Module of Study**

4.7.1 Where a module includes a mandatory research element and where ethical approval must be obtained for all relevant students, the module lecturer/course coordinator must make an application to the appropriate REC as set out in 4.5 or 4.6 above.

4.7.2 All students enrolled on the module should be required to complete and sign a form which includes an alert on ethical issues associated with the research work to be undertaken and which seeks their agreement to abide by the rules set out.

4.7.3 The module lecturer/course coordinator will make a new ‘blanket’ application each academic year, for as long as the module is provided.

## **4.8 Outcomes of Ethics Applications**

4.8.1 In all cases where research ethics approval is required, the RECs may:

- (a) Approve an application;
- (b) Provisionally approve an application (subject to recommended revisions to the proposal or answers to questions posed to the applicant); or
- (c) Refuse approval.

4.8.2 Once ethical approval has been received in writing from the relevant REC, the applicant and their Principal Investigator/Supervisor will be informed directly by the REC committee chairperson and the research proposal will be assigned a unique number. Again, **research must not commence prior to receipt of this written approval.**

4.8.3 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. 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 the next scheduled meeting of ULREG, unless an extra ordinary meeting is required (as decided by the Chairperson of ULREG);
- The decision of the committee will be relayed to the REC Chairperson, and the applicant, within 5 working days of the meeting;
- The decision of ULREG is final.

## **5. INSURANCE REQUIREMENTS**

- 5.1 Confirmation of insurance cover is a requirement for **all** research ethics applications submitted to a REC for consideration. It is the responsibility of the Principal Investigator/Supervisor to ensure that research to be undertaken is covered by the University's insurance policies.
- 5.2 The University is, in the main, indemnified by the various policies forming part of its Insurance Programme in respect of approved research undertaken by employees, students and other persons acting on behalf of the University.
- 5.3 Details of the University's insurance cover and the University's 'Guidelines on Insurance Cover for Research' are located at [www.ul.ie/insurance](http://www.ul.ie/insurance).
- 5.4 Where there is any query whatsoever about whether or not there is insurance cover for a proposed research project, the Principal Investigator/Supervisor must contact the University's Insurance Administrator at [cliona.donnellan@ul.ie](mailto:cliona.donnellan@ul.ie) to confirm that the required level of insurance cover is in place.
- 5.5 Where more than one institution/organisation is involved in a research project, each institution/organisation is responsible for providing its own insurance cover and written confirmation of the other organisation's cover must be appended to the UL REC Application Form.

## **6. ETHICS APPROVAL FOR JOINT UL / HEALTH SERVICE EXECUTIVE (HSE) RESEARCH PROJECTS**

- 6.1 For all research projects of a clinical/medical nature which include HSE participation or which are to take place in a HSE establishment, requests for ethics approval must be submitted to the relevant HSE Research Ethics Committee (REC) on the designated HSE application form.
- 6.2 Once research ethics applications have been approved by the HSE REC, the relevant UL REC must be notified of the proposed research and evidence of HSE REC approval must accompany the notification. Research may not commence until such time as the HSE REC has provided full approval in writing and until written evidence is provided to the relevant REC.

## **7. CLINICAL TRIALS / MEDICAL MALPRACTICE**

- 7.1 The University's ethics approval process does not apply to clinical trials on the University Campus at present and the University does not purchase clinical trials/medical malpractice insurance cover currently. In the event that a Principal Investigator/Supervisor plans to undertake a clinical trial then the Vice President, Research must be notified, and subsequently, the Principal Investigator/Supervisor must contact the University's Insurance Administrator ([cliona.donnellan@ul.ie](mailto:cliona.donnellan@ul.ie)) prior to commencing any such research in order to secure the required insurance cover.

## **8. DURATION OF ETHICS APPROVAL**

- 8.1 Ethics approval for individual modules, final year or taught postgraduate projects will cease after the examination period of the module, final year or taught postgraduate project. Repeat projects must reapply for ethics approval even if the project remains the same.
- 8.2 Research ethics approval will cease on the date indicated on the REC ethics report form. This should not exceed the maximum allowable registration as indicated in the University's Academic Regulations. The submission of a thesis ends the ethics approval, and can be considered as the completion report.
- 8.3 A cessation report submitted by the Principal Investigator will be necessary if the project ends without completion. This should be noted at the end of the REC ethics report form with the original approval code.

## **9. IN THE EVENT A PI/SUPERVISOR LEAVES POSITION OF EMPLOYMENT AT THE UNIVERSITY**

- 9.1 In the event that a Principal Investigator/Supervisor leaves their position of employment at the University of Limerick, any current research ethics approval lapses with their departure and the research project(s) ceases to have ethics approval. In the event that a new Principal Investigator/Supervisor who is an employee of the University is assigned to a previously approved research project, they are required to reapply for ethics approval for the given project.

## **10. TIME LIMIT FOR RECEIPT OF APPLICATIONS**

- 10.1 In the event that a research project is granted full ethics approval, there will be no limitation on the commencement date, as long as the conditions under which ethics approval was granted remain unchanged.
- 10.2 The granting of provisional ethics approval remains in place for a period of 12 months following the relaying of the REC's decision to the researcher. In the event that commencement of the related research is delayed beyond a period of 12 months for whatever reason, then, a further ethics application must be submitted prior to the research commencing.

## **11. PROCEDURES FOR APPROVAL WHERE AN EXTERNAL RESEARCH PARTNER HOLDS A LICENCE FOR UNDERTAKING RESEARCH / OBTAINS ETHICS APPROVAL FROM THEIR REC**

- 11.1 In the event that there is one or more collaborating external partners in a proposed research project (other third level institution or semi state not for profit body) and where the ethics application has been approved by the REC of one of the other research partners, UL researchers involved in the project must ensure that that ethics approval is submitted to the relevant UL REC for noting in advance of the commencement of research. In the event that collaboration is with an external 'for profit' organisation, UL researchers must continue to seek ethics approval from the relevant UL REC in advance of commencement of the planned research.

## **12. EXTRA-JURISDICTIONAL RESEARCH PROJECTS**

- 12.1 In the event that a UL Principal Investigator/Supervisor intends to conduct research overseas which requires prior ethics approval, they must gain relevant UL REC approval and where appropriate and/or possible, local REC approval in the country where the research is proposed to be undertaken prior to the research commencing. In the event that local REC approval cannot be obtained, evidence of having sought such approval must be submitted to the relevant UL REC.

## **13. GATEKEEPERS**

- 13.1 For the purposes of research ethics matters, a gatekeeper is defined as an individual who controls access to information in an organisation/body. A gatekeeper may also serve to protect the interests of research participants and to ensure that they are not under any pressure to participate.
- 13.2 In certain limited cases, research participants in a research project may require gatekeeper approval from their professional/governing body prior to their partaking in the research (this may include, but is not limited to An Garda Siochana, the Judicial System etc.). In such cases, while the research participants are expected to be aware of this requirement, the Principal Investigator/Supervisor should ensure that gatekeeper approval is secured by the research participant, prior to the commencement of the research.

## **14. GUIDANCE REGARDING INTENTION TO SOURCE DATA FROM INTERNET/SOCIAL MEDIA SITES FOR RESEARCH PURPOSES**

### **14.1 Introduction**

- 14.1.1 Data obtained from observing human behaviour and/or communication with individuals may be intimate and personal irrespective of where or how the data was collected. This includes data sourced from the internet/social media sites and therefore Internet Mediated Research (IMR) needs to be subject to oversight from the RECs. This is the case regardless of any legal understanding of the distinction between public and private domains as the presence of personal data in public domains cannot always be taken as implicit consent. Issues around the vulnerability of groups or individuals interacting on social media still needs to inform research practice in this area. The ethical oversight of IMR is therefore complex and implies a need for consideration of a high degree of reflexivity on the part of the researcher.

### **14.2 Website Providers - Terms & Conditions, Privacy, Copyright etc**

- 14.2.1 Social media websites are usually hosted by a website provider and the content of such sites is created by the users of the sites. Most websites require a user to have some form of username and password, indicating the expectation of some level of privacy, and/or the necessary requirement of traceability of the user, or the imposition of an age restriction. Social media websites are regularly subject to terms & conditions/a privacy statement, and may, for example, include a prohibition on the harvesting of data without prior permission. In addition, copyright and data protection rules apply to the content of such sites.

14.2.2 A reasonable expectation of privacy by the website user can be gauged by the intended use of the website and the website's privacy rules. To this extent PIs/Supervisors must abide by the terms and conditions set out in the relevant privacy statement of the individual site and where necessary, should obtain the appropriate permission for use of data from the website provider (e.g. copyright permission, permission to harvest data etc.).

### **14.3 Data Sourced in the Internet/Social Media sites and Data Protection**

14.3.1 Regardless of the foregoing, users of the Internet/social media sites post information on these sites of their own freewill and often, this data is identifiable personal data. Even where personal data is placed in the public domain in this way, it remains subject to the Data Protection Acts 1988 & 2003 (e.g. the rights to fair collection/processing, informed consent including that of a parent/guardian in the case of minors, appropriate security and retention measures etc. apply).

### **14.4 Data Sourced in the Internet/Social Media sites and Ethics Approval**

14.4.1 In the event that a PI/Supervisor intends to access data of individuals (identifiable/anonymised) through internet/social media sites, a research ethics application must be submitted as set out in either 4.5 or 4.6 of this procedures document.

### **14.5 Use of Internet/Social Media websites –Additional Responsibilities**

- PIs/Supervisors/Researchers shall be responsible for:
  - avoiding direct quotations from websites that could subsequently be used in a search engine search in order to identify an individual unless consent to do so has been obtained from the individual concerned;
  - fully acquainting themselves of and abiding by the stated privacy requirements of the relevant website/social media site(s);
  - avoiding deception and relationship development;
  - awareness of data retention and transfer laws in the jurisdiction of the data subjects;
  - awareness of the intended use of the site.

## **15. Responsibility**

15.1 While the University has overall responsibility for ensuring compliance with Data Protection, other relevant legislation and the Research Ethics Governance function, Principal Investigators/Supervisors have operational responsibility for ensuring compliance with the legislation and procedures in place when research data is being collected and processed.

## Appendix 1: REC Application Form Checklist

### HUMAN PARTICIPANTS (INCLUDING PERSONAL DATA COLLECTED IN AN ANONYMOUS MANNER)

Does the research proposal involve:	Yes/No
Working with participants over 65 years of age?	
Any person under the age of 18?	
Adult patients?	
Adults with psychological impairments?	
Adults with learning difficulties?	
Adults under the protection/ control/influence of others (e.g. in care/prison)?	
Relatives of ill people (e.g. parents of sick children)	
People whose comprehension of the research and its requirements might be compromised by their linguistic competence?	
Hospital or GP patients recruited in medical facility?	
Human Tissue/Samples	

### SUBJECT MATTER

#### Does the research proposal involve:

Sensitive personal issues? (e.g. suicide, bereavement, gender identity, sexuality, fertility, abortion, gambling)	
Illegal activities, illicit drug taking, substance abuse or the self-reporting of criminal behaviour?	
Any act that might diminish self-respect or cause shame, embarrassment or regret?	
Research into politically and/or racially/ethnically and/or commercially sensitive areas?	

### RESEARCH PROCEDURES

#### Does the research proposal involve:

Use of personal records without consent?	
Deception of participants?	
The offer of large inducements to participate?	
Audio or visual recording without consent?	
Invasive physical interventions or treatments?	
Research that might put researchers or participants at risk?	
Storage of results data for less than 7 years?	

### AREAS OTHER THAN HUMAN

#### Does the research proposal involve:

Use of animals?	
Military technology?	
Hazardous biological materials?	
Genetic modification?	
Nuclear reaction?	
Any field that may bring the University adverse attention?	