



ICHAS

Section 8 - Student Supports

Subject:	Procedures associated with the Conduct of Ethical Research within the College		
Date Approved by Board of Directors:			July 2019
Policy Version	1/2019	Date due for Revision	February 2024
Parent Policy	Policy on the Conduct of Ethical Research within the College		

INTRODUCTION

The Human Research Ethics Committee of the College has delegated responsibility for considering and monitoring the ethical implications of research within the College, carried out by students, faculty or staff. The College's HREC is responsible for:

- Developing, monitoring and refining the Institutional Human Research Ethics Policy
- Reviewing staff and students' Human Research Ethics proposals/protocols (where submitted for consideration).

The HREC will not normally review research proposals, projects or coursework in terms of their research merit or integrity. This will normally be subject to peer review within the College's academic structures. However, where the research integrity is deemed to have ethical implications, it reserves the right to comment on such proposals/protocols.

Within that context, the HREC

- Reviews all research proposals/protocols that involve human participants emanating from student coursework.
- Reviews student projects and coursework that involves publication output.

The HREC report directly to the Governing Authority, through the Vice President (Academic Affairs).

As a matter of principle, there is general consensus that any research involving human participants has to be reviewed and considered by an appropriately constituted research ethics committee, which has the necessary competence to advise upon and make recommendations in relation to research involving humans. Such consideration is undertaken in advance of the commencement of any research of this nature. Consideration may be by full review or in some instances may be expedited and undertaken by way of Chair's action or the action of a dedicated sub-committee. The

Irish National Council on Bioethics (2004: 8-9) sets out the type of research activities that normally require review by a HREC.

They include but are not necessarily limited to the following:

- Clinical trials involving human participants
- New treatment or interventions
- Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), biological fluids
- Physiological studies
- Comparing an established procedure, whether therapeutic, non-therapeutic or diagnostic, with other procedures which are not recognised as established by virtue of their recent development, discovery or use in a new or unfamiliar way
- Innovative practices in health and disability services
- Research conducted by students, which includes all activities that meet the definition of research with human participants
- Observational clinical research
- Access to personal information by means of questionnaires, interviews or other techniques of information gathering
- Research involving the secondary use of data (use of data not collected for that research purpose), if any form of identifier is involved and/or if health information pertaining to individuals is involved
- Case studies, when a series of subject observations allow possible extrapolation of generalisation of the results from the reported cases and when there is intent to publish or disseminate the data

There are a number of circumstances/situations in which an expedited process (e.g. Chair's action) may be appropriate, but in the case of supervised research in educational settings, the HREC also has a responsibility in terms of contributing to students' knowledge and appreciation of research design and practice, as well as scientific and ethical principles of research. Therefore, all actual research work being proposed by students or faculty of the College is referred to the College's HREC for consideration. This does not apply to the development of Research proposals, where, for example it is not intended that the actual research will be conducted.

The Irish National Council on Bioethics (2004) also indicates that in the following cases, review by a HREC may not be necessary;

- (Research utilising existing publicly available documents or data
- Observational studies in public places in which the identity of the participants remains anonymous
- Case study of one patient with the proviso that written informed consent has been obtained from the relevant participant
- Quality assurance studies
- Audits

It is especially important to remember, in relation to the studies above that the issue of capacity to provide fully informed consent needs to be considered. The HREC of ICHAS

recommends that all such case studies be forwarded to it for consideration, given the population who engage in interpersonal therapeutic engagement. In any event, it is advised that if any doubt exists relating to the applicability of this guidance to any research project, the advice of the HREC of the College has to be sought.

The HREC of the College is mandated to: determine and provide advice on whether or not proposed research projects involving human participants are acceptable on ethical grounds.

monitor as far as is practicable, the progress of research projects to ensure continued compliance with approved ethical standards. They have to maintain a register of proposed research projects involving human participants and communicate information on request to appropriate bodies.

Through its Chairperson, the HREC undertake expedited review of ‘negligible risk’ human research projects.

RESPONSIBILITIES

ROLE/ PERSON	RESPONSIBILITY
Research Applicant	Prepare and Present completed Ethics Applications for Consideration and approval by the HREC
HREC	Consider and approve, require amendments to or reject (as appropriate) Research Proposals. Provide oversight of Human Research within the College
Vice President (Academic Affairs)	Establish, Update and Maintain a College Register of Research Projects

PROCEDURES

The HREC promotes a responsible research ethics culture in relation to studies involving human participants within the College and, where appropriate, within the wider community in relevant fields of enquiry.

The HREC Chairperson approves all projects deemed to be ‘negligible risk’ and notifies the full HREC of such decisions. Any project inadvertently presented for Chair’s action which is classified as carrying a ‘negligible risk’ but that the Chair agrees are potentially of a higher level of risk will be forwarded to HREC for full review.

The HREC maintains an effective process for the consideration of research proposals/ protocols. This process is consistent with current best-practice principles and commits to having timely, transparent and defensible procedures for:

- Receiving and reviewing applications,
- For expediting consideration of projects with ‘negligible risk’ by the Chairperson
- Making and communicating decisions regarding the suitability of the proposal/protocol.

- The HREC maintains accurate records of ongoing committee activity and provides an annual report to the Vice President (Academic Affairs) of the College.
- Any conflict of interest by a member of the HREC regarding proposals presented to it for review are declared. The committee has to decide on the appropriate level of involvement of the relevant member in the decision-making process. The actions decided upon can range from non- participation in discussion or voting to abstention/exclusion from the meeting or the portion of the meeting during which the relevant proposal/protocol is being considered.

The following decisions are made in relation to any proposal/protocol considered. The proposal/protocol may be granted:

- Full approval,
- Approval with recommendations,
- Conditional approval subject to ratification by chairperson,
- Approval not granted but the applicant is invited to resubmit or Rejection.
- Applicants are normally notified of the Committee's decision within five working days of the meeting. Communication is directed through the named applicant *only*, unless another researcher has been designated as contact person in the application form.

Ethical Approval is normally granted subject to the researcher(s) informing the College's HREC of:

- any potential difficulties that may arise in relation to ethical issues in a prompt manner,
- any substantial change to the research design or methodology.
- The applicant(s) is required to make themselves available to the HREC in order to explain the proposal and/or to address any relevant questions of the Committee or the Chair.
- All submissions to the HREC have to be made in writing and signed by a qualified researcher who assumes overall responsibility for the conduct of the study. This will usually be the principal investigator or in the case of students will be the Academic Supervisor who has experience and competence in relevant areas of research. In the case of supervised research, this person will normally be a member of Faculty of ICHAS.
- Applications for Review normally include the following items;
- Letter of introduction;
- Completed application form
- Documentation stipulated in the application form (e.g. participant information sheet, copy of recruitment advertisement, informed consent form, letters to participants, relevant 'gatekeepers' etc).

- Statement of approval of research (where appropriate), letters granting site access (where relevant).

The applicant has to submit all documentation required for a thorough and complete ethical review of the proposed research.

Applicants to the HERC are advised:

- That they cannot make substantial changes to an approved research proposal.
- Minor changes may be allowed but only subject to supervisor approval (normally in the case of students) or the approval of the Chair of the Ethics committee as appropriate (normally if a member of Faculty).

Research projects cannot proceed without prior consideration and approval of a written proposal/ protocol by the College’s HREC. Where a proposal has achieved approval by another appropriately constituted Ethics committee, the proposal must still be presented to the College’s HREC for consideration. The HREC will normally endorse the approval of appropriately constituted Ethics Committees but will record the research on the College’s register of research projects. A copy of all approvals and appropriate documentation must be provided.

The granting of approval for research to proceed, does not guarantee that the conduct of research will be ethically undertaken, therefore any research undertaken by students in the College will be under the supervision of an appropriately qualified member of Faculty and any research undertaken by a member of Faculty should be monitored by the Chair of the HREC (or their nominee). Researchers (including students), must always ensure the integrity of their research. The findings of any research should be shared with the College Community, so Dissertations etc should be lodged on completion with the College and this must be made known to research participants.

Linked Policies and Procedures

Linked Policies	Policy on the conduct of Ethical Research within the College
Linked Procedures	