University of Malta
MRI Research
Platform

Information sheet for UMRI scanning service applicants

These instructions are intended for individuals/entities who would like to collect MRI data for research purposes ('primary' data) rather than those who want to use secondary data from the UMRI data repository. The highlighted documents are not relevant if data will be acquired from phantoms (artificial objects).

1) If your use of UMRI (University of Malta MRI Platform) services does not concern a student project, skip step 1 and go to 2. Otherwise, you must first submit your research proposal to your Faculty / Institute / Centre (ensure you follow the respective policies and procedures). Once this has been approved, proceed to step 2.

2) Fill in the UMRI **project application form**❖. Upon submission, you will automatically be sent the research volunteer consent form and information sheet. A template data management plan will also be sent. Once submitted, forward the application form to the UMRI platform (umri.platform@um.edu.mt). Kindly be aware that your application will NOT be considered administratively compliant unless:

- You also provide:
  - A detailed **data management plan** (prepared with the UMRI template❖)
  - A **data acquisition protocol** (only If you intend to use your own)
  - Any requisite **data sharing agreements** (not needed unless data from human subjects will be shared with researchers at entities external to the University of Malta). More information may be found in the project application form.
- The principal investigator for this project submits the completed **UMRI principal investigator compliance form**❖, and **all** researchers who will be handling the collected MRI data likewise fill out the **UMRI researcher compliance form**❖.

❖ Available at https://www.um.edu.mt/platforms/umri/documents-forms/

3) Your application will be reviewed to ascertain that all the necessary information has been supplied. If deemed satisfactory, it will then be forwarded to the UMRI application review committee. The role of this committee is to go over your application and make sure that UMRI can indeed provide the services required for the project. The committee may moreover give general advice on, and/or suggest improvements to, aspects of your project proposal like the study design, the research ethics, and the data management plan.

4) Your application will be classified by the committee as needing **major, minor** or **no** amendments.

- In the last two cases, make any recommended changes and proceed to step 5.
- If a major revision is in order, your application will have to be re-assessed by the committee after the necessary modifications have been implemented.

5) Prepare your Research Ethics and Data Protection (REDP) application for submission to the (Faculty) Research Ethics Committee (FREC/REC) of your Faculty/Institute/Centre. The form you have to fill in can be accessed at https://www.um.edu.mt/research/ethics/ (URECA Form), where you may also find links to

several resources, including a set of FAQs (**make sure you familiarise yourself with these** before you start, as well as with the University's **Research Code of Practice**, available at www.um.edu.mt/research/ethics/researchethicsatum/. Additionally, the various FRECs/RECs may have distinct guidelines. You are thus encouraged to consult the FREC/REC page of your particular Faculty/Institute/Centre for more information). **IMPORTANT:** Since MRI images can be considered health and biometric data, which are both classified as special categories of personal data in the General Data Protection Regulation (GDPR), the FREC/REC will need to refer your application to UREC-DP, the data protection branch of the University Research Ethics Committee (UREC). The whole process may therefore take a number of months. PLEASE FACTOR THIS IN when planning your project.

6) Attach the following documents to your URECA form (and don't forget to make any amendments suggested by the UMRI application review committee):

- A copy of the **email received from UMRI** confirming that UMRI has approved the use of the University's MRI equipment for your project, and specifying the number of scanning hours allotted to you. This email should contain two attachments that need to be included with your URECA form:
    - A **declaration** that your application is submitted in accordance with the MRI scanner agreement executed between the University of Malta and the Ministry for Health;
    - The **radiographer consent form**, filled in and signed by the radiographer who will be operating the MRI scanner during data collection for your project.
- The **information sheet for research participants***;
- The **consent form*** to be signed by research participants;
- Any **recruitment letter/s** and **questionnaire/s**;
- Your **data management plan***;
- A copy of the completed **UMRI researcher / principal investigator compliance form** (depending on which of the two applies to you; you should have received a copy of your answers automatically when you submitted the form).
- The **data sharing agreement/s** (if applicable).

Reply 'YES' to Question 22 of the URECA form ('Official statement: Do you require an official statement from the F/REC that this submission has abided by the UM's REDP procedures?')

*Available as templates from https://www.um.edu.mt/platforms/umri/documents-forms/. They must be modified to reflect the objectives and research methods of your particular project. **Ensure that you are explicit about who will have access to your copy of the data** (for example, you might be planning to store the data on a UM-managed computer cluster. In this case, the data would also be accessible to the personnel in charge of the cluster).

Note 1: *The URECA form specifically states, in relation to the information sheet, recruitment letter and consent form, that these materials should be provided in English and/or Maltese and/or any other relevant language, or as equivalent text that may be communicated orally to those who do not read. The information sheet and consent form templates supplied by UMRI are in English. Kindly keep this in mind when enlisting research volunteers.*

Note 2: *If you will be asking participants to fill in a questionnaire, mark the questionnaires with the respective codes (constructed as explained in point 9 below) rather than with names or ID card numbers. If the questionnaire is online, put in the FREC/REC study code part of the participant code yourself, so that the research volunteers only need to add the participant number (which you can communicate to them during the scanning session). This precludes the need of issuing the code in its entirety to the volunteers via electronic means or on paper, and helps keep the code separate from information that can potentially be used to identify individuals.*

7) Submit the URECA form and wait until you receive ethical clearance from the FREC/REC of your Faculty/Institute/Centre. In the meantime, start recruiting your research volunteers, which has to be done informally at this stage.
Remember that spectacles cannot be worn inside the scanner room. If you are planning to use visual material during data collection, therefore, make sure your participants are either not spectacle wearers, or else are willing to use contact lenses on the day (not cosmetic or prosthetic contacts though).

8) Once the relevant FREC/REC has indicated that you may proceed with your research:

- Forward a copy of the official statement from FREC/REC (the one confirming that your URECA submission is conformant with the REDP procedures established by the University) at umri.platform@um.edu.mt. **If, following any recommendations by the UMRI application review committee and/or FREC/REC, you have made changes to the information specified in (or provided with) the UMRI application form (project title, aim, research methodology, data management plan and/or data collection requirements), please provide UMRI with the updated documents.**
- Get in contact with the UMRI scientific officer to schedule data collection.
- Send the information sheet and consent form to the research volunteers some days prior to the (first) scanning session, so that they have the opportunity to read them in their own time.

9) On the day:

- Remember to have your FREC/REC study code (also referred to as the REDP form application ID) readily available†, as this is needed to generate a code for each participant. You should additionally take along some hard copies of the consent form.
- Tell the radiographer to fill in the Patient ID field with the **participant code**, which must have the following pattern:
  UMRI_<FREC study code>_<3-digit participant number>
  e.g. UMRI_ENG-2023-00007_001 (copy the FREC/REC code exactly as is!).
  The 3-digit participant number should moreover be entered into the **First name** field, and the FREC/REC code into the **Last name** field.

† The following are examples of FREC/REC study codes: MED-2022-00300, ENG-2023-00007.

10) Remember that:

- Completed consent forms must be stored by the principal investigator. Once all data has been collected, any information that could be used to identify participants should be disposed of in a way that rules out reconstruction, save for a list of participant names and the associated codes, to be retained securely by the principal investigator;
- Participant codes are not to be written on consent forms;
- **You will have access to the data collected once this has gone through the necessary UMRI pipelines. Attempting to obtain a copy in any other way will be considered a breach of trust;**
- Only principal investigators are authorised to share the raw data (or any derivatives not in aggregate form).

11) UMRI encourages the principal investigator to email a summary of the research findings to the recruited volunteers once the study has been concluded. If you are not the principal investigator yourself, it would be a good idea to remind him/her of this.