



L-Università ta' Malta
Faculty of Medicine & Surgery

List of documents requested by FREC to be uploaded in Part 3 Submission in the URECA Form:-

1. Exact wording of what is being said to patients
2. Consent Form (English and Maltese) (*if study includes patients)
3. Information Letter (English and Maltese) (*if study includes patients)
4. Questionnaire (English and Maltese)
5. Data Protection Form (signed by Data controller of relevant Institution)
6. Permission from MDH CEO (*if study is done in Mater Dei Hospital)
7. Permission from MDH Data Protection Officer (*if study is done in Mater Dei Hospital)
8. Permission from Head of Department/s
9. Any other permissions which are crucial for your study
10. Detailed Protocol (detailed account of study)
11. Proposal (overview of study)
12. CV of researcher/s
13. Permission of consultants if applicable

Note: Include the following sentence within your **Information Letter** and **Consent Form** (English and Maltese)

'Under the General Data Protection Regulation (GDPR) and national legislation that implements and further specifies the relevant provisions of said Regulation, you have the right to obtain access to, rectify, and where applicable ask for the data concerning them to be erased' (English)

'Taht ir-Regolament Generali dwar il-Protezzjoni tad-Data (GDPR) u l-legislazzjoni nazzjonali li timplimenta u tispecifika aktar id-dispozizzjonijiet rilevanti ta' limsemmi Regolament, ghandek d-dritt li tikseb access ghal, tikkoregi, u fejn applikabbli titlob li d-data li tikkoncerna lilek tithassar.'

(Maltese)

Note: It is important to provide the **Proposal** and **Protocol** into two separate documents (and in PDF version), since the Proposal is an overview of the study, whilst the Protocol is a detailed account of the study. Since the Proposal, the Protocol and the CV are not listed in the attachments list, kindly click on Other.