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. Ethics Forms are initially vetted by the Faculty of Health Sciences Research Ethics Committee (FREC). Those proposals that present data protection issues are subsequently referred to the University Research Ethics Committee (UREC-DP) for approval. Applications which do not abide by these guidelines will be referred back to the applicant.

The Research Ethics Forms

1. New applications requiring Ethics and data protection approval are to be made online and may be accessed through the UREC homepage at https://www.um.edu.mt/urec. This form consists of four parts: Part 1. Applicant and Project Details; Part 2. Self-assessment; Part 3. Detailed Evaluation; Part 4. Submission details. Applicants who complete the Self-assessment (Part 2) without issues will not be exposed to the Detailed Evaluation (Part 3). Such applicants must still submit the form to their FREC for filing and audit purposes, but may commence the research DIRECTLY. Applicants who flag an issue in the Self-assessment checklist (Part 2) will be required to elaborate on ONLY the relevant issue/s in the detailed evaluation (Part 3) and must seek FREC permission prior to data collection.

2. On completing the online application, the form will be automatically generated as a PDF document and will be sent to the applicant by e-mail, with a unique ID. This PDF document must be sent to the FREC secretary, Ms Christabel Vella (christabel.vella@um.edu.mt) with a zipped folder of attachments (e.g., approvals obtained, copies of the information letter and consent form). You are expected to title your email and folder using your unique form ID and write "For FREC Review" or "For FREC Records". Online forms received by FREC and marked "Submitted for FREC Records" are for filing and for possible eventual audit (similar to the previous Form A); forms marked "Submitted for FREC Review" are for consideration and review by the FREC (as was the case with the previous Form B).

3. When sending the pdf version of the online form to the FREC, students are instructed to copy in their principal supervisor, who should then send an e-mail back to the FREC, copied to the student, that s/he approves the contents of the form.

4. Ahead of completing the online form, users are advised to read the UM Research Code of Practice and the UM Research Ethics Review Procedures, refer to any relevant Frequently
Asked Questions, and to familiarize themselves with the requirements of the form, which is available as a downloadable replica. Full details are available on the UREC website at https://www.um.edu.mt/urec

5. When planning their study researchers must keep in mind that the first contact with potential participants cannot be made by the applicant.

6. Students registered with foreign institutions and requiring ethical clearance are to submit their application directly to FREC.

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. Maltese text should be written in proper Maltese fonts.

8. Applicants should indicate if any video/audio-recording (digital or otherwise) will be used for data collection. Any digitally recorded data will be stored in an encrypted format on a password protected device. This must be clearly indicated in the Information Sheet and Consent Form.

9. Applicants should indicate HOW confidentiality, anonymity and/or pseudonymity will be maintained throughout the study. If the researcher retains codes linking personal data to research participants, that data is pseudonymised, and participants remain identifiable to whoever has access to the codes and personal data. It is only if and when all personal data (information relating to an identified or identifiable natural person) are deleted that the research data is considered to be anonymised.

10. Postgraduate applicants are also to submit a proposal which should not be longer than 1 page, targeting methodology and ethical issues (how they were tackled). Literature review, data analysis and references should not be included.

**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., university 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. When participants have possible language and/or communication impairments (e.g. patients with aphasia following stroke) the information letter must be written in an aphasia-friendly format (please refer to the available templates ‘The Research Story’ on the website). Both English and Maltese versions are required.

5. It should clearly be indicated if audio/video-recording will be used for data collection. In such cases, both the information letter and consent form should state that the data collected will be
anonymised/pseudonymised (see point 11 on page 2) and stored separately from any codes and personal data to ensure confidentiality.

6. It should indicate the duration of the intervention e.g., interview, if applicable.

7. The information letter and consent form (if applicable) should identify who will have access to the data. This normally includes the researcher/s, supervisor/s and examiners.

8. It must state that participants are free to withdraw from the study at any time without the need to give a reason and that data from participants who withdraw from the study should either be deleted altogether, or retained only in an anonymised form.

9. Information letters must be proof-read and should be free from any grammatical and spelling mistakes in any language used.

10. 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.

11. Information regarding what will happen to data and samples on completion of the study, should be included e.g., that the data will be erased.

12. To state that the participant can keep a copy of the information letter and (if applicable to the study) the consent form.

13. If data is not collected anonymously to include in both the Information Letter and Consent Form that: “As a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation to access, rectify, and where applicable ask for the data concerning you to be erased”.

14. To include a statement describing any benefits to the participant or to others which may be reasonably expected from this research. If no benefits are foreseen to the participants or to others, this should be clearly stated.

15. A statement that participants will only be asked to share data that is necessary for the research.

16. If the intervention is an extension of a standard procedure e.g., medical, the researcher must indicate which parts of the procedure are standard clinic practice carried out on all patients presenting with the same symptoms and the part of the procedure that is only done to research participants.

**Consent Form**

1. Consent form should include statements on the purpose of the research, the duration of the participant’s involvement, any possible risk/discomforts and any benefits.

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. When participants have possible language and/or communication impairments (e.g. patients with aphasia following stroke) the consent form must be written in an aphasia-friendly format (please refer to the available templates on the website). Both English and Maltese versions are required.

5. It must state that the participant is free to withdraw from the study at any time without giving a reason and that data from participants who withdraw from the study should either be deleted altogether or retained only in an anonymised form.

6. It should specify if an audio/video-recording, digital or otherwise, will be used during data collection.

7. For data that is collected anonymously 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.

8. If the research opts to gather demographic information and consent forms, then a statement should be included in both the information letter and consent form that under the General Data Protection Regulation (GDPR) and national legislation the participants have the right to access, rectify, and where applicable erase the data concerning them.

9. It should state that participant identity and personal information will not be revealed in any publications, reports or presentations arising from this research.

10. Consent forms must be proof-read and free from any grammatical and spelling mistakes in any language used.

Research Tools

1. If a research tool e.g., questionnaire was 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.

2. Any questionnaire, interview schedule, or any other research tools to be used in the study must be forwarded to the FREC secretary as part of a zipped folder of attachments (see page 1 point number 2).

3. 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.

4. 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 Sir Anthony Mamo 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 Long Term Care Facility: 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 Director of Nursing Management are required.

8. 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.

9. 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.

10. Participants recruited from public/private institutions, NGOs etc.: permission should be sought from the appropriate authorities of the respective institution.

11. Specific officers may be in charge of nursing staff/healthcare professionals; in this instance permission of respective officers is required.

12. In the case of minors under 18 years of age a written consent from parent/guardian is also required.

13. In the case of minors between the ages of 12 and 17 years their assent is also required; for those who are younger an explicit acceptance of their willingness to participate is encouraged, even if not written. This means that they can refuse to take part.

14. Print Screen and Text messages indicating permission are not accepted.

15. All permissions received electronically are to be submitted as original e-mails.
16. All communication should be made through the University of Malta e-mail address.

17a. For research in state schools applicants are first expected to submit their Ethics Forms to FREC. Once the institutional approval has been granted, the researcher can then complete the online application to conduct research in state schools. This is provided on the website of the Education Department: https://researchandininnovation.gov.mt/en/Pages/Request-for-research-in-state-schools.aspx. Once permission has been granted from the Education department, a copy of this approval is to be provided to FREC, before the student can commence data collection in state schools.

17b. For research in church schools applicants should send an email with the details and request to the Administrative Assistant, Secretariat for Catholic Education. Permissions should also be sought from the respective Heads of schools.

17c. For research in private schools applicants should contact each Head of school directly.

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 forms be needed; this also applies to a change in title.
Study with more than one phase

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

These procedures are available to all University of Malta (UM) staff, students, and anyone else carrying out research under its auspices. This includes visiting staff and students from other institutions (in Malta or overseas) who intend to conduct research in Malta. **External Applicants are charged a fee by the University and are requested to append a copy of the receipt with the application when this is submitted to FREC.** Kindly refer to UREC’s Homepage for further details (https://www.um.edu.mt/urec).

*Research Ethics Committee, FHS*

*24 January 2019*