L-Università ta' Malta
Faculty of Health Sciences

**_Guidelines_ for Applicants submitting Research Ethics Form**

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/forms** . This form consists of three parts: Part 1. Applicant and Project Details; Part 2. Self-assessment and Details; Part 3. Submission. Fill in Parts 1, 2 and 3. If any of the questions in Part 2 are marked as 'Yes/Unsure', the application will be REVIEWED by the FREC before any data collection may commence. In cases where none of the questions in Part 2 are marked as 'Yes/Unsure', the application will still be received by the FREC for filing and kept for RECORDS and audit purposes; in such cases, data collection may start immediately.

2. When filling in the form, applicants should make sure to type their supervisor's UM email address correctly since, upon submission, the supervisor will receive an automated email to endorse the submitted documents. If an application is not endorsed, it will remain pending and will not be reviewed by FREC.

3. Researchers are instructed to keep their principal supervisor in copy in every correspondence to FREC.

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. External Applicants are charged a fee by the University and are requested to attach a copy of the receipt with the application. Kindly refer to UREC's page for further details re External Applicants - https://www.um.edu.mt/research/ethics/forms .

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. Applicants

should indicate if any video/audio-recording (digital or otherwise) will be used for data collection. Any digitally recorded data should be stored on an encrypted external hard drive or flash drive and kept in a locked secure place when not in use / on a secure UM-approved server with the appropriate access settings applied, to ensure data security. This must be clearly indicated in the Information Sheet and Consent Form.

8. 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.

9. Ethics form needs to be duly filled even if the information is in the consent form or information letter. Follow the instructions on the REPD replica form which may be downloaded from the UREC page.

10. Applicants should understand that when FREC grants approval, *that* approval is only for data collection as declared in the application form.

<u>Information Letter to Participant</u>

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 and phone number).

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 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 pseudonymised meaning that codes will be assigned to the transcripts/recordings and that this data will be stored securely and separately from any codes, and personal data will be stored separately 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 personal data. This normally includes the researcher/s and supervisors only. Examiners will typically have access to coded data only. There may be exceptional circumstances which allow examiners to have access to personal data too, for verification purposes.

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 be deleted altogether. It may only be retained in an anonymised form IF it has already been anonymised and is therefore impossible to identify and delete.

9. Information letters must be proofread 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. The researcher can provide participants with a list of services that they can use (Please refer to the relevant document on the FREC resources webpage).

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. On completion of the study, data can be retained in anonymous form. However, any personal details must be destroyed and the month and year of when this will be done, need to be provided. All personal data (including recordings) should be stored in an offline manner on an encrypted external hard drive or flash drive and kept in a locked secure place when not in use or on a secure UM-approved server with the appropriate access settings applied, to ensure data security. This must be clearly indicated in the Information Sheet and Consent Form.

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 the Information Letter that: "As a participant, you have the right, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, 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 and that their identity and personal information will not be revealed in any publications, reports or presentations arising from this 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

17. When participants approached are current patients, one must specify that refusing to participate or withdrawing from the study would involve no penalty or loss of benefits to which they are otherwise entitled.

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 (email address and phone number).

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 the need to provide a reason and that data from participants who withdraw from the study will be deleted altogether. It will be retained in an anonymised form only if it has already been anonymised and is therefore impossible to identify and delete.

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 the consent form that "As a participant, under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said regulation, I have the right to access, rectify, and where applicable ask for the data concerning me to be erased".

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 proofread and free from any grammatical and spelling mistakes in any language used.

11. Consent forms need not repeat all the elements if they are listed in the recruitment form/information letter, provided that they are incorporated into the consent form by reference.

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 proofread and free from any grammatical and spelling mistakes in any language used.

Permissions required

1. For participants recruited from Mater Dei Hospital, the following permissions are required:

   a. permission from the Data Protection Officer (DPO) and the Chief Executive Officer (CEO).

   b. permission from the respective director or chairperson of the department, depending on the department involved in the data collection. If participants shall be recruited from nursing staff from Mater Dei Hospital, a permission letter from the Director of Nursing Management are required.

   c. for participants recruited from Sir Anthony Mamo Oncology Centre (SAMOC): an additional approval form should be completed.

2. For participants recruited from Mount Carmel Hospital: permission letters from the Chief Executive Officer, Medical Chairperson and Data Protection Officer are required, depending on the nature of the research.

3. For participants recruited from St Vincent de Paul Long Term Care Facility, a permission letter from the Chief Executive Officer is required.

4. For participants recruited from the Primary Health Care Clinics: a permission letter from the Data Protection Officer is required.

5. For participants recruited from Karen Grech Hospital: permission letters from the Chief Executive Officer and from the Chief Operation Officer are required.

6. On a unit, specific officers may be in charge of nursing staff/healthcare professionals; in this instance permission of respective officers is required.

7. Participants recruited from University students: permission from the Registrar is required if the Registrar shall assist in the recruitment of participants. In the case of students who are under the age of 18 years, permission from the Dean would be required. If research will be conducted within a faculty department, then approval from the Head of Department is required. If research will be conducted across the whole faculty, then approval from the Dean is required.

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

9. In every study, consent should be sought from individuals who are legally able to give consent (i.e. the participant himself/herself or a legal guardian). This should be specified in the URECA form.

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

11. 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.

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

13. All permissions received electronically are to be submitted as original e-mails, saved as pdf – the applicant's original request email (and not just the responder's reply) should be submitted to FREC.

14. All communication should be made through the University of Malta e-mail address.

15. a. **Before submission to FREC, applicants are required to obtain all the necessary institutional permissions and tick Question 17 on the REDP form as 'No'.** However, for those applicants who will be researching in state schools, 'conditional' approval is needed from FREC before state schools are approached. Therefore, in these cases the applicant should tick 'Yes/Unsure' to Question 17. Once FREC approval is granted conditionally, the applicant can then complete the Ministry's online application to conduct research in state schools. This is provided on the website of the Education Department: https://researchandinnovation.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.

b. 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.

c. 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.

5. For commercial cell lines: If cell lines are purchased commercially, there is no requirement for SCPD. Therefore, studies involving these cell lines do not need to be submitted to UREC-DP. If cell lines are derived from **human** tissue by the researcher(s) or their associate(s) (i.e., not commercially purchased), the research proposal must be submitted to UREC-DP due to potential SCPD issues.

6. UREC must review all research involving human tissue / samples and forward their recommendation to the IDPC for approval (or otherwise). Once approval from the IDPC is granted, the researchers may seek clearance from the MDH DPO.

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.

Studies with more than one phase

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

Studies using secondary data

1. Researchers are requested to submit an application form to FREC. The original FREC approval number and data controller should be stated.

Researchers involved in joint projects

1. Each researcher should submit an application form and request approval individually.

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.

Guidance in relation to researchers joining larger studies

1. If a researcher is submitting a proposal that is part of a larger study which has received both ethics and, where applicable, data protection clearance, and there are no new elements added to the approved study, or deviations therefrom, then approval will only be required from the Faculty/Research Ethics committee. The researcher is to give the unique identification code of the originally approved study and may be required to provide clarifications by the F/REC.

2. If a new member:

(i) joins the research study but not in the capacity of a student, and

(ii) assuming that the original applicant of the study (i.e. the primary individual responsible for the research) still retains responsibility for the project and any related ethics/data protection issues, then there is no need for a new submission to the Faculty/Research Ethics committee; however, the F/REC should be informed through a written notification that quotes the unique identification code of the originally approved study.

**This does not apply to students, since all students are required to submit a REDP form (URECA form); however, it should be noted in the application that this forms part of an already-approved project and quoting the unique identification code, since this will expedite the approval process.**

Useful resources (amongst others) for Health Sciences Researchers – can be accessed from https://www.um.edu.mt/research/ethics/resources/

Criteria for Medical Image Data to be Considered Anonymous
Good Practice in Inclusive Language
Obtaining Consent from Online/Remote Participants
UM Ethical Guidelines for Carrying Out Research with Disabled People
UM Research Ethics and Data Protection on the Use of Data from Social Media
UREC Data Management Plan
Guidelines for research involving persons with mental disorders

*Research Ethics Committee, FHS*
*March 2025*