



UCC

Coláiste na hOllscoile Corcaigh, Éire
University College Cork, Ireland

Research at UCC

An Introduction to Research Ethics at UCC



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Overview

This introductory guide is designed to give researchers an overview of UCC's framework for regulation and support of research ethics.

Section 1

Who are we?

The research ethics framework within UCC comprises the **University Research Ethics Board (UREB)** and the three Committees that report to it.

- The function of UREB is to formulate and monitor the University's policy on research ethics. UREB is appointed by the Academic Council. It reports to the **Academic Council Research Committee**.

UREB has four main responsibilities:

- to promote an ethical approach to research across UCC;
- to develop and refine research ethics governance policy and strategy;
- to liaise with University management, staff and students with regard to research ethics;
- to ensure the establishment and oversight of Research Ethics Committees in UCC.

Research Ethics Committees

UREB does **not** process individual research proposals for ethical approval. This responsibility currently falls to three Research Ethics Committees. The nature of the research proposal determines the appropriate Committee. The membership of each Committee reflects academic diversity and concentrates particular expertise and experience.

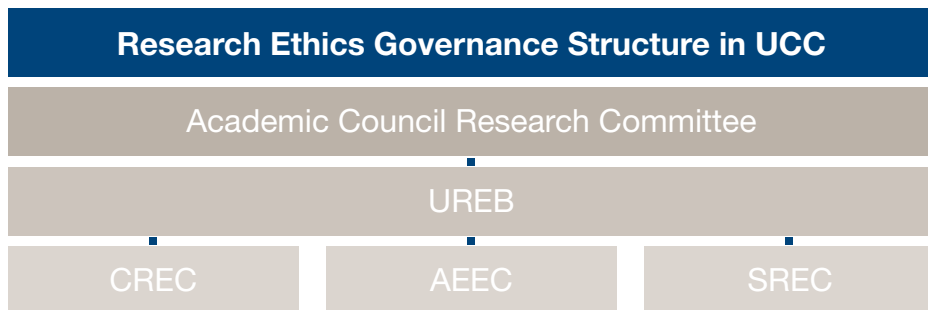


Fig 1: Research Ethics Governance Structure in UCC

The three Committees currently established are as follows:

The Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) deals with clinical research involving human participants, their identifiable data or tissue. Its remit comprises the granting or refusing of permission on ethical grounds for research projects entailing:

- clinical trials (of treatments or of diagnostic processes);
- epidemiological or other studies involving the collection of personal healthcare related data;
- behavioural studies of persons in a healthcare setting;
- studies on tissues and tissue extracts obtained in a healthcare setting.

This Committee is recognised by the Department of Health and Children as a nationally competent ethics committee for clinical trials under the European Communities (Clinical Trials on Medicinal Products for Human Use) Regulations (S.I. 190/2004) (http://www.dohc.ie/legislation/statutory_instruments/pdf/si20040190.pdf?direct=1). It also assesses clinical trial protocols submitted to it by researchers who are not staff members either of UCC or of the hospitals affiliated to UCC for teaching.

It should also be noted that CREC reserves the right, as a matter of institutional authority, to modify research validated by an external research ethics committee on the basis of local competence to deliver. UCC, through CREC, retains an institutional interest in preserving public confidence in the research conducted by its employees.

- **The Animal Experimentation Ethics Committee (AEEC)** deals with proposals to use animals in research. AEEC approval is required for animal experiments carried out by UCC staff. It should be noted that AEEC approval is in addition to the legal requirement for a licence granted by the Minister for Health prior to conducting animal experiments. The AEEC is guided by legislative requirements, in particular the Cruelty to Animals Act (1876) as amended and supplemented by the European Communities (Amendment of Cruelty to Animals Act, 1876) Regulations 2002 (<http://www.irishstatutebook.ie/ZZSI566Y2002.html>). The AEEC works in liaison with the UCC Biological Services Unit (BSU) and the relevant government departments.
 - **The Social Research Ethics Committee (SREC)** has responsibility for ethical oversight of non-clinical research involving human participants. Such research might include direct or indirect interaction with human participants for the purpose of data collection using research methods such as questionnaires, interviews, observations, focus groups etc. SREC is an inter-disciplinary Committee; its remit includes, but is not limited to, research concerning sociology, psychology, economics, politics, marketing, social work, law and epidemiology.
- Where it is not clear to a researcher to which Ethics Committee a protocol should be submitted, the Chairperson of the UREB may be consulted for guidance in advance of submission.





Section 2

What is Research Ethics Governance?

Research ethics governance is a systemic tool used by many institutions that undertake research. Where proposed research may engage potentially ethically sensitive issues (such as the involvement of human participants in research), it is important to provide institutional safeguards to promote best practice.

Research ethics governance has long been a hallmark of higher education institutions. Within the Republic of Ireland, all universities (and some Institutes of Technology) have systems in place that promote and regulate ethical practice in research.

Section 3

Why is Research Ethics Governance Important?

A robust and suitable model of Research Ethics Governance confers the following benefits on a university:

- it helps in fulfilling institutional and individual responsibilities under the law;
- it promotes public confidence and trust in the research activity of the university;
- it helps in fulfilling institutional and individual responsibilities to behave in an ethical and equitable manner toward research participants, employees and funding bodies;
- it helps in protecting the interests of all parties involved in research; research participants/donors, investigators, funding bodies and the host institution;
- it makes research proposals more attractive to funding bodies (very often, local ethical review is a prerequisite to release of funds);
- it helps in fulfilling obligations to indemnity insurers;

- it may be an explicit requirement for publication of research;
- it promotes efficiency and clarity in research protocols;
- it reduces any propensity toward development of a “blame” culture within the institution. If a Committee endorses a research proposal then, in so far as the protocol is properly followed, the institution must accept corporate responsibility for the conduct of the research;
- it may provide specific guidance with regard to, *inter alia*, informed consent, confidentiality, data protection policies, and protection of vulnerable groups where these do not already exist by statute or by international norms.

Principles of Ethical Research

UCC is committed to promoting consistent ethical behaviour as an integral element of its research culture. Whilst a research project conducted within the University may engage different ethical principles, the following represent broad values that UREB will always strive to ensure are upheld:

Research Using Human Participants, Tissue or Data

All human participants in research are entitled to be dealt with in an ethical manner. UCC is committed to promoting respect for the dignity of individual participants.

UCC requires, without exception, that its researchers performing clinical research working with human participants are fully familiar with and observe The World Medical Association Declaration of Helsinki 1964 “*Ethical Principles for Medical Research Involving Human Subjects*” (as amended 2004, <http://www.wma.net/e/policy/b3.html>). UCC also requires, without exception, that its researchers performing clinical trials are fully familiar with and observe:

- ICH Harmonised Tripartite Guidelines, *Good Clinical Practice: Consolidated Guidelines* (as current) (<http://www.ich.org/cache/compo/276-254-1.html>);
- Directive 2001/20/EC of the European Parliament and Council of 4 April 2001 *on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use* (http://eudract.emea.eu.int/docs/Dir2001-20_en.pdf);

- European Communities (*Clinical Trials on Medicinal Products for Human Use*) Regulations 2004 (SI 190/2004) (http://www.dohc.ie/legislation/statutory_instruments/pdf/si20040190.pdf?direct=1).

The Principle of Respect for the Individual extends as much to Social Science research as it does to Clinical Research. This Principle includes, *inter alia*, the requirements for *participant autonomy, properly informed consent obtained in writing, privacy, and beneficence or at least non-maleficence*. UREB strongly recommends that Social Science researchers adhere to guidance set out in *The World Medical Association Declaration of Helsinki 1964 “Ethical Principles for Medical Research Involving Human Subjects”* (as amended 2004, <http://www.wma.net/e/policy/b3.html>), even for non-medical research on human participants.

In particular, if a research project proposes to involve members of vulnerable groups (such as children, individuals with mental or physical disabilities, etc.), then every care should be taken to treat these participants with respect and sensitivity and all possible efforts should be made to promote the autonomy of such participants.

Particular care must be taken to avoid conflicts of interest or potential abuse of position when recruiting as research participants:

- (a) students
- (b) UCC employees.

Privacy and Confidentiality

Researchers have a responsibility to safeguard the privacy and the personal information of participants. Much useful and important research involves the use of highly sensitive personal data. Misuse or inadequate protection of such data violates participants’ rights and may have legal consequences for the University.

Therefore, the requirements of the Data Protection Acts, 1988 (<http://www.irishstatutebook.ie/ZZA25Y1988.html>) and 2003 (<http://www.irishstatutebook.ie/ZZA6Y2003.html>) and Freedom of Information Act, 1998 (<http://www.irishstatutebook.ie/ZZA13Y1997.html>) must be fulfilled. In particular, identifiable data ought to be rendered irreversibly anonymous wherever practicable. Where such action is not possible, stringent measures in relation to data protection must be taken, such as security of records, encryption, coding, use of pseudonyms and removal of identifying contextual information.



Animal Experimentation

When research involves animals, different ethical values are engaged. UCC is dedicated to ensuring that animal experimentation is conducted in a respectful and sensitive manner, in compliance with legal requirements. The Animal Experimentation Ethics Committee (AEEC) promotes the application of the “3 Rs” to animal experimentation:

- **Refinement** of procedures so that the degree of suffering is kept to a minimum.
- **Reduction** of the number of animals used in research to the minimum necessary for meaningful results.
- **Replacement** of live animals by non-animal alternatives where possible.

Researchers ought to familiarise themselves with these principles. Information can be obtained from the UK National Centre for the Replacement, Refinement and Reduction of Animals in Research (www.nc3rs.org.uk).

Other ethical principles which are associated with animal experimentation can be generalised as follows:

- *Proportionality* – animals should be used only where this is necessary to further the aims of the research. Moreover, the number of animals used should be the minimum necessary to meet the stated aims.
- *Minimisation* of pain and suffering in animals.
- *Justification* – the potential benefits or gains to be secured from the research ought to outweigh the pain, suffering or death inflicted upon the animals.
- *Ethical sourcing* of animals from reputable or appropriate sources (where animals have not been bred within the institution).
- Promotion of the *welfare and safety* of animal subjects used in research.
- Adherence to *professional and legal requirements*, including Government licensing where necessary.

Both the AEEC and Biological Services Unit (BSU) will provide guidance to researchers in ensuring that animals used in experimentation are treated in accordance with these principles.



Section 4

Who Has Responsibility for Ethics in Research?

It is the responsibility of **all researchers** to adhere to all legal requirements associated with their research. Furthermore, it is the responsibility of each individual researcher to adhere to the principles of good research practice and other ethical requirements. In particular, researchers ought to ensure that all relevant guidelines and regulations are followed, and that they abide by any directions from the relevant Committee or UREB. Once a research protocol has been authorised by a Committee, the researcher must adhere to the approved methodology. Any proposed deviation from the protocol must be resubmitted to the relevant Committee for reappraisal.

Additionally, restrictions or stipulations may be placed on researchers by statutory bodies, funding bodies, professional organisations and, in the case of medical researchers, by hospital and health authorities. It is the responsibility of the researcher to bring any such factors to the attention of the Committee as part of the review process.

Research projects conducted by students (undergraduate or postgraduate) may also require approval from an appropriate research ethics committee. Supervisors of such projects have a responsibility to ensure compliance by their students.

Progress Reports

The approving Committee may require the researcher to submit progress reports at periodic intervals. If an adverse incident should occur, this must be reported in appropriate detail to the Committee immediately. An adverse incident is, in general, an event occurring in the course of a study which has a significant and unfavourable effect on the welfare of any research participant. The reporting requirements for adverse events which occur in clinical trials must be strictly observed.



Section 5

Which Ethics Committee Should You Contact?

First, it should be noted that a large proportion of research conducted within UCC **does not** need prior ethical review. For example, library-based research, or research using non-identifiable data does not raise concerns for the dignity or safety of participants. Other than following principles of good research practice, no further ethical dimension to the conduct of the research is apparent.

However, much research within UCC does necessitate the support and safeguards provided by ethical review. UREB considers that prior scrutiny by a Committee is necessary where a research project proposes to:

- involve interaction with, or observation of, human participants;
- access, use or process personal information or data which could identify individuals;
- access or utilise human tissue samples; or
- use animals in experimentation.

Review by a Committee may not be required for:

- research utilising existing publicly available documents or data;
- observational studies in public places in which the identity of the participants remains anonymous;
- quality assurance studies;
- audits.

Researchers are required to submit research proposals to the Committee most relevant to their research methodology.

It should be stressed that UCC has no desire to place unnecessary administrative burdens on researchers. It is not envisaged that multiple review by several Committees should take place. However, following preliminary examination a Committee might deem it appropriate to refer a proposal to a different Committee.

Clinical Research

If the research project is clinical in nature, then it must be referred to the Research Ethics Committee of the Cork Teaching Hospitals (CREC). The requirements of CREC are set out in the Committee's manual which is freely available from its secretariat. In broad terms, prior approval is necessary where the research methodology involves:

- therapeutic interaction with a human participant;
- a clinical trial of, *inter alia*, a medical device, medicinal product or clinical technique as stipulated under relevant legislation;
- development of diagnostic techniques using human participants;
- access to, or utilisation of, human tissue and body fluids;
- access to, or utilisation of, identifiable medical data concerning individuals (such as clinical records) by parties not directly concerned in the provision of care to these individuals;
- interaction with / observation of individuals in a healthcare context or setting.

Email contact: crec@ucc.ie

Social Research

Non-clinical research which involves human participants comes within the remit of the Social Research Ethics Committee (SREC). Ethical review by SREC is strongly recommended where the methodology is not clinical or therapeutic in nature and proposes to involve:

- direct interaction with human participants for the purpose of data collection using research methods such as questionnaires, interviews, observations, focus groups etc.;
- Indirect interaction with human participant for example using observation, web surveys etc.;
- access to, or utilisation of, data concerning identifiable individuals.

Please note, if a research protocol falls into both the jurisdictions of CREC and SREC, then the application will usually be referred to CREC. This is to safeguard the proportionality of clinical risk versus therapeutic benefit.

Email contact: srec@ucc.ie

Animal Experimentation

Any research which involves experimentation on animal subjects must be approved by the Animal Experimentation Ethics Committee (AEEC). This is in addition to obtaining the necessary licences for animal experimentation as prescribed by law. If seeking to apply or renew an animal experimentation licence, the researcher must first refer to the AEEC.

Email contact: aeec@ucc.ie

The following appendix should prove useful when deciding to which committee, if any, an application should be made.





Appendix 1

Which is the Appropriate Research Ethics Committee?

Please note: The following questionnaire is intended as a **guide** only. It is the responsibility of each researcher to reflect on whether his/her proposed research engages ethically sensitive issues and therefore requires ethical scrutiny. If a researcher is in any doubt as to whether s/he needs prior ethical approval, then it is his/her responsibility to contact UREB to discuss the matter.

Question 1. Does the research project you wish to pursue involve:

- direct or indirect interaction with human participants?
- gathering, accessing, using or processing personal information or data which could identify individuals?
- accessing or using human tissue?
- using animals in experimentation?

If you have ticked any of the above boxes, then you need to obtain prior approval from a relevant Research Ethics Committee. Please go to Q. 2 below.

Question 2. Does the research project you wish to pursue involve:

- therapeutic interaction with a human participant?
- a clinical trial of a medical device, medicinal product, clinical technique, etc?
- development of diagnostic techniques using human participants?
- access to, or utilisation of, human tissue or body fluids?
- access to, or utilisation of, identifiable medical data concerning individuals (such as clinical records) by parties not directly involved in the care of these individuals?
- interaction with, or observation of, participants in a healthcare context or setting?

If you have ticked any of the above boxes, then your research proposal must be reviewed by the Research Ethics Committee of the Cork Teaching Hospitals (CREC). You do not need to obtain approval from more than one Research Ethics Committee.

Question 3. Is the research you wish to pursue non-clinical in nature and does it involve:

- direct interaction with, or observation of, human participants outside of a healthcare context or setting?
- gathering, accessing or using identifiable data concerning individuals outside of a healthcare context or setting?

If you have ticked any of the above boxes, then you must refer your proposal to the Social Research Ethics Committee (SREC).

Question 4. Does the research you wish to pursue involve:

- using animals as subjects in experimentation?

If you have ticked the above box, then you need to refer your proposal to the Animal Experimentation Ethics Committee (AEEC).

Contacts

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