

FAHSS RESEARCH ETHICS COMMITTEE

OPERATING PROCEDURE

Approved by	Faculty Research Committee, 20 May 2015
Contact	FAHSS Administrator, ext. 2026, vsmith@tcd.ie
Responsible	Chair of FREC
Date Effective	Michaelmas Term 2015
Date of next review	Trinity Term 2018

REMIT OF THE COMMITTEE

The Faculty Research Ethics Committee (F.R.E.C.) will review research projects in the following categories:

- Applicants based in Schools without direct access to a Level 1 or Level 2 Research Ethics Committee
- areas of research and academic activity that require ethical clearance that are outside the current remit of the existing ethics research committees in College.

Note: The F.R.E.C. will not be subsuming the role of existing Ethics Committees and therefore if permission can be obtained through a local procedure there would be no requirement to apply through the F.R.E.C. Schools which do not have a local Ethics Committee should have an agreement with another School to avail of theirs.

MEMBERSHIP:

- Chair (Nominated annually by the Dean of Faculty of Arts, Humanities and Social Sciences)
- 5x Faculty Representatives – normally Directors of Research (one to be from the School of Law)

A quorum of four members, including the Chair, is required for a meeting to take place.

CONTACT DETAILS FOR COMMITTEE:

Postal Address: FREC
 c/o Faculty Office
 Room 2016
 Arts Building
 Trinity College

Email: artshss@tcd.ie

Phone: 01- 8961200

Visit: <https://ahss.tcd.ie/Faculty%20Ethics%20Committee/FacultyEthicsCommittee.php>

TERMS OF OFFICE

The Term of Office for the Chair will be one year, after which time it may be renewed. Other members are eligible to be members as long as they are Directors of Research.

DUTIES OF MEMBERS

- To read and review relevant applications, with a view to identifying potential ethical issues and thereby granting or refusing consent.
- To detail any concerns regarding the application from an ethical perspective.
- To review any notification of adverse effects.
- To review any monitoring reports submitted to the Committee.
- To review any end of project reports submitted to the Committee.
- To keep up to date with legislative / best practise guidelines in the Ethics arena.

REQUIREMENT FOR ETHICAL APPROVAL

Ethical approval is required before any studies involving human participants can commence. Retrospective approval will not be given

This requirement applies to studies to be undertaken by staff, postgraduate and undergraduate students.

In the first instance, researchers should review the [checklist](#) on the Faculty Ethics Committee website to ascertain whether their project needs to come to the FREC. In the case of studies undertaken by students, the supervisor should ask the student to fill in the checklist to ascertain whether the project needs to come to the FREC.

In the case of collaborative projects involving researchers from outside the School, where ethical approval has been obtained from an external research ethics body, the project must still come before the FREC for review.

For the purpose of this document a “study” may be understood to involve a potentially staged series of different experiments to be conducted over a period of time.

If substantive changes are made to a study following receipt of ethical approval, this will constitute a new study for which further ethical approval must be obtained.

DOCUMENTATION

All documentation necessary for submitting an application to the FAHSS Research Ethics Committee is available at:

<http://ahss.tcd.ie/Faculty%20Ethics%20Committee/FacultyEthicsCommittee.php>

The dates for submission of applications and meeting dates, Application form, Appendices, Guidelines on Frequently Asked Questions, and the standard documentation on international and Irish guidelines for research are posted on this website.

Please note that applicants should email one signed soft copy of their application to the Secretary of the Faculty Research Ethics Committee by the deadline as indicated on the online schedule.

APPLICATION AND EVALUATION:

Completed application forms together with supporting documentation should be submitted electronically to artshss@tcd.ie by the date specified on-line. If the proposal is from an undergraduate or postgraduate student, the supervisor must be copied in on the email submission. TCD e-mail addresses only are accepted.

Applications will only be accepted on the latest version of the application form, as available on-line.

Applicants that sign the application form are making a commitment to review the provisions of the Data Protection Act, like legislation and College Policy on Good Research Practice.

Applications must:

- identify actual and potential ethical issues that might arise;
- reflect on how these will be addressed; and
- formulate procedures to deal with all such issues.

All eligible applications for review will be listed on a spreadsheet distributed to the Committee at least 10 days before the next scheduled meeting.

Any concerns identified should be entered on the spreadsheet and returned to the Committee Secretary on the Monday prior to the scheduled meeting.

A log of the notes from members of the committee will be circulated to members at least two days in advance of the meeting.

The Committee will discuss the proposal, and reach a consensus on the request to grant consent. In the event that a proposal is from the same school as a Committee member, that Committee member will not take part in the decision about that proposal.

In the event that all members of the Committee cannot review an application, a quorum is considered to have been achieved when 3 members agree.

In the event that the Committee cannot reach a consensus, advice will be sought from the legal representative on the Committee before a decision is made.

The Committee will consider each application and normally provide a response within two weeks but not more than one month later. The applicant will be notified of the Committee decision within 6 working days of the Committee meeting where it was presented.

AUTOMATIC REJECTION:

Applications will be rejected without further consideration if;

- the application does not reach the Faculty Office by 5.00pm by the published deadline. These will be referred to the next meeting
- the form used is not the current version as posted on the website
- the cover sheet checklist is not completed
- participant information sheets and/or consent forms are not submitted
- appropriate documentation referred to in the application is not submitted
- the Lead Investigator declaration is not completed in full
- in the case of student applicants, the research supervisor has not completed the requisite section
- the application is without the following signatures: applicant signature, research supervisor signature (applicable in student applications)
- the application is not received by the publicised deadline

AMENDMENTS TO CONSENT:

If amendments are requested please send them via email to artshss@tcd.ie; ensuring that amendments are highlighted in the original document either by underlining the appropriate sections or using the tracked changes facility in Word.

If these amendments are satisfactory a formal letter of approval will issue.

CONFLICT OF INTEREST

In the event that a member of the Committee has a conflict of interest, they must declare that to the Administrator when the summary sheet is sent in advance of the meeting. The member will be excused from reviewing the application. The application will then be judged by quorum.

APPEALS PROCESS

Applicants whose projects are rejected will receive feedback from the FREC within a week of the Committee meeting. An amended project may be submitted to the next FREC meeting. Where a dispute cannot be resolved, the input of another REC will be sought.

MONITORING OF ON-GOING PROJECTS

During the research project researchers should:

- implement the ethical procedures;
- obtain continuous feedback from participants about ethical issues;
- periodically review the ethical strategy in the light of feedback received; and
- if required, update their ethical procedures;
- retain copies of consent forms signed by the participants.

Projects that apply for ethical approval for in excess of 8 months must submit a monitoring report every 6 months to the Committee for review.

Report is available for download on the website.

If a 6-monthly monitoring report is not submitted, consent will be withdrawn.

END OF PROJECT REPORT

Every application given consent will be required to submit a short end-of-project report within 4 weeks of completion.

Reports are available for download from the Faculty website.

Reports should be submitted to artshss@tcd.ie

Applicants / supervisors with outstanding reports will not be granted additional consents until all end-of-project reports have been received.

ANNUAL REPORT

The FREC will produce an annual report in Sept each year (to cover the previous academic year), to include:

1. Total number of applications
2. Total number of consents
3. No of applications processed within timeframe
4. Summary table showing reasons for rejections
5. Summary table showing any changes in process / procedures of the FERC

REGISTRATION AND ARCHIVING

Every application that is received by the Administrator will be logged on a spreadsheet database, showing the following as a minimum:

- Project Title:
- Name of Lead Researcher (student in case of project work):
- Name of Supervisor:
- TCD e-mail:
- Contact Tel No.:
- Course Name and Code (if applicable):
- Estimated start date of survey/research:
- Date received by Administrator
- Committee decision
- Date of Committee decision

The database will be available for download from the Ethics section of the Faculty website.

Any further details will be subject to a Freedom of Information (FOI) request.

FOI requests will be addressed using standard FOI procedures.

All documentation (soft copy) will be held for a minimum of 5 years before being destroyed in a confidential manner.

REVIEW OF FREC

A review of FREC will take place as required, but at a minimum of every three years. A review may also be initiated in response to a fundamental change in remit or procedures.

The review will include:

- Remit of the Committee
- Membership of Committee
- Process and procedures
- Consents and non-consents
- Timeliness of consent
- Forms
- Storage and archiving of material

The review will be conducted by an independent panel with ethics experience.