Gleneagles Hospital HONG KONG 港怡醫院

Research Application Form

This form is to be completed by Principal Investigator (PI) and submitted to the HKU-GHK IRB Secretary. The HKU-GHK IRB will notify the Principal Investigator about the approval outcome within 4 – 8 weeks, depending on the complexity of the study. Research activity cannot begin until the protocol has been approved by the HKU-GHK IRB.

1. Research Study Details

Research Study Title	
Proposed Study Start Date	Proposed Study End Date

2. Principal Investigator (PI)

Name	Position
Department/ Unit/ Ward	Institution/ Hospital
Contact Number	Email
Qualifications & Relevant Experience *(Please add in your short CV if there is not enough space)*	

3. Co-Investigators *(Please provide short CV)*

Name	Position	Institution & Department	Email

4. **Background, Current Evidence & Major Ethical Issues** *(Limit to 300 words)*

5. Aim of Study

6. Hypothesis, if any

7. Primary/ Secondary Outcome(s)

8. Study Participants

Inclusion Criteria
Exclusion Criteria
How will participant be identified and recruited?
Sample Size and Calculation
Number of participants to be recruited in the study site(s)

9. Study Design & Methodology

Study Design
Method in obtaining the data required
Who will perform the data collection?
Where will the data collection take place?

10. Methods of Analysis

11. Anticipated Benefits to Participants

12. Potential Risk

Will the study procedures impose side effects to participants? ☐ No

☐ Induce discomfort or stress
☐ Increase physical or psychological risk
☐ Involve radiation or radioactive substance
☐ Perform invasive procedure
☐ Involve a potential toxin
☐ Incur other hazards

If yes, please provide details:

If yes, measures to minimize risks:

Will the study involve the following vulnerable participants? ☐ No

☐ Fetuses in uteri/ non-viable fetuses/ abortus
☐ Infants (age 0 to <1)
☐ Children (age 1 to <13)
☐ Adolescents (age 13 to <18)
☐ Pregnant/ Lactating women
☐ Unequal relationship with investigator (E.g. employee, student)
☐ Special population (E.g. mentally disabled, prisoner)
Other than the above, please specify:

If yes, any precautions to protect the interest of the vulnerable participants?

13. Information & Consent

Will consent be obtained? ☐ Oral ☐ Written ☐ No *Go to Section 14*

Who will explain the study and collect the consent?

☐ Principal Investigator
☐ Co-investigators
☐ Research Assistant
☐ Others, *specify*:

Will an interpreter be available when required? ☐ Yes ☐ No

If participants are incompetent in giving consent, to who will the study be explained?

Do participants have a right to withdraw from the study at any time without any penalty or any consequences of any kind? ☐ Yes ☐ No

14. Medical Product

Will any medical product be administered to participants? ☐ No *Go to Section 15*

☐ Drugs ☐ Chinese or Herbal medicines

☐ Medical Device ☐ Appliance, Diagnostic test

☐ Others, *specify:*

Is this study sponsored by the industry/ commercial agency? ☐ Yes ☐ No

If yes, specify nature of sponsorship:

Is the product licensed in Hong Kong? ☐ Yes ☐ No

If no, state its regulatory status overseas and whether a Certificate for Clinical Trials will be obtained?

15. Confidentiality & Data Protection

Will the study involve:

☐ Meeting and anonymity of participants?
☐ Anonymized data?
☐ De-identified data?
☐ Pseudonymous participant in publication?

Other method(s) of protecting the privacy of participants? *Please specify:*

How will the data be handled and stored during and after completion of the study?

☐ Data to be kept in a locked cabinet
☐ Data and identifiers to be kept in separate and locked filing cabinet
☐ Computer files to be accessed by password
☐ Electronic, not limited to, to be encrypted Storage at GHK
☐ Store at other study site, portable storage (e.g. Laptop, flash drive) *specify:*

Who will have access to the data?

☐ Principal Investigator ☐ Research Assistant

☐ Co-investigators ☐ Others, *specify:*

How long will the data be kept and what will be done with them after completing of storage period?

16. Funding & Resources

Source of Funding

Will this study provide benefit to the investigators or host institution? ☐ Yes ☐ No
If yes, provide details:

Will the study use GHK resources? ☐ Yes ☐ No
If yes, provide details:

17. Expenses & Payments to Participants

Will there be any financial cost to the participant? ☐ Yes ☐ No
If yes, provide details:

Will participants receive any payment from the study? ☐ Yes ☐ No
If yes, provide details:

18. Indemnity

Will there be any indemnity? ☐ Yes ☐ No
If yes, provide details:

Is the indemnity supported by an insurance policy ☐ Yes ☐ No
If yes, please provide an insurance certificate for review

19. Publication & Dissemination of Research Results

Will the results of the research be reported and disseminated? ☐ Yes ☐ No
If yes, provide details:

20. Other Ethical Issues

Are there Any other ethical issues that have not been addressed? ☐ Yes ☐ No
If Yes, provide details:

21. Declarations by Investigators

A. The information contained in this application, including any accompanying information, is true and accurate.
B. I/We have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge my obligations and the rights of the participants.
C. I/We shall comply with the principles enunciated in the 2017 or a later version of the Research Policy of Gleneagles Hong Kong Hospital.
D. I/We agree to report study progress to HKU-GHK IRB as requested, and to submit a final report at the end of the research project.
E. I/We agree to report to HKU-GHK IRB any planned change in the study, and do not implement any change without receiving prior approval, except to eliminate immediate hazard to participants or when the change involves only logistical or administrative issues.
F. I/We agree to report to HKU-GHK IRB any unanticipated problems involving risks to participants such as a serious adverse event in accordance with IRB's SOP. I/We shall report potential conflict of interest to the HKU-GHK IRB that may arise in the course of the approved study.
G. I/We agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

Principal Investigator		
Title & Name	Signature	Date
Co-investigators		

22. Endorsement by COS or Department Heads

A. I hereby endorse this application and authorized the study to be undertaken in my department upon approval by the HKU-GHK IRB.
B. I confirm that the investigator(s) are appropriately qualified in the research area involved to conduct the proposed research project, and the study site(s) under my supervision have access to adequate facilities and support for the research to be conducted in a safe manner.
C. I support the study and verify that the workload to be incurred will not interfere with the department's service priority.

Name	Signature	Post, Department, Ward/Centre	Date

FOR HKU-GHK IRB
Office Use

Application Log		
Submission	☐ Initial Submission	☐ Re-submission ( )
Application Reference Number	HKU-GHK IRB-____-_____	_____ DD-MM-YYYY
Date of Application Received		_____ DD-MM-YYYY
Acknowledgement Receipt to Applicant		_____ DD-MM-YYYY
Submit to HKU-GHK IRB Members		
Type if Review	☐ Full Panel Review	☐ Expedited Review
Approval Outcome	☐ Approved ☐ Approval Deferred	☐ Conditionally Approved ☐ Not Approved
Notify Applicant of Approval Outcome		_____ DD-MM-YYYY

Documents Enclosed		Yes	No
Research Protocol		☐	☐
Ethical Clearance Checklist		☐	☐
Participant Consent Form	☐ Chinese ☐ English	☐	☐
PI's short CV		☐	☐
Co-investigators' short CV		☐	☐
Written Information to Participant (E.g. Information sheet, Invitation letter, recruitment advertisement, etc.)	☐ Information Sheet ☐ Invitation Letter ☐ Recruitment advertisement ☐ Other, *specify:*		
Questionnaires		☐	☐
Investigator's Brochure		☐	☐
Indemnity Agreement		☐	☐
Insurance Certificate with Number:	Validity Date:	☐	☐
Other Research Ethics Approval		☐	☐
Others:		☐	☐

Study Monitoring	
Study Start date	DD-MM-YYYY
Study end date	DD-MM-YYYY
Planned first Progress Report date	DD-MM-YYYY
Date of SAE (Local)	DD-MM-YYYY
Date of SAE (Overseas)	DD-MM-YYYY
Date of amendment notification	DD-MM-YYYY
Extension approved study period	DD-MM-YYYY
Date of termination	DD-MM-YYYY

The checklist should be completed by Principal Investigator. The Checklist lists the key points of good practice in research for a research project, and can assist Principal Investigator in fulfilling the requirements of the HKU-GHK IRB and ensure that important issues have not been overlooked.

Research Study Title:	

NA – Not Applicable

Research Design/Methodology	**Yes**	**No**	**NA**
Have all conflicts of interest related to the study been identified, declared and addressed?	☐	☐	☐
Is the study to be conducted by experienced and skillful research team?	☐	☐	☐
Does the study involve medical research with humans, clinical trials or use of human tissue / DNA samples or body fluid?	☐	☐	☐
Will the research involve the participants being deceived?	☐	☐	☐
Risk and Precautions	**Yes**	**No**	**NA**
Could the study induce any psychological stress or discomforts?	☐	☐	☐
Does the study involve any physically invasive or potentially harmful procedures?	☐	☐	☐
Does the study adversely affect participants in any other way?	☐	☐	☐
Does the study involve participants who are in any way vulnerable or may have difficulty in giving consent?	☐	☐	☐
Are there any special precautions to protect the interest of vulnerable participants?	☐	☐	☐
Are there any compensation and treatment available to participants on trial-related injury?	☐	☐	☐
Are the risks to participants minimized and reasonable in relation to anticipated benefits, with adequate monitoring mechanism to detect adverse events or risk?	☐	☐	☐
Confidentiality & Data Protection	**Yes**	**No**	**NA**
Will the study involve invasion of privacy or access to confidential information about participants without their permission?	☐	☐	☐
Are there any measures taken to protect privacy or participants and data confidentiality?	☐	☐	☐
Will the data be handled and stored during and after completion of the study?	☐	☐	☐
Consent	**Yes**	**No**	**NA**
Will participants be fully informed of the objectives of the study and all details disclosed?	☐	☐	☐
Will it be necessary for participants to take part in the study without their consent at the time?	☐	☐	☐
Are the potential benefits, possible risks, discomforts or potential hazards stated and informed to participants?	☐	☐	☐
Does the activity raise issues involving the potential imbalance of power and authority which might compromise the validity of participants' consent?	☐	☐	☐
Do participants have a right to withdraw from the study at the time without any penalty or any consequences of any kind?	☐	☐	☐

NA – Not Applicable

Research Design/Methodology	**Yes**	**No**	**NA**
Will the independence of the research be affected by the source of the funding?	☐	☐	☐
Are there payments to researchers/participants that may have an impact on the objectivity of the research?	☐	☐	☐
Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?	☐	☐	☐

Signature of Principal Investigator		
Name of Principal Investigator		
Date		(DD-MM-YYYY)