Research Ethics

Human Research Ethics Committee (HREC)

Guideline:
Research Ethics Submissions, Review & Approvals Process

Introduction

The Human Research Ethics Committees (HRECs) are committed to ensuring that the research activities in UCD are carried out to the highest standards and in a way that respects the dignity, rights, and welfare of subjects, and which minimises risk to subjects, researchers, third parties, and to the University itself.

It is a formal requirement of UCD that all research involving humans conducted within UCD, or other locations, by UCD staff or students, requires the individual researcher and/or teams of researchers to obtain ethics approval via a full review or a low-risk review.

All UCD staff and students are required to comply with best and ethical practice and abide by the regulations, policies and guidelines of the University in the conduct of their research. All research involving human subjects requires a research ethics approval from one of the UCD Human Research Ethics Committees (HREC). Approval can only be provided for studies that have not been started before submission for review. **There are no retrospective ethics approvals provided for any study in UCD.**

Overview

Low Risk Study Review (Tiers 1 & 2): applications that meet the criteria for a low-risk study review are a submitted by email to research.ethics@ucd.ie. These submissions are assessed to determine which of the two-tier low-risk review processes they require. This is carried out by the Office of Research Ethics (ORE). Whether the submission receives an ORE or Chairs review approvals are subject to conditions and maybe required to provide further clarifications.

Full Ethics Review (Tier 3): applications that meet the criteria for a full review are submitted via the UCD Connect Infohub/SISWeb to one of the HREC reviewing committees - HREC-Humanities or HREC-Sciences – where the members of the committee review the proposed study by providing comments, decisions and final approval.

Criteria for Full Ethics Review: In general, a study that involves human subjects including vulnerable groups, sensitive topics, or expose participants to risk or harm to a degree that is greater than they would normally be exposed to in everyday life, requires a full ethics review.

Research Requiring Full Review AND Low-Risk Study Review: there are some categories of research that must first be reviewed and approved by an appropriate local REC. Such as:

- Research involving recruitment of patients from a hospital must first be approved by the local hospital REC. Where such approval has been granted, UCD HREC Low Risk Study approval may be obtained without the need for further full review.
- Subject to meeting certain criteria, other research protocols may obtain a Low Risk Study approval from the UCD HREC without undergoing full review by the HREC (see page 7 below).
- Where UCD researchers have obtained research ethics approval from an outside body, researchers must submit a Low Risk Study Review Form and a copy of the approval they have received from the appropriate local REC from whom they obtained primary approval for thier research to the relevant HREC.

Low-Risk Study Review Process

Research that involves human but does not require a full ethics review may require a Low-Risk Study Review because the risk to participants is low. There are two tiers for the low-risk study submmisison which include, but are not limited to the following:

- Tier 1: low-risk review by ORE – those that have obtained REC approved elsewhere, or public office/professionals and other non-vulnerable, non-sensitive, anonymous and some secondary data studies.
- Tier 2: low-risk review by HREC Chairs – those that involved UCD students, studies overseas (including EU), some secondary data studies.

Before deciding whether you require a Low-Risk Study Review please read all the relevant documentation on www.ucd.ie/researchethics and consult with your Supervisor and/or Head of School.

A study is usually considered to be a **Low-Risk Study** if it involves the following:

- Standard educational practices;
- Standard psychological tests;
- Anonymous surveys and interviews;
- Public observation;
- Research involving persons elected to or candidates for public office;
- Research which uses only existing data which is publicly available;
- Research which uses only existing, non-public data from a previous ethically-approved study, to which access in anonymised form has been officially granted by the data controller, and for which the subjects consented to such secondary use ;
- If the study has already been reviewed and approved by recognised external REC (unless you are using participants from UCD – in this case you may need full ethics review).

Once the researcher has established that their research is low-risk, they should complete the Low-Risk Study Form. When completing this, please ensure the following:

- Complete all sections of the form (typed text only) and in word format only;
- Place responses within the boxes provided;
- Do not use bold type or all capital letters for responses;
- Write"N/A" in the space provided where a section or question is not relevant;
- Do not cross-reference answers (e.g., responses such as "see above");
- Avoid using jargon and unexplained abbreviations, and please explain technical terms.

Once the form is completed the researcher or supervisor (if applicable) should submit the form by email to research.ethics@ucd.ie.

Please note the following:

- Whether your low-risk study is Tier 1 or Tier 2 will be determined by the Office of Research Ethics (ORE);
- If the study has obtained research ethics approval from another recognised external REC please submit a copy of that approval letter with the form.
- A copy of the Low-Risk Study Form is retained by the researcher's School.
- Upon receipt of the form, the submisison will be processed any requests to access UCD Students.
- Once the submission has been deemed to meet the Low-Risk Study criteria the researcher will be issued with a Research Ethics Reference Number.
- Please note that should the nature of the research change and thereby alter the low-risk status the researcher may be obliged to submit for a full review.
- Any amendments or extensions to a Low-Risk Study should be submitted by email using the HREC Request to Amend/Extend Form.
- Always quote your reference in the subject line of your email when corresponding with the Office of Research Ethics (ORE) to ensure a fast response.

Full Ethics Review & Approvals Process

The HREC Application Form (HR1) should be completed for all research requiring a full ethics review and is intended for the researcher to describe their study in terms of ethical concerns and dilemmas and their duty of care to the particpants and their data, and this should be done in as concise and clear a way as possible.

In addition to describing the study the form also allows the researcher to complete questions on insurance, indicate their intention to access UCD students, confirm a declaration that they have read the conditions under which ethics approval is provided.

You will require a **full review** if your research involves any of the following:

- Any vulnerable groups e.g. children, incarcerated prisoners, patients, disabled people;
- Sensitive topics that may make participants feel uncomfortable (I.e., sexual behaviour, illegal activities, racial bias etc.);
- Use of drugs;
- Invasive procedures (e.g., blood sampling);
- Physical stress/distress, discomfort;
- Psychological/mental stress/distress;
- Deception of/or withholding information from subjects;
- Access to data by individuals or organisations other than the investigators;
- Conflict of interest issues;
- Ethical dilemmas.

Submitting for a Full Ethics Review

Submissions are reviewed subject to a full and complete submission that provides all information pertaining to the proposed study. The following requirements are mandatory:

- The HREC will only accept and review fully completed HREC Application forms in word format;

- The HREC will only accept and review fully completed HREC Support Document Templates (HR2) in word format;
- The information contained in the HREC Support Documentation must be reflected in the application form, the form must independently represent your research. Failure to do so may result in a delay in your review and/or decision as you may be requested to complete the application form again;
- The HREC do not accept research proposals.

The **support documents** are usually made up of any, or all, of the following:

- Information Sheet: formatted according to the headings provided in the current version of HREC Application Form which is always available on the website www.ucd.ie/researchethics under 'How to Apply'.
- Consent Form: with each aspect of the study clearly making a provision for the participant to both sign and tick a box to indicate their consent. This should always be presented to the potential participant as a separate document from the Information Sheet;
- Assent Form (for children), if applicable, and separate from the Information Sheet;
- Letter of Endorsement from your supervisor or/head of school - this can be provided by your supervisor as an email if preferred;
- Questionnaires and proof from the copyright holder that you have permission to use and/or adapt, and/or are trained in their use if necessary;
- Interview Schedules and/or protocols for focus groups - the committee need to see the topics and if possible, the questions to be asked;
- Any other document that the participant might be given;
- Any specific information that supports the study (see paragraph below);
- Advertising Posters or texts that will be used to advertise your study in any publication and/or broadcast;
- Garda Vetting Certificates: (if applicable) for studies involving children – it is mandatory to provide a copy of your certificate in your support documents.

Please note that information sheets and consent forms must be presented to prospective participants on UCD Headed Paper from your school/unit, with the researcher's contact details or the with supervisor's contact details if the researcher is a student.

Specific Information that supports the study, if applicable:

In some situations, researchers may encounter participants who may feel or become stressed or distressed during their interview/questionnaire/focus group. You, the researcher, have a duty of care to put in place a mechanism that will deal with this type of situation. In some cases, providing a listing of specific external support groups is sufficient. In others, arranging to have qualified personnel available to deal with the stressed or distressed participants will be necessary. There are many support organisations and charities available and you should be aware of those relevant to your research and make them known to the participants. A useful listing of support groups can be seen on Student Advisers website.

The Full Review Process

In the process of ethics review, the HREC examines the application form and support documents to ensure that the investigator has addressed the risks and benefits which potential research participants may be exposed to or experience, that the proposed selection of participants is equitable, and that the informed consent process will provide sufficient information to potential participants so that they can make informed decisions about participating in the research, that all issues relating to the particpant's data have been presented to the committee clearly and in line with legal and compliance regulations including GDPR. If any issues or concerns are identified by the HREC during the review process, these will be conveyed to the researcher after the review is completed. These issues or concerns should not be viewed as negative comments about the content of the research.

The outcome categories of an ethics review include:

- *Approved* (approved, as is, with no conditions attached);
- *Approval subject to clarifications*: contingent approval (subject to implementation of recommended changes);
- *Resubmit* (requires that the researcher resubmits the application and addresses the decision points posed by the Committee);
- *Rejected* (the Committee will provide written reasons for the decision, and the application may be submitted for reconsideration when reasons for rejection have been addressed by the researcher).

Once the recommended changes are recieved and approved, the revised application and supporting documents will be uploaded to Infohub for the sign off process by the Head of School, the supervisor (if applicable) and the applicant. When the sign-off is completed the researcher receives an approval letter thereby indicating that the study/data collection can begin.

Revocation and suspension of Approvals

All approvals are subject to the policies and guidelines issued by the University and can be revoked, suspended, modified, altered or the approval decision reconsidered Any such action by the University to suspend, revoke, alter, modify or to reconsider shall have immediate effect. The matter may be placed back on the Committee agenda for the purpose of further consideration.

Adherence to the Approval Decision

It is the sole responsibility of the researcher to adhere fully to the approval decision and to any conditions or contingencies laid out within the same. Furthermore, the researcher should ensure that they do not extend the research, modify or alter it in a material way without reverting to the Committee for the purpose of obtaining approval to any proposed extensions,

modifications or, alterations or other changes of design. Any research conducted on a UCD campus must be covered by insurance and the researcher will be automatically obliged to comply with the terms of any insurance policy applicable to that research.

The decisions of the Human Research Ethics Sub Committees can be appealed by writing to the UCD Research Ethics Committee.

Terms of the HREC Ethics Approval

The Human Research Ethics Committee (HREC) grants approval on the basis that a number of important conditions are adhered to:

- Research **must not begin** until the Human Research Ethics Committee (HREC) has granted full ethics approval and the final sign-off process via Infohub has been completed – researchers are issued with specific instructions for sign off when the HREC have given final approval;

- The approval will be granted for the work and the time period specified in the protocol;
- If applicable, all permissions to access participants, whether internal (heads of Schools/Registrar) or external are obtained before the recruitment of the participants is commenced;
- Any amendments or requests to extend the original approved study will need to be approved by the relevant HREC. Therefore the researcher will need to submit by email the *Request to Amend/Extend Form* (HR4);
- Any unexpected adverse events that occur during the research should be notified to the Committee. Therefore the researcher will need to submit, by email, an *Unexpected Adverse Events Report* (HR5);
- The researcher and/or supervisor (if applicable) are required to submit a signed *End of Study Report Form* (HR6) to the Committee upon the completion of the study;

- Approval is granted on condition that the researcher/supervisor ensures that, in compliance with the Data Protection Acts 1988 and 2003 and with the EU General Data Protection Regulations (GDPR). If applicable, all data will be destroyed or achived in accordance with the approved application and that the researcher/supervisor will confirm this in the *End of Study Report*, or indicate when this will occur and how this will be communicated to the Human Research Ethics Committee;
- The granting of ethics approval is premised on the assumption that the research will be carried out within the limits of the law;
- All approved applications and any subsequent amendments are subject to a Research Ethics Compliance Review.

Some schools may have local Undergraduate Research Ethics Committess (URECs) or Taught Masters Research Ethics Committee (TMRECs) that provide ethics reviews and approvals of undergraduate and taught masters research. Please ensure that you know if you shcool has a UREC or a TMREC. Some schools have both and some have joint RECs (UTMRECs).