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THE UNIVERSITY OF HONG KONG

Human Research Ethics Committee for Non-Clinical Faculties

Application Form for Ethical Approval

Notes:

(1) Please read carefully the University's *Policy on Research Integrity*, the *Operational Guidelines and Procedures* *for the Human Research Ethics Committee for Non-Clinical Faculties*, and the summary of the *Belmont Report* available from the Research Services website before completing this Form.

(2) The completed application form, together with all related documents, should be sent to the Secretary, HRECNCF, c/o Research Services, Registry.

(3) No data can be collected/analyzed before ethical approval is obtained from the Committee.

Part A – Outline of Application

1. Research Proposal	
Study title:	
Data Collection Period: Please only check and fill out the one that applies: ☐ **Data collection/analysis will start as soon as ethical approval is obtained.** ☐ **From _____ to _____ (dd/mm/yyyy).** **Note: Ethical approval MUST be obtained prior to any data collection or analysis taking place.**	
Project Start / End Dates: From _____ to _____ (dd/mm/yyyy)	

2. Principal Investigator (PI)					
Title:		**Surname:**		**First name:**	
Department:					
Position / Staff Grade:			**Staff No.:**		
Contact - Tel:			**Email:**		
For student PI only:					
Degree Programme / Year:			**Student No.:**		
Name of Supervisor:			**Supervisor Email:**		

3. Co-Investigators (Co-I), if any					
Name (Surname, First name)	**Department / Institution, if not HKU**	**Position (For staff Co-I only)**	**Programme (For student Co-I only)**	**HKU Staff/ Student No., if at HKU**	**Email Address**

4. Funding		
Funding source	**Please check all that apply, and then specify the funding scheme below:**	
HKU internal research grants		
Research Grants Council		CRF / GRF / PPR / Others:
Other external grant		
Contract Research		
No funding		

Part B – Proposal/Project Details

Please provide a summary of the below sections in layman terms. (Do not enter "see attached".)

5. Objectives of Study
(1)
(2)
(3)
(4)
(5)

6. Hypothesis, if any

7. Elements of research methodology that involve human participants (not more than 1/2 page)

Part C – Data collection

8. Sources of data

Please check all that apply:

- ☐ **New data to be collected from human participants**
  - ☐ Experimental procedures / Treatment / Intervention
  - ☐ Focus group
  - ☐ Internet survey
  - ☐ Observation
  - ☐ Personal interviews
  - ☐ Self-administered questionnaire
  - ☐ Telephone survey
  - ☐ Others: please specify
- ☐ **Pre-existing data from human subjects**

9. Study participants – for <u>new</u> data to be collected

(a) Recruitment and selection of participants

(i) How will participants be recruited?

(ii) Participant inclusion criteria (e.g. Hong Kong residents aged 18 years and above):

(iii) Participant exclusion criteria (e.g. people with metal implants need to be excluded from MRI):

(b) Who will perform the data collection?

(c) Where will the data collection take place, and how long will it take?

(d) Possible benefits to participants:

10. Risk assessment – for <u>new</u> data to be collected from human participants

(a) Will the study involve intervention, such as action research / treatment of any type? **Yes** ☐ **No** ☐

If "<u>Yes</u>", please give details:

(b) Will the study involve initial deception of the full context of the study to avoid bias? **Yes** ☐ **No** ☐

If "<u>Yes</u>", please provide details and attach the debriefing form:

(c) Before any attempts are made to minimize privacy risk (e.g. making the forms anonymous), is it possible that the study will involve greater than minimal privacy risks to research participants, either due to collection of sensitive data, such as political behaviour, illegal conduct, drug or alcohol use and sexual conduct, or because there is some risk of re-identification using a unique identifier such as DNA? **Yes** ☐ **No** ☐

(d) Is it possible that the duration of the procedures will induce greater than minimal stress, in particular, for children, given their age and capacity? **Yes** ☐ **No** ☐

(e) Is it possible that the study will induce greater than minimal psychological stress/pain/discomfort? **Yes** ☐ **No** ☐

(f) Is it possible that the study will expose participants to greater than minimal physical **Yes** ☐ **No** ☐

or medical risk?
Note: 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.

If "Yes" to any of Questions (c) to (f), please state the precautions taken to minimize such stress/pain/discomfort/risk:

(g) Will photography or video-recording of participants be used during the study? **Yes** ☐ **No** ☐

(h) Will audio-recording be used during the study? **Yes** ☐ **No** ☐

If "Yes" to Questions (g) and/or (h), please provide details and justifications for the recording, and storage strategies:

(i) Will the study involve vulnerable participants who are unable to give informed consent, e.g. under the age of 18, mentally handicapped individuals? **Yes** ☐ **No** ☐

If "Yes", please specify details of the age group and/or vulnerability, and attach a Parent/Guardian Consent form:

(j) Is there any potential conflict of interest? (e.g. financial gain to the investigators, power over participants such as teacher/student relationship) **Yes** ☐ **No** ☐

If "Yes", please state details about the conflict of interest and state how that potential conflict will be addressed:

11. Informed consent – for new data to be collected from human participants

- **When conducting research where seeking written consent is not practical or too sensitive, audio-recorded oral consent or email recorded consent might be less of a privacy risk than written consent and can be considered as an alternative.**
- **The waiver of recorded informed consent is normally only applicable to newly collected data without personal identifiers. In this case, PIs are required to clearly specify that they are recording data without personal identifiers in their research grant proposals.**

(a) How will you record informed consent? (Please check all boxes that apply)

(i) Written consent ☐ **(ii) Audio-recorded consent** ☐ **(iii) Online/Email recorded consent** ☐

If you will not record informed consent, please complete the following Questions (b) to (d) below and submit an information sheet.

(b) Please explain why the proposed study presents no more than minimal risk to the participants?

(c) Why does a waiver of recorded informed consent not adversely affect the rights and welfare of the participants?

(d) Do you know the identity of respondents? **Yes** ☐ **No** ☐

Note: Knowing the identity of respondents is distinct from whether their identity is recorded.

If "Yes", please explain why the study is not practicable with recorded informed consent.

12. Pre-existing data from human subjects

(a) What is the source of the original dataset?

(b) Are the original dataset in existing documents/records publicly available? **Yes** ☐ **No** ☐
Note: "publicly available" means that the data can be accessed without an approval process.

If "No", please specify the approving authority for access: (_____)

(c) Were the original dataset originally collected for research purpose? **Yes** ☐ **No** ☐

If "Yes", please attach a copy of the Consent Form for the original collection of data.
If "No" please attach a copy of 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:

(d) Are the original dataset sensitive? (e.g. sexual preference, health status, criminal activity) **Yes** ☐ **No** ☐

Please provide full details on types of personal data to be used:

(e) Do the original dataset contain any personal identifiers? **Yes** ☐ **No** ☐

If "No", it means neither the researcher nor the source providing the data can identify a subject based upon the information provided with the data.

If "Yes, is the personal identifier direct or indirect? **Direct** ☐ **Indirect** ☐
Direct identifier – e.g. name, address, ID card no., medical record no., etc.
Indirect identifier – e.g. assigned code that can make a subject reasonably identifiable.

If "Yes", will you abstract/record any subject identifiers in the data extraction process? **Yes** ☐ **No** ☐ **N/A** ☐

(f) Will any new data be collected from subjects, other than the data obtained from the original dataset? **Yes** ☐ **No** ☐
If "Yes", please complete Questions 9 to 11.

Part D – Attachments

Please check the boxes 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[(i)]	
(2) Parent/Guardian Consent Form (sample documents)	
(3) Informed Consent Form (standard templates of Informed Consent Form and sample language)[(ii)]	
(4) Consent script, for oral consent or email reply for consent (sample documents)[(ii)]	
(5) Deception: post debriefing consent form (sample documents)	

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

Part E – Declaration

In making this application, I certify that I have read and understand the University's *Policy on Research Integrity*, the *Operational Guidelines and Procedures of the Human Research Ethics Committee for Non-Clinical Faculties (HRECNCF)*, and the summary of the *Belmont Report*, and I will comply with the ethical principles of these documents. I will report to the HRECNCF if there is any amendment, new information on the project and any research-related incidents, such as physical or emotional harm to the participants during the research process or breaches of confidentiality. I will also submit a final completion report on the request of the HRECNCF. I undertake not to proceed with data collection/analysis before I receive the letter of approval of this application, and understand that failure to do so will lead to disciplinary action.

Name of Principal Investigator	Signature	Date

I/We 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.

Name of Supervisor (for RPG students only)	Signature	Date

Name Head of Dept/Dean of Faculty/Faculty Reviewer*	Signature	Date

**Please delete as appropriate.*

May 2014