



# Research Ethics Policy

Policy for ethics for research and innovation activities carried out at TU Dublin and/or by TU Dublin staff and students

Dr Steve Meaney

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## 1. Document Control Summary

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## 2. Introduction / Context

The staff and students of TU Dublin engage in a wide variety of different research and innovation endeavours, both internally and in collaboration with external academic, community, society and industrial partners. TU Dublin is committed to ensuring that all of our research is conducted in accordance with international best practices for responsible research and innovation, i.e.

- that researchers will adhere to a local code of conduct for good research practice;
- that research involving human participants or experimental animal models will be reviewed by an independent review board.

Fostering and supporting good research practice is essential to minimise the significant risks of research misconduct, given the potential for reputational damage to the University and individual researchers, and the subsequent impact on the ability to attract funding and the best staff and students. A robust, independent ethics review framework is one of the primary measures to protect against poor research conduct (see TU Dublin Research Integrity policy for additional details in relation to responsible conduct of research).

## 3. Purpose

The University expects that all research and innovation activities carried out by, or on behalf of, TU Dublin adheres to the highest standards of ethical research practice. This document describes the core policy for research ethics at TU Dublin. It has been designed to support TU Dublin researchers in the conduct of research and to facilitate a unitary approach to research ethics across the University. This will enable the conduct of research that is responsible, ethical and intellectually honest, and which minimises the risks of poor research conduct.

## 4. Scope

This policy applies to all TU Dublin researchers – including those with positions as emeritus/emerita staff, visiting scholars and those with adjunct status – who are engaged in research, in any domain of inquiry, and at all levels of the national framework for qualifications.

All those engaged in research have a responsibility to facilitate the ethical conduct of research. Given the highly collaborative nature of modern research, this policy will apply to TU Dublin researchers wherever research takes place.

This policy does not apply to data collection and analysis activities that are carried out within TU Dublin which lack an explicit research intent (e.g. internal service evaluation, audit, employee surveys).

It does not apply to colleagues who undertake research work in their own right in a private capacity without recourse to any form of TU Dublin Resources, facilities or insurance indemnification. If a colleague engages in research and innovation activities, including dissemination of outputs of these activities, in a manner facilitated by or conditional on the use of their TU Dublin affiliation, they shall be considered subject to this policy, even if the research is carried out in a private capacity as noted above.

## 5. Definitions

The following are some identified core definitions used in this document. These include:

- Conflict of Interest - refers to a conflict between the duties of an individual as researcher at TU Dublin on the one hand and their personal interests on the other.
- Domain – a broad area of related research and innovation activity within which researchers share broad methodological approaches and epistemological viewpoints, (e.g. Clinical, Life and Biomedical Science or Arts, Humanities and Social Sciences).
- Ethics dumping – the process by which researchers export unethical research practices to jurisdictions where the legal and ethical standards are less stringent
- Research and innovation - Research and innovation activities are creative and systematic efforts carried out with the intention to expand the boundaries of human knowledge and/or to create novel applications of knowledge.
- Research integrity – the performance of research to the highest standards of professionalism and rigour, to support the patency and reliability of the research record (i.e. as published in peer-reviewed publications or otherwise disseminated)
- Research ethics review – the process which ensures that, when engaging in research with human participants or using experimental animal models, all researchers engage in best practice that protects all such participants/subjects.
- Research misconduct – any activity that compromises the outputs of a research work, including (but not limited to) data fabrication and/or falsification, plagiarism, poor publication practice, poor data stewardship, financial malpractice and unethical research methods.
- Researcher – staff and/or students of TU Dublin – including those with positions as emeritus/emerita staff, visiting scholars and those with adjunct status – who are engaged in activities with a clear and explicit research intent.
- Responsible conduct of research – the constellation of research behaviours, supports and practices that enables research and innovation activities to be conducted with integrity, being mindful of the ethical, legal and social dimensions of the activity



- Reviewing Research Ethics Committee – a domain-aligned subcommittee of the University Research Ethics Committee responsible for the independent review of domain-aligned submissions.
- Student – an individual who is registered within TU Dublin for a defined award at any level of the national framework for qualifications.
- University Research Ethics Committee – a cross-domain university committee which is responsible for overall oversight and direction of research ethics

## 6. Policy Details:

### 6.1 Policy Overview

This document outlines the core policy by which the University will support and facilitate the conduct of research and innovation activities that are responsible, ethical and intellectually honest, and which minimises the risks of poor conduct. It describes the core policy for research ethics at TU Dublin and the general framework to facilitate research ethics review at the University.

Further procedural details are contained in RESOP00X – TU Dublin Guidelines for Ethics Review Committees.

### 6.2 Principles of Ethical Conduct of Research

The general principles for the ethical conduct of research and/or innovation activities, and the consideration of the ethical dimension of such activities at TU Dublin, are aligned with best national and international practices and guidelines (e.g. the Declaration of Helsinki, The Belmont Report, the Report of the Irish Council of Bioethics, the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights, the Council for International Organizations of Medical Sciences Guidelines, the Health Research Regulations, the DCYA Guidance for developing ethical research projects involving children).

In brief, all researchers should:

- Respect the agency, autonomy and privacy of all research participants, via a clear process of consent and assent;
- Carry out research which maximises the benefit while minimising any harms, for society, the researcher and the participant,
- Ensure that all research participants are treated fairly and justly, research practices are not discriminatory and that the benefits of research outputs are distributed fairly,
- Ensure that they are competent to carry out the proposed research,
- Ensure that all proposed research is designed and carried out in alignment with best practices with the research area, and that the design is appropriate to answer the research question posed,
- Ensure that they have considered the impact of potential conflicts of interest
- Consider the societal impact of their research,
- Ensure that ethical authorship, publication and dissemination practices are followed,
- Be compliant with all relevant legislation related to their work,
- Ensure that data is collected and managed in line with FAIR principles (i.e. Findable, Accessible, Interoperable and Reusable).

Note that as the ethical principles applied to research are not static, this is not to be considered to be an exhaustive list and that lack of mention of particular broad principles or omissions in this overview should not be taken as conclusive in any use of this policy to support a particular position in relation to the principles of the ethical conduct of research.

### 6.3 Responsibilities of those engaged in research and innovation

All those involved in research and innovation activities, including research support staff and University leadership, must familiarise themselves with the University's requirements in relation to research ethics and complete a baseline training in Ethical Conduct of Research.

Research Postgraduate student and postdoctoral researcher supervisors, and line managers of contract research staff, are responsible for the review and approval of submissions to a reviewing research ethics committee in advance of their submission. They must ensure that all researchers reporting to them are facilitated to complete required training and that research and innovation activities are aligned with the highest standards of research ethics.

Individuals who are registered for a research degree at another higher educational institute outside of TU Dublin must ensure that they are compliant with all relevant ethics policies at that institution and the requirements of any partner organisations, including TU Dublin, which may be required to complete research with that organisation (e.g. access of participants) are met.

### 6.4 Responsibilities of the University

To support the conduct of research as noted above, the University will:

- Establish and maintain structures and processes to support independent review of the ethical perspective of research that is proportional to the ethical risk of the activity,
- Facilitate the provision of training in research ethics and maintaining a record of this training,
- Maintain oversight of the research ethics review structures of the University,
- Provide clear guidance on ethical best practice and University expectations for different types of research activity,
- Support a research culture that facilitates researchers to conduct themselves in a manner that ensures ethical behaviour and supports good research conduct.

### 6.5 Principles for Ethical Review

All research and/or innovation activities will be subjected to an independent review, which may be by a designated committee or via a self-assessment process. The general framework applied to the review of broad categories of research and innovation activities carried out at TU Dublin are as noted below, recognizing that it is not practicable to account for every activity. In each principle the first bullet (○) notes the scope of the activity and the second bullet (●) notes the review requirement.

- Research and/or innovation activities which are based in a laboratory, workshop (engineering or otherwise) and/or studio (artistic, design or performance), and which only use research materials from reputable research suppliers.
  - No formal committee review of these research and innovation activities is required. A self-assessment and declaration process will apply to ensure compliance with other relevant University policies (e.g. data protection, genetically modified organisms).

- Activities which relate to research and innovation capacity building and/or infrastructural development.
  - No formal committee review of these research and innovation activities is required, as these activities do not in-and-of-themselves have a research intent. A self-assessment and declaration process will apply to ensure compliance with other relevant University policies.
- Research and/or innovation activities which involve the interaction with and/or involvement of human participants in any setting (e.g. on campus, in the field), but which does not include collection of biological material from them (e.g. interviews, sensory testing).
  - All such research and/or innovation activities **must** be formally reviewed by a reviewing research ethics committee of TU Dublin before their commencement.
- Research and/or innovation activities which involve interaction with human participants in any setting, outside of the context of regulated activities (e.g. the Clinical Trials Regulation) and which involve the collection of biological material.
  - All such research and/or innovation activities **must** be reviewed by a reviewing research ethics committee of TU Dublin before their commencement.
- Research and/or innovation activities which fall under an applicable directive, e.g. the Clinical Trials Regulation, and which may involve the collection of biological material as noted in point 3. above.
  - All trials which fall under one of more of the statutory regulations which govern the conduct of such trials (e.g. the Clinical Trials Regulation, the Medical Device Regulation) **must** be reviewed by the relevant National Research Ethics Committee (NREC), the statutory body which reviews clinical trials and/or investigational medical devices, and where relevant the Health Protection Regulatory Authority (HPRA) or other relevant regulatory bodies. Such reviews should take place in advance of the review by a reviewing ethics committee of TU Dublin. Note that for collaborative research a review by a hospital research ethics committee may also be required.
- Research and/or innovation activities which require the use of live animal models.
  - TU Dublin does not have the capacity to accommodate the use of advanced experimental animal models (e.g. mouse models). Research using such models is carried out in collaboration with research performing organizations which have appropriate facilities should be approved by the Animal Research Ethics Committee of that organization, in advance of a review by a reviewing ethics committee of TU Dublin. The research must comply with all relevant requirements of the HPRA and other relevant regulatory bodies.
- Recognition of external ethical approval
  - TU Dublin recognises that our researchers have an extensive collaborative network and that research and innovation activities may take place across and between different research performing organisations. Ethical approval received from an external ethics committee may be recognised as valid by the domain-relevant reviewing ethics committee of TU Dublin who will ensure that the approved activities are in alignment with TU Dublin's standards and that no 'ethics

dumping’ is taking place. A formal submission to the reviewing research ethics committee will be required to support the decision to recognise such external ethical approvals. The University may request modifications and/or amendments to any research protocol previously approved by an external ethics committee.

Note that in relation to assessing the **requirement** for a particular form of review, no distinction is made between the mode of the activity, e.g. in-person or online, the age or perceived vulnerability of the participant. The key criterion is that there is a participant with agency and autonomy who can make, directly, with support or by proxy when appropriate, a decision to participate in the research activity.

The requirement for a Data Protection Impact Assessment (DPIA) should be determined in consultation with Data Protection Officer and the Office for Information Compliance. As a general rule, all research which involves human participants will require as a minimum the completion of the University’s DPIA screening process.

## 6.6 Research ethics committee structure

Research ethics committees at TU Dublin are arranged in a hierarchal structure as follows:

- The TU Dublin University Research Ethics Committee (UREC) is responsible for overall oversight of research ethics at the university, provision of advice on policy and standards for research ethics monitoring and review. It oversees the independent review decisions on ethical aspects of research as determined by domain-aligned subcommittees. The UREC is chaired by the university head of research ethics and integrity.
- Domain-aligned sub-committees of the UREC (Reviewing Research Ethics Committees, RREC) are responsible for the day-to-day review of submissions for ethical opinion by researchers and provision of domain-aligned advice. RRECs will be established by the UREC along broad disciplinary lines (e.g. clinical and life sciences, humanities and social sciences) to carry out this work and the complement of RRECs may be expanded or reduced by the UREC as required. As these are pan-University committees, researchers are expected to apply to the committee most appropriate to the nature of the research, rather than any academic affiliation. In the event of multidisciplinary research, a specific domain-committee may co-opt members of another RREC to ensure that the relevant expertise is available.
- School-level discipline-based committees are responsible, with the support of the UREC, for the evaluation of matters of research ethics for students registered on undergraduate and taught postgraduate programmes.

Further details of the ethics review process and associated review principles are provided in RESOPxx – TU Dublin Guidelines for Ethics Review Committees.

## 6.7 Independence of the REIC

Notwithstanding the submission of reports of its work to UET, in terms of setting principles and guidelines for review practices and advising on matters of ethical standards, the UREC and the Office of Research Ethics and Integrity are considered independent.



## 6.8 Approval process

Amendments to this policy must be approved by Governing Body.

## 6.9 Change Process

TU Dublin Research and Innovation provides administrative support, and the Vice President for Research and Innovation has responsibility for this Policy.

This policy will be reviewed at least every three years and more often if needed, including within six months of the publication of any new or updated Policy Statement on Ensuring Research Integrity in Ireland, the Health Research Regulations or change in other relevant national policy or guidance.

## 7. Related Documents

This Policy refers to other TU Dublin policy documents including:

- RESOPxx – TU Dublin Guidelines for Ethics Review Committees (in preparation)
- TU Dublin IP Policy 2023

## 8. Document Management

### 8.1 Version Control

VERSION NUMBER	VERSION DESCRIPTION / CHANGES MADE	AUTHOR	DATE
V0.1	Initial draft	Steve Meaney	27 <sup>th</sup> April 2023
V0.2	Updated draft for R&I review	Steve Meaney	28 <sup>th</sup> April 2023
V0.3	Updated draft for UET review	Steve Meaney	14 <sup>th</sup> August 2023
V0.4	Updated drafts following UET feedback	Steve Meaney	5 <sup>th</sup> September 2023
V0.5	Updated draft for R&I review	Steve Meaney	19 <sup>th</sup> September 2023
V0.6	Updated draft for UET review	Steve Meaney	11 <sup>th</sup> October 2023
V0.7	Updated draft following UET feedback	Steve Meaney	25 <sup>th</sup> October 2023
V0.8	Updated draft following GB-ARC feedback	Steve Meaney	14 <sup>th</sup> November 2023
V0.9	Updated draft following GB feedback	Steve Meaney	28 <sup>th</sup> November 2023

### 8.2 Document Approval

VERSION NUMBER	APPROVAL DATE	APPROVED BY (NAME AND ROLE)
V0.9	10 <sup>th</sup> January 2023	Governing Body

### 8.3 Document Ownership

Accountability to defining, developing, monitoring and updating the content of this document rests with the Vice President for Research and Innovation

### 8.4 Document Review

The Vice President for Research and Innovation is accountable to review this document. This document should be approved by both the University Executive Team and Governing Body.

### 8.5 Document Storage

This document will be stored on the TU Dublin content management systems under the Policies INTRANET folder.

### 8.6 Document Classification

As this document is a policy it is classified as TU Dublin Public.