

GUIDELINES

for

Applicants submitting Research Ethics Form

Faculty of Health Sciences (FHS)

The following guidelines are for applicants seeking ethical approval to perform research on Human Subjects.

Proposals are vetted by the Faculty of Health Sciences Research Ethics Committee (FREC) and subsequently referred to University Research Ethics Committee (UREC) for approval.

Research proposals which do not abide by these guidelines will be referred back to the applicant.

The Research Ethics Form

1. The University Research Ethics form (Request for Approval of Human Subjects Research) may be downloaded from <http://www.um.edu.mt/healthsciences/resources>.
2. Applicants must submit (in four separate plastic folders) an original hard-copy of the research ethics form signed by both applicant and supervisor as well as another three hard copies to Secretary, FREC, Room 6, Faculty of Health Sciences.
3. A soft copy, either in PDF or ZIP file (but NOT in .rar format) is to be also sent to Secretary, Faculty Research Ethics Committee via e-mail: bertha.darmanin@um.edu.mt.
4. The checklist on the first page of the UREC form must be duly completed. Incomplete forms will not be accepted.
5. The application should specify in detail the procedure by which prospective research applicants will be invited to participate in the research study. Please note that first contact, with patients/clients receiving service from the Health Division, cannot be made by the applicant (UREC Form - Section 2a).
6. Students registered with foreign institutions should submit their application directly to UREC.
7. It is considered unethical for researchers to send forms, letters, etc. with grammatical typographical and/or translation errors. FREC/UREC will request editing/further proof-reading as applicable.
8. A statement indicating whether the research tool was self-designed or not should be included in Section 2d. If not designed by the researcher and the research tool is not available in the public domain, a letter of permission from the originator must be submitted. This letter should clearly indicate whether permission has been sought and granted to:

- (a) use the tool as is; and/or
 - (b) use a modified version of the tool, whether in part or in full; and/or
 - (c) translate the tool into another language.
9. Applicants should indicate if any video/audio-recording (digital or otherwise) will be used for data collection.
10. Any digitally recorded data must be password protected. This must be clearly indicated in the UREC form.
11. Applicants should indicate HOW confidentiality and/or anonymity will be maintained throughout the study.
12. Hospital names, clinics, specific schools, etc. should not be mentioned, e.g., Mater Dei Hospital should read: 'a state general hospital'.
13. Postgraduate applicants are also to submit a proposal which should not be longer than 1500 words.

Information Letter to Participant

1. The information letter should be in letter format and signed by the applicant.
2. It must show the researcher's AND supervisor's official contact details (e.g., email address).
3. When participants are all professionals it is acceptable to submit the information letter only in English. In all other cases a Maltese version is also required.
4. It should clearly be indicated if audio/video-recording will be used for data collection.
5. It should indicate the duration of the intervention e.g., interview, if applicable.
6. It must state that participants are free to withdraw from the study at any time without any prejudice.
7. Information letters must be proof-read and should be free from any grammatical and spelling mistakes in any language used.
8. Any potential risks or discomforts should be specified and support given as needed. In the latter instance, written consent of the respective professional should be mentioned and included.
9. Information regarding what will happen to data and samples on completion of the study, should be included.

Consent Form

1. Consent form for participants should be signed by both applicant and supervisor.
2. It must show the researcher's AND supervisor's official contact details.

3. When participants are all professionals it is acceptable to submit the consent form only in English. In all other cases a Maltese version is also required.
4. It must state that the participant is free to withdraw from the study at any time without prejudice.
5. It should specify if an audio/video-recording, digital or otherwise, will be used during data collection.
6. The information letter should state clearly that filling in and returning a questionnaire constitutes giving consent. In this case the information letter needs to be signed by the supervisor and a consent form is not required
7. Consent forms must be proof-read and free from any grammatical and spelling mistakes in any language used.

Research Tools

1. Any questionnaire, interview schedule, or any other research tools to be used in the study must be appended to the UREC form, unless these need to be constructed during the study. In this case, this needs to be presented at a later stage for approval by FREC/UREC.
2. When participants are all professionals it is acceptable to submit the research tool only in English. In all other cases a Maltese version is also required.
3. Research tools must be proof-read and free from any grammatical and spelling mistakes in any language used.

Permissions required

1. Participants recruited from Mater Dei Hospital: permission letters from the A/Data Protection Officer and the Chief Executive Officer are required.
2. Participants recruited from the Oncology Centre: permission letter from the Chief Operation Officer is required.
3. Participants recruited from Mount Carmel Hospital: permission letters from the Hospital Principal and the Chief Operations Officer are required.
4. Participants recruited from St Vincent de Paul Residence: permission letter from the Chief Executive Officer is required.
5. Participants recruited from the Primary Health Care Clinics: a permission letter from the Senior Medical Officer is required.

6. Participants recruited from Karen Grech Hospital: permission letters from the Chief Executive Officer and from the Chief Operation Officer are required.
7. Participants recruited from nursing staff from Mater Dei Hospital: permission letters from the Nursing Services Directorate and the Director of Nursing Management are required.
8. Also permissions from the respective Departmental and Ward Nursing Managers are required.
9. Participants recruited from patients in hospitals or other health care institution: permission is always required from the corresponding consultant/manager/nursing officer of that particular department/ward where data will be collected.
10. Participants recruited from University students: permission from the Registrar is required. In the case of students who are under the age of 18 years, permission from the Dean would be required.
11. Participants recruited from public/private institutions, NGOs, etc.: permission should be sought from the appropriate authorities of the respective institution.
12. Specific officers may be in charge of nursing staff/healthcare professionals; in this instance permission of respective officers may also be required.
13. In the case of minors under 18 years of age a written consent from parent/guardian is also required.
14. In the case of minors over the age of 12 years a written consent is also required; for those who are younger an explicit consent is encouraged, even if not written. This means that they can refuse to take part.
15. Print Screen and Text messages indicating permission are not accepted.
16. All permissions received electronically are to be submitted as original e-mails.
17. All communication should be made through the University of Malta e-mail address.

Blood, Tissue and other Biological Samples

1. When the research project involves the collection of biological samples or the use of archived samples the following additional permissions must be obtained:
 - (a) A permission letter from the holder of the bank or archive if archived samples are to be used.
 - (b) A permission letter from the consultant in charge of the patients if fresh samples will be collected specifically for the project.

2. Permission also needs to be obtained to use the laboratory facilities as follows:
 - (a) The Chair of Pathology if work will be carried out at the pathology labs.
 - (b) The Head of the blood donor unit if samples will be collected from blood donors.
 - (c) The Head of the relevant laboratory if the work will be carried out in the research laboratories of the University.
3. If fresh samples are to be collected an information letter and a consent form for participants should be submitted.
4. For archived samples (anonymous/anonymised samples) information letter and consent form are not required.

Amendments after UREC's approval

1. Applicants are to seek approval from FREC/UREC should amendments to their approved research proposal be needed; this also applies to a change in title.

Proposal with more than one phase

1. Applicants are requested to seek permission for every phase of their study.

Research Ethics Committee, FHS
24 February 2015