

Code: QA512
Title: **Research Ethics Committee**
Date: 05/09/2017

1.0 Purpose

Remit, composition, and terms of reference for the University Research Ethics Committee (UREC).

2.0 Description

2.1 Remit, responsibilities, and composition

The objectives of the Committee are:

- To safeguard the health, welfare, and rights of human subjects and researchers in research studies, and to afford dignity to the handling and treatment of biological materials, taking into account the scientific procedures and concerns of the local community. For any research proposal to gain ethical approval it must be valid and valuable and of a design that minimises predictable risk to both the research participant and the researcher.
- To examine applications for ethical approval from full-time staff members and research students (PhD and Masters by research) for research involving human participants and/or personal information (Personal information is any personally identifiable information, i.e. information that can be linked to a particular person. Human participants are any persons that participate in research projects contributing some kind of data.)
- To provide timely, comprehensive, and independent reviews of applications for ethical approval, acting in accordance with the Declaration of Helsinki, other international good practice guidelines on Research Ethics, statements of appropriate ethical practice produced by relevant professional organisations, relevant EU Directives, national guidelines, and national legislation pertaining to the ethical conduct of research, and acting in good faith with respect to both applicants and the community.
- Through its operation, to provide Galway researchers (staff and research students) with the feedback for understanding and addressing ethically significant problems which might arise in their research and to promote responsible research and practice, including both advice prior to submission of applications and meaningful feedback on the application to the applicant after review.
- In carrying out these objectives, to respect academic freedom and remember that research is an important activity within the academic community, and that care should be taken not to hinder research without good cause.

Informed by good practice, and the operational guidelines of Irish Council for Bioethics (2004), the composition of the REC shall include:

- A chairperson and vice-chairperson, who shall be from or additional to the other categories of members listed below.
- One-two persons with a legal qualification.
- A minimum of four members with knowledge of, and current experience in, the areas of research that are regularly considered by the Committee, ensuring inclusion of

representation from all Colleges or large schools that regularly engage in human subjects research.

- Two members with knowledge of, and current experience in, the area of social science research.
- Three members with knowledge of, and current experience in, the professional care and treatment of people (e.g. practising clinicians, nurses), one of whom shall be a specialist in mental health (e.g. clinical psychologist, psychiatrist, qualified counsellor).
- One-two members with training in ethics (e.g. ethicist, philosopher, moral theologian).
- Two lay members.

Appointment to the University Research Ethics Committee:

- Appointments must be supported by the Research Committee and by the Head of the relevant academic unit.
- The term of appointment will be 3 years.
- A member should not serve more than two consecutive terms.
- Renewal of membership for a second consecutive term will be the decision of the Research Committee, on the recommendation of the Research Ethics Committee chairperson.
- Should a member wish to resign from the committee, they should inform the chairperson in writing of their intention, allowing at least 1 month from the date of receipt of their letter of resignation in which to find a replacement.
- Members must be willing to have their name, profession, and affiliation published on the Committee page of the university website.
- A member is expected to attend AT LEAST half of all scheduled Committee meetings in each year.
- Members are expected to treat as confidential all applications, meeting deliberations, information on research participants/volunteers, and related matters.
- A member must agree to take part in education and on-going training appropriate to their role on the Committee.
- External members will receive reasonable reimbursement of expenses for travel and training.
- At the appropriate academic unit level, where decisions are made on staff workloads, recognition should be given to the significant time commitment involved in being a member of the Committee and in particular in the position of Vice-Chair or Chair of the Committee.

2.2 Operating procedures

Detailed operating procedures are captured in the institutional 'Research Ethics Committee Standard Operating Procedures' (2013).

- A minimum of five members of the Committee are required to be present at a meeting held to determine an opinion in relation to an application to the Committee.
- Each application will be assigned two reviewers, and their comments on the application will be discussed at the meeting, while low-risk studies may be reviewed by the Chair him/herself.
- The minutes of the meeting will record, for each application, the decision of the Committee on the application including a summary of the main ethical issues considered.
- The possible Committee decisions are full approval, provisional approval, deferral, or approval declined.
- As a minimum, the Committee will require an annual statement of compliance from the Principal Investigator, but the Committee can agree more frequent reporting at the time of approval of the application. The Principal Investigator is also required to submit a final

statement of compliance. Any significant alterations to a previously approved proposal must receive prior approval from the Committee before implementation.

- All documentation and communications of the Committee are to be dated, filed, and archived according to written procedures.
- The Committee should produce an annual report containing information relevant to its procedures: this report should be sent to the Research Committee and to the Research Ethics Policy and Governance Committee (REPGC).

3.0 Responsibilities

Name	Responsibility
VP for Research	Policy Owner
Research Committee	Execution and Oversight of Good Practice