University of Malta
Research Code of Practice

1.0 Introduction

One of the principal and essential functions of a university is the carrying out of research in all areas of human knowledge and experience. The University of Malta 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 at the University.

This Code of Practice provides guiding principles and standards of good practice in research across all subject disciplines and areas of study in the University. It applies to all those undertaking research on the University's premises using its facilities, or on behalf of the University, including staff, students, visiting or affiliate staff, associates, contractors and consultants.

2.0 Principles of Ethical Research Conduct

The following principles have been adapted from the "Golden Rules to Ethical Research Conduct" published in the European Commission Ethics for Researchers (2013).

All research carried out at the University shall adhere to the following thirteen principles.

1. Observe and comply with all legal, regulatory and ethical requirements in Malta and in countries where research is conducted or participants are from, relevant to the field of study and any funding bodies or collaborative partner organisations.

2. Respect the integrity and dignity of persons notwithstanding any perceived greater benefits.

3. Follow the "Do no harm" principle; any risks must be clearly communicated to participants involved in the research.

4. Recognise the rights of individuals to privacy and personal data protection.

5. Honour the requirement of informed consent and continuous dialogue with research participants.

6. Treat animals with respect and work under humane conditions before, during and after the research.

7. Design animal research in accordance with the following 3 Rs Principles:

   (A) Reduce – methods should be used that enable researchers to obtain comparable levels of information from fewer animals, or to obtain more information from the same number of animals;

   (B) Replace – non-animal methods are preferred above animal methods whenever it is possible to achieve the same scientific aim; and

(C) Refine - all methods used for the research should alleviate or minimize the potential pain, suffering and distress and enhance the animal welfare for the animals used.

8. Respect the principle of proportionality: not imposing more than is necessary on research participants or going beyond stated objectives (mission creep).

9. Treat societal concerns seriously - the first obligation of all those who carry out research is to listen to the public and engage with them in constructive dialogue, transparently, honestly and with integrity.

10. Recognise the wholeness of an individual and that any modification (genetic or technological) does not interfere with this principle.

11. Respect biodiversity and not impose irreversible change that threatens the environment or ecological balance.

12. Try to prevent being openly available for misuse or malignant dual use by terrorists or military organisations.

13. Build on the understanding that any benefits are for the good of society, and any widely shared expressions of concern about threats from research must be considered (with the acceptance that perhaps certain research practices might have to be abandoned).

3.0 Guidelines on the application of the Principles

The section contains practical guidance on how some of the principles outlined in Section 2.0 above are to be applied in practice.

3.1 Obtaining Consent from Research Participants

3.1.1 To satisfy the requirement for informed consent and continuous dialogue with research participants (Principle 5), it is very important that all research in which personal data is being collected has the consent of each research participant and that research participants are informed about the research and any risks that they may be exposed to (Principle 3).

3.1.2 Principal Investigators (PIs) shall obtain consent from participants in their research **prior to** processing any personal data. The consent needs to be specifically related to the research being undertaken. Suitable consent forms need to be used to obtain consent in writing.

3.1.3 Consent forms shall contain the following:

A. A statement that the study involves research;

B. A short explanation of the purpose of the research;

C. The expected duration of the research participant’s involvement;

D. A description of the procedures to be followed;

E. A statement on whether it can be reasonably foreseen that research participants may experience any risks or discomfort, which may be psychological or/and physical. If any such risks or discomforts are reasonably foreseen, a description of such risks or discomforts shall be included in the consent form, together with information about where research participants may obtain psychological and emotional support;

F. A description of any benefits to the participant or to others which may reasonably be expected from the research;

G. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;

H. A statement describing the extent to which confidentiality of records identifying the subject will be maintained and who has access to them;

I. A statement informing research participants about their rights under the Data Protection Act to access, rectify, and where applicable erase the data concerning them;

J. Name and contact details of the PI and supervisor (if applicable). This enables research participants to exercise the right to request written information about their personal data being processed and to request further information about the research.

3.1.4 For research involving more than minimal risk, the consent form shall also contain an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained, and whom to contact in the event of a research-related injury to the research participant.

3.1.5 If applicable, the consent form should also contain full disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the research participant.

3.1.6 If the research involves research participants who are unable to give informed consent (e.g., children), the consent form shall be signed by the research participant's legally authorized representative. It is normally considered appropriate that in the case that research participants are children who are able to give assent , apart from the consent of their legally authorized representative, agreement to participate shall also be obtained from the children themselves.

3.1.7 PIs shall ensure that each person signing the written consent form is given a copy of that form. The PI shall give either the research participant or the research participant's legally authorized representative adequate opportunity to read the form before signing it.

3.2 Ensuring privacy and personal data protection

In order to ensure the rights of research participants to privacy and personal data protection (Principle 4), any personal data collected during the course of the research shall be processed fairly and lawfully. The personal data being processed have to be adequate, relevant and not excessive. All reasonable measures shall be taken to ensure that personal data are correct and if necessary, up-to-date. Personal data shall not be retained for a period longer than necessary. In relation to this, all measures shall be taken to anonymise data if possible and ensure confidentiality.

3.3 Research involving vulnerable populations

Research proposals in which some or all of the research participants are likely to be vulnerable to coercion or undue influence shall include a statement that the integrity and dignity of research participants shall be respected (Principle 2) and that informed consent shall be obtained (Principle 5). In particular, the statement should outline in detail the safeguards that will be used to ensure the rights and welfare of these participants.

For the purposes of this clause, vulnerable populations shall include children, prisoners, persons with disability, substance abusers, and economically or educationally disadvantaged persons.

4.0 Acknowledgements

European Commission Ethics for Researchers: Facilitating Research Excellence in FP7 (2013)
University of Cambridge Good Research Practice Guidelines (2015)
University of Warwick Research Code of Practice (2015)

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