Code of Good Practice in Research

UCD POLICY

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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, or on University premises, that involve human or animal subjects or personal data are undertaken in a way that safeguards the dignity, rights, health, safety, and privacy of those involved. This commitment extends to all researchers (staff and students), participants, 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 researchers in UCD 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 to promote and increase awareness of best practice in ethical research emphasising integrity and rigour, 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 Boards;
- UCD’s Biomedical Facility;
- UCD’s policy and procedures for investigating and resolving allegations of misconduct.¹

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 familiarize themselves with those requirements and ensure their compliance with them.

¹ See UCD Plagiarism Policy (13/10/05) and UCD Code of Practice for Supervisors and Research Degree Students (28/04/11).
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) in 2004 and by the UCD Governing Authority. Subsequent revisions were approved by the REC and Governing Authority in 2010. This code was approved by the REC in June 2014.

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 researcher, the research, the participants, and the university, the essential prerequisite for ethical research is the integrity of the researcher.

2.2 Research Integrity
Integrity can be defined as being truthful and living up to professional standards, in practice it means 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.²

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 results and committing any of these actions is regarded as a serious disciplinary offence.3 Researchers are required to declare conflicts of interest.

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).

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.

Research misconduct is least likely to arise in an environment where good research practice (e.g. documentation of results, peer review, regular discussion and seminars) is encouraged, and where there is adequate supervision at all relevant levels. It is the responsibility of Heads of Schools to clearly convey the standards and protocols for Research in their Schools and Units (e.g. supervisors' responsibilities including frequency of contact, scrutiny of primary data, development needs of research trainees) and to ensure that adherence to these standards is integral to the life of the School/Unit.

3 See UCD Plagiarism Policy (13/10/05) and UCD Code of Practice for Supervisors and Research Degree Students (28/04/11).
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 module, the UCD Research Careers Framework and specialist external training courses.

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.

3.6.1 **Conflict of Interest**: It is the responsibility of researchers, group leaders, senior staff and Heads of Schools to identify and declare any potential or actual conflicts of interest, whether financial, personal, ethical, legal, or other, so that this does not become a complicating or actionable issue, and to comply with the University’s policies on intellectual property, conflict of interest and consultancy and external work.

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 case questions are subsequently asked about either the conduct of the research or the results obtained.

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4 See the *European Charter for Researchers* which sets out the basic principles of ethical and professional conduct [http://ec.europa.eu/euraxess/index.cfm/rights/index](http://ec.europa.eu/euraxess/index.cfm/rights/index)

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. Depending on the nature of the research and its future use (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 (such as a period stipulated by a funding agency or UCD school of unit), or destroyed after the research degree has been awarded, if it is not required to be held under another applicable policy. The collection of data must anticipate the requirements of the data’s future use when obtaining consent from human participants.\(^6\)

3.7.3 **Personal Data:** All personal data collected and processed in the course of a research project is subject to the terms of the Data Protection Acts 1988 and 2003 (as may be amended), which safeguards the privacy of individuals regarding their personal data. All researchers must be familiar with the terms of this legislation and with UCD Data Protection policy and procedures ([www.ucd.ie/dataprotection](http://www.ucd.ie/dataprotection)).

3.7.4 **Personal Health Data:** Researchers collecting or accessing personal health data must be aware of the additional requirements covering sensitive personal data and all health research must conform to the guidelines covering research in the health sector as published by the Office of the Data Protection Commissioner.\(^7\) 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 and 2003), and the Freedom of Information Acts (1997 and 2003 as may be amended).

3.7.5 **Archiving Data:** Where possible, researchers are encouraged to archive their data in an anonymized state for future use. If archiving data, researchers must ensure that consent to archive the data for 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 is controlled by the researcher’s School or Institute 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.

3.7.7 **Policy on Breach of Data Protection:** Where there are concerns or questions related to Data Protection aspects of the research, researchers should contact the UCD Data Protection Officer via the UCD Legal Office. Where researchers become aware that they are, or may be in breach of the Data Protection Acts 1988 and 2003 (as may be

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\(^7\) [Data Protection Guidelines on research in the Health Sector](http://www.dataprotection.ie), available on the Commissioner’s website at [www.dataprotection.ie](http://www.dataprotection.ie).
amended), through having been granted access to personal data, and to which they are therefore not entitled, they must cease the research immediately and notify the Principal Investigator, the relevant Research Ethics Committee and Data Protection Officer.

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, usually 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.

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.

3.9 **Open Access**
Researchers are required to consider the potential benefits of Open Access for electronic scholarly research outputs. UCD and the Irish Universities Association (IUA) support the *National Principles for Open Access Policy Statement* which was launched by the Irish Government in October 2012.\(^8\) The outputs from publicly-funded research should be publicly available to researchers and to potential users in education, business, charitable and public sectors, and to the general public.\(^9\) UCD provides an institutional repository for Open Access which means that research outputs are made freely available on the Web to all, with, in-so-far-as it is possible, no license restrictions.

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: *The 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

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\(^9\) For further information on the UCD Repository see [http://researchrepository.ucd.ie/](http://researchrepository.ucd.ie/) and also [https://www.ria.ie/about/our-work/policy/research/open-access.aspx](https://www.ria.ie/about/our-work/policy/research/open-access.aspx)
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.

The basic ethical principles of respect for persons, beneficence, justice and competence are clearly defined in 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 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.

4.1.2 Beneficence and Non-maleficence
Beneficence and non-maleficence are concern for 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

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10 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).
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 all of the
Animal Research Ethics Committee Guidelines and requirements for research and
teaching with animal subjects. 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 rigor 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.

- **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 are expected to ensure that animal welfare is prioritised
  when designing experiments, and to possess appropriate training for whatever
  research is being carried out.
- **Replacement** researchers are expected to support the development and uptake of
  alternatives to live animals in teaching and research.
The University requires that researchers will ensure housing and husbandry is in accordance with best international practice guidelines.

### 4.2.2 Statutory Requirements for Research with animals:
Researchers must comply with the existing statutory requirements in Ireland regarding scientific animal protection as set out by the Health Products Regulatory Authority (HPRA), formerly known as the Irish Medicines Board (IMB). The University requires researchers to adhere to the Animal Research Ethics Committee Guidelines and requirements for research and teaching with animal subjects.

### 5. RESEARCH ETHICS IN UCD

All research carried out by UCD staff and students that involves either human or animal subjects, requires either ethical approval or an exemption from full ethical review.

- **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 and 2003), and the Freedom of Information Acts (1997 and 2003 as may be amended).

- **Research Involving Animals and Teaching** Ethical approval is required from the appropriate University Research Ethics Committee and the research must comply with all statutory licensing requirements. Researchers should ensure compliance with the Health Products Regulatory Authority (HPRA) the Competent Authority under the Directive 2010/63/EU since January 2013. The IMB is responsible for approval, oversight and compliance of research projects involving procedures on all vertebrate animals in Ireland. Researchers should consider, at an early stage in the design of any research involving animals, the opportunities for reduction, replacement and refinement of animal involvement.

All researchers are required to adhere to the Research Ethics Committee Policies and Guidelines.\(^{11}\)

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\(^{11}\) See [http://www.ucd.ie/researchethics/information_for_researchers/policies_guidelines/](http://www.ucd.ie/researchethics/information_for_researchers/policies_guidelines/)
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.\(^{12}\) Good practice in research includes reporting concerns about the conduct of research. Any member of the University who believes that an act of research misconduct has occurred or is occurring should, in a responsible and appropriate manner, notify the Head of the appropriate School and/or the College Principal. If, for any reason, this is not possible, the individual should contact the Vice President for Research.

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.