GUIDELINES FOR COMPLETING THE ETHICS APPLICATION FORM

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PRIOR TO COMMENCING RESEARCH

Familiarise yourself with the University of Malta (UM) "Research Code of Practice" found on the webpage of the University Research Ethics Committee (UREC): **https://www.um.edu.mt/urec**

Key aspects:

13 principles of ethical research conduct;

1. Observe and comply with all legal, regulatory and ethical requirements in Malta;
2. Respect the integrity and dignity of persons
3. Follow the "Do no harm" principle;
4. Recognise individuals' rights to privacy and personal data protection.
5. Honour the requirement of informed consent;
6. Treat animals with respect;
7. Design research on animals following 3Rs: Reduce, replace, refine;
8. Respect the principle of proportionality;
9. Treat societal concerns seriously;
10. Recognise the wholeness of an individual;
11. Respect Biodiversity;
12. Prevent misuse or malignant dual use by terrorists or military organisations.
13. Understanding that any benefits are for the good of society,

GUIDELINES ON THE APPLICATION OF THESE PRINCIPLES

- Important to obtain consent form research participants prior to data collection;
- Ensure privacy and personal data protection;
- integrity and dignity of research participants involving vulnerable populations;

RESEARCH ETHICS

- ALL research requires the filling in of an ethics Form.

Research is defined as:

'A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge'

- As stipulated in the *Research Ethics Review Procedures*, a student is expected to be guided by his/her supervisor in the compilation of the Research Ethics Form and documents.

ALL RESEARCH REQUIRES THE FILLING IN OF AN ETHICS FORM

This applies to all dissertations involving:

- literature reviews;
- research on secondary data (whether publicly available or not);
- research involving the collection of primary data.

A student is expected to be guided by his/her supervisor in the compilation of the Research Ethics Form and documents.

All students have to submit their REDP ethic form number with their dissertation.

RESEARCH ETHICS & DATA PROTECTION (REDP) ONLINE FORM

- The **online form** may be found on the UREC webpages of the UM website;
- https://www.um.edu.mt/research/ethics/forms
- This links to the page leading to the online form as well as to the Replica Form
- Before submitting the form download the Replica of the Form and work on it as a draft.

SOME THINGS TO REFLECT ON BEFORE FILLING IN YOUR ETHICS FORM

Ask Yourself:

- What type of data am I collecting?
- From where/whom am I collecting this data?
- Do I need permission to gain access to existing data or participants?
- How can I access research participants without collecting using their personal data without their permission?
- Are my participants vulnerable?
- How am going to obtain consent?
- Is the data that I am going to collect anonymous or is it identifiable?

FORMAT OF THE REDP FORM

The Online Form is divided into FOUR parts.

- Part 1: Applicant and Project Details
- Part 2: Self-Assessment
- Part 3: Detailed Assessment
- Part 4: Submission

SELF – ASSESSMENT ON ETHICS

Filling up the REDP Form is a self-assessment exercise:

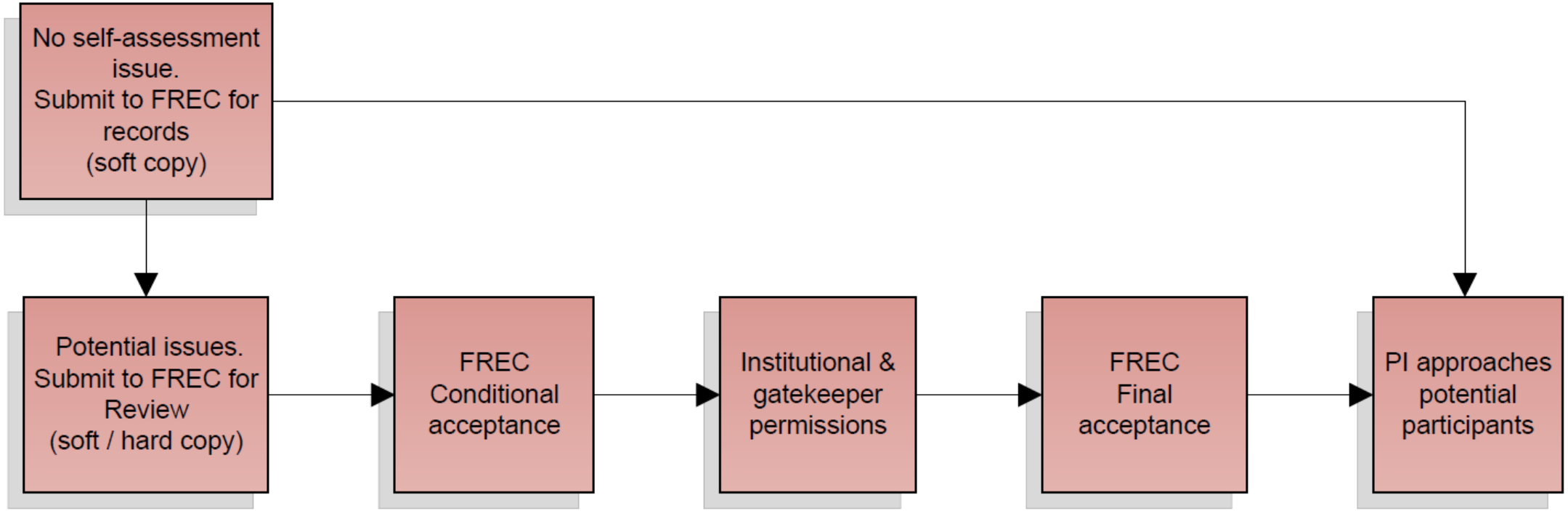
Two outcomes:

1) If **no potential issues are reported in Part 2** of the Form ('Self-Assessment' section), the Form and supporting documents (Information Letters, Consent Forms, etc.) are sent to FREC "**for FREC records**". You can then start your research as soon as you submit the REDP Form with research tools and any additional documents, and it is endorsed by your supervisor;

2) If **potential issues have been reported in Parts 2 and 3 of the Form,** the Form and documents should be sent "**For FREC review".** This means that the ethics application needs to be reviewed by FREC. So submit your REDP form with all the accompanying documents and when your supervisor endorses it, FREC will process it. Wait for feedback from FREC. **DO NOT COLLECT ANY DATA BEFORE GIVEN CLEARANCE FROM FREC TO DO SO.**

If you collect data before clearance from FREC you will be in breach of ethics and disciplinary action will be taken by University.

THE REVIEW PROCESS



PART 1: Q1-8 OF THE REDP FORM

1. Name and surname:
2. Applicant Status UM staff/UM student/Other :
3. Faculty (Faculty or institute, school or centre):
4. Department (Name of department, institute, school or centre)
5. If applicable: Principal Supervisor's name (Compulsory field for students).
6. If applicable: Co-Supervisor's name
7. If applicable: Course and Study-unit code (Compulsory field for students).
   Eg MTL (Early years and Primary)
8. If applicable: Student number (Compulsory field for students).
   This is your I.D. Card number

PART 1: Q 9-11 OF THE REDP FORM

*9. Title of research project :

Title must match that on dissertation approved

*10. Research question/statement & method:

It is important that you state the research questions as included in approved dissertation proposal (FREC checks this).

You must also describe the methodology – what research tools you are going to use e.g. online questionnaire, interview, focus groups

*11. Will project involve collection of primary data from human participants?

No (Proceed to Part 2. Self-Assessment) or **Yes/Unsure** (Please answer next question).

You have to answer YES if you plan to collect data from persons or animals

PART 1: Q12 OF THE REDP FORM

Q12 is the most important questions in PART 1:

Answer each part separately. Do not put all the information together!

12. Explain primary data collection from human participants. Please explain

a. salient characteristics (min-max participants, age, sex, other);

Give number of participants, where will they be recruited from without mentioning names of schools; age and sex; and other specific characteristics of participants in an anonymous way. If you have different types of data collection specify this

E.g. Interviews: 2 Year 3 teachers from one State primary school;
Questionnaire 250 (125 girls/125 boys) from Year 7 and Year 8 students

b. how they will be recruited;

- Include type of sampling used e.g. purposeful, random or convenience;
- Indicate from whom you need permission to carry out research – you need to prepare a permission letter;
- Identify for whom information letters and consent/assent forms are required;
- Identify who is going to be intermediary for the distribution of information letters and consent/assent forms;
- State how consent/assent forms will be collected;
- Recruitment ethical and conform with the General Data Protection Regulations (GDPR)

Example: Interviews with primary teachers in 3 schools – one State, one Church and one Independent:

Permissions: Directorate for Curriculum, Research, Innovation & Lifelong Learning (for State school); Secretariat for Catholic Education (Church School); and Heads of Schools (for each of the 3 schools) – Permission Letter;

Information letter for teachers, consent form for teachers; (No consent form is needed for an anonymous questionnaire)

If you have interviews with students you need Information Letters for both parents and children. Parents sign Consent Forms, students sign Assent Forms

c. what they will be required to do &d. duration;

Indicate: what information will be collected; how long the data collection takes; where it will take place; for interview/focus group whether it will be audio/video-recorded; and whether data will be anonymously;

E.G. interview with teacher about stress:

Interview will collect information related to how stressful the job of a teacher is. The interview will take about 45 minutes and will be carried out at school/at a time and place convenient to the participant/ online/remotely. The interview will be audio-recorded.

The online questionnaire will collect information about how stressed teachers feel about different aspects of their job. The questionnaire is anonymous and it takes around 10 minutes to complete.

a. e. if inducements/rewards/compensation are offered; f. how participants may benefit.

Inducements means giving something to attract participants; (you need to specify yes or no)

You can identify benefits for participants or not.

PART 2: Q 1-3

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.) **- In education this is usually - NO**
2. **Physical intervention:** Does your research involve non-harmful physical intervention on participants which may raise ethical concerns in your discipline? **In education this is usually - NO**
3. **Vulnerable participants**: Do you include participants who, in your study or discipline, would be considered vulnerable (e.g. children, prisoners, persons with disability, substance abusers, or economically or educationally disadvantaged persons, or other). **This is usually marked - Yes/Unsure - if you are collecting data from minors.**

4. **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?

This is usually ticked –YES –if you audio-video recording and you can identify a person from the voice. Or is you collect a questionnaire online and collect IP address or by email; You do not need to tick if you alter voice of recording.

5. Special Categories of Personal Data (SCPD): Do you plan to collect SCPD (sensitive personal data), which, for identifiable participants (in records, data and/or publication)

special categories of personal data' refer to personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation.

8. **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)?**

This is usually used in 2 main situations:

a.when collecting anonymous questionnaires with students in secondary school

b. When observing a class and data is collected about teacher's behaviour – but there may be incidental observations of children's behaviour

17. Cooperating Institution: If you need permission from a cooperating institution, do you require your FREC's approval prior to approaching the institution?

You tick this if you need permissions from gatekeepers e.g. MEDE research ethics Committee, Secretariat for Catholic Education, Heads of School etc.

21. Other potential risks: Does your research run other potential ethical or data protection risks? If you are doing action research with your students – dual role, if you are evaluating or researching something developed by your supervisor

PART 3:

If you do not tick any of the questions in Part 2 – you can submit 'Frec – for records'

If you tick just one aspect, you need to fill in part 3

For every issue you indicated in Part 2, an explanation must be given in Part 3.

Question 3: Vulnerable groups

- **Mention the nature of vulnerability e.g. minors**
- **Indicate what safeguards are taken e.g. not stigmatising, not putting undue pressure, safeguards while processing consent, assent from minors, providing contact details for professional help)**
- **If participants cannot consent (e.g. age) explain why, and how is assent going to be obtained, and consent from guardian**

4: Identifiable participants

- State the nature of the records, their storage, security, traceability, identifiability of participants and access to research records stated
- State how participants' identity will be protected when disseminating results (e.g. pseudonyms, coding, changing voice recording speed, making data attributable with consent)?
- State plans for retention and destruction of the records

Interviews : Participant is identifiable in the audio-recording. State that it will be transcribed and anonymised e.g. by using pseudonyms in the dissertation/report. Audio recording is stored on a computer (not laptop) in a secure place and saved password protected and saved in encrypted format.

Data (recording not transcript) is destroyed when study is over.

In case of interviewees in particular positions e.g. E.O., Directors – it is not possible to anonymised – so make the interview attributable i.e. referenced by position. This needs to be indicated in the information sheet and participant consents to it.

Question 5: Sensitive personal data

- state what type of sensitive data categories are collected (E.g. 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)

NOTE: If no. 4 has been marked ‘yes’? and this question is marked as ‘yes’ then the application needs to be sent on to UREC as it becomes a Data Protection issue

Question 8: Opt-out at consent/asset

- Does it explain how PI will ensure that participants are able to make an informed choice concerning whether to participate or opt out?

e.g. Questionnaire with secondary students - Parents are sent an information sheet about the study through official school communication, and if parents do not wish their son/daughter to participate, they sign and send in the opt-out form. Students received information sheet on same day as parents – if they assent to participate they just fill in the questionnaire;

Question 17: Permission from cooperating institution

Permissions:

State schools: MEDE research ethics committee;

Church Schools: Secretariat for Catholic Education;

For research in schools – Permission from Heads of Schools

To interviews Senior Management Teams – Permission from College Principal

Sport – e.g. to interview football players at a club one needs permission from the Club President

Question 21: Conflict of interest:

Dual Role in Action Research – teacher as researcher: It is often advised that researcher has a critical friend who will ensure that researcher does not put undue pressure for students to consent to participate. To ensure lack of bias ;

If supervisor is involved in what is researched e.g. a course developed, make sure that only anonymised data is available to supervisor

PART 4:

2. Attachments:

Make sure that you list all the documents to be attached: permission letters, information letters and consent/assent forms;

3. Additional note:

If you are doing research with another student make a note about it here.

PERMISSION LETTERS – PLEASE USE TEMPLATES

- Templates for all letters are provides on: https://www.um.edu.mt/research/ethics/resources/samples

To check what is to be included:

- **The researcher's name and surname, email and mobile number and signature at bottom of page, the supervisor's Name, email and office Tel. No;**
- **The title of the project/dissertation**
- **The aim of the study**
- **who the participants are, and how many will be required;**
- **what each participant is going to be asked to do as part of the study;**
- **how long each of the different data collecting activities would take;**
- **where the data collection is to take place;**

- asks for permission to carry out the research in a polite way;
- requests to act as intermediary to distribute Information Letters and consent/assent forms
- **It should also include Promises and guarantees:**
  - **A clear statement that participation is voluntary.**
  - **that participant/s can withdraw at any time and that if they do, there will be no negative consequences and any data collected relating to them will be destroyed (when possible).**
  - **A promise of how the participant/s identity will be protected.**
  - **A statement that the data will be stored safely.**
- **At the end of the letter, the recipient should be invited to contact the researcher in case of any queries, or should they wish further information or clarification.**

INFORMATION LETTERS

To check what is to be included:

- **The researcher's name and surname, email and mobile number and signature at bottom of page, the supervisor's Name, email and office Tel. No;**
- **The title of the project/dissertation**
- **The aim of the study**
- Invitation to participate in the data collection process: with all relevant information about data collection process;
- **It should also include Promises and guarantees:**
  - **A clear statement that participation is voluntary.**
  - **that participant/s can withdraw at any time and that if they do, there will be no negative consequences and any data collected relating to them will be destroyed (when possible).**
  - **A promise of how the participant/s identity will be protected.**
  - **A statement that the data will be stored safely.**
- **At the end of the letter, the recipient should be invited to contact the researcher in case of any queries, or should they wish further information or clarification.**

- Teacher interview: what it is about, length of interview, when and where it will be held, if it is to be audio recorded, if notes will be taken, etc.
- Lesson delivery to try out a new approach: how many lessons, duration, who will be planning them, who will be delivering them, whether observation notes will be taken, etc.
- Questionnaire: what is it about, approximately how long it will take to fill in, whether online, if it is anonymous;
- Children's activities: what types of activities, number of activities, duration of each activity, where they will be held, whether audio/video recorded, whether observation notes will be taken,

CONSENT FORMS

- Need to include title of study
- A statement saying ‘I have read the information Letter and had enough time and opportunity to ask questions about any query that I may have’
- A statement saying ‘ I consent to’ and add what the participant is to take part in e.g. I consent to participate in an interview.
- In the case of audio-video recording, consent form must include statement e.g. ‘I CONSENT to have my interview audio-recorded’

Assent forms:

In the case of assent forms for minors they cannot ‘consent’ but they can ‘agree’

LANGUAGE

- Information letters and consent/assent forms for parents and students are usually in English and Maltese;
- Use of one language only is accepted if a justification is provided;
- Information letters for students need to be simplified to ensure understanding;
- Letters to professionals (heads of school, teachers etc.,) are usually only in English

Further information on FREC Education website:
https://www.um.edu.mt/educ/aboutus/boardsandcommittees/frec

All information is provided in the Guidelines compiled by FREC:

https://www.um.edu.mt/__data/assets/pdf_file/0008/409409/FRECGuidelines2ndedition.pdf

SUBMISSION OF ETHICS APPLICATION

- Application is filled in online;
- As soon as you submit, you received by email a PdF of the application;
- The application is given a unique ID.
- You will also receive a link to use if you wish to change the application in the future;
- Number all the accompanied documents are directed in the guidelines;
- The PDF application Form and all supporting documents (e.g. approved dissertation proposal, information letters, consent forms, interview questions, etc.) should be filed in a Zipped folder and e-mailed to FREC.
- **The e-mail should be titled using the unique ID and EITHER "For FREC Records", if no issues have been flagged in the Self-Assessment section, OR "For FREC Review" if further details had been provided in Part 3 of the Form**.
- The Zipped folder should be sent to the following e-mail address: research-ethics.educ@um.edu.mt
- **In the case of students, the supervisor must be copied in the e-mail. The supervisor will then "Reply All", confirming that s/he has read and approved the documents that the student is submitting, thus endorsing the Application.**

Next steps: CASES for FREC review

- Wait for Feedback;
- When feedback is received, many times it is conditional and corrections requested;
- Make corrections and send in amendments as directed in the guidelines. Read feedback properly to avoid doing this process a number of times;
- Once all corrections are accepted you are invited to obtain permissions;
- Send out permission letters and obtain permissions. Forward these to FREC as PDF documents;
- Once you have submitted all the required permissions, FREC will give you clearance to start collecting data.

Now you can start collecting consent forms, after which you can start COLLECTING DATA

Thank you and Good Luck