Guidelines for UoM Research Ethics Committee

A Summary

1. The University Senate set up a Research Ethics Committee some years ago, and the committee appointed in June 2002 set itself the task of drawing up a set of guidelines which we are presenting together with this summary. These guidelines, first approved in 2004, were reviewed and slightly modified by Senate in September 2007.
2. The guidelines envisage a simple structure that can safeguard both ethical standards and efficiency while ensuring proper accountability. These guidelines were drawn up in close consultation with the Data Protection Commissioner’s Office, who have ensured that they are in accordance with the Data Protection Act.
3. The new set up involves the following steps:
   3.1 The Senate approved guidelines regulate all research involving human subjects carried out at the University, both by students and by members of staff. It has also appointed a University Research Ethics Committee (UREC).
   3.2 Each faculty will appoint its own Faculty Research Ethics Committee, whose membership will be proposed by the Faculty Board and approved by Senate, in a way similar to examination boards.
   3.3 Each university member, student or member of staff, undertaking research involving human subjects will fill the proposal form (also available on the website) and present it for approval to the faculty research ethics committee. Together with the proposal form, the researcher must present all other relevant information together with a sample consent form in Maltese and English. The form clearly identifies the person taking responsibility for the research and for compliance with the regulations and with Data Protection legislation.
   3.4 The faculty committee will discuss the research proposals according to the criteria set out in the guidelines, and will give its advice whether the research is to be approved or not, and for what reasons.
   3.5 This advice is passed on to the University committee, which will give the final approval.
   UREC’s approval is equivalent to approval by the Data Commissioner according to the requirements of the Data Protection Act.
   3.6 The names of the University and Faculty research ethics committees, together with the dates of the University committee meetings will be advertised in good time, so that researchers and faculty committees can plan their work without causing any unwarranted delays.

October 2007
Guidelines for UoM Research Ethics Committee

I. General Policy

1. 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 is committed to carry out all research involving human subjects in strict adherence to ethical principles set out in this policy and to all relevant laws and regulations.

2. This policy will apply to all research, as defined in this policy, that is conducted by University personnel, undergraduate and postgraduate students, and which involves human subjects.

3. The University ensures that before human subjects are involved in research, proper consideration will be given to:
   • the risks to the subjects;
   • the anticipated benefits to the subjects and others;
   • the importance of knowledge that may reasonably be expected to result;
   • the informed consent process to be employed;
   • the additional safeguards for vulnerable subjects; and
   • the data protection provisions.

4. It is the policy of the University that all research involving human subjects will be reviewed and approved by the respective Faculty Research Ethics Committee and by the University Research Ethics Committee. The collection of data and involvement of human subjects in research will not be permitted until the respective Faculty Research Ethics Committee and the University Research Ethics Committee have reviewed and approved the research protocol, and until informed consent has been obtained in accordance with these guidelines.

5. The University Research Ethics Committee has the responsibility and authority to review, approve, disapprove or require changes to appropriate research activities involving human subjects. The University Research Ethics Committee has the authority to suspend or terminate approval of research that is not being conducted in accordance with the University Research Ethics Committee's decisions, conditions and requirements or that has been associated with unexpected serious harm to subjects.

6. The University recognizes the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as children (under the age of 18), prisoners, mentally disabled persons or economically or educationally disadvantaged persons.

7. The University will provide adequate facilities and administrative support for the University Research Ethics Committee reviews and record keeping duties and will maintain documentation of University Research Ethics Committee activities.
II. DEFINITIONS

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

9. Human Subject. A human being and/or human tissue about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information.

10. Minimal Risk. The probability and magnitude of harm or discomfort anticipated in the research are intrinsically not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

11. Data Protection. The Data Protection Act provides for the protection of individuals against the violation of their privacy, by regulating the processing of personal data. The University shall give proper consideration to the principles of proper handling of information.

12. 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 Data Protection Act, namely the right to access, rectify, and where applicable erase the data concerning them. The data subject may also request written information about his personal data being processed by the researcher. In order to enable the data subject to exercise his right of access, when obtaining consent the researcher shall provide his identity and habitual residence. Therefore the data subject has the right to request the researcher to correct, and where applicable erase such personal data that has not been processed in accordance with the Act. The consent of the data subject may also be withdrawn at any time.

13. The principles of good information handling imply that, personal data, which should be collected for a specific purpose, shall be processed fairly and lawfully. Having regard to the processing purpose, the personal data being processed has to be adequate, relevant and not excessive. All reasonable measures shall be taken to ensure that personal data is 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.

III. University Research Ethics Committee (UREC)

14. Membership

1. UREC is established to review all research at the University which involves the use of human subjects. ¹

¹ Research proposals which raise issues of animal welfare, and which consequently may also give rise to ethical issues, should be passed on to the University Animal Welfare Officer for advice. The Officer will be invited to participate in the UREC meetings where these proposals will be discussed.
UREC must have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. If research subject to UREC approval regularly involves a category of vulnerable subjects, such as children, physically or mentally disabled persons or prisoners, UREC shall include one or more individuals knowledgeable about and experienced in working with these subjects.

The members will serve for a three-year term which can be renewed. The Chairperson and the members will be appointed by Senate.

2. UREC shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas. One of the members of the Committee will have expertise in ethics.

3. UREC shall include at least one member who is presently not otherwise employed with the University.

4. A member of UREC may not participate in a review of any project in which the member has a conflicting interest except to provide information.

5. A majority of the members of UREC must participate in the review.

6. A list of the names and qualifications of UREC members is included in the University Calendar.

15. UREC Approval

1. The main function of UREC review is to assure that:
   (a) risks to subjects are minimized and reasonable in relation to the anticipated benefits;
   (b) there is informed consent;
   (c) rights and welfare of subjects are maintained; and
   (d) requirements of data protection legislation are observed

2. UREC shall review and have authority to approve, require modification in, or disapprove all research activities covered by this policy.

3. UREC shall approve research based on a determination that all of the following requirements are satisfied:
   (a) Risks to subjects are minimized:
      • by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and,
      • whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
   (b) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, UREC shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). UREC shall not consider possible long-range effects of applying knowledge gained in the research as among those research risks that fall within the purview of its responsibility.
   (c) Selection of subjects is equitable. In making this assessment, UREC shall take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
(d) Informed consent will be sought from each prospective subject or the subject's legally authorized representative. When appropriate, the assent of children participating in the research should be obtained. In addition, consent should be obtained in the case of children over 12 years of age.

(e) Informed consent will be appropriately documented.

(f) Where appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

(g) Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(h) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as those mentioned in 14.1 above, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

4. UREC shall have authority to suspend or terminate approval of research that is not being conducted in accordance with UREC requirements or that has been associated with unexpected serious harm to subjects.

5. UREC shall meet at least once every two months to review protocols. The calendar of its meetings will be established every year published on the university website, http://home.um.edu.mt/urec/.

16. UREC Reporting:
1. The Faculty Research Ethics Committees shall report to UREC, and UREC shall report promptly to the Rector and copy to the respective Dean the following:
   (a) any serious or continuing non-compliance by investigators with requirements of UREC;
   (b) any suspension or termination of UREC approval;
   (c) any unanticipated problems or injuries involving risks to subjects or others; and,
   (d) any changes in the research activity which has been reviewed and approved by UREC.

2. UREC shall prepare and maintain, for a period of at least three years, adequate documentation of UREC activities including the following
   (a) Copies of all research proposals reviewed, approved sample consent documents, and reports of injuries to subjects. These documents shall be kept for three years in the case of undergraduate projects, and for five years for all other projects.
   (b) Minutes of UREC meetings.
   (c) Records of continuing review activities.
   (d) Copies of all correspondence between UREC and the investigators.
   (e) A detailed list of UREC members and of faculty research ethics committees.
   (f) Statements to subjects of significant new findings developed during the course of the research.

17. UREC Review Procedures:
1. All research protocols involving human subjects will be presented to the respective faculty research ethics committee, which will forward their advice to UREC. The final decision rests with UREC.

2. The Faculty Research Ethics Committee can approve minor changes in previously approved research during the period for which approval is authorized.
18. Notification of UREC Decisions:
1. UREC shall notify the respective Faculty or Centre in writing of UREC's decisions, conditions and requirements within two weeks of UREC review.

2. UREC shall also provide to the researcher reasons for UREC’s decisions to disapprove a research protocol and an opportunity for the researcher to respond.

IV. IMPLEMENTATION

19. Responsibilities of Deans and Heads of Department:
1. Deans and Directors of Institutes and Centres shall ensure that applicable University regulations and policies regarding the use of human subjects in research are followed.

2. Deans and Directors of Institutes and Centres shall ensure that the research activities covered by this policy are related to the academic programmes of the faculty and department.

20. Responsibilities of the Researcher:
1. Researchers shall prepare a protocol giving a complete description of the proposed research. In the protocol, researchers shall make provisions for the adequate protection of the rights and welfare of prospective research subjects and ensure that pertinent laws and regulations are observed.

2. Researchers are responsible for preparing and submitting a protocol to the Faculty Research Ethics Committee and for including a sample of proposed informed consent forms – in English and Maltese - with the protocol when appropriate.

3. Researchers shall submit a supplement to an original protocol to the Faculty Research Ethics Committee when:
   (a) it is proposed to involve human subjects, and the activity previously had only indefinite plans for the involvement of human subject; or
   (b) it is proposed to involve human subjects, and the activity previously had no plans for the involvement of human subjects, or
   (c) it is proposed to change the involvement of human subjects and that involvement is significantly different from that which was initially approved by UREC.

4. Researchers shall be responsible for complying with all Faculty Research Ethics Committee and UREC decisions, conditions and requirements.

5. Researchers are responsible for reporting promptly to UREC any injuries to human subjects, any anticipated problems which involve risks to the human subjects or others and any serious or continuing non-compliance with the requirements of this policy or the determinations of UREC. Prior to initiation, researchers shall obtain the review and approval of the Faculty Ethics Committee and UREC for any proposed changes in the research activity.

6. To facilitate the review of research and the protection of the rights and welfare of human subjects, researchers are encouraged to attend Faculty Committee and/or UREC reviews when invited to answer questions.
21. Responsibilities of Faculty Research Ethics Committees:
1. Each Faculty, Department, Institute and Centre in which staff and students conduct research projects involving the use of human subjects shall have a Research Ethics Committee and established guidelines for review and approval of such projects.

2. The Faculty Research Ethics Committee shall have at least three members who are appointed by Senate on the advice of the Faculty Board for a period of three years. The members shall have knowledge about the various types of research conducted within the faculty. At least one member should have expertise in ethics.

3. Faculty Research Ethics Committees shall be responsible for performing reviews of research projects as well as course-related research projects conducted by staff and students which involve human subjects.

4. Faculty Research Ethics Committees shall consider the research proposals and forward their advice to UREC on whether the proposal should be accepted or rejected. The research proposals and the faculty committee’s advice must arrive at UREC office at least two weeks before UREC meeting.

5. A member of the Faculty Research Ethics Committee may not participate in a review of any project in which the member has a conflicting interest (which includes being the supervisor of the project) except to provide information.

6. Faculties or departments which do not have a Research Ethics Committee shall each appoint a faculty member to coordinate human subject reviews and other related issues with UREC. A single research ethics committee may service more than one Centre or Institute.

7. In all cases, the rights and welfare of human subjects in research shall be protected in accordance with this policy.

V. INFORMED CONSENT
22. Researcher Responsibility:
1. Researchers shall be responsible for obtaining informed consent in accordance with these guidelines and for ensuring that no human subject will be involved in the research prior to obtaining such consent. Informed consent is not required for projects determined by the faculty research ethics committee and UREC to be exempt.

2. Unless otherwise authorized by UREC, researchers are responsible for ensuring that legally effective informed consent shall:
   (a) be obtained from the subject or the subject's legally authorized representative;
   (b) be in language understandable to the subject or the representative;
   (c) be obtained under circumstances that offer the subject or the representative sufficient opportunity to consider whether the subject should or should not participate; and
   (d) not include exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or release the Researcher, the Sponsor, the University or its agents from liability for negligence.

23. Basic Elements of Informed Consent:
1. Unless otherwise authorized by UREC, researchers as a minimum shall provide the following information to each subject:
   (a) A statement that the study involves research, an explanation of the purpose of the research and the expected duration of the subject's participation, a description of the procedures to be followed and identification of any procedures which are experimental.
   (b) A description of any reasonably foreseeable risks or discomforts to the subject.
   (c) A description of any benefits to the subject or to others which may reasonably be expected from the research.
   (d) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
   (e) A statement describing the extent to which confidentiality of records identifying the subject will be maintained.
   (f) For research involving more than minimal risk, 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.
   (g) An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the event of a research-related injury to the subject.
   (h) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. UREC may approve a consent procedure which does not include or which alters some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided UREC finds and documents that:
   (a) the research involves no more that minimal risk to the subjects;
   (b) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
   (c) the research could not practicably be carried out without the waiver or alteration; and
   (d) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

3. In the case of research on genetic material, the consent form must indicate under what conditions the participant is giving consent, if at all, to the use of this material in further studies.

24. Documentation of Informed Consent:
1. Researchers shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by UREC and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by UREC.

2. Researchers shall ensure that each person signing the written consent form is given a copy of that form.

3. In addition to the subject's signature, the consent form shall be signed by the Researcher and the supervisor.
4. The Researcher shall give either the subject or the subject's legally authorized representative adequate opportunity to read the form before signing it.

5. When the documentation requirement is waived, UREC may require the Researcher to provide subjects with a written statement regarding the research.

25. SANCTIONS FOR NON-COMPLIANCE

1. In instances of non-compliance, the individual(s) involved will be given notice by UREC that research involving the use of subjects should be terminated.

2. UREC shall inform the Rector and the respective Dean of instances of non-compliance.

3. As a minimum, the individual(s) involved will be reprimanded and reminded of their responsibilities.

4. In those cases determined to be serious violations, the Rector in consultation with the Dean and Head of Department, will recommend sanctions. Senate will make the final decision with regard to appropriate action against the individual(s) involved.

1st June 2007