

Human Research Ethics Committee for Non-Clinical Faculties

Application Form for Ethical Approval

Please complete Parts A - B and F – H. If you are collecting new data, please also complete Part C. If you are studying existing personal data, document or records, please also complete Part D. If you are collecting new data, and seeking a waiver of informed Consent, please also complete Part E.

Part A: Summary

Principal Investigator	
() * Surname: _____	First Name: _____
Department: _____	
Position / Staff Grade: _____	Staff No.: _____
Office telephone: _____	PI email: _____
For <u>students</u> , please provide the following additional information:	
Name: _____	Degree Programme/Year: _____
	Student No.: _____
Name of Supervisor: _____	Supervisor email: _____
Co-Investigator(s), if any	
*Name: _____	Staff No: _____
*Position: _____	*Department/Unit: _____
Degree Programme/Year (for students only): _____	
Name: _____	Staff No: _____
Position: _____	Department/Unit: _____
Degree Programme/Year (for students only): _____	
Name: _____	Staff No: _____
Position: _____	Department/Unit: _____
Degree Programme/Year (for students only): _____	
Research Proposal/Project:	
Title: _____	
Start date: _____	Expected completion date: _____
_____	_____

Research plan and methodology:

Part C: Risk Assessment for Newly Collected Data

Please answer the following questions, if your proposal involves any newly collected data, to decide if your proposal should be submitted for expedited review.		
	Yes	No
a) Will the study involve action/participatory/treatment research?	<input type="checkbox"/>	<input type="checkbox"/>
b) Is it possible that the study will involve greater than minimal privacy risks, which could induce stress to research participants, such as political behaviour, illegal conduct, drug or alcohol use and sexual conduct?	<input type="checkbox"/>	<input type="checkbox"/>
c) Is it possible that the participants' burden to complete the procedures will induce greater than minimal stress, in particular, for children, given their age and capacity?	<input type="checkbox"/>	<input type="checkbox"/>
d) Is it possible that the study will induce greater than minimal physical or psychological stress/pain/discomfort?	<input type="checkbox"/>	<input type="checkbox"/>
e) Is it possible that the study will expose participants to greater than minimal physical or medical risk?	<input type="checkbox"/>	<input type="checkbox"/>
f) Will deception be used during the study?	<input type="checkbox"/>	<input type="checkbox"/>
g) Will video-recording be used during the study?	<input type="checkbox"/>	<input type="checkbox"/>
h) Will audio-recording be used during the study?	<input type="checkbox"/>	<input type="checkbox"/>
i) Is there potential conflict of interests? (e.g. financial gain to the investigators, power over participants such as teacher/student relationship)	<input type="checkbox"/>	<input type="checkbox"/>
j) Will the study involve vulnerable participants who are unable to give informed consent, e.g. under the age of 18, mentally handicapped individuals?	<input type="checkbox"/>	<input type="checkbox"/>
<p>- If "Yes", please specify details of the age group and/or vulnerability:</p> <p>_____</p> <p>(Parent/Guardian Consent Form should be attached.)</p>		

For Expedited Review:

- If you have answered “No” to all of the questions (a) – (j) above, your application may qualify for an expedited review, meaning that your research involves minimal risk¹. However, informed consent is still required unless reasons why this is infeasible are adequately justified.

¹ Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

For Full Review:

- If you have answered "Yes" to any of the above questions (a) – (j), please give more details on your study design and methodology in the questions (k) to (t).

- k) The selection and recruitment of participants (Attach any initial letter of contact and Consent Form)
- l) Rationale for sample size calculation
- m) How will participants be recruited/identified?
- n) What are the inclusion and exclusion criteria?
- o) Description of any specific data collection, such as interviews, questionnaire (including telephone) survey or experimental procedures like deception (please attach Deception Form) and any treatment or intervention.
- p) Please state who will perform the data collection, how long it will take and where the data collection will take place.
- q) Can the participants be allowed to withdraw at any time without prejudice?
- r) Will there be any stress/discomfort to participants?
- s) Please provide details of any audio and/or video recording including the justifications for the recording.
- t) Please identify any potential conflict of interests and how that potential conflict will be addressed.

Part D: Using Existing Documents or Records containing Personal Data

Please complete this section if you are using existing documents or records that contain any personal data.

Will existing documents or records containing any personal data be used? Yes No

- If “Yes”, please give more details of the personal data being obtained by answering questions (a) – (h) in the following.

- If “No”, please skip this Part D.

a) What is the source of the data?

b) Were the data originally collected for research purposes? Yes No

- If “Yes” is checked, please attach a copy of the Consent Form for the original collection of data.

- If “No” is checked, please provide the Personal Information Collection Statement.

- For all situations, please explain how this research is consistent with the purpose and use specified when the data were originally collected.

c) Please list the types of personal data being used, if not already listed in the Consent Form for the original collection of data or Personal Information Collection Statement.

d) Are any of the data listed above sensitive? Yes No

- If “Yes”, please provide full details.

e) Is the source of data publicly available²? Yes No

² Please note that the term “publicly available” means that the general public can obtain the data. Sources are not considered “publicly available” if access to the data is limited to researchers.

f) How are data identified when they are made available to your research team? (Please indicate by marking the appropriate box below.)

i) Direct Identifier (i.e. name, address, ID card number, medical record number, etc.)

ii) Indirect Identifier (i.e. an assigned code which could be used by the investigator or the source providing data to identify a subject, such as tracking code used by the source.)

iii) No Identifier (i.e. neither the researcher nor the source providing the data can identify a subject based upon information provided with the data.)

g) If i) or ii) is checked above and you are requesting permission to study archived data, will you abstract and record any subject identifiers as a part of the data collection process?

Yes No Does Not Apply

h) Will any data be collected from subjects after the submission of this application?

Yes No

- If "Yes", please complete Part C

Part E: Assessment for a Waiver of Written Informed Consent

The waiver of written informed consent is only applicable to data without personal identifiers, e.g. where data are tabulated or where oral consent is audio-recorded, PIs are required to clearly specify that they are using data without personal identifiers in their research grant proposals.

Please answer the following questions if you are collecting new data, and wish to apply for a waiver of informed consent.

When conducting research where seeking written consent is not practical or too sensitive, oral consent might be less of a privacy risk than written consent and can be considered as an alternative. Please submit a full justification below and attach an information sheet to this application.

a) Will there be oral consent? Yes No

If "Yes", will the oral consent be audio recorded? Yes No

b) Is participation anonymous?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If “No”, i.e. participation is not anonymous, your proposed research is not normally qualified for a waiver of informed consent. Measures should be taken to code the data collected and delete all personal identifiers on the spot.		
c) If participation is not anonymous, please explain why the study is not practicable without a waiver.		
d) Please explain why the proposed study presents no more than minimal risk to the participants.		
e) Please explain why a waiver of informed consent will not adversely affect the rights and welfare of the participants.		

Part F: Benefits

Please state any possible benefit to participants.

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Part G: Attachments

Please tick as appropriate to indicate which of the following documents are enclosed to this application.

(1) Full research proposal including any questionnaire and/or interview script. (Note i)	<input type="checkbox"/>
(2) Parent/Guardian Consent Form	<input type="checkbox"/>
(3) Informed Consent Form (Note ii)	<input type="checkbox"/>
(4) Deception: post debriefing consent form	<input type="checkbox"/>

Notes:

(i) Mandatory

(ii) Mandatory unless waiver has been applied for or no data collection is being undertaken.

Part H: Declaration

In making this application, I certify that I have read and understand the University's <i>Policy for Ethical Practice</i> , and I will comply with the ethical principles of these documents. I will submit, as appropriate, a <i>Report for Research Progress or Amendment of an Approved Project</i> if there are significant changes to my research, or an adverse incident, or when the report for annual progress due.	
Date: _____	Signature: _____ (Signature of Applicant)
Date: _____	Signature: _____ (Signature of supervisor) (for RPG/TPG students only)
I hereby endorse this application with my approval and confirm that the investigator(s) are appropriately qualified in the research area involved to conduct the proposed research project, and am capable of undertaking this research study in a safe and ethical manner.	
Date: _____	Signature: _____ Head of Department/Dean of Faculty

Part I: Committee Approval

After discussion, this research plan is approved.	
Date: _____	Signature: _____

