|  |  |  |
| --- | --- | --- |
|  |  |  |

**URECA Replica**

**21 November 2023**

University of Malta staff, students, or anyone else planning to carry out research under the auspices of the University, must complete this form. The UM may also consider requests for ethics and data protection review by External Applicants.

Ahead of completing this online form, please read carefully the University of Malta [*Research Code of Practice*](https://www.um.edu.mt/media/um/docs/research/urec/ResearchCodeofPractice.pdf) and the University of Malta [*Research Ethics Review Procedures*](https://www.um.edu.mt/media/um/docs/research/urec/ResearchEthicsReviewProcedures.pdf). Any breach of the *Research Code of Practice* or untruthful replies in this form will be considered a serious disciplinary matter. It is advisable to download a full digital version of the form to familiarise yourself with its contents (https://www.um.edu.mt/research/ethics/forms). You are also advised to refer to the FAQs (https://www.um.edu.mt/research/ethics/faqs).

\* Signifies required field

**Part 1: Applicant and Project Details**

Applicant details

\*Name:

\*Surname:

\*Email:

\*Applicant Status: Student/ Academic staff and UM associates/UM staff submitting as students/External

\*Please indicate if you form part of a Faculty, Institute, School or Centre

\*Department (Name of Department, Institute, School or Centre)

\*\*If applicable: Principal Supervisor’s Name (Compulsory field for students).

\*\* If applicable: Principal Supervisor’s Email: (Compulsory field for students).

\*\*If applicable: Co-Supervisor’s Name

\*\*If applicable: Study Unit Code (Compulsory field for students).

\*\*If applicable: Course Title (Compulsory field for students).

\*\*If applicable: Student number (Compulsory field for students).

Project Details

\*Title of Research Project \_\_\_\_\_\_\_\_\_

\*Project description, including research question/statement and method, in brief \_\_\_\_\_\_\_\_\_

\*Will project involve collection of primary data from human participants? No or Yes/Unsure

Explain primary data collection from human participants:

Please explain the following aspects with regard to data collection from human participants.

\*a. Salient participant characteristics (e.g. min-max participants, age, sex, other);

\*b. How they will be recruited (e.g. sampled, selected, contacted etc);

\*c. What they will be required to do and for how long;

\*d. If inducements/rewards/compensation are offered;

\*e. How participants/society may benefit;

\*f. Is the participant’s identity recorded at any stage of the research (e.g. in consent forms, records, publications)?;

\*g. The manner in which you will manage and store the data.

\*Will project involve collection of primary data from animals? No or Yes/Unsure

Explain primary data collection from animals:

**Part 2: Self-Assessment**

In what follows, all questions have been answered as “No or Not Applicable” by default. Please mark “Yes or Unsure” to any of the issues that may apply to your research. In such cases, your research proposal presents potential issues in the domain of research ethics and/or data protection. In such cases, you are kindly asked to elaborate upon the specific issue/s you indicate, and you will need to seek FREC permission before data collection.

|  |  |
| --- | --- |
|  | Yes/Unsure |
| Human participants |  |
| Skip questions 1-10 if your project does NOT involve primary data collection from human participants (or their tissue/samples) |  |
| 1. Risk of harm to participants:   Are your participants at risk of harm? (Physical, psychological, legal, economic, social, etc.)  Please explain: i. whether and how participants risk any harm (physical, psychological, legal economic or social) by participating in the research; ii. why such risks are unavoidable; iii. what safeguards you have taken to minimise the risk. |  |
| 1. Physical intervention:   Does your research involve non-harmful physical intervention on participants which may raise ethical concerns in your discipline?  Please provide a brief risk assessment of each technique used and a brief overall risk assessment. |  |
| 1. Vulnerable participants:   Do you include participants who, in your study or discipline, would be considered vulnerable or may be more at risk of being in vulnerability than others (e.g. children, persons who are older, with dementia, patients, subject to discrimination, with disabilities, with mental health conditions, unable to give consent, in prostitution, incarcerated, substance abusers, economically or educationally disadvantaged or minorities)?  Please explain: i. the nature of the vulnerability; ii. what safeguards will be taken to protect vulnerable participants (e.g. by not stigmatising participants, not putting undue pressure, implementing safeguards while processing consent, providing contact details for professional help should this be required, safeguarding privacy, providing compensation, etc. If participants are unable to give consent, please explain how you intend to obtain their assent; if this is not possible,- please explain why. |  |
| 1. Identifiable participants:   Are there participants in your research whose identity may be revealed in your research data, even though they have not given explicit consent to be so identified/attributed?  Please elaborate on: i. the nature of the records, their storage, security, traceability, identifiability of participants and access to research records; ii. how participants will be protected when disseminating results (e.g. pseudonyms, coding, making data attributable with consent); iii. plans for retention and destruction of the records. Please submit a Data Management Plan. |  |
| 1. Special Categories of Personal Data (SCPD):   Do you plan to collect SCPD, which, for identifiable participants (in records, data and/or publication), reveals race or ethnic origin, political opinions, religious or philosophical beliefs, membership in a trade union, genetic or biometric data that may uniquely identify a natural person, health, sex life and/or sexual orientation?  Which of the following data categories are collected, if any? i. race and ethnic origin; ii. political opinions; iii. religious and philosophical beliefs; iv. trade union memberships; v. health status; vi. sex life or sexual orientation; vii. genetic information; viii. biometric data that may uniquely identify a natural person. Please describe. Please submit a Data Management Plan. |  |
| 1. Human tissue/samples:   Will your research involve the collection of human tissue/samples?  Please elaborate on: i. the nature of materials and/or biological tissue/samples, their storage, security, traceability, identifiability, and who has access to them; ii. plans for retention and destruction. |  |
| 1. Withheld info assent/consent:   Do you plan to withhold information from potential participants regarding the nature of the research when you seek to obtain assent/consent?  Please explain: i. the nature of the information withheld; ii. why withholding information is necessary; iii. whether and how participants may be given the information at any point during the research. |  |
| 1. ‘opt-out’ recruitment:   Will you use the ‘opt-out’ instead of the ‘opt-in’ method of obtaining consent when recruiting participants (i.e. will any participants be included in your study without providing explicit consent)?  Please explain: i. the nature of the consent; ii. why opt-out is necessary; iii. how you will ensure that participants are able to make an informed choice concerning whether to participate or opt out. |  |
| 1. Deception in data generation:   Do you plan to actively provide false/misleading information or passively withhold information during the process of data generation (e.g. experiments, use of placebos, scenarios, games)?  Please explain: i. the nature of the deception; ii. why this is unavoidable and why you have rejected alternative methods of conducting research; iii. whether the information is likely to be significant to subjects; iv. what explanation for deception and debriefing you give to participants following their participation. |  |
| 1. Incidental findings:   Could your research generate incidental findings that may need to be communicated to participants?  Please elaborate on: i. the nature of potential incidental findings; ii. how such findings will be managed (participant consent to be informed, communication of information, etc.) |  |
|  |  |
| Unpublished secondary data |  |
| Answer questions 11-13 if your research involves the use of unpublished secondary data. Otherwise skip to question 14. |  |
| 1. Human:   Was the data collected from human participants?  Please indicate the nature of the data collected. In the case of data that has not been anonymised/coded and that could lead to the identification of persons, provide evidence that the research project from which the data has been generated was covered by data protection and ethics review (including participant consent for secondary use), or (if administrative data) evidence that the data controller had permission from subjects for secondary use of data and conformed to the requirements of the Data Protection Act and GDPR. |  |
| 1. Animal:   Was the data collected from animals?  Please indicate the nature of the data collected. If the source was a research project, provide evidence that the project was covered by ethics review. |  |
| 1. No written permission:   Is written permission from the data controller of the original data still to be obtained?  Please elaborate. |  |
|  |  |
| Animals |  |
| Answer questions 14-16 if your project involves primary data collection from animals (non-human vertebrates and cephalopods) or their tissue/samples. Otherwise skip to question 17. |  |
| 1. Live animals, lasting harm:   Does your research involve taking live animals out of their natural habitat for use in procedures or where such removal may cause the animals lasting harm?  Please elaborate. |  |
| 1. Live animals, harm:   Is there a risk that your research causes harm to live animals?  Please elaborate. |  |
| 1. Source of dead animals, illegal:   Does your research involve the use of dead animals (or their tissue/samples) that have not been acquired legally or from a legal source?  Please elaborate. |  |
|  |  |
| General Considerations |  |
| **These questions are to be considered for all projects.** |  |
| 1. Cooperating Institution:   If you need permission from a cooperating institution, do you require your FREC's approval prior to approaching the institution?  Please explain: i. how the cooperating institution will be contacted; ii. whether the approval of another Research Ethics Committee or Data Protection Office is required. |  |
| 1. Risk to researcher/s:   Does this research expose any members of the research team to any significant foreseeable risk that would require precautionary measures over and above those typically required in their line of work?  Please elaborate on: i. the nature of the risk; ii. why it is unavoidable; iii. the mitigating and/or compensating measures you plan to implement. |  |
| 1. Risk to environment:   Is there significant foreseeable risk that your research can cause harm to the environment?  Please elaborate on: i. the nature of the risk of harm to the environment; ii. why it is unavoidable; iii. the mitigating and/or compensating measures you plan to implement. |  |
| 1. Commercial sensitivity:   Does your research make use of data that may be commercially sensitive?  Please elaborate on: i. the nature of the data; ii. how you plan to safeguard sensitive data. |  |
|  |  |
| Other potential risks |  |
| Other potential risks for research ethics and data projection may arise from conflict of interest; harvesting social media data; the involvement of low income and/or lower middle income countries; the import and/or export of records, data, materials and specimens; the need for special permits/licences to employ specific constructs/tests; the researcher/s having a dual role; and/or the dual use/misuse of research, among other. Applicants are advised to refer to the FAQs in case of doubt (https://www.um.edu.mt/research/ethics/faqs). |  |
| 1. Other potential risks:   Does your research run other potential ethical or data protection risks?   1. Dual use and/or misuse:   Please elaborate on: i. the nature of the risk of dual and/or misuse; ii. why this is unavoidable; iii. the mitigating and/or compensating measures you plan to implement.   1. Conflict of Interest:   Please elaborate on: i. the nature of the conflict of interest; ii. how you plan to guarantee the impartiality of the research process given such conflict.   1. Dual role:   Please elaborate on: i. the nature of the dual role; ii. how you plan to address issues that may arise, such as power imbalance, unwarranted surveillance, coercion of participants, exclusion of participants from other services, etc.   1. Permission/license to use research tools:   Please explain: i. how you satisfy such criteria; ii. how you will obtain permissions/licenses when required.   1. Collaboration/data/material collection in low/lower-middle income country:   Please elaborate on: i. the countries (of the researcher/s and the institution/s involved) and partners involved; ii. the resources, participants and materials involved; iii. whether and how you plan to implement capacity building measures, and if not, why not; iv. whether and how you plan to implement benefit sharing measures, and if not, why not.   1. Import/export of records/data/materials/specimens:   Please provide details on: i. the nature of the records, data and/or materials involved; ii. the countries involved; iii. legal and regulatory considerations; iv. licenses, permissions and/or safeguards necessary.   1. Harvest of data from social media:   Please provide details.   1. Criminal issues & incarcerated persons: Does your research involve dealing with personal data about criminal allegations, proceedings or convictions, or incarcerated persons?   Please provide details.   1. Other considerations:   Please provide details. |  |
| 1. Official statement: Do you require an official statement from the FREC that this submission has abided by the UM’s REDP procedures?\*   Please note that answering ‘Yes / Unsure’ here means that you may not start data collection until you receive FREC approval. You may also request a formal letter at a later date if you need it for publication/funding purposes.  *\*This question is automatically checked as “YES / unsure” for external applicants.* |  |

**Part 3: Submission**

You are now ready to submit your form to FREC.

\*Which FREC are you submitting to?

**Faculty applicants will submit automatically to the Faculty FREC. Non-Faculty applicants may refer to the UREC webpages and seek guidance from their Institute, Centre or School to identify which FREC they should apply to.**

Arts

Built Environment

Dental Surgery

Economics, Management and Accountancy

Education

Engineering

Health Sciences

Information and Communication Technology

Institute of Earth Systems

Laws

Media and Knowledge Sciences

Medicine and Surgery

Science

Social Wellbeing

Theology

Centre for Molecular Medicine & Biobanking

\*Attachments:

Please indicate which of the following materials you are attaching. Failure to provide these, where relevant, risks delaying approval to proceed with the research. Materials should be attached below. Students may be required to produce their DRAFT letters of request ahead of sending to cooperating institutions and to obtain their supervisor's signature on consent and assent forms.

Add Files

\*Please produce these materials in English and/or Maltese and/or any other relevant language (or equivalent text that may be communicated orally for those who do not read).

* Information and/or recruitment letter\*
* Consent forms (adult participants)\*
* Consent forms for legally responsible parents/guardians, in case of minors and/or adults unable to give consent\*
* Assent forms in case of minors and/or adults unable to give consent\*
* Data collection tools (interview questions, questionnaire etc.)
* Data management plan
* Data controller permission in case of use of unpublished secondary data
* Licence/permission to use research tools (e.g. constructs/tests)
* Any permits required for import or export of materials or data
* Letter granting institutional approval for access to participants
* Institutional approval for access to data
* Letter granting institutional approval from person directly responsible for participants
* Other (please specify in remarks below)

Please feel free to add a cover note or any remarks to FREC:

If this is a re-submission of a Form to FREC, please include previous form reference number. Please indicate if you require written approval for institutional/funding purposes. Please include reference to project grant and/or any previous ethics/data protection approval of related parent project. Please elaborate on any additional attachments you are providing.

Declarations:

* I hereby confirm having read the University of Malta Research Code of Practice and the University of Malta Research Ethics Review Procedures.
* I hereby confirm that the answers to the questions above reflect the contents of the research proposal and that the information provided above is truthful.
* I hereby give consent to the University Research Ethics Committee to process my personal data for the purpose of evaluating my request, audit and other matters related to this application. I understand that I have a right of access to my personal data and to obtain the rectification, erasure or restriction of processing in accordance with data protection law and in particular the General Data Protection Regulation (EU 2016/679, repealing Directive 95/46/EC) and national legislation that implements and further specifies the relevant provisions of said Regulation.

\*Applicant Signature:

Write your full name here. By doing so and submitting this form you are effectively signing the declaration.

\*Date of submission:

If applicable: Data collection start date

Please insert envisaged date of data collection

dd/mm/yyyy

|  |
| --- |
| Save REDP Application |

*Or*

|  |
| --- |
| Save Updated REDP Application |

(saves the application as a draft)

|  |
| --- |
| Submit REDP Application |

*Or*

|  |
| --- |
| Submit Updated REDP Application |

(submits the application to FREC/REC)

Is this form being submitted for records, or does it require FREC review?

Note: If you marked Yes/Unsure for any of the questions in the self-assessment checklist, you must submit the form for REVIEW. You may NOT start your data collection until you receive FREC/REC approval. If you marked none of the issues, you may proceed with data collection. In such cases, you must still submit the form to FREC/REC for RECORDS.

RECORDS / REVIEW / Cancel

(for students: the application is automatically submitted to the supervisor for endorsement, once the supervisor endorses the application, this is submitted automatically to the FREC for review or for records)

|  |
| --- |
| Export REDP Application |

(export to pdf)

|  |
| --- |
| Close |