# Research Ethics at University College Cork

Revised April 2024

## 1. Purpose of this Document

This document supplements the University College Cork Code of Research Conduct (Rev'd 2021) and provides further detail on the operation of research ethics governance at UCC.

## 2. Why is Research Ethics Governance Important?

The application of Research Ethics addresses the requirement to ensure that fundamental ethical standards are met in our work as researchers. Research ethics governance is used by institutions that undertake research. Ethical review and the practical application of ethics within research play an essential part in ensuring the integrity of research.

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

- It ensures that institutional and individual responsibilities under the law are complied with;
- 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, researchers, funding bodies, and wider society;
- It helps in protecting the interests of all parties involved in research; research participants/donors/citizens, investigators, funding bodies, and the host institution;
- It helps in fulfilling obligations to indemnity insurers.

This model has direct benefits for academic and research staff:

- It provides impartial ethical oversight of research projects;
- It assures institutional support to staff who have obtained institutional ethical approval;
- It makes research proposals more attractive to funding bodies and is necessary to obtain funding and to operationalise research activity;
- It is often an explicit requirement for publication of research;
- It promotes quality, efficiency, and clarity in research protocols;
- It may provide specific guidance with regard to, *inter alia,* informed consent, confidentiality, data management, data protection and privacy policies, protection of vulnerable groups (e.g., children, people with disability, representatives from ethnic and cultural groups etc.) and the implementation of the 3Rs principles (Replacement, Reduction, and Refinement) in animal experimentation.

## 3. Responsibility for Ethics in Research

It is the responsibility of **all researchers** (regardless of the nature and purpose of their research) and all **supervisors of student research** (undergraduate and postgraduate) to ensure that research is carried out in an ethical manner, with ethical approval where required, and to adhere to all legal requirements associated with their research.

Furthermore, it is the responsibility of all researchers and supervisors of research in UCC to adhere/ensure student adherence to the University College Cork *Code of Research Conduct.*

In addition to the generally applicable requirements, formal **prior** ethics approval by a recognised Research Ethics Committee (REC) is required for certain categories of research (see Section 5 below). Research ethics approval must always be obtained **in advance of carrying out research** and **ethical approval will not be granted retrospectively**.

Where prior approval is required, researchers must submit their research ethics applications for review to the REC most relevant to their research area (see Section 6 below). The Chairperson of the University Ethics Committee (UEC) or Chairperson of the relevant reviewing REC may be consulted for guidance in advance of submission. Following preliminary examination, a REC may deem it necessary to refer a proposal to a different REC.

All researchers/supervisors of research must ensure that all relevant guidelines and regulations are followed, and that they/their students abide by directions from the relevant REC in line with UCC's Code of Research Conduct. Once a research protocol has been authorised by a REC the researcher must adhere to the approved protocol. Any proposed deviation must be resubmitted as an ethics amendment request to the relevant REC. 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 REC as part of the review process.

The approving REC 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 REC 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. In addition to these requirements, any reporting requirements for adverse events which occur in clinical trials must be strictly observed.

## 4. Principles of Ethical Research

As stated in the *Code of Research Conduct*, UCC is committed to the European Code of Conduct for Research Integrity and 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 ethical values.

All research involving human participants, tissue or data must comply with the following international research ethics standards:

- Nuremburg Code (1947)
- World Medical Association Declaration of Helsinki (1964, as amended)
- Council for International Organizations of Medical Sciences (CIOMS) Guidelines.

In brief, these standards require that the follow principles are adhered to:

- The research must have a social, scientific, or clinical value;
- The research must be scientifically valid and must be carried out in a methodologically rigorous manner;
- All/any participants in the research must be fairly selected based on the goals of the study and not on matters of convenience;
- There must be a favourable risk-benefit relationship, including that all potential risks to participants are minimised and all potential benefits are maximised;
- The participant must have received accurate and adequate information about the research, have understood the relevance of this information and made a voluntary and uncoerced decision to participate in the research;
- All participants must be treated with respect at all times;
- Confidentiality of participants and their data must be respected.

## 5. Research involving Animal Experimentation

UEC is committed to ensuring that animal experimentation is conducted in a respectful and sensitive manner, in compliance with all legal requirements. The Animal Experimentation Ethics Committee (AEEC) promotes the application of the "3Rs" to animal experimentation:

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

Researchers ought to familiarise themselves with these principles. Further information can be found in the European Union Directive 2010/63/EU on the protection of animals used for scientific purposes, its transposition into Irish law (SI No 543 of 2012) and from Health Products Regulatory Authority (HPRA), the competent authority in Ireland responsible for the protection of animals used for scientific purposes.

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 and 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 stress, 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 authorisations where necessary;
- Culture of care: emphasising the ethical responsibility to ensure the welfare and humane treatment of animals used in scientific studies, through compassion, respect, and adherence to strict ethical and legal standards.

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.

## 6. Overview of UCC Research Ethics Governance Framework

The research ethics framework within UCC comprises the **University Ethics Committee (UEC)** and the three sub-Committees that report to it. UEC is a Committee of Academic Council, and it reports annually to Academic Council.

UEC promotes ethical approaches to research, teaching, and other related institutional activities across UCC, and develops research ethics governance, policy, and strategy in these areas. UEC advises Departments/Schools/Colleges and associated centres and units on good practice in research ethics.

UEC does **not** process individual research proposals for ethical approval. This responsibility lies with three Research Ethics Sub-Committees (RECs) which report to UEC. The nature of the research proposal determines the appropriate Committee. The membership of each Committee reflects academic diversity and concentrates particular expertise and experience. Research ethics approval must always be obtained in advance of carrying out research and ethical approval will not be granted retrospectively.

The three RECs are:

- The Clinical Research Ethics Committee of the Cork Teaching Hospitals (**CREC**);
- The Animal Experimentation Ethics Committee (**AEEC**);
- The Social Research Ethics Committee (**SREC**).

The **Clinical Research Ethics Committee of the Cork Teaching Hospitals** 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:

- Therapeutic interaction with human participant(s);
- A clinical trial of a medical device, medicinal product or clinical technique as stipulated under the applicable legislation, that does not come under the remit of the NREC;
- Development of diagnostic techniques using human participants;
- Access to, or utilisation of, human tissue and/or 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 those individuals;
- Interaction with/observation of individuals in healthcare settings.

The Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) is not recognised by the Department of Health under regulation 7 of the European Communities Regulations (Clinical Trials on Medicinal Products for Human Use (S.I. 190 of 2004)). The National Research Ethics Committees (NRECs) are responsible for the ethical review of Clinical Trials of Investigational Medicinal Products (CTIMPs) and the clinical

investigations of Medical Devices (MD) – see www.nrecoffice.ie/ for information

The **Animal Experimentation Ethics Committee** deals with proposals to use vertebrate animals (or cephalopods, as per 2010/63/EU) in research. AEEC approval is required for animal experiments carried out by UCC staff. AEEC approval is in addition to the legal requirement for authorisations granted by the Health Products Regulatory Authority (HPRA) prior to conducting animal experiments.

The AEEC is guided by legislative requirements, in particular the European Union Directive 2010/63/EU, transposed into Irish law in December 2012 by SI No 543 of 2012 and implemented by the HPRA.

The AEEC works in liaison with the UCC Biological Services Unit (BSU).

The **Social Research Ethics Committee** has responsibility for ethical oversight of non-clinical research involving human participants and their data. Ethical review by SREC is required where the study 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 observation with human participant for example using observation, web surveys etc.
- Access to, or utilisation of, data concerning individuals.

## 7. Identifying the Relevant REC

**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 CREC manual which is available from its secretariat. In broad terms, prior approval is necessary where the research methodology involves:

- Therapeutic interaction with human participant(s);
- A clinical trial of, *inter alia,* a medical device, medicinal product, or clinical technique; Note that falls outside the remit of the National Research Ethics Committee – NREC.
- 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 required 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 individuals.

Please note, if a research protocol falls into both the jurisdictions of CREC and SREC, then the application should usually be referred to CREC.
**Email contact:** *srec@ucc.ie*

**Animal Experimentation**

Any research which involves experimentation on vertebrate animals or cephalopods must be approved by the Animal Experimentation Ethics Committee (AEEC) with input from the Animal Welfare Body. This is a prerequisite to obtaining the necessary authorisations for animal experimentation as prescribed by law. If seeking to apply for or renew an existing animal experimentation authorisation, the researcher may first refer to the Animal Welfare Body, or the Biological Services Unit, or contact AEEC.
**Email contact:** aeec@ucc.ie

## 8. Research Ethics Review Appeals Procedure

This procedure applies to any researcher / research team, who wishes to appeal the decision made by a UCC research ethics sub-committee. A Supervisor / Principal Investigator may also bring forward an appeal on a student's /students' behalf in accordance with the procedure. The UEC is not expecting or soliciting appeals and this procedure should only be invoked when all avenues with the relevant UEC ethics sub-committee through its chair, have been exhausted.

https://www.ucc.ie/en/research/culture/ethics/applyforethicalapproval/#appeals-procedure

***Glossary of terms:***
*Animal Experimentation Ethics Committee (AEEC)*
*Biological Services Unit (BSU)*
*Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC)*
*National Research Ethics Committee (NREC)*
*Research Ethics Committee (REC)*
*Social Research Ethics Committee (SREC)*
*University Ethics Committee (UEC)*