RESEARCH ETHICS POLICY AND PROCEDURES

RESEARCH AND SCHOOL INTERNAL REVIEW DIRECTORATE

EDUCATION STRATEGY AND QUALITY ASSURANCE DEPARTMENT

MINISTRY FOR EDUCATION AND SPORT

GOVERNMENT OF MALTA
MINISTRY FOR EDUCATION AND SPORT
RESEARCH AND SCHOOL INTERNAL REVIEW DIRECTORATE

RSIRD
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1. Introduction

The Ministry for Education and Sport (MES) Research Ethics Committee (MREC) within the Research and School Internal Review Directorate (RSIRD), aims to promote, facilitate, and evaluate proposed research that benefits participants, the educational field, and society as a whole.

To achieve this, the focus is placed on the following key areas:

1. Promoting ethical standards: MREC is dedicated to upholding high ethical standards in research. This involves ensuring that all studies comply with both internationally and locally accepted ethical guidelines.
2. Protecting participants: The unit recognises its responsibility to safeguard the rights, safety, dignity, and well-being of all potential participants, as well as the communities involved in the research.
3. Authority over research studies: MREC has the authority to approve, reject, or halt studies, as well as to require modifications to research protocols when necessary.

By focusing on these areas, MREC seeks to ensure that research conducted is not only beneficial but also ethically sound and responsible.

2. Objectives

The Research Ethics Policy and Procedures is designed to:

1. Protect the dignity, rights, safety, and well-being of human subjects.
2. Clarify the Directorate's stance on research ethics concerning studies involving human subjects and personal data.
3. Establish a commitment to high-quality, transparent, and accountable research ethics, from senior management policymaking to the practical implementation in individual staff and learner research projects.
4. Provide support and guidance on research ethics.
5. Foster an organisational research culture based on robust and defensible standards of research practice.
6. Minimise risks to the MES, human subjects, and individual researchers.
7. Ensure compliance with data protection legislation.

3. Research Ethics Approval Requirements

1. Any research involving human or non-human participants requires ethics approval in accordance with this Policy before it can be conducted.
2. All requests for research must be submitted to MREC for review and approval.
3. Obtaining ethics clearance is essential to protect the welfare and rights of participants, researchers, the MES, and the broader community.
4. No researcher may begin a project until the necessary ethics approval has been obtained in accordance with the Ethics Regulations of MREC.
5. For the purposes of this Policy, research involving humans refers to studies conducted with or about people, or their data. Human participation may include, but is not limited to:
    a. Participation in surveys, one-on-one interviews, or focus groups.
    b. Undergoing psychological, physiological, or medical testing.
    c. Being observed by researchers.
    d. Allowing researchers access to personal documents or materials.
    e. Providing consent for researchers to access their information (whether individually identifiable, re-identifiable, or non-identifiable) from existing or unpublished sources or databases.
6. Researchers must obtain specific consent from data subjects before processing their personal data. During this process, researchers should inform data subjects about the purpose of data processing and their rights under the General Data Protection Regulation (EU) 2016/679 (GDPR) and the Data Protection Act (Cap 586), including the right to access, rectify, and, where applicable, erase their data.
7. Research that does not directly involve humans but could still affect them also requires ethics approval. Examples include:
    a. Research related to sites of community, cultural, historical, or religious significance to a specific group of people.
    b. Findings that may have a direct and significant impact on the personal or professional affairs of a definable group of individuals.

4. The Research Ethics Committee

MREC supports the ethical review of all research activities carried out within MES, particularly in state schools and other educational settings under its remit.

The Committee is composed of members from within RSIRD, who bring a range of perspectives to the review process. It is chaired by the Director of RSIRD and meets regularly

to review submissions and provide guidance. Its composition and meeting schedule are adapted as needed to respond to current demands and priorities.

5. Researcher Responsibilities

Researchers have an obligation to conduct their research with:

1. Honesty
2. Integrity
3. Minimal risk to participants and themselves
4. Cultural, gender, and ethnic sensitivity

Guidance on interpreting and applying these principles, including circumstances where deviations may be ethically justified, is provided in this Policy document.
These essential principles of research ethics are grounded in international agreements and national laws. Violations of these principles may sometimes result in civil or criminal penalties. While this Policy reflects fundamental ethical principles, it does not override a researcher's legal obligations. Conducting ethical research does not require avoiding high-risk studies; rather, it involves recognising, preparing for, and responsibly managing potential risks. Therefore, ethical research is about being risk-aware, not risk-averse.

6. The Research Ethics Committee within the RSIRD is tasked with:

1. Conducting regular reviews of the Research Ethics Policy and Procedures.
2. Providing interpretations of the Research Ethics Policy and Procedures.
3. Resolving disputed or ambiguous research proposals.
4. Periodically assessing the effectiveness of research ethics review procedures and ensuring compliance with data protection legislation.
5. Actively promoting awareness and understanding of the Research Ethics Policy, as well as broader research ethics principles within the educational sector.
6. Offering guidance on ethical issues related to research as referred from the Department and the broader MES.

7. Criteria for Ethical Review by MREC

Scope of Ethical Review:
All research involving human subjects should be assessed against the criteria listed below prior to the recruitment of study participants. Reviews should be conducted on a project basis. An application may cover a full study across its various phases or submissions may be made for individual stages or phases separately.

Extended Review Requirements by MREC:
Review by MREC is required for projects that meet one or more of the following criteria:

1. Projects that induce more than minimal stress, such as:
2. Procedures that pose any risk to a participant's health or well-being, including intrusive physiological or psychological measures.
3. Surveys, questionnaires, or research that may be offensive, distressing, or deeply personal for the target group, even if individuals are not directly identifiable. This may include questions on sensitive data such as ethnicity, political views, religion, health conditions, sexual orientation, or alleged offenses.
4. Protocols involving vulnerable groups such as children under 16 or individuals who may feel pressured to participate due to their relationship with the researcher.
5. Research involving prisoners, young offenders, or other marginalised groups.
6. Research accessing or collecting records containing personal confidential data concerning identifiable individuals, as defined by data protection legislation. This includes sensitive personal data, academic or career information, and protected characteristics under the Equal Opportunities Act of 2000 (e.g., disability, marriage, pregnancy).
7. Studies that link or share personal data beyond the initial consent given, especially when there's a risk of breaching confidentiality agreements with participants.
8. Research that involves collecting or accessing identifiable audio/video recordings, photographs, or quotations for dissemination outside the research team. This includes publicly available information from social media or participants recruited through online platforms, particularly when privacy expectations are unclear or sensitive issues are discussed.
9. Research protocols that require participants to partake without their knowledge or consent at the time (e.g., covert observation or emergency research).
10. Research involving deception beyond the withholding of the study's aims until the end of data collection.
11. Research where the safety or well-being of the researcher may be at risk. All researchers affiliated with the Institute must adhere to the relevant Health and Safety policies and procedures.

12. Research in which the researcher anticipates significant ethical concerns, even if they do not fall into the above categories.

'Light Touch' Ethical Scrutiny by MREC:

For an application to qualify for 'light touch' review by MREC, the research must not fall under any of the categories listed above. Low-risk research should be free from any of the components outlined. It is important to note that no category of research, such as undergraduate dissertations, automatically qualifies as low risk.

8. **Procedures**

Applications to MREC should provide sufficient detail to allow an ethical judgment to be made. The data submitted must include the following information:

1. Applicant details (name, affiliation, contact information).
2. Title of the investigation or consultancy.
3. Aims and objectives of the research proposal.
4. Methodology to be used.
5. The school sector, organisation or entity within MES where the research will be conducted.
6. The timeline for the research project.
7. Year/form and age range of participants (if applicable).

Proposed Information Sheet and Request for Permission:

An information sheet must be provided to the Head of the School/Organisation/Institute where the research is planned to take place. This should include a formal request for permission to conduct the research. A template for this form can be accessed here.

Informed Consent Forms:

1. Informed Consent for Adult Participants:
   In all research involving the collection of personal data, informed consent from participants is mandatory. Participants must be fully informed about the research, including any potential physical or psychological risks. Researchers must obtain explicit consent from participants before starting the research. The consent must be specific to the research being conducted. A template for this form can be accessed here.

2. Consent for Participants Unable to Give Informed Consent:
   If the research involves participants unable to provide informed consent (e.g., children or adults lacking capacity), their legally responsible parents or guardians must sign the consent form. A template for this form can be accessed here.

3. Assent from Minors:
   When research involves minors capable of providing assent, it is generally appropriate to obtain agreement from the minors themselves, in addition to the consent of their legally responsible parents or guardians. A template for this form can be accessed here.

Required Content for Consent Forms:

1. A statement that the study involves research.
2. A brief explanation of the research purpose.
3. The expected duration of the participant's involvement.
4. A description of the procedures to be followed.
5. A statement regarding any reasonably foreseeable risks or discomforts, whether psychological or physical. If such risks are anticipated, details should be provided along with information on available psychological or emotional support services.
6. A description of any potential benefits to the participant or others.
7. A statement that participation is voluntary, and that refusal to participate will not result in any penalties or loss of benefits to which the participant is otherwise entitled. Participants must also be informed that they can discontinue their participation at any time without penalty.
8. A statement outlining the extent to which the confidentiality of records identifying participants will be maintained and who will have access to these records.
9. Information regarding participants' rights under the Data Protection Act, including their right to access, rectify, and erase their personal data, where applicable.
10. Contact details of the Principal Investigator (PI) and supervisor (if applicable), enabling participants to request further information about their data or the research.

9. Applications

1. Applications for research should be completed online via this link. Applications are submitted for review to MREC.
2. MREC will register the application and assess whether to approve it or request additional information from the applicant.

3. In cases where MREC determines that the proposal raises no ethical or data protection issues, the researcher will be informed and provided with an Authorisation Letter issued by MREC.
4. If the proposal raises any ethical or data protection concerns, MREC may request clarifications or improvements on these issues. Feedback will be sent to the applicant at the address provided on the application, along with any relevant guidance.
5. Depending on the time of year when the application is submitted, this process may take up to four (4) weeks.

10. Conditions of ethics approval

Ethical approval is granted under specific conditions, and it is essential for researchers to understand and comply with these requirements:

1. *Reporting Adverse Effects:* Any serious or unexpected adverse effects on research participants must be reported to MREC immediately.
2. *Unforeseen Events:* Any unforeseen events that could affect the ethical acceptability of the research project must be promptly reported to MREC.
3. *Amendments to Research Protocol:* MREC must be notified of, and approve, any changes to the original research protocol. This includes, but is not limited to, changes in the research team, research design or methodology, research tools, or participant recruitment methods. All amendments must be submitted through a Request for Amendment to Approved Research Project.
4. *Data Protection Compliance:* Researchers must adhere to the General Data Protection Regulation (EU) 2016/679 (GDPR) and the Data Protection Policy throughout the project.

Data Protection

1. Data Controller and Processor

MREC shall be the Controller and Processor of data for the purposes of the General Data Protection Regulation (EU)2016/697 (GDPR) and the Data Protection Act chapter 586 of the laws of Malta. MREC collects and processes personal data limitedly for the performing of its functions pertaining to research, statistical and archiving purposes in accordance with the provisions of the prevailing National Laws and Regulations. Specifically, Article 16 (1) of the Education Act Cap. 327 of the Laws of Malta states that: *Every Directorate may request, collect, and verify any information, data and statistics, as may be required for the performance of its functions*.

2. Rights of the Data Subject

1. *The Controller and Processor* of personal data is MREC within the office of the Director General, Education Strategy and Quality Assurance Department.
2. The personal data collected shall be used solely for the purposes requested.
3. *The Data Subject* has the right to request from the Controller rectification or erasure of his/her personal data. This right is limited to the extent that the Directorate is obliged to abide by any law or regulation.
4. The Data Subject has the right to request withdrawal of his/her consent at any time, without affecting the lawfulness of processing of data subsequent to that consent before its withdrawal.
5. Should the Data Subject feel that his/her data protection rights have been infringed by the Controller, Processor, or any of his delegates, he/she a right to lodge a complaint with the supervisory authority, that is, The Information and Data Protection Commissioner. https://idpc.org.mt/en/Pages/dp/principles.aspx

3. Research

Research projects conducted by MREC may involve collecting and processing of personal data for specific purposes, such as for conducting surveys. In such events appropriate safeguards shall be adopted by MREC so that personal data shall be excluded from publishing of research reports. Furthermore, where possible, research data shall be collected in such a way as to exclude personal information, for example by enabling survey respondents to optionally submit all or some of their responses anonymously or pseudonymously.

4. Archiving, Scientific and Statistical Purposes

Personal Data processed by MREC for archiving, scientific and statistical purposes in the public interest shall be subject to appropriate safeguards in accordance with the GDPR Regulation and the Data Protection Act chapter 586 of the laws of Malta, for the preservation of the rights and freedoms of the data subject. Such safeguards shall ensure that technical and organisational measures are in place so that the principle of data minimisation shall prevail in all such circumstances.

5. Procedure for personal data access by Data Subject

The GDPR Regulations demand a formal procedure for dealing with personal data access requests by the data subject, which MREC follows. The data subject is entitled to know who has access to his/her personal data and why, how it is kept up to date and what MREC is doing to comply with its obligations under the Regulations. Should the data subject wish to know what personal information is held by MREC, he/she may submit a request in writing to the MREC Data Controller, including identification details, namely, name and surname, identity card or passport number and personal address. If required, the data subject will be asked to show the original identification documents when collecting or otherwise receiving personal information.

6. Compliance with request by data subject for access to personal data.

MREC strives to comply as expeditiously as possible with requests by data subjects for access to their own personal information, ensuring that it is provided within a reasonable time, (one month latest), unless there is good reason for delay. When a request for access cannot be met within such a reasonable time, the reason/s shall be explained in writing to the data subject making the request. A copy of this Data Protection Policy shall be made available to data subjects on the RSIRD website.