

Research Ethics at University College Cork

Revised 2016



1: Purpose of this Document

This document supplements the University College Cork [Code of Research Conduct \(rev'd 2016\)](#) 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 certain basic ethical standards are met in our work as academics. Research ethics governance is a systemic tool used by institutions that undertake research. Where proposed research may engage potentially ethically sensitive issues (such as the involvement of human participants), institutional safeguards must be put in place to promote best practice

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, 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 helps in fulfilling obligations to indemnity insurers

Such a model also 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 generally necessary in order to obtain funding
- It may be an explicit requirement for publication of research
- It promotes efficiency and clarity in research protocols

- 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.

3: Responsibility for Ethics in Research

It is the responsibility of **all researchers** (regardless of the nature of their research) and all **supervisors of student research** (undergraduate and postgraduate) to ensure that the research is carried out in an ethical manner 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 Research Ethics Committee (REC) is required for certain categories of research (see Section 5 below).

Where prior approval is required, researchers are required to submit research proposals to the REC most relevant to their research area (see Section 6 below). Where it is not clear to a researcher to which REC a protocol should be submitted, the Chairperson of the UEC may be consulted for guidance in advance of submission. On rare occasions, 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 any directions from the relevant REC. Once a research protocol has been authorised by a REC the researcher must adhere to the approved methodology. Any proposed deviation from the protocol must be resubmitted to the relevant REC 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 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

(i) Research Using Human Participants, Tissue or Data

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 be 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 must be respected.



(ii) 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

- 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. Further information can be obtained from the UK National Centre for the Replacement, Refinement and Reduction of Animals in Research.

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 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.

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.

5: 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 and to the Governing Body.

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

UEC does **not** process individual research proposals for ethical approval. This responsibility lies with three Research Ethics 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.

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
- 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.

CREC 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).

The **Animal Experimentation Ethics Committee** deals with proposals to use animals 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 (Protection of Animals Used for Scientific Purposes) Regulations 2012 as amended, with input from the Animal Welfare Body, UCC.

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. 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 identifiable individuals.

SREC is an inter-disciplinary Committee; its remit includes, but is not limited to, research concerning business, sociology, psychology, economics, politics, marketing, social work, law and epidemiology.

5: 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
- 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 identifiable 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 animal subjects 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 must first refer to the Animal Welfare Body and Director of the Biological Services Unit.

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