

# UNIVERSITY OF MALTA

## Request for Approval of Human Subjects Research

Please type, or print legibly with black pen. You may follow this format on separate sheets or use additional pages if necessary.

FROM: <i>(name, address for correspondence)</i>	PROJECT TITLE:
TELEPHONE: E-MAIL COURSE AND YEAR:	
ANTICIPATED FUNDING SOURCE: <i>(include grant or contract number if known)</i>	FACULTY SUPERVISOR'S NAME:
DURATION OF ENTIRE PROJECT: from _____ to _____.	

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*)



*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