Policy

Taught Programme Research Ethics Committees (TPRECs)

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Approval

This document requires the following approvals:

Name	Title	Date
	Academic Council	9th February 2018

Taught Programme Research Ethics Committees (TPRECs)

1. Research within Taught Programmes at GMIT

Many taught programmes at GMIT require students to conduct research as part of their studies. These programmes generally involve students who are completing the research within a relatively short timeframe. In addition, the target populations and topics that form the basis of the research being completed are likely to be very broad.

Each Academic Unit (School/Centre) is required to establish a Taught Programme Research Ethics Committee (TPREC). Within this context each TPREC aspires to provide independent, competent and timely reviews of the ethics of proposed research, which also have the potential to add to the development of the student researcher.

2. Function

The function of each TPREC is to support the conduct and completion of ethical research within GMIT's taught programmes. Within this context it also functions to safeguard the dignity, rights, safety and well-being of actual or potential research participants. Given these dual functions, however, the health, well-being and duty of care to research participants will always take precedence over the development of the student researcher.

3. Terms of Reference

3.1 The TPREC will review, approve, monitor and administer applications for approval of research to be conducted by students on taught programmes within the relevant Academic Unit (AU).

3.2 Research within GMIT proposed by research postgraduate, staff or on funded projects remains subject to separate research ethics procedures administered by the Research Sub-Committee (RSC-AC) of Academic Council.

3.3 All taught programme students or their relevant programme boards will be required to consider whether their research proposals requires ethical approval, or are exempt. (See Appendix A).

3.4 The TPREC will present annual reports to the RSC-AC on research proposals reviewed;

3.5 Reports from each TPREC will also be included in Academic Unit Annual Reports to the Academic Council.

3.6 Research involving the use of animals for scientific purposes (as defined in European Union legislation)[1] is not permitted on taught programmes at GMIT.

4. Membership

TPRECs function within each Academic Unit, however there are general principles in relation to membership:

4.1 Membership includes the Chair, two other staff members from the Academic Unit (AU), and one staff member from outside the AU.

4.2 TPRECs may seek advice from members of the discipline's professional body to inform their deliberations.

4.3 The role of the members will be to consider and decide on all ethical issues relating to all taught programme research within the relevant AU.

4.4 Membership of TPRECs will be approved by the RSC-AC.

4.5 Each TPREC will be chaired by the relevant Head of School or nominee.

5. Operating Procedures

5.1 Applicants may include students of GMIT's taught programmes or their programme boards.

5.2 Applicants will be required to submit an electronic application form (See Appendix B) and supporting documents to the TPREC, within a schedule to be agreed within the specific AU.

5.3 Applications must be submitted on the "Taught programme research ethics application" form developed for the purpose of evaluation.

5.4 Submissions will be circulated to members two weeks prior to the review meetings.

5.5 All applications will be reviewed by the TPREC and feedback provided within a two-to-four-week period.

5.6 The TPREC will examine applications to ensure that the applicant has addressed issues such as the risks and benefits which participants may be exposed to or experience, and the processes for informed consent.

5.7 The outcome of the TPREC review process will be notified to both the applicant, and to their supervisor, lecturer or Programme Board (as appropriate to each application).

5.8 The following outcomes will be available to the TPREC:

[1] Directive 2010/63/EU (http://www.hpra.ie/docs/default-source/3rd-party-documents/directive-2010-63-eu.pdf?sfvrsn=2), transposed into Irish law by SI No 543 of 2012 (as amended), (http://www.hpra.ie/docs/default-source/3rd-party-documents/si-543-(changed)-of-2012.pdf?sfvrsn=2).

- Approval (approved, as is, with no conditions attached);
- Contingent approval (approved, subject to implementation of recommended changes);
- Resubmission required (requires that the applicant addresses questions posed by the TPREC and communicate the changes to the TPREC);
- Rejected (written reasons for the decision will be provided to the applicant and resubmission will be possible).

5.9 Constructive comments and suggestions identified during the review process will be conveyed to the applicant and their supervisor, lecturer or Programme Board (as appropriate to each application).

5.10 Applicants, assisted by their supervisor, lecturer or Programme Board (as appropriate to each application), will be responsible for ensuring that any changes requested by the TPREC are addressed.

5.11 Applicants will submit a signed hard copy of the application form, along with a letter from their supervisor, lecturer or Programme Board (as appropriate to each application) confirming all requested changes have been made.

5.12 Any changes to research previously approved by a TPREC must be referred for re-approval by the TPREC.

5.13 The Chair of each TPREC committee will audit all processes for quality assurance.

5.14 Appeals to decisions of TPRECs may be referred to the RSC-AC. Decisions made by the RSC-AC on referred cases will be final.

Appendix A

When is Ethics Clearance Required?

- Research involving human experimentation – including surveys, behavioural observation, interviews etc.
- Research involving human remains, cadavers, tissues, discarded tissue (e.g. placenta), and biological fluids
- Genetic manipulation or GMOs
- The possibility of a conflict of interest due to financial incentives / benefits from a sponsor
- The collection, storage and use of data of a sensitive or confidential nature
- The potential for conflict over authorship; fair recognition of all the participants in the research
- If ethical clearance is a stated requirement of the funding agency
- Emerging areas of research not yet listed or any research where the researcher is uncertain of the requirement.

The onus is on the research supervisor to be aware of these requirements.

Research that is not permitted includes:

- Research involving animals for scientific purposes.
- Clinical trials involving human participants
- Use of known teratogens, carcinogens and any cytotoxic substances in clinical trials
- Use of harmful substances in human participants
- Use of ionising radiation with human participants

Review is not normally required for:

- Research utilising existing publicly available documents or data
- Observational studies of non-vulnerable people in public places in which the identity of the participants remains anonymous.
- Quality assurance studies
- Audits e.g. product audits, process audits, system audits.

If in doubt, complete the Taught Research Ethics Approval Form in Appendix B.

Appendix B

Taught Programme Research Ethics Approval Application Form

Research undertaken by taught students must receive ethical approval unless deemed exempt. This application form may be completed by an individual student or by a Programme Board/Lecturer for a group of similar research projects.

This application is completed by:

Student: ☐ OR Lecturer on behalf of Programme Board: ☐

PART A

Applicant Details	
Name:	
Student ID: (if relevant)	
Programme Title:	
Programme Stage:	
Research Supervisor's Name: (if relevant)	

Project Details	
Research Study Title:	
Research Study Summary (max 100 words):	

Risk Checklist Please answer ALL the questions in each of the sections below – Tick YES or NO			
	Will the research study….?	YES	NO
1	Involve direct and/or indirect contact with human participants?		
2	Involve analysis of pre-existing data which contains personal or sensitive information not in the public domain?		
3	Require permission or consent to conduct?		
4	Require permission or consent to publish?		
5	Have a risk of compromising confidentiality?		
6	Have a risk of compromising anonymity?		
7	Collect/contain personal data i.e. any information that relates to an identified or identifiable individual?		
8	Collect/contain sensitive personal data e.g. health data, sexual orientation, race religion?		
9	Contain elements which you OR your supervisor are NOT trained to conduct?		
10	Use any information OTHER than that which is freely available in the public domain?		
11	Involve respondents to the internet or other visual/vocal methods where participants may be identified?		
12	Include a financial incentive to participate in the research?		
13	Involve our own students or staff?		
14	Take place outside Ireland?		
15	Involve participants who are vulnerable or at risk?		
16	Involve any participants who are unable to give informed consent?		
17	Involve data collection taking place BEFORE informed consent is given?		
18	Involve any deliberate deception or covert data collection?		
19	Involve a risk to the researcher or participants beyond that experienced in everyday life?		
20	Cause (or could cause) physical or psychological harm or negative consequences?		
21	Use intrusive or invasive procedures?		
22	Involve a clinical trial?		
23	Involve the possibility of incidental findings related to participant health status?		
24	Involve the remuneration of research participants?		

If, as a student, you answered **NO** to all the above questions your research supervisor will review, and if in agreement sign below to indicate that this form does not have to submitted to the Taught Programme Research Ethics Committee.

Name	Research Supervisor	*Signed*		*Date*	

If you answered **YES** to any of the above questions, you need to complete part B below.

PART B

1	Project Overview

Please give a brief overview of the study, including a summary of the aims and objectives.

Help: Describe the purpose of the research and what question(s) the project should answer.

2	Methodology

Please give a description of the methodology, including any data collection and analysis methods.

Help: Give an outline of the study here. If the project is complex, you can also submit the research proposal/protocol (no more than 2-3 A4 sides) if this would help the reviewer's understanding of the project. Include details of your (or the Research Supervisor's) appropriate skills and qualifications to carry out this research. Consideration of how, and for what duration are stored should be provided under Section 7 below.

3	Main Ethical Considerations

Please give a brief description of the main ethical considerations involved in the study.

Help: Highlight here the main ethical considerations for the study (which may concern, e.g., the type of participants, the sensitive nature of the study, the data collection process, security-sensitive research) and advise how the main issues will be addressed. If the project is funded, give details here, and whether there are any potential conflicts of interest involved in the study. NB: Section 5 below addresses: recruitment; voluntary participation; consent; and, the right to withdraw. Those details need not also be entered here.

4	Human Participants

If the study includes Human Participants (or their data), please give a description of who will be included.

Help:

- Please note this should include sample size/number of participants, whether the project will focus on any particular groups/individuals, if it will include any at risk or vulnerable participants, participants aged 16 years or under, etc. Please also specify the rationale for including / excluding groups of participants.
- If the research involves secondary data not in the public domain, give details in this section.

5	Recruitment, Voluntary Participation, Consent and Right to Withdraw

If the study includes Human Participants, please give a brief description of the recruitment process, how voluntary participation will be ensured, if (and how) informed consent will be obtained prior to participants taking part in the study, and the right of withdrawal from the research process.

Help:

- This should include clear information on how participants will be identified, approached and recruited; whether the study will include any covert research or deliberate deception; whether help is required from a third party/ gatekeeper to access participants; what information will be given to participants, etc.
- If expenses or any incentives are to be offered to participants, give full details.
- If research involves students, colleagues and/or other employees then specify the rationale for this and how issues of coercion or feelings of obligation will be addressed.
- If data is held on participants, research using that data may require permission from the participant.
- Regarding withdrawal from the study, discuss the different stages/dates a participant could withdraw or withdraw their data, and how they could do this.

6	Risks and Benefits

Please give a brief description of how, when and where the research will take place and whether there are any risks and/or benefits involved.

Help:

- This should include information on what participants will be required to do, the rationale for this and the level of risk involved.
- When considering risks, please refer to risks to the participants (e.g., for research in sensitive areas, where there is a balance of power), the researcher, any other parties to the research; and also any health and safety issues for anyone involved (e.g., for lone researchers carrying out fieldwork).

7	Personal Data, Anonymity and Confidentiality

Please specify what type of information/data will be collected/analysed and the source(s). In addition, specify if and how the anonymity of participants will be ensured, and information be kept confidential.

Help: This should include information on whether new information/data are being collected or uses data that are already in the public domain; whether the data includes personal data; whether the data includes sensitive personal data e.g. health data, sexual orientation, race, religion; how the data will be processed and stored; who will have access to it; who it will be shared with; how long data will be retained; how it will be destroyed; the Data Protection requirements for any sensitive personal data, etc. In addition, include whether there may be any requirements for disclosure of information to other parties due to professional practice or legal reasons. If there are limits to confidentiality, explain clearly how the participants would be advised about these limits and possible outcomes.

8	Reporting and Dissemination

Please give details of the planned dissemination and specify if the findings from the research will be published and whether any permission is required for this.

Help: This should include information on the methods of dissemination (e.g., dissertation/thesis) and/or what will be published and where (research papers, conference presentations). Specify if any permission is needed (e.g., from participants, clients, gatekeepers, etc.) prior to publication, and whether there are any potential issues relating to Intellectual Property Rights when creating or using materials.

9	Location of research

Will the research take place outside of Ireland?

YES ☐ **NO** ☐ **If yes, give details below.**

Help: If yes, please specify where the research will take place. Research must comply with the laws of the country where it is taking place and also comply with local Data Protection and Intellectual Property legislation: you must confirm that your research is compliant with local requirements and how you have ascertained this. Advise if the project requires ethical approval in-country and how this has been ascertained. If approval is required, a copy of this should be included in the application or details of the process of how it will be obtained. Please make reference to insurance and indemnity cover for the project where relevant.

Note: If data is to be processed or stored outside the EEA contact dpo@gmit.ie

10	Collaborative Projects

Is the research a collaborative project (i.e., it involves more than one institution)?

YES ☐ **NO** ☐ **If yes, give details below.**

Help: If yes, please specify the other institutions involved and if ethical approval needs to be / has been given by them. Please also specify what procedures have been put in place to ensure ethical compliance from all partners.

Note: If personal data is being shared between institutions then a data sharing agreement must be in place. Contact dpo@gmit.ie

11	Any other permission or external ethical approval required to undertake the project

Please specify if the project requires any other ethical approval or permissions not mentioned previously in this application and how and when these will be obtained.

Help:

• Other permissions: ethical approval does not give the right of access to the Institute's students, staff or the use of Institute premises to carry out research, and you may need to contact an appropriate Institute gatekeeper for agreement to approach potential participants or for the use of premises, so please give details. • Gatekeepers: permission of a gatekeeper for initial access to participants may be required or to carry out data collection on their premises. • If the project requires approval from an external ethics committee, this should normally be obtained prior to submitting this application. • If a Disclosure and Barring Service check is required due to the specific participant group, give details. • Regarding insurance and indemnity cover, some projects will require individual confirmation of cover. See the Research Ethics Procedures document for more details.

SUPPORTING DOCUMENTATION: what to submit with the application

For projects involving human participants, you must submit, where appropriate, the Participant Information Sheet/s and consent form/s. You must also submit every communication a participant will see or receive. Failure to do so will cause delays to the application.

DECLARATIONS AND SIGNATURES

STUDENT			
I confirm that I will undertake this project as detailed in Part A and Part B of the application. I understand that I must abide by the terms of this approval and that I may not make any substantial amendments to the project without further approval. I understand that research with human participants or their data must not commence without ethical approval.			
Signed		*Date*	

RESEARCH SUPERVISOR RECOMMENDATION FOR STUDENT PROJECT					
I confirm that the committee has considered part A and part B of the application. The project is viable and the student has appropriate skills to undertake the project. Where applicable, the Participant Information Sheet and recruitment procedures for obtaining informed consent are appropriate and the ethical issues arising from the project have been addressed in the application. I understand that research with human participants must not commence without ethical approval. I recommend this project for approval.					
Name	Research Supervisor	*Signed*		*Date*	
Comment(s): E.g. if similar research projects have been previously approved.					

LECTURER ON BEHALF OF PROGRAMME BOARD			
I confirm that the project will be undertaken as detailed in stage one and stage two of the application. I understand that I must abide by the terms of this approval and that I may not make any substantial amendments to the project without further approval. I understand that research with human participants or their data must not commence without ethical approval.			
Signed		*Date*	

PROJECTS APPROVED BY THE RESEARCH ETHICS SUB-COMMITTEE					
I confirm that this project was considered by the Taught Programme Research Ethics Committee and has received ethical approval.					
Chair		*Signed*		*Date*	

This form will be retained for the purposes of quality assurance of compliance and audit for THREE years

Appendix C

Guidelines for Taught Programme Research Ethics Committees

1. The decisions of the TPREC should be guided by the following set of generic ethics principles:
    a. Respect for the dignity, worth and self-determination of all participants
    b. Responsibility to the research participant and to society
    c. The conducting of research which is within the competence of the researcher.
2. The decision-making process of the TPREC is governed by the following factors:
    a. Transparency and accountability of ethics decision making
    b. Awareness of the limitations of the competence of the TPREC
    c. Obligation to accumulate and disseminate a knowledge-base of ethics issues and procedures to inform future ethics decision making.
3. Committee members should review each application form to:
    a. Ensure that the applicant has addressed the risks and benefits which potential research participants may be exposed to or experience.
    b. Ensure that the proposed selection of participants is equitable
    c. Ensure that the informed consent process will provide sufficient information to potential participants, so they can amend informed decisions about participating in the research.
4. The committee should identify if there are any issues or concerns, which should be conveyed to the applicant with the decision of the committee.
5. Where it is considered appropriate, the TPRC may invite the Applicant or their supervisor to attend a meeting and participate in discussions about their proposal. However, they must not be present during the decision-making discussion.
6. In addition to being communicated to the applicant and supervisor, the decision of the TPREC must be recorded on the application form. Application forms and other related documents will be maintained in the School Office for a period of three years.