

UNIVERSITY OF MALTA

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 were approved at the July Senate meeting.
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 Senate has now approved the guidelines that will regulate all research involving human subjects carried out at the University, both by students and by members of staff. It has also appointed a new University Research Ethics Committee.
 - 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 and present it for approval to the faculty research ethics committee. 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 present 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. The dates of the University committee meetings will be advertised in good time, so that faculty committees can plan their work without causing any unwarranted delays.
4. There is no need to stress that for this system to function properly, the University needs to provide training for the members of the different committees, and give the University committee sufficient administrative support.

30 July 2004

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 is committed to carry out all research involving human subjects in strict adherence to ethical principles as set out in this policy.
2. This policy will apply to all research, as defined in this policy, that is conducted by University personnel or students and which involves human subjects.
3. Research on human subjects is a common feature of university life, both inside and outside the lecture room. In all such instances, the faculty member and the respective Faculty Research Ethics Committee has the responsibility to protect human subjects and to decide whether a project is exempt or needs to seek the University Research Ethics Committee approval.
4. The University acknowledges and accepts its responsibility for protecting the rights and welfare of human research subjects, and acknowledges that it bears full responsibility for the performance of all research involving human subjects and for complying with laws and regulations that relate to such research.
5. 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 data protection provisions; and
 - the additional safeguards for vulnerable subjects.
6. 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 informed consent has been obtained in accordance with these regulations. Special provisions must be made for soliciting the assent of children to be involved in research.
7. 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.

8. 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.

9. 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.

10. The University will exercise appropriate administrative overview carried out at least annually to assure that its practices and procedures designed for the protection of the rights and welfare of human subjects are being effectively applied.

II. DEFINITIONS

A. Research:

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

B. Human Subject:

A living individual 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.

C. Minimal Risk:

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

D. 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 good information handling.

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, the researcher shall provide his identity and habitual residence, when obtaining consent. 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.

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.

E. Exemption Categories:

Research activities and certain course-related, classroom research projects are exempt from this policy for the protection of human subjects when the **ONLY** involvement of human subjects falls within one or more of the categories below:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behaviour, **unless:** (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation.
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

III. University Research Ethics Committee (UREC)

A. Membership:

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

The 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 regularly involves a category of vulnerable subjects, such as children, handicapped or mentally disabled persons or prisoners, the 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. The 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. The UREC shall include at least one member who is presently not otherwise affiliated with the University. A member of the UREC may not participate in a review of any project in which the member has a conflicting interest.
4. A list of the names and qualifications of the UREC members is included in the University Calendar.

B. UREC Approval:

1. The main function of the UREC review is to assure that (1) risks to subjects are minimized and reasonable in relation to the anticipated benefits; (2) there is informed consent; (3) rights and welfare of subjects are maintained; and (4) the requirements of data protection legislation are observed
2. The UREC shall review and have authority to approve, require modification in, or disapprove all research activities covered by this policy.
3. The UREC shall approve research based on a determination that all of the following requirements are satisfied:
 - a. Risks to subjects are minimized:
 - i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk; and,
 - ii) 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, the 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). The 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, the 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.
 - 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 (3.c.) above, additional safeguards have been included in the study to protect the rights and welfare of these subjects.
4. The 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. The UREC shall meet at least once every two months to review protocols. The calendar of its meetings will be established every year and communicated to faculty ethics committees at the beginning of the academic year.

C. UREC Reporting:

1. The Faculty Research Ethics Committees shall report to the UREC, and the 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 the 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 the UREC.
2. The 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, progress reports submitted by the Faculty Research Ethics Committees and reports of injuries to subjects.
 - b. Minutes of UREC meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the UREC; the vote on these actions including the number of members; the basis for requiring changes in or disapproving research; and a written summary of the issues discussed and their resolution.
 - c. Records of continuing review activities.
 - d. Copies of all correspondence between the UREC and the investigators.
 - e. A detailed list of UREC members and of faculty research ethics committees.
 - f. Detailed written procedures for the UREC.
 - g. Statements to subjects of significant new findings developed during the course of the research.

D. 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 the 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.
3. Research which involves no more than minimal risk to the subjects **and** in which the only involvement of human subjects will be in one or more of the following categories shall normally be approved:
 - a. Collection of: hair and nail clippings, in a non-disfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.
 - b. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labour.
 - c. Recording of data from subjects 18 years of age or older using non invasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, microwaves).
 - d. Collection of blood samples by venipuncture, in amounts not exceeding 450 millilitres in an eight-week period and no more often than two times per week, for subjects 18 years of age or older and who are in good health and not pregnant.
 - e. Collection of both supra- and subgingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

- f. Voice recordings made for research purposes such as investigations of speech defects.
- g. Moderate exercise by healthy volunteers.
- h. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.
- i. Research on individual or group behaviour or characteristics of group behaviour or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the investigator does not manipulate subjects' behaviour and the research will not involve stress to subjects.
- j. Research on drugs or devices for which an investigational new drug exemption or an investigational device exemption is not required.

E. Full Committee Review:

- 1. If research does not satisfy the guidelines of exemption and/or external funding is being sought, UREC full-board review shall be conducted. A majority of the members of the UREC must participate in the review.
- 2. At least one member whose primary concerns are in non-scientific areas must participate in the review. UREC members who have a conflicting interest in a research project cannot participate in the review except to provide information.
- 3. Research protocols scheduled for review, as well as the advice from the Faculty Research Ethics Committees, shall be distributed to all members of the UREC in advance. When the UREC determines that consultants or experts will be required to advise the UREC in its review of a protocol, the research protocol shall also be distributed to the consultants or experts prior to the review.

F. Notification of UREC Decisions:

- 1. The UREC shall notify the research investigators and their respective Dean in writing of the UREC's decisions, conditions and requirements within two weeks of UREC review.
- 2. The UREC shall also provide to the research investigator reasons for the UREC's decisions to disapprove a research protocol and an opportunity for the researcher to respond. The UREC shall also inform the respective Dean of the reasons for disapproval.

IV. IMPLEMENTATION

A. 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.

B. Responsibilities of the Research Investigator:

- 1. Research Investigators shall prepare a protocol giving a complete description of the proposed research. In the protocol, research investigators 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. Research Investigators are responsible for preparing and submitting a protocol to the Faculty Research Ethics Committee and for including a sample of proposed informed consent forms with the protocol when appropriate.
3. Research Investigators 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 the UREC.
4. Research Investigators shall be responsible for complying with all Faculty Research Ethics Committee and UREC decisions, conditions and requirements.
5. Research Investigators 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 the UREC. Prior to initiation, Research Investigators 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, Research Investigators are encouraged to attend Faculty Committee and/or UREC reviews when invited to answer questions.

C. 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 an 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 the Senate on the recommendation 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 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 Ethics Committees shall consider the research proposals and forward their advice to the UREC on whether the proposal should be accepted or rejected. The research proposals and the faculty committee's advice must arrive at the UREC office at least two weeks before the UREC meeting.
- All projects which are to be submitted to external sponsors must be submitted to the UREC, regardless of whether they qualify for exemption or not .**
5. 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 the UREC.
 6. In all cases, the rights and welfare of human subjects in research shall be protected in accordance with this policy.

V. INFORMED CONSENT

A. Research Investigator Responsibility:

1. Research Investigators shall be responsible for obtaining informed consent in accordance with these regulations 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 department/school human subjects committee and the UREC to be exempt.

2. Unless otherwise authorized by the UREC, Research Investigators 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 Research Investigator, the Sponsor, the University or its agents from liability for negligence.

B. Basic Elements of Informed Consent:

1. Unless otherwise authorized by the UREC, Research Investigators at 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 the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

2. The 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 the UREC finds and documents that:

- a. the research involves no more than 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.

C. Documentation of Informed Consent:

1. Research Investigators shall be responsible for ensuring that informed consent is documented by the use of a written consent form approved by the UREC and signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the UREC. The informed consent form must be printed on University of Malta letterhead.

2. Research Investigators 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 Research Investigator and a witness, if appropriate.

4. The Research Investigator shall give either the subject or the subject's legally authorized representative adequate opportunity to read the form before signing it.

5. The UREC shall require documentation of informed consent by use of the written consent form or may waive the requirement for the Research Investigator to obtain a signed consent form for some or all subjects if the UREC determines that:

a. The only record linking the subject and the research would be the consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject's wishes will govern; or

b. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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

VI. SANCTIONS FOR NON-COMPLIANCE

1. External funds may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

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

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

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

5. 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.

8 July 2004

Research Ethics Committee Guidelines