UNIVERSITY OF MALTA

UNIVERSITY RESEARCH ETHICS COMMITTEE

Check list to be included with UREC proposal form

Please make sure to tick **ALL** the items. Incomplete forms will not be accepted.

		YES	NOT APP.
1a.	Recruitment letter / Information sheet for subjects, in English		
1b.	Recruitment letter / Information sheet for subjects, in Maltese		
2a	Consent form, in English, signed by supervisor, and including your contact details		
2b	Consent form, in Maltese, signed by supervisor, and including your contact details		
3a	In the case of children or other vulnerable groups, consent forms for parents/ guardians, in English		
3b	In the case of children or other vulnerable groups, consent forms for parents/ guardians, in Maltese		
4a	Tests, questionnaires, interview or focus group questions, etc, in English		
4b	Tests, questionnaires, interview or focus group questions, etc, in Maltese		
5a	Other institutional approval *for access to subjects*: Health Division, Directorate for Quality and Standards in Education, Department of Public Health, Curia...		
5b	Other institutional approval *for access to data*: Registrar, Data Protection Officer Health Division/Hospital, Directorate for Quality and Standards in Education, Department of Public Health…		
5c	Approval from person *directly responsible for subjects*: Medical Consultants, Nursing Officers, Head of School…		

Received by Faculty office on	
Discussed by Faculty Research Ethics Committee on	
Discussed by university Research Ethics Committee on	

UNIVERSITY OF MALTA

Request for Approval of Human Subjects Research

Please type. Handwritten forms will not be accepted
You may follow this format on separate sheets or use additional pages if necessary.

FROM: *(name, address for correspondence)*	PROJECT TITLE:
TELEPHONE:	
E-MAIL	
COURSE AND YEAR:	
DURATION OF ENTIRE PROJECT: from _____ to _____	FACULTY SUPERVISOR'S NAME:

ANTICIPATED FUNDING SOURCE:
(include grant or contract number if known)

1. Please give a brief summary of the purpose of the research, in non-technical language.

2. Give details of procedures that relate to subjects' participation
(a) How are subjects recruited? What inducement is offered? *(Append copy of letter or advertisement or poster, if any.)*

(b) Salient characteristics of subjects—number who will participate, age range, sex, institutional affiliation, other special criteria:

(c) Describe how permission has been obtained from cooperating institution(s)—school, hospital, organization, prison, or other relevant organization. *(Append letters.)* Is the approval of another Research Ethics Committee required?

(d) What do subjects do, or what is done to them, or what information is gathered? (Append copies of instructions or tests or questionnaires.) How many times will observations, tests, etc., be conducted? How long will their participation take?

(e) Which of the following data categories are collected?

Data that reveals – race or ethnic origin	YES / NO
political opinions	YES / NO
religious or philosophical beliefs	YES / NO
trade union memberships	YES / NO
health	YES / NO
sex life	YES / NO
genetic information	YES / NO

3. How do you explain the research to subjects and obtain their informed consent to participate? (If in writing, append a copy of consent form.) If subjects are minors, mentally infirm, or otherwise not legally competent to consent to participation, how is their assent obtained and from whom is proxy consent obtained? How is it made clear to subjects that they can quit the study at any time?

4 .Do subjects risk *any* harm—physical, psychological, legal, social—by participating in the research? Are the risks necessary? What safeguards do you take to minimize the risks?

5. Are subjects deliberately deceived in *any* way? If so, what is the nature of the deception? Is it likely to be significant to subjects? Is there any other way to conduct the research that would not involve deception, and, if so, why have you not chosen that alternative? What explanation for the deception do you give to subjects following their participation?

6. How will participation in this research benefit subjects? If subjects will be "debriefed" or receive information about the research project following its conclusion, how do you ensure the educational value of the process? *(Include copies of any debriefing or educational materials)*

TERMS AND CONDITIONS FOR APPROVAL IN TERMS OF THE DATA PROTECTION ACT

- Personal data shall only be collected and processed for the specific research purpose.
- The data shall be adequate, relevant and not excessive in relation to the processing purpose.
- All reasonable measures shall be taken to ensure the correctness of personal data.
- Personal data shall not be disclosed to third parties and may only be required by the University or the supervisor for verification purposes. All necessary measures shall be implemented to ensure confidentiality and, where possible, data shall be anonymised.
- Unless otherwise authorised by the University Research Ethics Committee, the researcher shall obtain the consent from the data subject (respondent) and provide him with the following information: The researcher's identity and habitual residence, the purpose of processing and the recipients to whom personal data may be disclosed. The data subject shall also be informed about his rights to access, rectify, and where applicable erase the data concerning him.

I, the undersigned hereby undertake to abide by the terms and conditions for approval as attached to this application.

I, the undersigned, also give my consent to the University of Malta's Research Ethics Committee to process my personal data for the purpose of evaluating my request and other matters related to this application. I also understand that, I can request in writing a copy of my personal information. I shall also request rectification, blocking or erasure of such personal data that has not been processed in accordance with the Act.

Signature:

APPLICANT'S SIGNATURE: *I hereby declare that I will not start my research on human subjects before UREC approval* DATE	FACULTY SUPERVISOR'S SIGNATURE I have reviewed this completed application and I am satisfied with the adequacy of the proposed research design and the measures proposed for the protection of human subjects. DATE

Return the completed application to your faculty Research Ethics Committee

To be completed by Faculty Research Ethics Committee

We have examined the above proposal and advise

Acceptance **Refusal** **Conditional acceptance**

For the following reason/s:

Signature Date

To be completed by University Research Ethics Committee

We have examined the above proposal and grant

Acceptance **Refusal** **Conditional acceptance**

For the following reason/s:

Signature Date