RESEARCH ETHICS UCD

Code of Good Practice in Research with Humans and Animals

Version: 4

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1. INTRODUCTION

UCD is fully committed to the advancement of high quality academic research and to ensuring that all research activities undertaken by University employees and students, or on University premises, that involve human or animal subjects or personal data are undertaken in a way that safeguards the welfare, dignity, rights, health, safety, and privacy of those involved. This commitment extends to all researchers (faculty, staff and students), participants, research subjects, animals, and third parties.

1.1 Purpose of the code

The purpose of this code is to establish and maintain standards of best practice in research for all of UCD's researchers who are engaged in research with human or animal subjects.

1.2 Requirement of the code

The University maintains and requires the highest standards of integrity in all research activity conducted by all UCD researchers, which includes:

- honesty;
- openness;
- leadership and cooperation;
- supervision and training;
- guidance from professional bodies;
- best practice in managing research & conflict of interest;
- documenting research results and storing primary data samples;
- best practice in publication.

UCD's existing structures promote and increase awareness of best practice in ethical research emphasising integrity and rigour, and seek to sustain a culture in which the general principles listed in section 3 below are understood and observed. Such structures include:

- UCD's Research Ethics Committee (and its sub-committees dealing respectively with Human and Animal Research, the Human Research sub-committee drawing on the long-standing expertise of the Research Ethics Committees of UCD's associated teaching hospitals);
- UCD's Animal Welfare Bodies;
- UCD's policy and procedures for investigating and resolving allegations of misconduct.[1]

[1] See *UCD Research Integrity Policy* and *Procedures for Investigating Misconduct in Research*. All policies and policy related documents and forms are subject to amendment. Please refer to the UCD Governance Document Library website for the official, most recent version: https://www.ucd.ie/governance/documentlibrary/

These are underpinned by UCD's Human Resources / contractual policies and procedures. In addition, any member of UCD staff who is subject to ethical guidance from their professional bodies or external agencies should familiarise themselves with those requirements and ensure their compliance with them.

1.3 Status of the code

This code, the *Code of Good Practice in Research* was first approved by the UCD Research Ethics Committee (REC) and by the UCD Governing Authority (GA) in 2004. Subsequent revisions were approved by the REC and Governing Authority in 2010, and 2015.This fourth edition of the code was approved by the REC in September 2019.

2 DEFINITIONS

2.1 Research Ethics

Ethical Research can be defined as a refined and internationally recognized process that ensures that researchers are engaged in good practices for research involving human or animal subjects. Ethics can be defined as the morally right thing to do and in the context of research ethics this involves the protection of humans and animals in research. This means that researchers have a duty of care for their human or animal subjects and researchers are responsible for how they manage their research. Although Research Ethics in UCD strives to safeguard the participants, the researcher, the research, and the university**,** the essential prerequisite for ethical research is the integrity of the researcher.

2.2 Research Integrity

Research Integrity relates to the performance of research to the highest standards of professionalism and rigour in accordance with the law and in the public interest[2]. Integrity means being truthful and living up to professional standards, and in practice requires that research is conducted according to established rules, regulations, guidelines or professional codes. The researcher must only pursue research questions that are designed to contribute to knowledge, be committed to the pursuit and protection of truth, and rely only on research methods which are appropriate to the discipline and to the training and experience of the researcher.[3]

[2] See UCD Research Integrity Policy (https://sisweb.ucd.ie/usis/!W_HU_MENU.P_PUBLISH?p_tag=GD-DOCLAND&ID=184) and UCD Procedures for Investigating the Misconduct of Research https://sisweb.ucd.ie/usis/!W_HU_MENU.P_PUBLISH?p_tag=GD-DOCLAND&ID=185 , UCD Document Library https://www.ucd.ie/governance/documentlibrary/

[3] See The National Policy Statement on *Ensuring Research Integrity in Ireland (2014),* https://www.iua.ie/research-innovation/research-integrity/ *See also the European Code of Conduct for Research Integrity (2017)* https://www.allea.org/wp-content/uploads/2017/05/ALLEA-European-Code-of-Conduct-for-Research-Integrity-2017.pdf *European Science Foundation and ALLEA (All European Academies).*

3. GENERAL PRINCIPLES

3.1 Honesty

At the core of all research endeavour, regardless of discipline or institution, is the need for researchers to be honest in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research, including experimental design, generating and analyzing data, applying for research funding, publishing results and acknowledging the direct and indirect contributions of formal collaborators, principal investigators and other researchers. All individuals in the University's employment must refrain from plagiarism, deception (except where part of a study) or the fabrication or falsification of data or results. Committing any of these actions is regarded as a serious disciplinary offence.[4] Researchers are required to declare conflicts of interest[5]. Researchers are also required to undertake their research in accordance with any provisions that may be laid down by a Research Ethics Committee approval for said research. Researchers are also expected to comply with all statutory obligations that legislation may place upon them when conducting their research, inter alia animal welfare legislation, data protection legislation, etc.

3.2 Openness

Whilst recognizing the need for researchers to protect their own research interests in the process of planning their research and obtaining their results, the University encourages researchers to be as open as possible in discussing their work with other researchers and the public. Once results have been published, researchers are expected to make available relevant data and materials to others, on request (provided that this is consistent with any ethics approvals and consents which cover the data and materials and any intellectual property rights in them, and observant of regulations relating to data protection)[6]. This is in line with Ireland's 2019 "National Framework on the Transition to an Open Research Environment", which, in turn, is aligned with the developing European Commission policy in this area[7].

3.2.1 **Funders' Policies:** When submitting work for publication, authors should adhere to the specific policies, criteria and processes of the relevant funding body, including conditions regarding the publication of their research and its findings in any open access repositories within a set period of time. The vast majority of Irish, European and International funding agencies have open access requirements pertaining to publications arising from research and, increasingly, to research data [8]. Where research funders

[4] See *UCD Plagiarism Policy* and *UCD Code of Practice for Supervisors and Research Degree Students*. All policies and policy related documents and forms are subject to amendment. Please refer to the UCD Governance Document Library website for the official, most recent version.

[5] See *UCD Policy on Misconduct,* UCD Governance Document as above

[6] See *UCD Authorship Policy*, UCD Governance Document Library as above

[7] See https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018H0790&from=EN

[8] See https://libguides.ucd.ie/openaccess/funders; National Framework on the Transition to an Open Research Environment (2019)

include Open Access requirements as a condition of grant funding, researchers are expected to ensure that they comply with such requirements.

3.2.2 **Research Repository UCD:** Research Repository UCD is UCD's open access repository and contains the scholarly publications of researchers at the University. The Repository provides a permanent and stable archive for authors and offers the benefits of making research outputs freely available to a global audience. Depositing papers in the Repository also ensures compliance with funders' open access requirements. Submitting material to the Repository is not intended to be an alternative to standard publication. It is a complementary approach designed to showcase UCD's research output, and to provide a searchable, multi-disciplinary, managed and curated resource. The published version of a paper will also be available in a regular journal of your choice and there will be a link to this published version from the cover page of the Repository version. [https://libguides.ucd.ie/RRU]

3.3 Leadership and Cooperation

The culture and tone of procedures within any organization must be set by those in authority. Within the University it is the responsibility of the President and University Officers, the Principals of Colleges, Heads of Schools, Unit Managers, senior staff and principal investigators to ensure that a research climate of mutual cooperation is created which allows research to be conducted in accordance with good research practice.

Within a research group, responsibility lies with the group leader or principal investigator. These individuals should create a research environment in which all members of a research team are encouraged to develop their skills and in which the open exchange of ideas is fostered. They must also ensure that appropriate direction of research and supervision of researchers and research students are provided. This is underpinned by UCD's Structured PhD Programme and its Research Careers Framework.

3.4 Supervision and training

It is the responsibility of the Heads of Schools, Managers of Units and research group leaders to ensure that all researchers have the opportunity to receive appropriate research training including attendance as necessary on relevant courses and guidance from professional bodies. As part of this responsibility, the University makes available appropriate training courses. In this regard, the needs of new researchers are of paramount importance. Responsibility for ensuring that new researchers and students understand and adopt best research practice as quickly as possible rests with all members of the research community, but particularly with Heads of Schools and group leaders, supported by HR and the UCD Structured PhD Programme, the UCD Research Careers Framework and specialist external training courses. Where research involves personal data, it is the responsibility of the Heads of School and research group leaders to assure researchers are aware of their data protection obligations, and that training appropriate to the nature of the research undertaken, is provided and documented.

3.5 Guidance from professional bodies

It is the responsibility of the researcher to fully abide by the codes of ethics and standards of professional conduct relevant to their profession and any other existing guidance issued by their respective regulatory or professional bodies.

3.6 Best Practice in Managing Research

In research, the contributions of formal collaborators and other researchers who contribute to the research must be properly acknowledged. Principal Investigators must take all reasonable measures to ensure the professionalism, accuracy, integrity and completeness of information contained in applications for funding and in managing research projects, to ensure compliance with all sponsor, institutional, legal, ethical and moral obligations. Research integrity is not only essential to ensure that the research, the researchers, and UCD are held in high regard, but also to maintain a standard of excellence throughout.[9]

3.6.1 Conflict of Interest: It is the policy of UCD that all persons engaged in UCD activity have the obligation to manage or avoid ethical, legal, financial or other conflicts of interest, to ensure that their activities and interest do not conflict with their obligations to the University or its welfare, and to comply with the University's policies on intellectual property, conflict of interest and consultancy and external work.[10]

3.7 Documenting Research Results and Storing Primary Data

3.7.1 Accurate Records: Throughout their work, researchers are required to keep clear and accurate records of the research procedures followed, approvals granted and of interim and final results. This is necessary not only as a means of demonstrating proper research practice, but also in the event of subsequent queries about either the conduct of the research or the results obtained.

3.7.2 Securing Data: Data generated in the course of research, where consent has been obtained, whether electronic or paper format, must be stored securely in UCD and be compliant with all relevant data protection regulations and legal requirements. Any research involving personal data needs to put in place technical and organizational measures appropriate to the type of personal data involved. Depending on the nature of the research and its future use and what a participant consented to, data should either be archived in accordance with the UCD School/Unit guidelines, or held for a period of two years after the completion of a research project (or such period as stipulated by a

[9] See the *European Charter for Researchers* which sets out the basic principles of ethical and professional conduct https://euraxess.ec.europa.eu/jobs/charter/european-charter

[10] See *UCD Conflict of Interest Policy,* and *UCD Consultancy and External Work Policy* at UCD Governance Document Library

funding agency or UCD school or unit), or be securely destroyed after the research degree has been awarded, if it is not required to be held under another applicable policy. When undertaking research involving human subjects, it is essential to keep in mind that they have the legal right to be fully informed about the processing of their personal data. This includes anticipating the requirements of the data's future use when obtaining consent from human participants.[11] It is the responsibility of the researcher to assure compliance of all aspects of personal data processing.

3.7.3 Personal Data: All personal data collected and processed in the course of a research project is subject EU and national data protection legislation https://www.dataprotection.ie/en/legal/data-protection-legislation and to EU Charter of Fundamental Rights https://ec.europa.eu/info/aid-development-cooperation-fundamental-rights/your-rights-eu/eu-charter-fundamental-rights_en, which safeguards the privacy of individuals regarding their personal data.

All researchers must be familiar with the terms of the EU and national legislation and with UCD Data Protection policies and procedures www.ucd.ie/gdpr.Processing operations involving personal data can lead to risks resulting from such processing. It is the duty of the researcher to assess the degree of risk involved in a systematic way. For some research projects where processing risk may be an additional requirement, a Data Privacy Impact Assessment (DPIA) needs to be undertaken and where appropriate, the advice of the DPO sought. All documents that reflect key decisions made regarding the processing of personal data need to be kept for auditing purposes and to document compliance with data protection requirements.

3.7.4 Personal Health Data: Researchers collecting or accessing personal health data must be aware of the additional requirements covering the processing of special category personal data. In addition to the General Data Protection Regulation (GDPR) all health research must also conform to specific national legislation like the Data Protection Act 2018 (Section 36(2)) covering research in the health sciences. Researchers should also be aware that research involving special category data need, in addition to having one or more legal basing (GDPR Article 6), to satisfy one or more conditions that allow for the processing of special category data (GDPR Article 9). They need to put in place 'suitable and specific measures' (Health Research Regulations 2018, Regulation 3(1)(a)-(e)), to ensure the informed consent and confidentiality of personal information relating to the participants in their research and that the research fulfills any legal requirements that apply.

3.7.5 Archiving Data: Where possible, researchers are encouraged to archive their data in an anonymized state for future use. However, it is important to remember that an individual's permission is required to anonymize their personal data, as this usually means they are kept far longer than the duration of the project they were collected for. If archiving data, researchers must ensure that the archive used is appropriate to the

[11] See IT Security Guidelines for further information on the security of data http://www.ucd.ie/itservices/itsupport/itsecurity/
See: The right to be informed (transparency) (Article 13 & 14 GDPR)

nature of the personal data and that consent to archive the data for such future use is sought from participants at the consenting stage of their study. Researchers must ensure that arrangements are in place within their school/ institute or other UCD Unit for the secure storage and management of the archived data and that future access follows the spirit of the original consent and is controlled by the researcher's School or unit in UCD.

3.7.6 Data from another jurisdiction: Where researchers are gathering data in another jurisdiction (outside the Republic of Ireland), they must ensure that the relevant ethical approvals and permissions from the appropriate organization is obtained. Researchers are obliged to know of, understand and obey the laws of confidentiality and to be aware of procedures for collecting, storing, transferring and archiving data from other jurisdictions. Especially in health research, individual EU countries have the flexibility to modify some elements of the GDPR through national legislation.

3.7.7 Policy on Breach of Data Protection: Where there are concerns that personal data were affected by a security incident resulting in a breach of confidentiality, availability or integrity which has the potential to pose a risk to an individual's rights and freedoms, researchers must cease the research immediately and notify the Principal Investigator, the relevant Research Ethics Committee, IT Security (where appropriate) and Office of the DPO (gdpr@ucd.ie)

3.8 Best Practice in Publication

The University requires where possible, that that all research results (funded or not) are published in an appropriate form, such as papers in peer-reviewed journals. This has long been widely accepted as the best system for research results to be reviewed (through the refereeing process) and made available to the wider research community. The University expects, as a minimum, that anyone listed as an author on a paper should accept responsibility for ensuring that s/he is familiar with the contents and can identify their contribution to it.[12] Such papers can also be uploaded to Research Repository UCD, in a parallel process, thereby ensuring compliance with funders' open access requirements[13].

3.8.1 Journal Requirements: Researchers should be aware that many journal editors seek assurances that all research has been approved by an appropriate research ethics committee (REC) or institutional review board (IRB). In addition, journal editors may also seek evidence regarding research practices and ethical aspects of the research.

[12] See *UCD Policy on Authorship*, UCD Governance Document Library https://www.ucd.ie/governance/documentlibrary/
[13] See: https://libguides.ucd.ie/publishing

4. BASIC ETHICAL PRINCIPLES

4.1 Human Research

The University requires that researchers will be familiar with, and adhere to all of the Human Research Ethics Committee Guidelines, and requirements for research and teaching with human subjects.

The basic ethical principles of respect for persons – beneficence, justice and competence – are clearly defined in a number of important historical documents: T*he Nuremberg Code* (1947), *the Declaration of Helsinki* (1964), and *The Belmont Report* (1979).

The *Nuremberg Code*, established in 1947 and adopted internationally in 1949, provides the basic principles of respect for the voluntary nature of human participation in research, true informed consent, and ethical responsibilities of the researcher to ensure human welfare. The Code stipulates that research should involve minimal risk and harm, that the benefits should outweigh the risks, that only researchers who are scientifically qualified should conduct research, and that subjects should be free to withdraw from the research at any time. Subsequent codes have incorporated these principles.

The World Medical Association's 1964 *Declaration of Helsinki* made recommendations similar to those in the *Nuremberg Code* and established the International Code of Medical Ethics. The *Declaration of Helsinki* emphasizes that the needs of research are secondary to the care and well-being of participants and distinguishes between therapeutic and non-therapeutic research.

The *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of biology and Medicine: Convention on Human Rights and Biomedicine* states that the dignity and identity of all persons must be protected and that respect for the integrity, rights and fundamental freedoms of all people must be guaranteed, without discrimination.[14]

The Belmont Report, published in the United States in April 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research.

4.1.1 Respect for Persons

Respect for persons means that individuals should be treated as autonomous agents and persons with diminished autonomy must be protected. Ethics require that decisions are respected, and persons are protected from harm. Human dignity and individual rights

[14] Other documents, that are relevant to researchers while not directly addressing research ethics, include the UN Convention on the Rights of the Child (1989) and the UN Convention on the Rights of Persons with Disabilities (2006) and UNESCO Universal Declaration on Bioethics and Human Rights (2006).

must be treated with respect, and people should not be used merely as a means to an end. In practice, respect for individuals is ensured by the informed consent process in which a discussion of the research project occurs between the researcher and potential participants. Subjects are provided with full and comprehensible information about the research and are given clear assurance that participation is voluntary. Agreement to participate is indicated by a signature on a consent form. It is important to keep in mind that the concept of 'consent' and 'explicit consent' under GDPR is very specific [GDPR Article 4(11); Article 7; and GDPR Recital 32;] i.e. that consent in the traditional sense of research participation is not necessarily the same.

4.1.2 Beneficence and Non-maleficence

Beneficence and non-maleficence are concerned with the protection and well-being of subjects, the researcher is obliged to ensure that the possible benefits to the participants will be maximized and possible harm minimized. Harm includes physical discomfort, psychological or emotional distress, and social and economic disadvantages. Researchers must assess the potential for risks and the possibility of benefits to the participants and be sensitive to their rights and interests. In addition, researchers should reflect on the social and cultural implications of their research. In the end, the benefits to the individual or the importance of the knowledge gained should outweigh the risks.

4.1.3 Justice

Researchers must examine the questions of justice and right, in terms of fairness in distribution of the research benefits and burdens. The selection process must be scrutinized to determine whether participants are selected in a fair and equitable manner, and for reasons directly related to the problem being investigated and not for reasons such as availability or manipulability. Particular concern must be exercised in regard to vulnerable or dependent subjects. Researchers must only pursue research questions that are designed to contribute to knowledge, be committed to the pursuit and protection of truth, and rely only on research methods that are appropriate to the discipline.

4.1.4 Competence

Researchers must strive to ensure and maintain the highest standards of competence in their work. They should recognize the boundaries of their particular competence and the limitations of their expertise. In so doing, researchers should engage in only those research practices and techniques for which they are qualified by education, training or experience. Researchers must show ethical awareness, recognize the risk to subjects of exceeding the boundaries of their competence, and seek to terminate research activity when it is clear the activity is harmful. There is a duty on the researcher to maintain and develop competence by remaining up to date on relevant knowledge, research methods and techniques.

4.2 Animal Research

The University requires that researchers will be familiar with, and adhere, to:

a) All statutory requirements, specifically those in SI 543 of 2012.
b) The University's Policy on the Use of Animal for Research and Teaching.
c) All of the Animal Research Ethics Committee Guidelines

The University actively supports the implementation of the three R's - Reduction, Refinement and Replacement – on which much of the legislation is based.

4.2.1 Reduction, Refinement and Replacement: all research and teaching involving animals should be conducted with the same rigour as research involving human subjects. Researchers are expected to implement the 3Rs principles (Russell and Burch, 1959), which are a widely accepted ethical framework for conducting scientific experiments using animals humanely.

- **Replacement** researchers are expected to support the development and uptake of alternatives to live animals in teaching and research and obliged to use animals only when no alternative exists.
- **Reduction**: researchers are expected to provide statistical justification of animal numbers and ensure that only experiments that are rigorously justified are conducted. It is expected that researchers will maximise the amount of data emerging from animal experiments by judicious experimental design.
- **Refinement**: researchers must ensure that animal welfare is prioritised when designing experiments and must possess appropriate training for whatever research is being carried out.

The University requires that animal care staff ensure that housing and husbandry is in accordance with best international practice guidelines.

5. RESEARCH ETHICS IN UCD

All research carried out by UCD faculty, staff and students that involves either human or animal subjects, requires ethical approval. This can be obtained by submitting an application for full review or low risk review (exemption from full ethical review) to the relevant UCD research ethics committee.

5.1 **Research Involving Human Participants or Biological Samples** Ethical approval is required from the appropriate University and/or Hospital Research Ethics Committees and/or from other regulatory bodies or local research ethics committees as relevant, and as required by individual sponsors or funders (e.g. Horizon 2020 or the Wellcome Trust). Researchers should also ensure the informed consent and confidentiality of personal information relating to the participants in their research and that the research fulfills any legal requirements such as those of the Data Protection Acts 1988 to 2018, and the Freedom of Information Act 2014 as may be amended or revised.

- **External ethics committees:** where research subjects are being accessed through a hospital or other similar clinical setting and where that institution has an ethics committee, it will normally be for that body (and not the relevant UCD committee) to review the application and to give or withhold ethical approval for the study.

- **Clinical Trials:** Researchers carrying out studies that may fall within its scope, should consult the information provided by the Department of Health in relation to approval required for clinical trials involving medicinal products and how this should be obtained: https://health.gov.ie/blog/policy/clinical-trials-involving-medicinal-products/

- **HPRA Approvals:** Researchers should consult *Guide for Ethics Committees on Clinical Investigation of Medical Devices* (2010), section 8 ("Clinical Research Versus Clinical Investigation and 'Off-Label' Investigation") http://www.hpra.ie/docs/default-source/publications-forms/guidance-documents/aut-g0044-guide-for-ethics-committees-on-clinical-investigation-of-medical-devices-v2.pdf?sfvrsn=10

5.2 **Research Involving Animals and Teaching** Ethical approval is required from the University's Animal Research Ethics Committee and all research must also comply with all authorisation requirements under Statutory Instrument 543 of 2012.

6. RESEARCH MISCONDUCT

6.1 Allegations of Misconduct

The University takes seriously any allegation of research misconduct and has written procedures for investigating and resolving such allegations.[15] UCD is committed to promoting an environment that maintains the highest standards of integrity regarding all aspects of academic activity. All those engaged with research should maintain the highest standards of rigour and integrity in all aspects of research and ensure it is conducted according to ethical, legal and professional obligations and standards.[16]

6.2 Failure to comply

Failure to conduct research ethically, lawfully, or in compliance with this Code may be regarded as gross misconduct and may result in disciplinary action including summary dismissal at the suit of the University. Researchers are required to avoid unnecessary or unreasonable risk or harm to human or animal subjects and must ensure that correct procedures are followed for the collection and retention of data gathered during research.

[15] See UCD Procedure for the Investigation of Misconduct in Research, UCD Governance Document Library. See also http://www.ucd.ie/researchintegrity/#services

[16] All policies and policy related documents and forms are subject to amendment. Please refer to the UCD Governance Document Library website for the official, most recent version: https://www.ucd.ie/governance/documentlibrary/

VERSION HISTORY

Version	Date	Summary of changes	Changed by
1	27/10/10	Updated and revised by the REC & approved by the Governing Authority	REC
	26/06/14	Minor revisions suggested by REC	REC Policy Review Working Group
3	19/10/15	Revisions submitted to Governing Authority	REC
4	10/09/19	Revisions submitted to Governing Authority	REC