

Research Ethics Review Procedures

1.0 Definitions

Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Researcher: The primary individual (e.g., Principal Investigator, Research Support Officer, academic staff member) responsible for the preparation, conduct, and administration of a research project. In the case of student projects, the Researcher is the student, duly guided by an academic supervisor.

2.0 Scope

One of the principal and essential functions of a university is the carrying out of research. The University of Malta (UM) recognises its responsibility to researchers and the wider community to ensure that the highest standards of integrity and professionalism are observed in the conduct of research carried out under its auspices.

This document contains the UM's Procedures for the Review of Ethics in Research. It applies to all UM staff, students, and anyone else carrying out research under its auspices.

The committees established in this policy may consider requests for ethics and data protection review by Researchers external to the UM. This shall be done against payment to be determined by the Director of Finance, unless the research team includes UM staff or students, in which case no payment shall apply.

All research at the UM shall comply with the University's *Research Code of Practice* and be guided by the European Commission's Ethics for Researchers: Facilitating Research Excellence in FP7 (2013). Senate, on the advice of the University Research Ethics Committee (UREC), may also require that research in certain areas complies with research-related policies, guidelines and principles published by internationally recognised organisations. These additional requirements shall be published on the relevant Faculty Research Ethics Committee (FREC) website.

3.0 Overview of Research Ethics Review Procedure

The procedure commences with the Researcher completing a self-assessment exercise on Research Ethics and Data Protection (REDP). Depending on the outcome of this self-assessment, the Researcher may either commence the research or submit an application for REDP Review to the FREC.

FRECs are authorised to review and approve REDP review applications on behalf of the University, that are not automatically approved through the self-assessment process, except (a) if the proposed research involves special categories of personal data (SCPD) as defined in EU Regulation 2016/679, General Data Protection Regulation (GDPR) ¹, and (b) where ethics or data protection issues cannot be resolved with the Researcher. In these instances, the FREC shall review the application for any ethics considerations and make a recommendation to UREC.

In all instances, it is the FRECs that communicate with Researchers about the outcome of any REDP review. The FREC will, if necessary, assist with the resolution of any matters that require to be addressed and with the preparation of a revised REDP review application.

4.0 Research Ethics Committees

4.1 Faculty Research Ethics Committees

Faculties shall have a FREC to manage the research ethics review process within that entity and to ensure that the University's Research Code of Practice is adhered to. Institutes, Centres or Schools shall normally make arrangements with Faculties that carry out research in similar areas for research ethics and data protection reviews to be carried out by the appropriate FREC. Such arrangements need to be agreed by the relevant entity Boards and approved by Senate.

Each FREC shall have at least three members. These shall be appointed by Senate for a period of three years, on the advice of the Faculty Board. Members shall have knowledge about the various types of research conducted within the Faculty. Where necessary, FRECs may appoint sectoral sub-committees to advise them². FRECs shall normally provide a response to the Researcher within 30 working days of receipt of the application. Applications received should be assessed by a minimum of two FREC members and the FREC chairperson or their delegate.

¹ *Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation* (Article 9.1, GDPR)

² *For example, animal research.*

A member of a FREC may not participate in a review of research in which the member has a conflicting interest (including being the supervisor of the research), except to provide information.

4.2 University Research Ethics Committee

The University Research Ethics Committee (UREC) shall have a chairperson and a minimum of ten committee members. UREC is to have two streams: an Ethics stream and a Data Protection stream. The UREC chairperson shall chair the committees for both streams. The chairperson and the members of UREC shall be appointed by Senate for a two-year term, which can be renewed. The chairperson may propose a delegate from amongst the members of UREC to act on their behalf if necessary.

A member of UREC may not participate in a review of research in which the member has a conflicting interest (including being the supervisor of the research), except to provide information.

4.2.1 UREC-Ethics Committee

The UREC-Ethics Committee (UREC-E) shall be composed of the UREC chairperson and a minimum of six members from the UREC committee, who together, bring expertise in i. Arts and Humanities, ii. Social Sciences, iii. Natural sciences, iv. Applied sciences, v. Medical Science, vi. Animal Research. At least one of the members of the Committee shall have expertise in Research Ethics.

UREC-E meetings shall be held with an appropriate subset of members who are experts in the area of research of the proposals being reviewed. A UREC-E meeting shall have a minimum of two members from the UREC-E committee in addition to the UREC chairperson or the chairperson's delegate. The chair of the relevant FREC, or their delegate, shall also attend UREC-E meetings when research proposals processed by that FREC are being discussed.

The role of UREC-E is to:

- (a) Carry out annual audits of Research Ethics self-assessments carried out by Researchers and ethics reviews carried out by FRECs to ascertain that self-assessments and reviews are consistent with the policies approved by Senate;
- (b) Prepare an annual report to Senate summarizing activities carried out, including the results of the audit;
- (c) Arbitrate in those cases where Researchers do not agree with FREC decisions on research ethics issues; and
- (d) Prepare recommendations to Senate for improvement of Research Ethics policies or procedures.

4.2.2 UREC-Data Protection Committee

The UREC-DP Committee (UREC-DP) shall be composed of the UREC chairperson, or delegate, and a minimum of four additional members from the UREC committee who are knowledgeable in data protection.

UREC-DP meetings are to be held with an appropriate subset of members who are experts in the area of research of the proposals being reviewed. A UREC-DP meeting shall have a minimum of two members from the UREC-DP committee in addition to the UREC chairperson or the chairperson's delegate. The chair of the relevant FREC, or their delegate, shall attend UREC-DP meetings when research proposals processed by that FREC are being discussed.

The role of UREC-DP is to:

- (a) Liaise with the Malta Information and Data Protection Commissioner (IDPC) in terms of Section 7 of Chapter 586 of the Laws of Malta (Data Protection Act 2018) to obtain any necessary authorisation required for research proposals that have been referred to it;
- (b) Review research proposals, referred to it by the FRECs, that deal with special categories of personal data as defined in the GDPR.;
- (c) Carry out annual audits of research data protection self-assessments carried out by Researchers and reviews carried out by FRECs on data protection matters not related to special categories of personal data to ascertain that self-assessments and reviews are consistent with the policies approved by Senate, the GDPR, and Chapter 586 of the Laws of Malta (Data Protection Act 2018);
- (d) Prepare an annual report to Senate summarizing activities carried out, including the results of the audit;
- (e) Arbitrate in those cases where Researchers do not agree with FREC decisions on data protection matters not related to special categories of personal data; and
- (f) Prepare recommendations to Senate for improvement of Research Data Protection policies or procedures that deal with data protection.

5.0 Research Ethics Review Procedure

5.1 Self-Assessment

Figure 1 presents a diagram of the Research Ethics Review Procedure, following the preparation of the research proposal by the Researcher. All Researchers planning to undertake a research project must complete and submit a REDP form prior to undertaking any data collection. Within the REDP form, applicants first complete a self-assessment. Once

the self-assessment has been correctly completed, it will guide Researchers to the next step, which can be one of two outcomes (Figure 1: Decision 1, Outcome A or B):

- (a) the research project has no further Ethical and Data Protection review requirements. In this case, the Researcher sends the completed form to the appropriate FREC for record and audit purposes and the research may commence. FREC may be required to acknowledge receipt where formal records are required by the Researcher.³, or
- (b) the research project has some further Ethical or Data Protection review requirements. In this case, the Researcher completes the full REDP proposal form and submits it to the appropriate FREC. The Researcher must await FREC’s feedback before commencing any data collection.

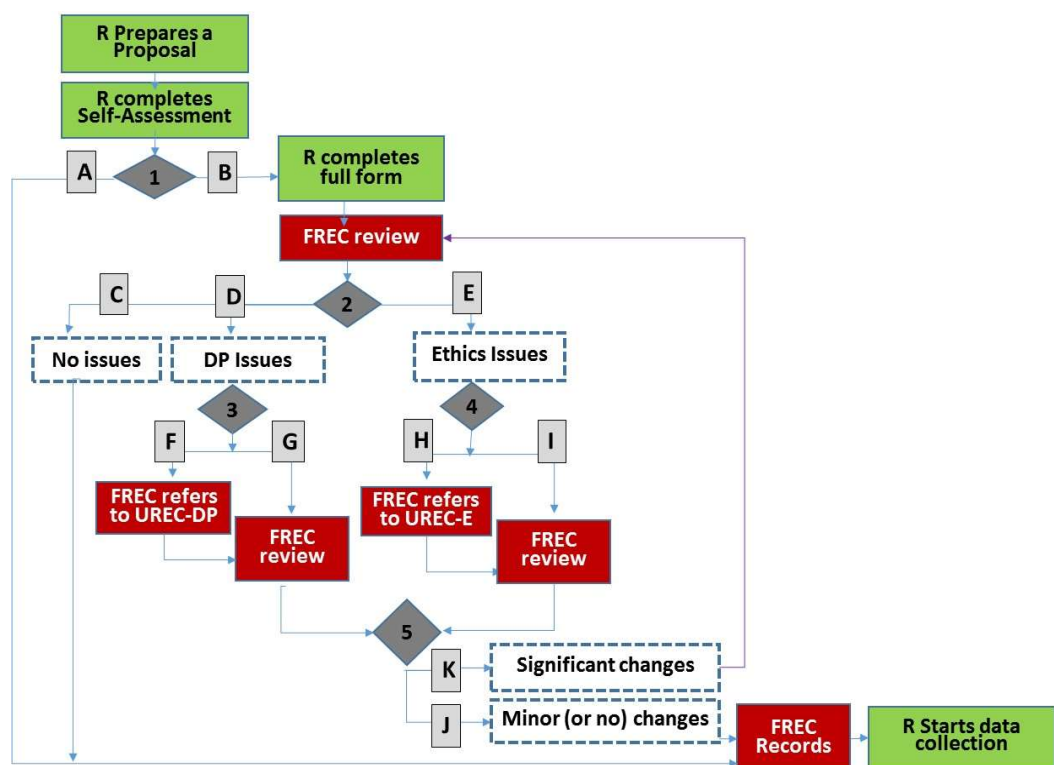


Figure 1: Research Ethics Review Procedure

In the case of students, the completion of the self-assessment and the full form (where required) shall be guided by the academic supervisor of the research who shall also be required to endorse the form eventually submitted to FREC. Supervisors should be aware that when endorsing the research proposals of their supervisees they are accepting responsibility for ensuring that the research proposal as presented is in conformity with Senate policies and procedures on research ethics.

³ For example, for publication or funding purposes.

5.2 FREC review

In the case of research proposals referred to FRECs for review (Figure 1: Decisions 2-5) FREC may decide that the issues flagged in the full form raise no serious ethical or data protection issues and duly informs the Researcher that they may commence research (Figure 1: C).

If the proposal does raise some issues (Figure 1: D/E), FREC may require some clarification or improvement on ethical issues and/or on data protection issues. The following outcomes are possible:

Concerns about Ethics

FREC provides feedback to the Researcher and attempts to resolve the issue with the Researcher by suggesting changes (Figure 1: I). If the changes requested by FREC and carried out by the Researcher address the concerns about Ethics, the FREC informs the Researcher that they may commence research (Figure 1: J).

If the issue cannot be resolved by dialogue between the FREC and the Researcher, the proposal is forwarded to UREC-E by the FREC (Figure 1: H). UREC-E communicates its decision to the FREC which will advise the Researcher on how to proceed. A change in the research plan and a revised REDP form may be needed in some cases (Figure 1: K).

Concerns on data protection matters not related to special categories of personal data

The FREC provides feedback to the Researcher and attempts to resolve the issue with the Researcher by suggesting changes (Figure 1: G). If the changes requested by the FREC and carried out by the Researcher address the concerns about data protection, the FREC informs the Researcher that they may commence the research (Figure 1: J).

If the issue cannot be resolved by dialogue between the FREC and the Researcher, the proposal is forwarded to UREC-DP by the FREC (Figure 1: F). UREC-DP communicates its decision to the FREC which will advise the Researcher on how to proceed. A change in the research plan and a revised REDP form may be needed in some cases (Figure 1: K)

5.3 UREC-DP Review

Concerns on data protection matters dealing with special categories of personal data

After reviewing the proposal for any ethics issues, the FREC forwards the proposal together with a recommendation to UREC-DP (Figure 1: F). UREC-DP reviews the proposal, submits its recommendation to the IDPC, and communicates the IDPC's decision to the FREC, which will advise the Researcher on how to proceed. If no changes to the research proposal are required, approval is granted and the FREC informs the Researcher that they may commence the research. If only minor changes to the research proposal are required to address the concerns about data protection, approval is granted on condition that the amendments are carried out by the Researcher as requested by UREC-DP, endorsed by the supervisor (if Researcher is a student) and verified by the

FREC. The FREC then informs the Researcher that they may commence the research (Figure 1: J). If significant changes are required, the Researcher must submit a point-by-point response to the issues raised in the UREC-DP report, together with any amended documents as required to the FREC for further review by UREC-DP (Figure 1: K). These materials must be endorsed by the supervisor in the case of students. Once the FREC has vetted the response and other material and is satisfied that all the issues raised by UREC-DP have been addressed, the FREC submits these materials together with a recommendation to UREC-DP. UREC-DP reviews these materials and communicates the decision to the FREC, which will advise the Researcher on how to proceed.

5.4 Accelerated Approval Procedure

In most instances, it will be possible to proceed with research upon completion of the self-assessment form. In a scenario where research requires to go to FREC the initial response shall normally take no more than 30 working days from the time of submission of the application form to the relevant FREC. If the proposal also needs to be submitted to UREC-DP, then the initial response shall normally be given within an additional 30 working days.

Certain projects, especially those linked with funded programmes, may involve a specific tight deadline that would make it impossible to go through the Research Ethics Review Procedure outlined above.

In such cases an accelerated approval process should be applied without prejudice to the quality of the ethical review. For this purpose, the Researcher shall submit a request to the UREC Chairperson for an accelerated approval procedure. The UREC Chairperson shall consult with a UREC subcommittee convened for this purpose in order to assess whether the request is justified. If justified, the UREC Chairperson shall request the relevant FREC to review the application with urgency. FRECs shall consider such requests and provide a response to the Researcher within 10 working days. Except that, should the application require review by UREC-DP, then the FREC will forward the application together with its recommendation to UREC-DP within a maximum of 10 working days. UREC-DP shall provide a response to the Researcher within 10 working days.