FAHSS RESEARCH ETHICS COMMITTEE

OPERATING PROCEDURE

<table>
<thead>
<tr>
<th>Approved by</th>
<th>FREC, September 2020</th>
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<tbody>
<tr>
<td>Contact</td>
<td>FAHSS Administrator, ext. 2026, <a href="mailto:vsmith@tcd.ie">vsmith@tcd.ie</a></td>
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<tr>
<td>Responsible</td>
<td>Chair of FREC</td>
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<tr>
<td>Date Effective</td>
<td>Michaelmas Term 2020</td>
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<tr>
<td>Date of next review</td>
<td>Trinity Term 2021</td>
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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 (e.g. library)

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 level one 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)
- Representative from each School in the Faculty – normally Directors of Research

A quorum of four members, including the Chair, (one to be from the School of Law), 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 should be Directors of Research or Chairs of School Ethics Committees, or other nominees.

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 and 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, including 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 information necessary for submitting an application to the FAHSS Research Ethics Committee is available by clicking here.

The dates for submission of applications and meeting dates, link to Application form, list of documentation required, Guidelines on Frequently Asked Questions, and the standard documentation on international and Irish guidelines for research are posted on this website.
APPLICATION AND EVALUATION:

Applications forms together with supporting documentation should be submitted electronically at this [link] by the date specified on-line. If the proposal is from an undergraduate or postgraduate student, the supervisor must have signed the Declaration and Data Protection Form. To be able to upload documents, you must be logged on through a TCD account. If you do not have a TCD account, please contact artshss@tcd.ie.

Applications will only be accepted via the online application form.

Applicants that sign the application form are making a commitment to review the provisions of the Data Protection Act and similar 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.

Standard procedure will require each application to be reviewed by at least three members of the committee prior to the meeting. At least one application will be reviewed by all members and discussed at each meeting to ensure consistency of approach.

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 each 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.

A decision is considered to have been achieved when three members agree, with no objections from others.

In the event that the Committee cannot reach a consensus, advice will be sought from a relevant source (e.g. RECP) 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 by the FREC Administrator without further consideration if;

- the application is not submitted using the online form by 5.00pm by the published deadline. These will be referred to the next meeting
- the checklist part of the online form is not completed
- the Declaration and Data Protection is not included, or does not contain the required signatures
- participant information sheets and/or consent forms are not submitted
- appropriate documentation referred to in the application is not submitted

AMENDMENTS TO STUDY

If amendments are requested please submit using the online form; ensuring that amendments are highlighted in the original document either by underlining the appropriate sections or using the tracked changes facility in Word. If amendments are substantial, they may have to be reviewed at a subsequent meeting.

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. This 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 from the AHSS Level Two committee 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 or 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 September each year (to cover the previous academic year), to include:

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

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

This will be stored on the Microsoft Team site for the FREC. 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.