



*UCD Research Ethics Committee*

## **Summary of Human Research Ethics Committee**

*Guidelines & Requirements*

**Version No: 2**

*Approved by the UCD Research Ethics Committee on 11<sup>th</sup> February 2015*

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## Introduction

There are two Human Research Ethics Committees (HRECs) in UCD and both are sub-committees of the UCD Research Ethics Committee (REC). HREC-Sciences and HREC-Humanities oversee the review of research involving human subjects so as to safeguard the dignity, rights, safety, and well-being of actual or potential research participants, as well as the researchers. The health, well-being, and care of research participants will always take precedence over the goals of the research and teaching.

### **1 Human Research Ethics at UCD**

- 1.1 The HREC has jurisdiction over the research of all UCD researchers (paid and honorary) and research students, and all academic visiting researchers to UCD, including those using UCD facilities, who wish to perform research using human participants.
- 1.2 The HREC is responsible for conducting a review of the proposed research before it commences and for ensuring that there is a regular evaluation of the ethics of ongoing research studies that receive their approval.
- 1.3 The HREC is responsible for acting in the full interest of potential research participants and communities, taking into account the needs of the researchers and having due regard for the requirements of relevant regulatory agencies and applicable laws.
- 1.4 The HREC aspires to providing independent, competent and timely reviews of the ethics of proposed research. The composition, procedures and decision-making engaged in are made independently free from political, professional, and market influences.
- 1.5 The HREC oversees the operating procedures for each School's Undergraduate Research Ethics Committee (UREC) and Taught Masters Research Ethics Committee (TMREC)<sup>1</sup>.

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<sup>1</sup> Outlined in the *UREC & TMRE Terms of Reference* Document

## **2 Function of the HREC**

- 2.1 The main function of the HREC is to increase awareness of ethical principles in research amongst the university community through the reviewing of research proposals, the provisions of advice, the development of best practice guidelines, and the provision of seminars and training in research ethics to students and staff, and all engaged in the delivery and practice of research.
- 2.2 The HREC reviews proposed research projects involving human subjects that fall within the jurisdiction of UCD, and approves all research projects that meet UCD requirements and are ethically acceptable. It fosters awareness and concern amongst UCD researchers and supervisors for all dimensions of ethical practice in human subjects. The HREC advises on policies and practices for the review, approval, monitoring, post approval reporting and administration of ethical research practice in UCD.
- 2.3 The HREC adjudicates on the ethics of proposed research projects it reviews using criteria developed and elaborated in reference to international best practice benchmarks and articulated in the Research Ethics Committee (REC) Policies and Guidelines. From this process it develops and publishes best practice policy in conducting ethical research.
- 2.4 The HREC aspires to engage all relevant members of the university research community proactively in delivering research with human subjects that meets the highest international standards of ethical practice.

## **3 Terms of Reference of HREC**

- 3.1 To promote awareness of ethical principles governing research involving human subjects.
- 3.2 To review, approve, monitor and administer applications for research from staff and students.

- 3.3 To publish policy, procedure and best practice documents which support the researcher in designing and delivering ethical research.
- 3.4 To identify educational needs amongst committee members and researchers related to ethical issues.
- 3.5 To design and deliver seminars and training related to the educational needs identified.
- 3.6 To audit ethical awareness across the relevant research community from time to time.
- 3.7 To audit and review its own functions, procedures and outcomes for the purposes of quality assessment and quality improvement.
- 3.8 To present to the REC regular reports on research proposals reviewed.
- 3.9 To advise and assist the REC on matters of policy, procedure and best practice arising from its research application reviewing function.
- 3.10 To advise and assist the REC on the development of School-level Ethics Committees to review, approve, monitor and administer undergraduate or taught postgraduate research projects.
- 3.11 To make recommendations to the REC regarding membership and composition of the HRECs.
- 3.12 To assist the University in the formulation of university policies, procedures and best practice in relation to ethical research.

#### **4 Membership of the HRECs**

The REC will appoint nominees of each Human Research Ethics Committee in accordance with the Research Ethics Sub-Committee Membership Policy. The membership will normally include:

- Nominees from UCD Schools and Units as are required to fulfil the terms of reference;
- Nominees from the Research Ethics Committee;
- Student member of the University;

- Lay persons;
- The sub-Committees may also consider accepting members, who need not be staff members of the University, from the research ethics committees of institutions closely affiliated with UCD (e.g. Mater Misericordiae University Hospital and St Vincent's University Hospital);
- The sub-Committee will have the power to invite additional persons, who need not be staff members of the University, to act as advisors for the review of specific research proposals;
- Persons with experience and expertise of the issues involved will act as Chair person.

## **5 Role of HREC Members**

- 5.1 The key function of the members will be to consider and decide on all ethical issues relating to all categories of research and studies involving human subjects.
- 5.2 Members will facilitate an ongoing review and discussion on matters of ethical issues and will ensure, as best as possible, that they are conversant with all appropriate best practice and legislation.
- 5.3 They will also assist in the development and implementation of best international standards in any research involving humans.
- 5.4 School representatives will also act to promote the awareness of the University's ethical policies and procedures within their school (regardless of the field of research involved), facilitate school members to submit appropriate applications and help to highlight and advise on ethical issues specific to their application.
- 5.5 Members will have a responsibility to declare any conflict of interest which could affect their role as members of the committee.

## **6 HREC Operating Procedures**

6.1 All proposals for research work in the Colleges and units (referred to in points 6.3 and 6.4 below) involving human subjects by UCD staff or students ,or to be undertaken on UCD premises, must be approved in advance by the relevant UCD Human Research Ethics Committee.

6.2 In respect of such work, carried out by UCD staff or students, on premises other than UCD premises and where a local ethics committee exists, proposals must be approved in advance by the local Ethics Committee and an *Exemption from full ethical review form* (HREC Doc 8) should be submitted. Failing that, approval must be obtained from the relevant UCD Human Research Ethics Committee.

6.3 The **HREC –Sciences** reviews applications from the UCD Schools in the following Colleges and Institutions:

- College of Engineering & Architecture
- College of Health Sciences
- College of Science
- College of Agriculture, Food Science & Veterinary Medicine
- The Conway Institute
- The Charles Institute
- and any other related research Institute or group concerning life sciences, medical and medically related studies

6.4 The **HREC-Humanities** reviews applications from the UCD Schools in the following Colleges and Institutions:

- College of Arts & Celtic Studies
- College of Business & Law
- College of Human Sciences
- The Geary Institute

- The Humanities Institute
  - And any other related research Institute or group concerning social, education and psychological studies.
- 6.5 The HRECs will meet at least eleven times a year or when it is required so as to deal with individual applications on a timely basis, which may involve an electronic review.
- 6.6 Dates of meetings will be circulated in September of each year and will be available on the Research Ethics Website [www.ucd.ie/researchethics](http://www.ucd.ie/researchethics).
- 6.7 Applications are to be submitted via UCD InfoHub/SISWeb using the relevant application form for the appropriate committee (HREC Doc 9) and completed in accordance with the instructions provided and following a consultation with the *UCD Code of Good Practice in Research* and the guidelines and policy documents that are available at [www.ucd.ie/researchethics](http://www.ucd.ie/researchethics).
- 6.8 Completed application forms for full ethical review will be submitted via UCD InfoHub/SISWeb no later than the deadline date provided, which is approximately 16 days before the date of the next HREC meeting for consideration at that meeting as per 6.6 above.
- 6.9 Applications will be made available to Committee members for consideration and comment one week prior to meetings via InfoHub.
- 6.10 Applications will be reviewed and discussed at the meeting which will be quorate – that is one third of the total membership of the committee will be required to carry out the review.
- 6.11 Following consideration at a meeting of the HREC a decision is made and is recorded in the minutes of the meeting. There are four possible decisions: approved, approval subject to clarifications, resubmit, and refused. One of these decisions will be communicated in a letter which is emailed to the applicant. Where a decision is approval subject to clarifications, the decision letter requires a response from the applicant who is required to provide that response within three months of receiving



the decision letter. Where a decision cannot be made by the reviewing committee the application will be referred to the Research Ethics Committee.

- 6.12 Final approval of an application is subject to satisfactory responses to the decision letter, which will be reviewed by the relevant committee Chair, and also to application sign-off via Infohub/SISweb by the relevant Head of School, by the Supervisor (if applicable) and the final Declaration sign-off by the Researcher/Principal Investigator (PI), which will include all the relevant changes and amendments therein.
- 6.13 For applications “approved subject to clarifications” or “resubmit” the revised application/resubmission application can be approved by the Chair or vice Chair but if required will be distributed to the Committee members for final approval either at the next meeting or by electronic approval as long as a quorum of responses are received.
- 6.14 If a protocol is rejected, the applicant may be invited, or can request to meet, with members of the committee to discuss the application prior to resubmission. Any rejected application can be appealed to the Research Ethics Committee. All resubmissions are reviewed again by the relevant sub-committee which may be at the next meeting or via electronic review.
- 6.15 During the course of the study, amendments and extensions can be submitted using the *Human Research Ethics Amendments & Extensions Form* (HREC Doc 10). These requests will be reviewed by the Chair or vice- Chair and, depending on the nature of the amendment or extension, can be (a) approved by the Chair or vice-Chair who will inform the committee of the decision at the next meeting or (b) will be sent to the Committee for approval at the next meeting or by electronic approval as long as a quorum of responses is received.
- 6.16 In the event of an unexpected adverse event a *Human Research Ethics Unexpected Adverse Event Report* (HREC Doc 11). These reports will be reviewed by the Chair or vice-Chair and depending on the nature of the Unexpected Adverse Event action will be taken (a) directly by the Chair or vice-Chair who will inform the Committee of the decision at the next meeting or (b) will be sent to the committee for appropriate

approval of action. Action may include “continue the study as described”, “amend the study” or “discontinue the study”.

- 6.17 Upon the completion of the study a *Human Research Ethics End of Study Report* (HREC Doc 12). This is the responsibility of the applicant, and their supervisor (if applicable). It provides the HREC with a record of specific data management and research publications.

## **7. Insurance Criteria**

Any research or teaching conducted on a UCD campus must be covered by insurance and the Researcher will be automatically obliged to comply with terms of any insurance policy applicable to that research or teaching. Staff and students are obliged to fully complete the insurance section in either HREC Doc 8 or 9 as part of their submission for full ethical review or exemption. The Office of Research Ethics will liaise with the insurers with regard to public liability insurance cover on behalf of the researcher. Other types of insurance, such as travel etc. must be arranged by the researcher who should seek advice from the UCD SIRC (Safety, Insurance, Risk, and Compliance) Office.

## **8 Schools Level Research Ethics Committees in UCD**

A number of programmes at the undergraduate level and taught masters level in UCD require students to conduct research with human participants as part of their studies. These programmes generally have significant numbers of students, who are:

- conducting their research within a very short timeframe;
- targeting populations and topics that form the basis of the research being conducted are very broad;
- engaged with research being carried out as part of an educational activity.

Within this context school level RECs aspire to providing independent, competent and timely reviews of the ethics of proposed research, which also have the potential to add to the development of the student researcher.

## **8.1 Undergraduate and Taught Masters Research Ethics Committees**

- 8.1.1 There are a number of Undergraduate Research Ethics Committees (URECs) in UCD specifically responsible for carrying out ethical reviews of undergraduate research studies. The terms of reference for the URECs (below) have been approved by the Human Research Ethics Committee (HREC) and the Research Ethics Committee (REC).
- 8.1.2 There are a number of Taught Masters Research Ethics Committees (TMRECs) in UCD specifically responsible for carrying out ethical reviews of research studies at taught masters level. The terms of reference for the TMRECs (see 8.6 below) have been approved by the Human Research Ethics Committee (HREC) and the Research Ethics Committee (REC).

## **8.2 Function of UREC**

- 8.2.1 The function of each UREC is to support ethical research at undergraduate level in UCD.
- 8.2.2 The UREC safeguards the dignity, rights, safety, and well-being of actual or potential research participants. Given these dual functions, however, the health, well-being, and care of research participants will always take precedence over the development of the student.

## **8.3 Terms of Reference for URECs**

- 8.3.1 The UREC will review, approve, monitor and administer applications for approval from undergraduate students within the relevant School.

- 8.3.2 The UREC will use the standard Terms of Reference as approved by the REC that set out best practice for all of the UCD Research Ethics Committees.
- 8.3.3 All undergraduate students will be required to submit their research proposal to UREC for approval; either as an application for full review or using the exemption process.
- 8.3.4 The UREC may refer any undergraduate application to the relevant HREC.
- 8.3.5 The UREC will present regular reports to the relevant HREC on research proposals reviewed.
- 8.3.6 Reports from each UREC will also be included in HREC reports to the REC annually.

#### **8.4 Membership for URECs**

The UREC sub-Committees function within specific Schools, however there are general Principles in relation to membership:

- 8.4.1 Membership includes at least two members from the relevant Human Research Ethics Committee (HREC), three other staff members from the School and two others from outside the School.
- 8.4.2 In appropriate cases a member of the discipline's professional body will also be invited to be a member.
- 8.4.3 The role of the members will be to consider and decide on all ethical issues relating to all undergraduate research within the relevant School.
- 8.4.4 Membership will be recommended for appointment by the HREC to the REC.

#### **8.5 Operating Procedures for URECs**

- 8.5.1 Students will be required to submit the relevant school-specific application form and supporting documents to the UREC, within a timeframe to be agreed within the specific School.
- 8.5.2 The UREC application form is developed in recognition of the nature of the research conducted by undergraduate students.

- 8.5.3 Submissions will be circulated to members two weeks prior to the review meetings or as per the URECs specific requirements for review.
- 8.5.4 All applications will be reviewed by UREC and feedback provided within a two- to four-week period.
- 8.5.5 The number of members reviewing each application will vary across the URECs (to account for the number of students in the programme group) however the minimum is two reviewers. In addition studies that explore sensitive topics, target vulnerable groups or use deception are normally allocated to one of the external members of the committee to ensure that they are appropriate.
- 8.5.6 A series of meetings may then be held to discuss the feedback in order to ensure a level of consistency. A (final) review meeting will be held to review all of the decisions made and the issues that have been identified.
- 8.5.7 As is the case with submissions to HREC, the UREC will examine applications to ensure that the student has addressed issues such as the risks and benefits which participants may be exposed to or experience, and the informed consent process.
- 8.5.8 The outcome of the UREC review process will be notified to both the student and their supervisor.
- 8.5.9 The following outcomes will be available to the UREC (as per HREC documentation):
- Approval (approved, as is, with no conditions attached).
  - Contingent approval (approved, subject to implementation of recommended changes).
  - Resubmit (requires that the student and supervisor address questions posed by the UREC and communicate the changes to the UREC).
  - Rejected (written reasons for the decision will be provided to the student and supervisor and resubmission will be possible).
- 8.5.10 Constructive comments and suggestions identified during the review process will be conveyed to the student and their supervisor.

- 8.5.11 It is the responsibility of the student, and his or her supervisor, to ensure that any changes requested by the UREC are met. However, the Chair of the committee will audit a number of these.
- 8.5.12 Any changes to the original research design will need to be approved by the UREC.
- 8.5.13 Finally, students will submit a signed hard copy of the application form, along with a letter from their supervisor confirming all requested changes have been made.

## **8.6 Function of TMREC**

- 8.6.1 The function of each TMREC is to support the completion of ethical research at taught masters level in UCD.
- 8.6.2 Within this context, and as a subcommittee of the relevant HREC, it also functions to safeguard the dignity, rights, safety, and well-being of actual or potential research participants. Given these dual functions, however, the health, well-being, and care of research participants will always take precedence over the development of the student.

## **8.6 Terms of Reference for the TMREC**

- 8.6.1 The TMREC will review, approve, monitor and administer applications for approval from Taught Masters students within the relevant School. (All postgraduate research by major thesis and staff research within the School remains subject to an application to the relevant HREC).
- 8.6.2 The TMREC will use the standard Terms of Reference as approved by the REC that set out best practice for all of the UCD Research Ethics Committees.
- 8.6.3 All taught masters students will be required to submit their research proposal to TMREC for approval, either as an application for full review or using the exemption process.
- 8.6.4 TMREC may refer any taught masters application to the relevant HREC.

8.6.5 The TMREC will present regular reports to the relevant HREC on research proposals reviewed.

8.6.6 Reports from each TMREC will also be included in HREC reports to the REC annually.

## **8.7 Membership for TMRECs**

TMREC sub-committees function within specific Schools, however there are general principles in relation to membership:

8.7.1 Membership includes at least two members from the relevant Human Research Ethics Committee (HREC), three other staff members from the School and two others from outside the School.

8.7.2 In appropriate cases a member of the discipline's professional body will also be invited to be a member.

8.7.3 The role of the members will be to consider and decide on all ethical issues relating to all taught masters research within the relevant School.

8.7.4 Membership will be recommended for appointment by the HREC to the REC.

## **8.8 Operating Procedures for TMRECs**

8.8.1 Students will be required to submit the relevant school-specific application form and supporting documents to the TMREC, within a timeframe to be agreed within the specific School. An adapted application form has been developed in recognition of the nature of the research conducted by taught masters students.

8.8.2 Submissions will be circulated to members two weeks prior to the review meetings.

8.8.3 All applications will be reviewed by TMREC and feedback provided within a two- to four-week period.

8.8.4 The number of members reviewing each application will vary across the TMRECs (to account for the number of students in the programme group) however the minimum is two reviewers. In addition studies that explore sensitive topics, target vulnerable

groups or use deception are normally allocated to one of the external members of the committee to ensure that they are appropriate.

- 8.8.5 A series of meetings may then be held to discuss the feedback in order to ensure a level of consistency. A (final) review meeting will be held to review all of the decisions made and the issues that have been identified.
- 8.8.6 As is the case with submissions to HREC, the TMREC will examine applications to ensure that the student has addressed issues such as the risks and benefits which participants may be exposed to or experience, and the informed consent process.
- 8.8.7 The outcome of the TMREC review process will be notified to both the student and their supervisor.
- 8.8.8 The following outcomes will be available to the TMREC (as per HREC documentation):
- Approval (approved, as is, with no conditions attached).
  - Contingent approval (approved, subject to implementation of recommended changes).
  - Resubmit (requires that the student and supervisor address questions posed by the UREC and communicate the changes to the TMREC).
  - Rejected (written reasons for the decision will be provided to the student and supervisor and resubmission will be possible).
- 8.8.9 Constructive comments and suggestions identified during the review process will be conveyed to the student and their supervisor.
- 8.8.10 It is the responsibility of the student, and his or her supervisor, to ensure that any changes requested by the TMREC are met. However, the Chair of the committee will audit a number of these.
- 8.8.11 Any changes to the original research design will need to be approved by the TMREC.
- 8.8.12 Finally, students will submit a signed hard copy of the application form, along with a letter from their supervisor confirming all requested changes have been made.

## **8.9 UREC & TMREC Reporting Requirements**



- 8.9.1 The UREC/TMREC will report directly to the relevant HREC.
- 8.9.2 At least two members of the UREC/TMREC will be members of the relevant HREC.
- 8.9.3 The UREC/TMREC will provide full details of all applications submitted, and decisions reached, to the relevant HREC.
- 8.9.4 A report from UREC/TMREC will be made available to each meeting of the relevant HREC.
- 8.9.5 A final report will also be issued to the REC at the end of the academic year.

## VERSION HISTORY

Version	Date	Description	Author/Changed by
1	14/01/14	Revised Document	Office of Research Ethics
2	28/01/14	Review by Policy Revision Working Group- comments provided	Office of Research Ethics
	20/02/14	2 <sup>nd</sup> Review by Policy Revision Working Group	Office of Research Ethics
	05/08/14	Revisions and reformatting	Office of Research Ethics
	29/10/14	Minor Revisions	Office of Research Ethics
	11/11/14	Review by HREC members -comments provided and document revised and updated	Office of Research Ethics
	02/02/15	Minor revisions	Office of Research Ethics
	05/02/15	REC Review	Office of Research Ethics
	11/02/15	REC Final Approval	Office of Research Ethics