Gleneagles Hospital
HONG KONG
港怡醫院

Hospital Policy – Quality Safety and Risk Management

Research Policy

Document No.:	Version:	Original Date:	Effective Date:
HP_GQSR_009	03	14.01.2020	28.08.2020
Process Owner:		**Approval:**	
SM, Quality Safety & Risk Management Department		COO	CEO
Description of Content/Change:			
- Changed the minimum number of members for expedited panel review from three to one.			

Objective

1.0 Objectives

1.1 The objectives of this policy are to:

(a) ensure clinical research within the hospital complies with mandatory ethical principles of research and that the hospital meets its obligations as a research institute; and

(b) establish the University of Hong Kong - Gleneagles Hospital Hong Kong Institutional Review Board (HKU-GHK IRB) as an ethics review and oversight mechanism and as an added layer of protection for Research Subjects.

Scope

2.0 Scope

2.1 Applies to clinical research involving the hospital's patients or conducted within the hospital premises.

2.2 Clinical research is defined as research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects.

2.3 Clinical research includes:

(a) ***Patient-oriented research*** – this type of research involves a particular person, group of people, or uses materials from humans, including:

i. drugs (e.g. chemical drugs, biologics and vaccines);

ii. human beings (e.g. randomized controlled trial on a medical product or clinical procedure/ method);

iii. identifiable human materials (e.g. genetic analysis of archived human specimens); and

iv. identifiable human data (e.g. questionnaire survey, medical chart review and case series).

(b) ***Medical product research***, including:

i. drugs (e.g. chemical drugs, biologics and vaccines);

ii. devices (e.g. implants, diagnostic kits, imaging machines and radiotherapy devices);

iii. Chinese medicines / herbal medicines;

iv. health supplements (e.g. vitamins and nutritional supplements); and

v. alternative therapies (e.g. acupuncture);

(c) ***Outcomes and health services research*** – This type of research seeks to identify the most effective and most efficient interventions, treatments, procedures and services (e.g. clinical examinations; surgical procedures; nursing procedures; psychotherapies; behavioural therapies; and imaging methods).

Policy

3.0 Policy

3.1 Clinical trials and clinical research (collectively referred to as "Clinical Research") are necessary if medicine is to progress. They contribute to the generation of knowledge and development of technology for healthcare advancement. Such objectives, however, do not take precedence over the interests of the Research Subjects.

3.2 Clinical Research conducted within the hospital must be designed and conducted in accordance with the International Conference on Harmonization – Good Clinical Practice Guidelines (ICH-GCP Guidelines) and the applicable regulatory requirements, and be ethically reviewed and monitored in accordance with the Declaration of Helsinki.

3.3 Research Governance Structure and Responsibilities

3.3.1 The Hospital Board has delegated oversight of the hospital's Research Governance to the Education, Training and Research Committee.

3.0 Policy

3.3.2 To help meet this responsibility, the Education, Training, and Research Committee has established the ***University of Hong Kong - Gleneagles Hospital Hong Kong Institutional Review Board*** (HKU-GHK IRB) to ensure that:

(a) Research Subjects' rights, safety and welfare are protected;

(b) research is conducted ethically and lawfully within the hospital;

(c) public confidence is sustained by an environment that upholds scientific and ethical integrity; and

(d) liabilities to the hospital are minimised.

3.3.3 ***University of Hong Kong - Gleneagles Hospital Hong Kong Institutional Review Board*** (HKU-GHK IRB)

(a) Terms of Reference: While reporting to the Education, Training and Research Committee, it should function as independently as possible and is responsible to:

i. establish hospital Clinical Research ethics policy and guidelines;

ii. facilitate ethical research through efficient and effective review processes;

iii. conduct ethics reviews of proposed Clinical Research studies;

iv. monitor and evaluate the progress of approved Clinical Research studies to ensure that they fall within the guidelines provided;

v. maintain a central database on Clinical Research studies for risk management;

vi. provide advice on the medical-ethical issues; and

vii. provide medical ethics education.

(b) Authority of University of Hong Kong - Gleneagles Hospital Hong Kong Institutional Review Board

The HKU-GHK IRB has the authority to oversee all Clinical Research within the hospital, including:

i. approving, disapproving, requiring modification or amendment of any Clinical Research;

ii. monitoring progress of Clinical Research through study progress reports and serious adverse events reports;

iii. terminating or suspending any Clinical Research; and

iv. initiating an audit.

3.0 Policy

(c) Composition of University of Hong Kong - Gleneagles Hospital Hong Kong Institutional Review Board

i. The HKU-GHK IRB shall be chaired by a University Seconded Practitioner or a University Professoriate staff member.

ii. Other members of HKU-GHK IRB are selected from a wide variety of medical and non-medical fields within the hospital and community. The composition of the HKU-GHK IRB will include at least the following personnel:

- at least two members with knowledge of, and current experience in the professional care or treatment of patients;
- at least one member who has neither scientific or healthcare background;
- at least one member who is not affiliated with the hospital; and
- at least one member with experience in quality assurance.

iii. Experts can also be invited to provide scientific, legal or ethics input but they are not entitled to vote. To facilitate their contribution, they should have access to the application documents.

(d) Confidentiality Undertaking and Conflict of Interest Declaration

i. A HKU-GHK IRB's opinion must be free, and must be seen to be free, from conflicts of interest.

ii. All the information disclosed to a HKU-GHK IRB member/seconded expert will be deemed confidential and shall not be disclosed to any third party or used for any purpose other than performing the responsibilities of a HKU-GHK IRB member.

iii. Accordingly, HKU-GHK IRB members and experts invited to provide scientific, legal or ethics input are required to sign the Confidentiality Undertaking and Conflict of Interest Declaration.

3.4 Application for ethics approval

3.4.1 All Clinical Research studies require formal approval in the form of a favourable ethics opinion from the HKU-GHK IRB before they commence. Such studies include:

3.0 Policy

(a) Clinical Research with humans as Research Subjects.

(b) Research on materials of human origins, such as body tissue and fluid, including "waste" or "leftover" from diagnosis and treatment, or archiving such materials for future studies;

(c) Collation of records/data (whether existing or to be collected) where there is a reasonable likelihood that such may link to the individuals' identifiable particulars or identifiers; and

(d) Clinical Research on cognitive / mental phenomena.

3.4.2 Ethics approval is not required for non-research activities, such as: clinical audit; service/ practice evaluation; and surveillance projects.

3.4.3 Besides ethical approval by the HKU-GHK IRB, Clinical Research must comply with relevant regulatory requirements, if applicable, (e.g. Clinical Trial Certificate by Department of Health and Personal Data (Privacy) Ordinance).

3.5 Research Review / Monitoring

The HKU-GHK IRB must continuously review and monitor all approved Clinical Research studies until completion or termination.

3.6 HKU-GHK IRB Accountability Reporting

The HKU-GHK IRB shall make an at least annual accountability report to the Education, Training, and Research Committee on its work in the achievement of its terms of reference.

Guideline

4.0 Guidelines

4.1 Ethical Requirements in Clinical Research

The mandatory ethical requirements are the principles of the Declaration of Helsinki and, whenever applicable, ICH-GCP Guidelines. Some of the more important requirements are:

4.0 Guidelines

(a) Clinical Research methodology must be scientifically valid and adequate in addressing the questions posed.

(b) Clinical Research design must minimize the potential risks to the Research Subjects, and its anticipated benefits must justify the potential risks.

(c) Equipoise must exist between different arms of a therapeutic trial comprising different interventions or different dosages.

(d) To ensure voluntary participation in Clinical Research, Research Subjects must be adequately informed of the experimental nature of the undertaking; the nature of the Clinical Research, its risks, burdens and benefits; and their right to withdraw at any time, which will not affect the care they entitle.

(e) As each person weighs risks and benefits differently, we must respect other's freedom to decide, based on their own value and belief, without coercion and undue influence.

(f) Special precautions should be taken to protect vulnerable Research Subjects.

(g) Throughout a trial, Research Subjects should be provided with updated information about the Clinical Research (including adverse events) so that they are free to decide whether or not to continue.

4.2 Investigator Responsibility

4.2.1 Fundamental responsibilities of investigators are:

(a) human subject protection;

(b) compliance with regulatory, ethical and institutional requirements on research conducts; and

(c) fair conduct and fair reporting of clinical trials, including comprehensive and accurate documentation of research procedures and data, and handling and storage of trial documents in adherence to chosen and approved option delineated in the research application form during and after the study.

4.2.2 The Principal Investigator (PI) is ultimately accountable for all study-related activities, including those delegated to others. The PI, therefore, has additional responsibilities of:

4.0 Guidelines

(a) ensuring the trial is scientifically sound and ethically justified; and

(b) managing the research study and supervising the research team to ensure the research is conducted according to protocol and study plan.

4.3 *Application for Ethical Approval*

The PI must submit the following documents, through the relevant Chair of Specialty (COS), to Secretary of HKU-GHK IRB in applying for ethics approval:

, (a) The research protocol;

(b) A duly completed and signed Research Application Form (Appendix A) and Ethical Approval Checklist (Appendix B);

(c) Consent form and information to be provided to participants (such as invitation letter and safety information) in suitable language(s);

(d) Investigator's brochure (if available);

(e) Documents/Materials (e.g. recruitment notice or poster, participant-administered questionnaire or diary); and

(f) Curriculum vitae and relevant experience, training and qualification on research of the PI and other investigators;

(g) For sponsored Clinical Research studies or where commercial interest is involved, the following additional documents must be submitted:

- a draft Clinical Trial Agreement (CTA);
- conflict of interest declaration by the PI;
- a certificate of insurance; and
- a letter of indemnity for the standard indemnity agreement and procedure.

4.4 Types of HKU-GHK IRB Reviews

The HKU-GHK IRB will conduct two types of review i.e. Full Panel Review and Expedited Review.

4.4.1 *Full Panel Review*

All clinical research proposals involving more than minimal risk to participants are to be reviewed by all members of HKU-GHK IRB.

4.0 Guidelines

4.4.2 ***Expedited Review***

All research proposals involving no greater than minimal risk to participants will be considered under expedited review. The proposal is sent to a minimum of one assigned Scientific Member of HKU-GHK IRB. The criteria for an expedited review are that the research study:

(a) should not involve clinical intervention (drug, device or invasive procedure);

(b) should not include vulnerable participants; and

(c) should not raise sensitive privacy concerns.

4.5 Review Procedures & Records

4.5.1 The HKU-GHK IRB should adopt a structured review process to address all important considerations.

4.5.2 Reviewers who have conflict of interest in any application should abstain from the meeting.

4.5.3 The review process should be documented, and records maintained, for each application that would permit the subsequent evaluation of the review and the decision.

4.6 Review Consideration

In performing a review, the HKU-GHK IRB members will evaluate the study's ethical aspects in accordance with the ethical principles of research and other ethical considerations such as potential benefits, risks and related scientific rationale.

4.7 Approval Outcomes

4.7.1 The HKU-GHK IRB will normally notify the PI in writing of the approval outcome within 4 – 8 weeks from receipt of the duly completed application with all required documents. An Approval Notification providing the review outcome and comments will be issued to the PI. Research activity cannot begin until the protocol has been approved by the HKU-GHK IRB.

4.0 Guidelines

4.7.2 Where relevant, the notification will also set out conditions of approval, the violation of which invalidates the ethics approval granted.

4.8 Process Monitoring

The HKU-GHK IRB will continuously review or monitor all approved Clinical Research studies until completion or termination. PI has responsibility to update the HKU-GHK IRB on the status of the research study through submission of the following reports. Such reporting is necessary for the HKU-GHK IRB to consider whether the approval status can be maintained.

4.8.1 Progress Reporting

PI should report to the HKU-GHK IRB any amendments, new information on the study, extension of research approval period, any complaints and any research-related incidents, such as physical or emotional harm to a participant during the research process or breaches of confidentiality. PI is also required to submit the Research Progress Report at least annually (from approval date) during the period of the research.

4.8.2 Final Report

PI has the responsibility to submit the Research Final Report for notification of completion, abandonment or premature termination of the research study within three months from the date of formal closure of the study. Each final report will be reviewed by the HKU-GHK IRB members through an expedited review process.

4.8.3 In the event that the PI fails to submit a progress or final report to the HKU-GHK IRB by the deadline, the HKU-GHK IRB may refuse to accept any new application for initial review of research study submitted by that principal investigator and their participation in any new research study.

Reference

5.0 References

5.1 Legislation and Regulations

5.0 References

5.1.1 *Code of Practice for Private Hospitals, Nursing Homes and Maternity Homes Oct 2016.*

5.1.2 *International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use.*

5.1.3 *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects.*

5.1.4 *Hospital Authority (HA) Guide on Research Ethics, February 2015.*

5.1.5 *Investigator's Code of Practice, Hospital Authority Research Ethics Committee, Hospital Authority, Revision Number 2, August 2008.*

5.2 GHK Documents

5.2.1 *NA*

5.3 JCI Standards

5.3.1 *HRP.1* *Hospital leadership is accountable for the protection of human research subjects.*

5.4 Definitions

5.4.1 *NA*

5.5 Others

5.5.1 *NA*

Appendix

6.0 Appendices

6.1 *Appendix A*: Research Application Form

6.2 *Appendix B*: Ethical Approval Checklist

Research Application Form

Appendix A
HP_GQSR_009
01.01.2017

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	
HKU-GHK IRB Approval Date (DD-MM-YYYY)	
Study Start Date	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)*	

For Student PI

University	Program (Year)
Name of Supervisor	Supervisor Email

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

Name	Position	Institution & Department	Email

4. **Background & Current Evidence** *(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 recruited?
Sample Size and Calculation

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?
Study Start and End Dates (DD-MM-YYYY)

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 risk:

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
- ☐ Medical Device
- ☐ Others, *specify:*
- ☐ Chinese or Herbal medicines
- ☐ Appliance, Diagnostic test

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 clinical certificate has been obtained?

15. Confidentiality & Data Protection

Will the study involve:

- ☐ Complete anonymity of participants? — PI will not meet, or know the identity of participants, as participants, as participants are a part of a random sample and are required to return responses with no form of personal identification.
- ☐ Anonymized data? — An irreversible process whereby identifiers are removed from data and replaced by a code, with no record retained of how the code relates to the identifiers. It is then impossible to identify the individual to whom the sample of information relates.
- ☐ De-identified data? — A reversible process whereby identifiers are replaced by a code, to which the researcher retains the key, in a secure location.
- ☐ 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 data 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
- ☐ Co-investigators
- ☐ Research Assistant
- ☐ 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 thathave 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 severe adverse event within 24 hours of its identification.

G. I/We shall report potential conflict of interest to the HKU-GHK IRB that may arise in the course of the approved study.

H. 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.

☐ I/We declare that I have no conflict of interest.

☐ I/We declare the following conditions concerning me and my family members which could cause conflict of interest.

Principal Investigator		
Title & Name	Signature	Date
Co-investigators		
Supervisor (For student project)		

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

Research Application Form

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	DD-MM-YYYY
Date of amendment notification	DD-MM-YYYY
Extension approved study period	DD-MM-YYYY
Date of termination	DD-MM-YYYY

Ethical Approval Checklist

Appendix B
HP_GQSR_009
01.01.2017

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?			
Does the study involve the handling of any sensitive information?			
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 knowledge and 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?			

Ethical Approval Checklist

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)