Mary Immaculate College Research Ethics Committee

Introduction

Mary Immaculate College Research Ethics Committee (MIREC) was established to support supervisors and researchers in ensuring that research involving human participants by staff and postgraduate students is carried out to the highest possible standards, with regard for the welfare of human participants and in accordance with recognised legal, professional and ethical standards.

All research involving human participants conducted by a member of staff and/or research postgraduate student as part of his/her professional activity / course of study requires prior approval by MIREC. Research involving human participants includes the physical participation of people in research projects as well as their involvement through provision of or access to personal data not already in the public domain.

The information requested by MIREC is based on the principles operant in the University of Limerick research ethics guidelines. Applications to the Research Ethics Committee must be submitted on the designated Application Form(s).

Research Ethics Issues

In general issues arise under the following five headings:

Informed Consent

Researchers must provide clear and open information concerning the research project and the procedures involved to human participants. Participation must be voluntary and participants must be clearly informed that they have a right to withdraw their participation at any time. Where appropriate the researcher must obtain written informed consent from the participant and / or his/her parent/guardian/responsible other in advance. A responsible other is somebody who has responsibility for the welfare and wellbeing of the participant.

Privacy and Confidentiality

Researchers must ensure the confidentiality of data gathered in the course of research (i.e. where that data is not already in the public domain). Where appropriate they must ensure the privacy or anonymity of human participants.

Risk Assessment

Research must be carried out with a view to benefiting human participants and society in general. Research must not cause unacceptable harm. Researchers are obliged to identify potential risks to human participants arising from their participation in a research project.

Remuneration

The remuneration of participants in research projects is permissible, but only where this constitutes recompense (for example, for out-of-pocket expenses, time or inconvenience). Remuneration is not permissible where is might act as an inducement to participate or where it has the potential to discriminate between different kinds of participants or participants and non-participants.

Using Students as Research Participants

In cases where the proposed research necessitates the participation of the researcher’s students a justification must be provided and the steps that will be taken to ensure that participation is voluntary and that participants may withdraw at any time without consequence or fear of consequence must be outlined.

Lecturers may not present their research project to students but must ask a fellow researcher or colleague to do so.

However, other research ethics issues may arise from time to time and in these cases guidance may be sought from the MIREC Chair.
Guidelines on Using Students as Research Participants

If it is necessary that students that you teach participate in the research, steps must be taken to ensure that their participation is voluntary and that they may withdraw at any time without consequence or fear of consequence. Examples of these steps include:

**Questionnaires**

Administration of research instruments such as questionnaires by an independent party e.g. if a lecturer / tutor wishes to distribute a paper questionnaire at the end of a lecture they would explain what the research is about (including voluntary nature of it and the right to withdraw), introduce the person administering the research and then leave the room.

If research is conducted by an independent third party who is employed on a temporary contract, arrangements must be made to ensure that documents that identify participants such as consent forms are handed over to the MIREC Administrator for retention.

Administration of questionnaires in a way that ensures the anonymity of participants e.g. distribute an Information Sheet along with the questionnaire that explains that completion of the questionnaire implies consent in relation to statements in the Information Sheet such as how the information provided will be used and disseminated and eligibility to participate. These statements could also be incorporated into the beginning of the questionnaire with tick boxes beside them.

**Focus Groups**

Engage an independent party to conduct Focus groups e.g. Research Assistant Where focus groups are conducted by an independent party the recordings should be transcribed and anonymised. The digital recordings should not be retained and only the anonymised transcripts should be available to the researcher.

Procedures for Research Ethics Approval at MIC

It is the responsibility of the researcher to ensure that his/her research complies with relevant legal, professional and ethical standards and to seek approval from MIREC before contact is made with human participants.

Researchers must complete the Mary Immaculate College Research Ethics Application Form, together with all relevant documentation, and submit it as one document in signed hard copy and electronic copy format to the MIREC Administrator.

Research postgraduate students must follow the same process, but must submit documentation to their supervisor in the first instance. The supervisor will indicate his/her approval as appropriate and forward the application to the MIREC Administrator.

All material relating to the application must carry the College logo e.g. Information Sheets, Consent Forms etc.

One application should be submitted per project. In cases where more than one researcher is involved in a project, the Principal Investigator named on the application form is deemed to have overall responsibility for the project.

In cases where there are other institutions/organisations involved in the study, apart from the College, details of each institution/organisation involved, the nature of their involvement, and the signature of a representative of each institution/organisation must be appended to the Application Form.

The MIREC Administrator will distribute the submitted application to the members of MIREC. Members will provide feedback to the MIREC Chair, who will formulate a response and inform the applicant of the decision. The review of applications will typically take up to 20 working days during term time but in some circumstances may take longer.

Period of Approval

Approval is normally given for a project of up to four years duration. If the project has not started within one year approval will be rescinded. If the study is to exceed 4 years duration, approval must be sought from the Committee and the researcher will be required to check in with the committee after 4 years. If approval is granted for a project of four years duration and an extension is required approval must be sought from MIREC.

In the event that the Principal Investigator is a member of staff, but is not a permanent employee of the College, please note the guidelines provided at 3a below.

In cases where a project continues after a Principal Investigator leaves the employment of the college, the replacement Principal Investigator should notify the change of personnel to MIREC in writing.
Adaptation of Research

Where research instruments and protocols are adapted in a significant way subsequent to the granting of approval by MIREC, a revised application must be submitted to MIREC for approval. Research postgraduate students must consult with their supervisor in the first instance.

Researchers should contact the MIREC Administrator for advice concerning adaptation of research instruments and protocols in the first instance.

Research Ethics approval from another HEI

In cases where joint projects involving staff and postgraduate students have been approved by a Research Ethics Committee at another Higher Education Institute (or equivalent), evidence of approval must be provided to MIREC.

Applications and requests for information must be submitted to:

MIREC Administrator
Mary Immaculate College
South Circular Road
Limerick
061-204980
mirec@mic.ul.ie

The relevant forms are available electronically on the MIREC web page http://www.mic.ul.ie/research/mirec.

Applications must be submitted in both hard copy and electronically.

Guidelines on Completing the MIREC Application Form

The information provided on the MIREC Application Form must be comprehensible to non experts.

Applications may be submitted in any language. However, it is the responsibility of the applicant to provide an English translation of the application.

1a Title of Research Project
The title should be as short a possible but still fully reflect the topic and scope of the project.

1b Brief Outline
Provide a brief and accessible outline of the project (50-75 words).

2 Period for which approval is sought
Please provide the proposed start date and the anticipated completion date of the project. Approval is usually granted for a maximum of four years, but can be extended if necessary by contacting the committee (see Period of Approval above).

3 Project Investigators
3a Principal Investigator
Please complete the required details for the Principal Investigator. The Principal Investigator may be a member of staff, an external researcher and/or a research postgraduate student.

3b Other Investigators
Please complete the details for other investigators involved in the project. This may include other researchers, including post-doctoral researchers, students (undergraduate and postgraduate) and technicians. Remember to include the affiliations of each of the other investigators. For example, if one of the other investigators worked for an external company or institution, include these details in this part of the form. All other investigators must read the application form and sign this part of the form.
3c **Foresight**
If it is foreseen that the Principal Investigator or another member of the research team are likely to change institutional affiliation during the course of the research project, a summary must be provided showing how the ethical issues will be handled in this situation.

3d **Ethical Guidelines / Ethical Clearance from Another Source**
Are there Ethical Guidelines (other than MIREC) to which you must adhere in your field of study?
- YES
- NO

Do you require Ethical Clearance from another source?
- YES
- NO

If you answer Yes to either of these questions, please specify the Ethical Guidelines / Ethical Clearance that is required.

4 **Supervisors**
In cases where the applicant is a research postgraduate student, the Supervisor(s) is (are) required to approve and sign the declaration in the relevant section of the form. Please note that consent relates to Research Ethics issues only.

5 **Study Descriptors**
Please mark with a ✓ all the terms that apply to this study. If you have ticked a particular box, then remember you will have to complete the requirements as indicated below.

Seeking the consent of participants under the age of 18 is normally required. In the event that informed consent is not being sought from these participants, justification must be provided.

<table>
<thead>
<tr>
<th>Healthy Adults</th>
<th>Vulnerable Adults</th>
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<tr>
<td>Requirements:</td>
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<tr>
<td>Participant Information Sheet</td>
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<td>Participant Informed Consent Form</td>
<td>Responsible Other Information Sheet</td>
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<td>Responsible Other Informed Consent Form</td>
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<td>Participant Information Sheet</td>
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<td>Parental Information Sheet</td>
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<td>Participant Informed Consent Form</td>
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<td>Parental Informed Consent Form</td>
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<td>Requirements:</td>
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<td>Completion of Sections 6b and 8 of Form</td>
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<td>Completion of Section 6b of Form</td>
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<td>Requirements:</td>
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<td>Completion of Section 8 of Form</td>
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<td>Requirements:</td>
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<td>Questionnaire/Sample Questions Required</td>
<td>Chaperoning of Participants may be Necessary</td>
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<td>Chaperoning of Participants Necessary</td>
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<td>Completion of Section 6b of Form</td>
<td>Completion of Section 8 of Form</td>
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<th>Project is Off-Campus</th>
<th>Other</th>
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<tr>
<td>Requirements:</td>
<td>Requirements:</td>
</tr>
<tr>
<td>Details of Location</td>
<td>Specify descriptor and indicate requirements</td>
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</table>
6 Project Design & Methodology
6a Rationale, Purpose and Benefits of Research Project
This section should contain reference to literature and should not be longer than 200 words. When referencing literature/research provide a full reference in the text or in an attached list of references.

6b(i) Research Methodology
Outline the research methods that will be used.

6b(ii) Research / Data Collection Techniques
Outline the research techniques that will be used.

6c Steps taken to minimize risk
Please indicate any reasonable risks associated with this project. Outline all steps taken to minimize these risks.

6d Location(s) of Project
Please identify the location(s) of the proposed research project.

6e Questionnaires and Interview/Survey Questions
If you are conducting a project involving a questionnaire, interview or survey, outline the questionnaire, interview questions or survey questions on the application form and attach them to the application. Alternatively, please provide a sample questionnaire, interview questions or survey questions.

In particular cases MIREC may ask for additional detail with regard to questionnaires, interviews and surveys.

7 Participants
7a How will potential research participants be identified and selected?
Please indicate the criteria by which the participants will be selected (e.g., age, gender, nationality) if relevant. If an advertisement is to be used it must be approved by MIREC.

7b This section should be completed if the proposed research necessitates the recruitment of participants from a student cohort taught by the researcher in the same academic year that the research is conducted

7b (i) Provide a justification as to why it is necessary that students that you teach participate in the research.
7b (ii) Specify the steps you will take to ensure that participation is voluntary and that participants may withdraw at any time without consequence or fear of consequence.

7c How many participants will be recruited?

7d Will participants be recompensed for expenses incurred due to taking part in this research project?

\[
\text{YES} \quad \text{NO} \quad \text{N/A}
\]
If YES, please provide details.

7e Will incentives / inducements be provided to participants for taking part in this research project?

\[
\text{YES} \quad \text{NO}
\]
If YES, please provide details.

7f Recruitment Letters/Advertisements/e-mails, etc
If you are using a letter, an advertisement, an e-mail or something similar to recruit participants or to ask for permission to use persons within an institution (e.g. school), they must be listed on the application form and a copy of each must be attached to the application. They must outline in detail what the project is about, whom to contact for further information, etc.

7g Permission to Conduct Research within an Institution
Permission to conduct research within an institution should be obtained in writing from an individual with the authority to give that permission. The authority to grant such permission is determined by the institution’s policies or terms of reference.

Written permission may be:
- A signed permission form provided by the researcher which clearly outlines what is involved in the research and what is being agreed to – a copy of the form should be included in the MIREC application
- A signed letter or e-mail from the person granting permission that clearly references the research title and outlines what is being agreed to.

8 Confidentiality of collected data
8a What measures will be put in place to ensure confidentiality of collected data?

8b Where and how will the data be stored / retrieved?
8c Who will have custody of, and access to, the data?

8d For how long will the data from the research project be stored? (Please justify)

Please indicate and justify for how long any collected data will be stored. Please refer to the MIC Record Retention Schedule for guidance on the appropriate retention period for research records.

Please note that the collection, storage and use of data should comply with current Data Protection legislation. For information see: http://www.dataprotection.ie

9 Information Documents

Indicate which information documents are applicable to your Research Project and attach a copy of each applicable information document to the application.

9.1 Participant/Parent/Responsible Other Information Sheet

The information sheet must include the full title of the study. The information sheet must be written using lay terms, and must not contain any technical or specialist terms that may not be understood by the potential participants. Ideally, a sufficient amount of time must be allowed to read and to consider the contents of the information sheet (this might be an hour, a day or a week).

Different study groups may require separate information sheets. Children, vulnerable children and vulnerable adults will require suitably worded information sheets. Parent/responsible other information sheets must be written with their child or the person for whom they care in mind. In the case of vulnerable children and vulnerable adults, the research subject should be facilitated as much as possible to give fully informed consent. Evidence of these efforts should be presented in the application.

The following is a list of the items that you may address when preparing your information sheets. You can include these as subheadings on the information sheet.

1. MIC Logo and name at top of page
2. Title of project
3. What is the project about?
4. Who is undertaking it?
5. Why is it being undertaken?
6. Exactly what is involved for the participant? (time, location, etc)
7. What are the benefits and risks? (If appropriate),
8. Right to withdraw/not answer questions.
9. How will the information will be used / disseminated?
10. How will confidentiality be kept? (If appropriate)
11. What will happen to recordings, transcriptions, after research has been completed? (If appropriate)
12. Contact details for the Project Investigator(s)
13. The following standard paragraph must also be included:

If you have concerns about this study and wish to contact someone independent, you may contact:
MIREC Administrator
Mary Immaculate College
South Circular Road
Limerick
061-204980
mirec@mic.ul.ie

Please note: It is important that a copy of any information sheets are made available for the participants / parents / responsible others to keep for their future reference.

9.2 Informed Consent Forms

The Committee places great emphasis on a suitably worded consent form and information sheet.

Note that these must be two separate documents.

The consent form must include the full title of the study. The participant must not feel coerced in any way and it must be clear to the participant (or their parent/guardian/responsible other) that they may decline to take part, or withdraw at any time, without affecting them in any way. In most cases, the decision to participate and give informed consent must take place after an interval (hours or days) allowing the participant time to read the information sheet and discuss further with relatives or friends. In some cases it may be appropriate to allow a period of time of up to three days between giving consent and the initiation of data collection.

There must be a place for the participant to sign and date that they have understood fully what will be involved. If the participants are children*, vulnerable children* or vulnerable adults, then their legal guardians/responsible others must
give consent. Children, vulnerable children or vulnerable adults should be offered an opportunity to give consent and a suitably worded/visual consent form must be provided. In the event that informed consent is not being sought from these participants, justification must be provided. Children, vulnerable children or vulnerable adults have a right to withdraw their consent at any time, regardless of the fact that their legal guardian/responsible other has given consent.

Please find below an example of what to include on an informed consent form:

- I have read and understood the **participant/parent/responsible other information sheet**.
- I understand what the project is about, and what the results will be used for.
- I have completed the **pre-test questionnaire** (if necessary)
- I am fully aware of **all** of the procedures involving myself, and of any **risks and benefits** associated with the study.
- I know that my participation is voluntary and that I can withdraw from the project at any stage without giving any reason.
- I am aware that my results will/will not be kept confidential (delete as appropriate)


10 Declaration

The relevant person(s) must sign the declaration.