RESEARCH ETHICS POLICY AND PROCEDURES

DIRECTORATE FOR RESEARCH, LIFELONG LEARNING AND EMPLOYABILITY
MINISTRY FOR EDUCATION AND EMPLOYMENT

1. Introduction

The MEDE Research Ethics Committee (MREC) within the Directorate for Research, Lifelong Learning and Employability was set up in February 2019. The principal function of the MREC is to promote, facilitate and review proposed research that is of potential benefit to participants, the educational field and society in general. Its ultimate goal is to promote high ethical standards in research, ensuring that they conform with internationally and locally accepted ethical guidelines. MREC acknowledges its responsibility to protect the rights, safety, dignity and well-being of potential participants in the research, and the community in which the research will be carried out. The MEDE Research Ethics Committee has the authority to approve, reject or stop studies, or require modifications to research protocols.

2. Objectives

2.1 The MREC's Research Ethics Policy and Procedures is intended to:

- Protect the dignity, rights, safety and well-being of human subjects;
- Codify MREC's position on research ethics for research involving human subjects, and personal data;
- Establish a commitment to high quality, transparent and accountable research ethics from senior management policy-making to the practicalities of individual staff and learner research projects;
- Provide support on research ethics;
- Encourage an organisational research culture based upon defensible standards of research practice;
- Reduce risks to the MEDE, and to the human subjects or to individual researchers;
- See that the requirements of data protection legislation are observed.

3. General Principles

3.1 Any research involving humans or non-human participants requires ethics approval in accordance with this Policy before the research can be carried out.

3.2 All requests for research must be referred to the MEDE Research Ethics Committee for review and approval.

3.3 The necessity to obtain ethics clearance is based on the need to protect the welfare and rights of participants in research, the researcher(s), MEDE and the community in general.

3.4 No research project is to be commenced by a researcher until the required ethics approval as per Ethics Regulations of MREC, within the Directorate for Research, Lifelong Learning and Employability, Ministry for Education and Employment has been obtained.

3.5 Research involving humans, for the purposes of this Policy, is research conducted with or about people, or their data. Human participation in research includes, but is not limited to, the involvement of human subjects through:

- Participation in surveys, one-to one interviews or focus groups;
- Undergoing psychological, physiological, or medical testing;
- Being observed by researchers;
- Permitting researchers access to their personal documents or other materials;
- Consenting access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing or unpublished source or database.

3.6 Researchers shall obtain the consent, which has to be specific, from the data subjects prior to processing their personal data. In obtaining the consent, the researcher shall inform the data subjects about the purpose of processing, and about their rights under the General Data Protection Regulation (EU) 2016/679 (GDPR) and the Data Protection Act (Cap 586), namely the right to access, rectify, and where applicable erase the data concerning them.

3.7 Research that does not directly involve humans but can affect them also requires ethics approval. Examples of this may include research involving:

- Sites of community, cultural, historical or religious significance to a definable group of humans;
- Findings that have a direct and significant impact upon the personal or professional affairs of a definable group of humans.

4. Researchers' obligations

4.1 Researchers have an obligation to ensure that their research is conducted with:

- Honesty;
- Integrity;
- Minimal possible risk to participants and to themselves;
- Cultural, gender and ethnic sensitivity.

4.2 Guidance on the interpretation and application of these principles, including circumstances where a departure from these principles may be ethically justified, is detailed in this Policy document.

4.3 These essential principles of research ethics are established in international agreements, as well as national laws. Violation of these principles may, in some occasions, be a civil or criminal offence. The principles and requirements outlined in this Policy reflect the fundamental principles but do not displace a researcher's legal obligations. Ethical research conduct does not require the avoidance of potentially high-risk research. An ethical approach to research involves, rather, proper recognition of, and preparation for, risks, and their responsible management. Ethical research is therefore a matter of being risk aware, not risk averse.

5. The Research Ethics Committee

5.1 The MEDE Research Ethics Committee must have at least five (5) members, with varying backgrounds to promote complete and adequate review of commonly conducted research activities.

5.2 The members will serve for a period of three (3) years, which can be renewed. The committee shall meet at least twice every year to review protocols. The calendar of its meetings will be established every year.

5.3 The Research Ethics committee is currently composed as follows:

- Director, Directorate for Research, Lifelong Learning and Employability (DRLLE)
- Member, (Secretary to the Committee, Officer in charge Requests for Research)
- Member, (Legal Officer, DRLLE)
- Member
- Member

5.4 The Research Ethics Committee is responsible for:

- Periodically giving guidance on reviewing the Research Ethics Policy and Procedures;
- Offering guidance on the interpretation of the Research Ethics Policy and Procedures;
- Settling disputed or uncertain ethics approval decisions;
- Periodically monitoring the effectiveness of research ethics review procedures and make sure the requirements of data protection legislation are observed;
- Actively promoting awareness and knowledge of the Research Ethics Policy and Procedures, and research ethics more generally, within the Educational field;
- Providing advice on ethical matters relating to research that are referred to it from within the Directorate and the MEDE in general.

6. Criteria for ethical review by the MEDE Research Ethics Committee

6.1 All research involving human subjects should be evaluated against the criteria listed below for review by the MEDE Research Ethics Committee before recruitment of study participants begins. Research should be reviewed on a project basis. An application may cover a complete study in all of its different phases or stages or submissions may be made for each individual stage or phase separately.

6.2 Review by the Research Ethics Committee is required for projects meeting one or more of the following criteria:

- Projects that involve the inducement of more than minimal stress such as:
- Procedures involving any risk to a participant's health or well-being (for example intrusive physiological or psychological procedures).
- Surveys, questionnaires and any research, the nature of which might be offensive, distressing or deeply personal for the particular target group, even if individuals are not identifiable. This may include questions on sensitive data, i.e. ethnicity, political views, religion, physical or mental health/condition, sexual life/orientation and alleged offences.
- Protocols involving children under the age of 16 or other vulnerable groups, or those who may feel under pressure to take part due to their connection with the researcher;
- Research concerning prisoners and young offenders;
- Research involving the access of and/or collection of records of personal confidential data, concerning identifiable individuals as defined by data protection legislation. Personal data means data that relates to a living individual who can be identified. These personal data include, but are not limited to, sensitive personal data as well as academic and career information, and some protected characteristics according to the Equal Opportunities Act of 2000, e.g. disability, marriage and pregnancy;
- Studies that link or share personal data or confidential information beyond the initial consent given, for example where the research topic or data-gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants;
- Research involving the collection of or access to audio/video recordings, photographs, or quotations within which participants are identifiable and with the intention to be disseminated beyond the research team. This includes publicly available information, for example on social media, and participants recruited or

identified through the internet, if the understanding of privacy in these settings is contentious, where sensitive issues are discussed, or where visual images are used;

- Research protocols that require participants to take part in the study without their knowledge and/or consent at the time (e.g. covert observation, emergency research).
- Research which involves deception other than withholding information about the aims of the research until the interview;
- Research where the safety or well-being of the researcher may be in question. Anyone who either works or studies within MEDE must adhere to the relevant Health and Safety policies and other local procedures.
- Research where for any other reason the researcher feels significant ethical concerns may arise.

6.3 In order for an application to qualify for 'light touch' scrutiny by the MEDE Research Ethics Committee, the research must not fall into any of the categories mentioned above. Low risk research should therefore be characterised by the absence of any of the above components. It should be noted that no category of research (e.g. undergraduate research dissertations) will always meet the low risk criteria.

7. Procedures

7.1 Applications to the MEDE Research Ethics Committee should provide sufficient information for an ethical judgment to be reached by the Committee.

7.1.1 Data should include the following:
Details of applicant(s);
Details of Research to be carried out, including:

- The title of the investigation/consultancy;
- The aims and objectives of the proposal;
- The methodology to be used;
- The place and dates during which the work is planned to be done;
- Time frame;
- Year/Form and age range of students.

7.1.2 Attachments:

- *Information Letter and Request for Permission to carry out Research*: To the Head of School / Organisation / Institute where the research is to take place.

- *Informed Consent Forms*:

    - Informed consent of research participants is a requirement: Research in which personal data is being collected requires the consent of each research participant. Research participants should be informed about the research and any physical or psychological risks that they may be exposed to. Researchers are required to obtain consent from participants prior to commencing the research. The consent needs to be specifically related to the research in question.
    - In the case of research involving research participants who are unable to give informed consent (e.g., children or adults unable to give consent), the research participant's legally responsible parents / guardians shall sign the consent form.
    - In the case where research participants are children or minors who are able to give assent, it is normally considered appropriate that apart from the consent of their legally responsible parents / guardians, agreement to participate shall also be obtained from the children or minors themselves.

- A copy of *the questionnaire / interview questions / other relevant material* to be used for data collection.
- *Licence / permission* to use research tools
- *Approval from the Ethics Review Board* of the respective institution (where applicable)
- The completed *Self-Assessment Form*.

8 Applications

8.1 Applications for research in schools should be completed online .

8.2 Applications are submitted for review to the MEDE Research Ethics Committee (MREC).

8.3 The Research Unit within the Directorate for Research, Lifelong Learning and Employability will register and acknowledge the application. The Committee will form a collective judgment on whether or not to approve the application or seek further information from the applicant. In those cases where the MREC decides that the proposal raises no ethical or data protection issues, the Researcher is duly informed through an Authorisation Letter that will be issued by the Research Unit.

8.4 In a scenario where the proposal raises some issues, the MREC may require some clarifications or improvements on ethical issues and /or data protection issues. In this case, MREC will provide feedback. Depending on the time of year at which the application is submitted, this process may take up to four (4) weeks. The outcome of the Committee deliberations will be notified to the applicant at the address on the application. Generally, any feedback resulting from the review will be made available to the applicant.

8.5 Applicants are encouraged to regard the comments and feedback from a research ethics committee as helpful and to respond constructively, especially where further work is required, for the committee to be able to recommend ethical approval.

9 Conditions of ethics approval

Ethics approval is granted based on a number of conditions. It is important that researchers are familiar with, and abide by, these conditions:

- Any serious or unexpected adverse effects on research participants must be reported immediately to the Research Ethics Committee;
- Any unforeseen events which might affect the continued ethical acceptability of the research project must be reported immediately to the Research Ethics Committee;
- The Research Ethics Committee must be notified of, and approve, any amendments to the original protocol, including but not limited to, changes to the membership of the research team, the research design or methodology, research tools, or research participants' recruitment method (such changes to be notified by submission of a Request for Amendment to Approved Research Project form).
- The General Data Protection Regulation (EU) 2016/679 (GDPR) and the Data Protection Policy must be adhered to at all times.

10 Version history

Originator	Version	Date	
Research Unit, DRLLE	V.1	April 2019	First Release