RESEARCH ETHICS UCD

Research Ethics

UCD POLICY

V:2

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1. INTRODUCTION

The UCD *Research Ethics Policy* presents an overview on how research ethics is managed University-wide. It provides the basic principles of best practice in research for all research involving human and animal subjects in research. The Policy is applicable to all UCD researchers, (staff, students and postdoctoral researchers) and should be read in tandem with the UCD *Code of Good Practice in Research* and the REC *Operating Procedures and the Policy on the Use of Animals for Teaching and Research*. These documents underpin the UCD Research Ethics Approvals System, and all of the approved Research Ethics Committee (REC) policies and guidelines. The approvals system is the process by which all submissions to the Office of Research Ethics and Integrity for ethical review, and all reviews, decisions and approvals are carried out on behalf of the university.[1] It is overseen by the UCD Research Ethics Committee which derives its operating authority from the UCD Governing Authority. The Research Ethics Committee oversees and advises on policy regarding the work carried out by the sub-committees The Research Ethics Committee facilitates and promotes research in UCD based on internationally accepted ethical norms and with attention to the welfare of study participants.

2. PURPOSE & SCOPE

All research that involves either human or animal subjects carried out by UCD researchers requires either full ethical review or low risk study review. This policy is intended to provide all researchers, with an overview of research ethics in UCD and the requirements of the Research Ethics Committee and its sub-committees regarding the Research Ethics Approvals System.

3. GENERAL PRINCIPLES

There are a number of key principles which underpin the University's commitment to achieving the highest standards of excellence and best practice in research ethics. This policy aims to provide researchers with guidance on quality and best practice relating to seeking, obtaining and maintaining ethical approval. Researchers are therefore required to seek ethical approval using the relevant application forms provided on the Research Ethics website and to follow the submission instructions provided there.[2]

[1] Ethical review refers to both full ethical review and low risk application reviews (formerly known as exemptions from full ethical review).

[2] http://www.ucd.ie/researchethics/information_for_researchers/

4. ROLES & RESPONSIBILITIES

The University requires that researchers adhere to the policies and guidelines laid down by the Research Ethics Committee when obtaining ethical approval or exemption.

All UCD researchers are required to know how to obtain ethical approval for their study. Academic Supervisors of undergraduates and postgraduates are required to provide clear guidance as to the procedures involved in obtaining an ethical review in the University. Academic Supervisors are required to endorse their student's submissions for all reviews. All researchers must be familiar with the policies and guidelines relevant to their research and provided by the Human Research Ethics Committee and the Animal Research Ethics Committee.

4.1 **Research Involving Human Subjects or Biological Samples:** Ethical approval is required from the appropriate university human research ethics committee, and/or (if applicable) the appropriate hospital research ethics committee and/or from other regulatory bodies as relevant, and as required by individual sponsors.

4.2 **Low Risk ethical review**: A low risk ethical review is only applicable to the Human Research Ethics Committees.[3] Researchers decide if they meet the criteria for low risk as listed in the HREC Guidelines. They notify the Office of Research Ethics and integrity by email that they self-declare that they meet the criteria for a low risk submission by submitting a completed low risk form available on the Research Ethics website.

4.3 **Research Involving Animal Subjects:** Ethical approvals required from the appropriate University animal research ethics committee and the research must comply with all statutory licensing requirements of the Health Products Regulatory Authority (HPRA)[4], SI 543 of 2013 European Union (Protection of Animals used for Scientific Purposes) Regulations 2012. The university actively supports the implementation of the 3Rs – reduction, refinement and replacement (Russell & Burch, 1959) on which much of the legislation controlling the use of animals for research is based.

4.4 **Legal Considerations:** Researchers are responsible for their own research and are therefore required to be aware of and comply with all applicable legal requirements and specifically required to be aware of the following:

4.4.1 The University's Research Ethics Approval System involving the submission and review of applications to one of the UCD Ethics Committee is an internal matter within the University and will not satisfy the Irish or European legislation should statutory consents also be necessary. Researchers must ensure that research fulfills any legal requirements such as those of the *Data Protection Acts* (1988 –

[3] Exemptions for human subject research are submissions that do not require a full committee review they are not exemptions from ethics

[4] *Formerly known as the Irish Medicines Board (IMB)*

2003 as may be amended) and the *Freedom of Information Acts* (1997 – 2003 as may be amended;

4.4.2 From the 1st of January 2013, the Health Products Regulatory Authority (HPRA) under the Directive 2010/63/EU, is responsible for ethical review of all research projects involving procedures on living animals in Ireland;

4.4.3 Human rights are protected by the Constitution of Ireland and the European Convention on Human Rights which has been bolstered in Irish domestic law by the *European Convention on Human Rights Act,* 2003 (as may be amended);

4.4.4 Under the *Control of Clinical Trials Act* 1987 and the *Control of Clinical Trials & Drugs Act* 1990 (as may be amended) certain types of clinical trials e.g. invasive or administering drugs or substances to human beings must be conducted in accordance with a statutory permission to undertake such a clinical trial. *EU Directive 2001/20/EC* deals with principles of good clinical practice, and directs that certain permissions should be obtained in relation to clinical trials involving medicinal products. It is the sole responsibility of the researcher and sponsor to apply and obtain any necessary permission for clinical trials;

4.4.5 Under the Medical Devices Directive (93/42/EEC and S1.252 1994, as may be amended)'Non CE-marked medical devices'[5] must undergo a 'clinical investigation' required to gather clinical data that is sufficient to demonstrate conformity of a device to the requirements of the Medical Devices Regulations (MDR). In Ireland, 'Clinical investigations', as required by the MDR, are subject to ethical review by a relevant University research ethics committee and review by the HPRA. Both ethical approval letter and HPRA 'letter of no objection' are required before any 'clinical investigation' can begin.It is the responsibility of the researcher to ascertain whether the device they wish to use in a research project should be classified as a 'medical device' and comply with the MDR.

4.4.6 Neither the University, the Committee, nor individual members of the Committee accept any legal liability, or other liability whatsoever, for any advice or assistance offered to the researcher or to any third party in the processing of the application or for the subsequent supervision or conduct of the research;

[5] 'Non CE-marked medical devices' are devices classified as 'medical devices' under the Medical devices Regulations (MDR) but have not yet received the 'CE (Conformité Européene) mark', which is an EU-wide legal designation that the manufacturer's product has met the requirements of the MDR.