

## **Research Ethics Code of Practice and Procedures**

### **1.0 Introduction**

One of the principal and essential functions of a university is to carry out research. The University of Malta (UM) recognises its responsibility to ensure that the highest standards of research ethics are observed in the conduct of research.

This Research Ethics Code of Practice and Procedures (RECoPP) constitutes the UM policy on good practice in research across all subject disciplines and areas of study at the UM.

### **2.0 Definitions**

**Research:** Any systematic investigation designed to develop or contribute to scholarly and/or generalisable knowledge. In this context, knowledge refers to research output that is published, disseminated, made available or retained so that it can form the basis of further study.

**Researcher:** The individual (e.g., Principal Investigator, Research Support Officer, academic staff member, or student) 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.

**URECA:** The University Research Ethics Committee Application (URECA) comprising a web-based platform used to assess and manage Research Ethics and Data Protection issues.

**SCPD:** Special Categories of Personal Data as defined in EU General Data Protection Regulation (GDPR)<sup>1</sup> and further implemented through Maltese Law.<sup>2</sup>

### **3.0 Scope**

RECoPP applies to all those undertaking research on the UM's premises using its facilities, or elsewhere under the auspices of the UM, including staff, students, visiting or affiliate staff, associates, contractors, consultants, or any other person.

---

<sup>1</sup> <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32016R0679>

<sup>2</sup> <https://legislation.mt/eli/cap/586/eng/pdf>

Researchers external to the UM may apply for Research Ethics and Data Protection (REDP) review. This shall be done against payment, the value of which is to be determined by the Director of Finance, unless the research team includes staff or students carrying out research at UM or under its auspices, in which case no payment shall apply.

All research at UM or under its auspices shall comply with RECoPP and shall be guided by The European Code of Conduct for Research Integrity (Revised Edition, 2023). Breaches of RECoPP shall be considered as breaches of discipline. In the case of students, the disciplinary measures shall be guided by the UM Student Discipline Regulations (2016).<sup>3</sup> In the cases of members of staff, the disciplinary measures shall be guided by the UM Manual of Conduct and Procedures (2019).

#### **4.0 Principles of Ethical Research Conduct**

All research carried out at UM or under its auspices shall observe and comply with all legal, regulatory and ethical requirements in Malta and in countries where the research is conducted, relevant to the field of study and any funding bodies or collaborative partner organisations.

In particular, all such research shall adhere to the “Twelve golden rules to ethical research conduct” listed in the European Commission’s publication *Ethics for Researchers* (2013, p.24).<sup>4</sup> That is, researchers must ensure that their research:

1. Respects the integrity and dignity of persons (that this intrinsic worth protects them from being used for greater perceived benefits)
2. Follows the “Do no harm” principle. Any risks must be clearly communicated to subjects involved
3. Recognises the rights of individuals to privacy, personal data protection and freedom of movement
4. Honours the requirement of informed consent and continuous dialogue with research subjects
5. Treats animals with respect and works under humane conditions before, during and after the research
6. Designs animal research in accordance with the 3 Rs: Replacement, Reduction, Refinement
7. Respects the principle of proportionality: not imposing more than is necessary on your subjects or going beyond stated objectives (mission creep)
8. Treats societal concerns seriously - a researcher’s first obligation is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity

---

<sup>3</sup> Legal Notice 68 of 2016 - Malta Government Gazette No. 19,543 – 4 March 2016; Amended by: Legal Notice 239 of 2017 - Malta Government Gazette No. 19,865 – 19 September 2017  
<https://www.um.edu.mt/media/um/docs/about/governance/regulations/general/UniversityStudentDisciplineRegulations.pdf>

<sup>4</sup> European Commission (2013). *Ethics for researchers: Facilitating research excellence in FP7*. Author.

9. Tries to prevent being openly available for misuse or malignant dual use by terrorists or military organisations
10. Recognises the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle
11. Respects biodiversity and does not impose irreversible change that threatens the environment or ecological balance
12. Builds on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from your research must be considered (with the acceptance that perhaps certain research practices might have to be abandoned).

Researchers are to be particularly vigilant when conducting research involving:

- i. The collection of data from human participants where there is risk of harm to participants; or involving physical intervention; or conducted with vulnerable participants; or where participants are identifiable in data without explicit consent; or involving Special Categories of Personal Data (SCPD); or involving human tissue/samples; withholding information when obtaining assent/consent; or requiring 'opt-out' recruitment; or involving deception in data generation; or possibly generating incidental findings;
- ii. Unpublished secondary data involving humans or animals; or where no written permission can be obtained from the data controller;
- iii. Harm to live animals; or involving dead animals acquired illegally;
- iv. A cooperating institution for which FREC approval is required prior to contact; or risk to researcher/s; or risk to environment; or commercial sensitivity;
- v. Other potential ethical or data protection risks including dual use and/or misuse; or conflict of interest; or dual role; or where permission/license is required to use research tools; or collaboration/data/material collection in low/lower-middle income country; or import/export of records/data/materials/specimens; or the harvest of data from social media; or criminal issues and incarcerated persons.

The application of these Principles is guided by the FAQs provided by UREC.<sup>5</sup>

---

<sup>5</sup> <https://www.um.edu.mt/research/ethics/faqs/>

## **5.0 Research Ethics Committees**

### ***5.1 Faculty Research Ethics Committees***

Faculties shall have a Faculty Research Ethics Committee (FREC) to ensure compliance with RECoPP and to manage the process at the Faculty level.

Institutes, Centres or Schools (ICS) shall make arrangements for their REDP process to be affiliated to the FREC of an appropriate Faculty which conducts research in similar areas. Such arrangements need to be agreed by the Faculty and ICS Boards and approved by the UM Senate. In exceptional circumstances, ICS may request to establish their own Research Ethics Committee (REC), which request shall be considered by the UM Senate. RECs shall follow the same procedures as FRECs.<sup>6</sup>

Each FREC shall have at least four members including the Chairperson. These shall be appointed by the UM Senate for a period of three years, which appointment can be renewed, on the advice of the Faculty Board. Members shall collectively have knowledge about the various types of research conducted within the Faculty, and about the UM's REDP procedures.

Where necessary, FRECs may appoint sectoral sub-committees and appropriate experts to advise them.

### ***5.2 University Research Ethics Committee***

The UM shall have a University Research Ethics Committee (UREC) to ensure compliance with the RECoPP, and to manage the process at the University level.

UREC shall offer training to researchers at UM and carry out annual audits of FRECs' REDP procedures. It shall prepare an annual report for the UM Senate summarizing activities carried out, including the audit results and UREC's recommendations.

UREC shall have at least eleven members including the Chairperson. These shall be appointed by the UM Senate for a three-year term, which can be renewed. UREC members shall collectively have knowledge about the various types and paradigms of research conducted within the UM (including i. Arts and Humanities, ii. Social Sciences, iii. Natural sciences, iv. Applied sciences, v. Medical Science, vi. Animal Research) and about the UM's REDP Procedures. The Chairperson may propose a delegate from amongst the other members of UREC to act on their behalf if necessary.

Members of UREC may not concurrently be members of a FREC.

UREC shall have two sub-committees: an Ethics sub-committee (UREC-E) and a Data Protection sub-committee (UREC-DP). All UREC members shall sit on at least one of the two sub-committees. The UREC Chairperson shall chair both sub-committees.

---

<sup>6</sup> In the rest of the document FREC also refers to REC.

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

#### *5.2.1 UREC-Ethics Committee*

The role of UREC-E is to arbitrate in those cases where Researchers do not agree with FREC decisions on research ethics issues.

It shall be composed of the UREC Chairperson and a minimum of five other members from UREC, as appointed by the Chairperson.

UREC-E shall consider submissions by both the Chairperson of the relevant FREC, or their delegate, and the researcher when cases by that FREC are being arbitrated.

#### *5.2.2 UREC-Data Protection Committee*

The role of UREC-DP is to (a) review URECA submissions that deal with SCPD as referred to it by the FRECs; to (b) 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 for SCPD-related URECA submissions; and to (c) arbitrate in those cases where Researchers do not agree with FREC decisions on data protection matters.

UREC-DP shall be composed of the UREC Chairperson and a minimum of five other members from UREC, as appointed by the Chairperson.

For (a) and (b) above, UREC-DP shall invite the Chairperson of the relevant FREC, or their delegate, to attend meetings when URECA submissions processed by that FREC are being discussed. For (c) UREC-DP shall consider submissions by both the Chairperson of the relevant FREC, or their delegate, and the researcher when UREC-DP submissions processed by that FREC are being arbitrated.

## **6.0 Research Ethics Review Procedure**

### ***6.1 Self Assessment***

All Researchers carrying out research at UM or under its auspices are obliged to fill in a URECA form. The REDP procedure commences with the Researcher completing a self-assessment exercise using the URECA system.

Where Researchers are students, they shall be duly guided by an academic supervisor, who shall also be required to endorse the URECA submission, thereby confirming that it represents the true nature of the research and its ethical and data protection implications, if any.

Depending on the outcome of this self-assessment, the Researcher will either (a) submit the URECA form for records and commence the research or (b) provide further details and submit the URECA form to the relevant FREC for review.

Submissions received by FREC for records should be acknowledged but should not be evaluated by the FREC. These submissions may be subject to UREC audit procedures.

## **6.2 FREC Review**

FRECs are authorised to review and approve URECA submissions on behalf of the UM, except if the proposed research involves SCPD and/or where ethics or data protection issues cannot be resolved between the FREC and the Researcher. In both these instances, the FREC shall review the submission and make a recommendation to UREC. In all instances, it is the FREC that communicates with the Researcher the decision of UREC.

Submissions received for review shall be evaluated by the FREC Chairperson or their delegate and a minimum of two other FREC members. Decisions regarding approval, or otherwise, of submissions are taken by the FREC, who will be collectively responsible for such decisions. The FREC is to keep written records of key deliberations and decisions with regards to submissions. A member of FREC may not participate in the review of research in which said member has a conflicting interest (including being the supervisor of the research), except to provide information.

FRECs shall normally provide an initial response to the Researcher within 30 working days of receipt of the URECA form. The following outcomes are possible (where a Review is needed): (a) application approved; (b) application provisionally approved subject to minor amendments; (c) application to be revised and resubmitted; (d) application requires UREC-DP review before further processing by the FREC. For FRECs which require review prior to the Researcher approaching cooperating institution/s, an application may be provisionally approved subject to permission by cooperating institution/s.

FRECs are to meet as needed and normally no less frequently than on a monthly basis, keeping minutes of all meetings. FRECs shall publish the dates and deadlines for URECA submissions on their website.

## **6.3 UREC-DP review**

In cases where the FREC refers the application to UREC-DP on SCPD issues, UREC-DP reviews the submission, where required provides its recommendation to the IDPC, and communicates the decision to the FREC. The following outcomes are possible where a UREC-DP review is required: (a) application approved; (b) application conditionally approved (if minor changes are indicated, approval is granted on condition that the amendments are carried out by the Researcher, endorsed by the supervisor (in the case of students) and verified by the FREC); (c) application approval withheld (if major concerns are indicated, 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, for further review by UREC-DP).

UREC-DP shall normally provide an initial response to the FREC within an additional 30 working days of receipt of the URECA form.

#### **6.4 UREC-E review**

In cases where Researchers and FREC require arbitration on matters related to ethics, the matter shall be referred to UREC-E which shall evaluate the URECA submission and FREC's recommendation. It is the FREC that communicates with the Researcher the decision of UREC-E.

UREC-E shall normally provide an initial response to the FREC within an additional 30 working days of receipt of the URECA form.

#### **6.5 Accelerated Approval Procedure**

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

In such cases an accelerated approval process is applied without prejudice to the quality of the 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 of communication by the Chairperson. Except that, should the application require review by UREC-DP, then UREC-DP shall provide a response to the FREC within a further 10 working days.

*Approved by Senate at its meeting of 23 April 2026*