Gleneagles Hospital
HONG KONG
港怡醫院

Standard Operating Policy – Quality, Safety & Risk Management

University of Hong Kong – Gleneagles Hospital Hong Kong Institutional Review Board

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Objective

1. Establishment, Mission and Standards

1.1 Establishment

1.1.1 Establishment of HKU-GHK IRB: University of Hong Kong – Gleneagles Hospital Hong Kong Institutional Review Board ("**HKU-GHK IRB**") was established by University of Hong Kong ("**HKU**") and Gleneagles Hospital Hong Kong ("**GHK**") in accordance with its terms of reference for overseeing research involving human subjects (hereinafter referred to as "clinical studies") undertaken by and/or conducted in the premises owned, managed and/or controlled by GHK, and/or involving patients and/or staff thereof as human subjects in such clinical studies.

1.1.2 Research Policy: GHK's research policy, including the responsibilities and authority of the HKU-GHK IRB is set down in HP_GQSR_009.

1.2 Governance

1.2.1 Governance Authority: The HKU-GHK IRB is governed by GHK's Hospital ("**Governing Body**") through the Education, Training and Research ("ETRC").

1.3 Mission

1.3.1 HKU-GHK IRB's Mission: The mission of the HKU-GHK IRB is to ensure:

(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 minimized.

1.4 Standards of Establishment and Operations

1.4.1 Core Standards: The HKU-GHK IRB is established and operates primarily in compliance with:

(a) the Declaration of Helsinki of the World Medical Association ("**Declaration of Helsinki**"); and
(b) the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use Guideline for Good Clinical Practice ("**ICH GCP**") (if applicable).

1.4.2 Standards under Accreditations or Quality Assurance Schemes: The HKU-GHK IRB, in performing its responsibilities of ethics and scientific review and oversight of clinical studies, will observe and comply with the standards as required under the ACHS accreditation requirements and any other standards it deems appropriate.

Scope

2. Scope

2.1 Activities under Jurisdiction

2.1.1 HKU-GHK IRB's Jurisdiction: The HKU-GHK IRB shall be responsible for performing ethics and scientific review and oversight of clinical studies if it fulfills any or all of the following conditions:

(a) undertaken by GHK (and/or the employees/appointees/students of GHK);
(b) conducted wholly or partially in the premises owned, managed and/or controlled by GHK; and/or
(c) involving the patients and/or employees/appointees/students of GHK as

human subjects.

Notwithstanding the above, the HKU-GHK IRB's review and approval shall not release a principal investigator from the responsibility of obtaining other necessary approvals for his/her study (e.g. management approval from his/her institution/department, regulatory approval through the Hong Kong Department of Health, or approval by the research ethics committee of a collaborating institution if required).

2.1.2 Definition of Clinical Study: For the purpose of this SOP, a clinical study means any systematic investigation in any medical or scientific discipline with the objective of answering question(s) that may contribute to establishment of theory(ies), principle(s) or generalizable knowledge by processing, analyzing and reporting of information collected from:

(a) human beings (e.g. randomized controlled trial on a medical product or clinical procedure, or observational study following the progression of a disease);
(b) identifiable human materials (e.g. genetic analysis of archived human specimens); and/or
(c) identifiable human data (e.g. medical chart review or case series).

2.1.3 Appendix A shows examples of Medical Products, Clinical Procedures & Others Activities covered by the HKU-GHK IRB's scope.

2.1.4 Discretion to Review Other Research Projects: Notwithstanding the scope defined under this Section 2.1, the HKU-GHK IRB shall have the discretion to accept applications for ethics and scientific review of other research projects of a healthcare nature or otherwise (e.g. anonymous health survey or research on anonymised patient data) as it deems appropriate.

Policy

3. Structure and Composition

3.1 Organizational Structure

3.1.1 Organizational Components: The HKU-GHK IRB consists of:

(a) a chairman ("Chairman");

(b) vice chairmen ("Vice Chairmen") to be appointed by Chairman as needed;

(c) review panels; and

(d) secretariat ("Secretariat").

3.1.2 Organization Chart: The HKU-GHK IRB's organization chart is set out in Appendix B.

3.2 Composition

3.2.1 Membership Composition: The HKU-GHK IRB shall consist of both genders and with a minimum of five (5) members, including:

(a) at least two members with knowledge of, and current experience in the professional care or treatment of patients ("**Scientific Members**");

(b) at least one member who has neither scientific or healthcare background ("**Non-scientific Member**"); and

(c) at least one member who is not affiliated with the hospital ("**Independent Member**").

(d) at least one member with experience in quality assurance.

For the avoidance of doubt, the roles of Non-scientific Member and Independent Member may be assumed by the same HKU-GHK IRB member.

3.2.2 Appointment of Members: The ETRC shall appoint a suitable number of candidates with a suitable mix of backgrounds and expertise as appropriate for supporting the HKU-GHK IRB's responsibilities. All HKU-GHK IRB members shall be appointed by the ETRC in writing.

3.2.3 Members' Responsibilities: A HKU-GHK IRB member has the responsibilities to support accomplishment of the mission and fulfillment of the responsibilities of the HKU-GHK IRB by contributing to ethics and scientific review and oversight of clinical studies, such as:

(a) receiving and reviewing documents and information of clinical studies through the Secretariat;
(b) participating in HKU-GHK IRB review meetings;
(c) giving his/her opinions on any application, submission or issue of which he/she participated in review; and
(d) keeping the information of clinical studies he/she reviewed confidential.

3.3 Chairmanship

3.3.1 Appointment of Chairman: The HKU-GHK IRB shall be chaired by a University Seconded Practitioner or a University Professoriate staff member appointed by the ETRC.

3.3.2 Chairman's Authority: The Chairman has the authority to:

(e) appoint Vice Chairmen;
(f) exercise discretion on accepting applications for ethics and scientific review;
(g) initiate audits of clinical studies to assess compliance with study protocols, the HKU-GHK IRB's requirements and other applicable standards and requirements;
(h) disclose information of clinical studies to the ETRC, the Governing Body and competent regulatory authorities; and
(i) exercise other authorities related to ethics and scientific review and oversight of clinical studies as maybe delegated by the ETRC.

3.3.3 Chairman's Reporting: The Chairman shall report to the ETRC the status of operation of the HKU-GHK IRB and any significant issue with respect to the clinical studies under the HKU-GHK IRB's oversight

3.4 Vice Chairmanship

3.4.1 Appointment of Vice Chairmen: The Chairman may appoint any HKU-GHK IRB member as a Vice Chairman as he/she deems fit to assist him/her to perform the Chairman's responsibilities. There is no limitation on the number of Vice Chairmen.

3.5 Conflicts of Interest of Members

3.5.1 Avoidance of Conflicts of Interest: A HKU-GHK IRB's opinion must be free, and must be seen to be free from conflicts of interest. Conflicts of interest may

lead to bias in ethics and scientific review and oversight and should be avoided.

3.5.2 Declaration of Interest: Each HKU-GHK IRB member participating in reviewing a study shall, prior to the review, make a declaration for the absence of any of the interests. Any HKU-GHK IRB member having any declared interest shall not participate in reviewing the study.

3.6 Confidentiality Obligations of Members

3.6.1 Members' Confidentiality Obligations: All the information disclosed to a HKU-GHK IRB member 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, save and except for disclosure to the ETRC, the Governing Body or the relevant regulatory authorities.

3.6.2 Statement of Confidentiality: Upon acceptance of an appointment as a HKU-GHK IRB member, the member will be required to sign a statement of confidentiality to confirm his/her agreement to the confidentiality obligations in the HKU-GHK IRB.

3.7 Training and Continuous Education for Members

3.7.1 Continuous Education: HKU-GHK IRB members need to acquire knowledge in the core principles and to receive continuous education in respect of ethics and scientific review and oversight of clinical studies, including:

(a) the Declaration of Helsinki;
(b) the ICH GCP;
(c) this SOP; and
(d) any applicable guideline or working manual issued by the HKU-GHK IRB.

3.7.2 Training Records: Any relevant training or continuous education received by a HKU-GHK IRB should be recorded by the Secretariat.

4. Compositions and Functions of Review Panels

4.1 Review Panels in the HKU-GHK IRB

4.1.1 Standing Review Panels: The HKU-GHK IRB's responsibilities of ethics and scientific review and oversight shall be performed by its review panels. The

standing review panels include:

(a) a Standard Review Panel ("**Standard Panel**"); and
(b) an Expedited Review Panel ("**Expedited Panel**").

4.1.2 Members' Participation in Review Panels: Each HKU-GHK IRB member may be delegated to join one or more review panels.

4.2 Standard Review Panel

4.2.1 Standard Panel's Responsibility: The Standard Panel is responsible for performing initial ethics and scientific review of clinical studies assigned for initial review through "Channel A" as determined by the clinical study categorization mechanism stipulated in Section 7.3, and continuing review of subsequent applications/submissions that require full review by the Standard Panel as determined by the HKU-GHK IRB according to this SOP.

4.2.2 Composition of Standard Panel: The Standard Panel shall consist of both genders and with a minimum of five (5) members, including:

(a) at least one (1) Scientific Member;
(b) at least one (1) Non-scientific Member; and
(c) at least one (1) Independent Member.

For the avoidance of doubt, the roles of Non-scientific Member and Independent Member may be assumed by the same HKU-GHK IRB member.

4.2.3 Chairman's Authority to Assign Members to Standard Panel: The Chairman and Deputy Chairmen shall be members of the Standard Panel. Subject to compliance with the minimum requirements stipulated in Section 4.2.2, the Chairman may assign any number of HKU-GHK IRB members to the Standard Panel.

4.3 Expedited Review Panel

4.3.1 Expedited Panel's Responsibility: The Expedited Panel is responsible for performing initial ethics and scientific review of clinical studies assigned for initial review through "Channel B" as determined by the clinical study categorization mechanism stipulated in Section 7.3, and continuing review of subsequent applications/submissions that are eligible for expedited review as

determined by the HKU-GHK IRB according to this SOP.

4.3.2 Composition of Expedited Panel: The Expedited Panel shall consist of a minimum of one (1) members, whom must be Scientific Member.

4.3.3 Chairman's Authority to Assign Members to Expedited Panel: The Chairman shall assign any Scientific Member to review the research application. Subject to compliance with the minimum requirements stipulated in Section 4.3.2, the Chairman may assign any number of HKU-GHK IRB members to the Expedited Panel.

5. Secretariat

5.1 Composition of Secretariat

5.1.1 HKU-GHK IRB Secretariat: The Quality Safety and Risk Management Department shall act as the secretariat for the HKU-GHK IRB and be accountable to its Chairman. The Department shall designate a staff member to assume the role of a HKU-GHK IRB secretary ("**Secretary).**

5.2 Responsibilities of Secretariat

5.2.1 Secretariat's Responsibilities: The Secretariat has the responsibilities to support accomplishment of the mission and fulfillment of the responsibilities of the HKU-GHK IRB by providing professional management and administrative support to the HKU-GHK IRB.

5.3 Confidentiality Obligations of Secretariat Staff

5.3.1 Secretariat Staff's Confidentiality Obligations: Confidentiality obligations of HKU-GHK IRB membership also applies to the secretariat.

5.3.2 Statement of Confidentiality: Upon acceptance of an appointment as a Secretariat staff member, the staff member will be required to sign a statement of confidentiality to confirm his/her agreement to the confidentiality obligations in the HKU-GHK IRB.

6. Quality Assurance

6.1 Standard Operating Procedure, Guidelines and Working Manuals

6.1.1 Review of SOP: This SOP will be reviewed and updated as necessary at least

three (3) yearly.

6.1.2 Guidelines and Working Manuals: The HKU-GHK IRB may, as it deems required, develop and maintain guidelines and/or working manuals to supplement this SOP.

6.2 Audits and Inspections

6.2.1 Responsibility to Facilitate Audits/Inspections: The HKU-GHK IRB will allow and facilitate audits by the ETRC and inspections by competent regulatory authorities on the HKU-GHK IRB's composition, operations, records and facilities on reasonable request.

6.2.2 Follow-up on Audits/Inspections: After completion of an audit/inspection, the HKU-GHK IRB will:

(a) collect a written audit/inspection report from the auditor(s)/inspector(s);
(b) respond to the auditing/inspection body on any issue or finding highlighted in the audit/inspection report;
(c) take proper follow-up action(s) with respect to each issue or finding;
(d) issue a follow-up report to the auditing/inspection body upon completion of all follow-up action(s) if so required by the auditing/inspection body; and
(e) keep a complete record for the audit/inspection.

7. Initial Review

7.1 Initial Review as a Mandatory Requirement

7.1.1 Objective of Initial Review: An initial HKU-GHK IRB review is the ethics and scientific review by the HKU-GHK IRB prior to initiation of a proposed clinical study. The objective is to evaluate the ethical and scientific aspects of a proposed clinical study in order to protect the rights, safety and well-being of human subjects who may or will participate in the study.

7.1.2 Requirement for Prior Approval: The HKU-GHK IRB's initial review and prior written approval is a mandatory requirement for initiation of any clinical study under the HKU-GHK IRB's jurisdiction as stipulated in Section 2.1.

7.1.3 Processing Target Time: 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.

7.2 Application for Initial Review

7.2.1 Principal Investigators as Applicants: Submitting an application, through the relevant COS, to the HKU-GHK IRB for initial review of a clinical study is the responsibility of the study's principal investigator (who shall act as the applicant under the application). For the purpose of an application, the principal investigator of a study is the investigator who takes the final responsibility for the conduct of the study at his/her study site and shall be an employee/appointee/student of the Governing Body (irrespective of any other title assigned to him/her in the study). In the event of a multicentre study, the investigator who takes responsibility for the entire multicentre study may be referred to as the lead investigator (who may or may not be the same as the principal investigator).

7.2.2 Submission of Applications: All applications shall be submitted through the Secretariat. Principal investigators are required to observe the review meeting schedule and application submission deadlines announced by the HKU-GHK IRB, and shall comply with the HKU-GHK IRB's requirements in compiling and submitting their applications.

7.2.3 Application Documents: Each application shall include (but not limited to) the documents required as listed on Appendix C. The HKU-GHK IRB may request for additional documents, information or clarification as it reasonably deems required, and has the right to refuse performing an initial review if an application is incomplete and/or insufficient information is made available to the HKU-GHK IRB.

7.3 Categorization of Clinical Studies and Assignment of Review Channels

7.3.1 Principles of Study Categorization: To enhance the efficiency and effectiveness of initial reviews, the HKU-GHK IRB adopts a risk categorization approach by categorizing clinical studies based on six groups of risk factors including:

(a) involvement of human subject recruitment;
(b) subject vulnerability;
(c) subject assignment methods;
(d) involvement of medical products;

(e) involvement of clinical procedures; and
(f) study designs.

7.3.2 Mechanism for Study Categorization and Review Channels: The detailed mechanism for categorization of clinical studies is set out on the "Clinical Study Categorization Form" set out in Appendix D. Principal investigators are required to complete and submit the form together with each application for initial review. Upon receipt of an application, the Secretariat will verify the information on the form and arrange for initial review through one of the following review channels:

(a) Channel A: Full review by the Standard Panel
(b) Channel B: Expedited review by the Expedited Panel

7.3.3 Chairman's Authority to Assign Review Channel: Notwithstanding the result of categorization under the aforesaid mechanism, the Chairman or a Vice Chairman shall have the authority to:

(a) re-assign an application for expedited review if the study is a multicentre study which has already been approved by the research ethics committee under HKU, and no substantial difference is anticipated with respect to protection of the rights, safety and well-being of subjects whether the study is conducted by the applying principal investigator or by another approved principal investigator; or
(b) re-assign an application for review through any of the other channels at his/her reasonable discretion.

7.3.4 Continuing Review through the Review Channels: Unless otherwise specified in this SOP, continuing review of submissions for approved clinical studies will also be performed through the aforesaid review channels in accordance with the requirements detailed in Section 8.

7.4 Full Review by Standard Panel

7.4.1 Meeting Schedule: The Standard Panel shall perform full review of applications/submissions by holding regular review meetings at a frequency as the HKU-GHK IRB determines, and ad hoc review meetings as the HKU-GHK IRB deems necessary. The Secretariat will use its best endeavors to work out and make accessible to the investigators an updated meeting schedule for the regular review meetings, together with the submission deadlines corresponding

to the meetings, at least for the two (2) subsequent meetings at any point of time to facilitate time planning by investigators for their upcoming studies.

7.4.2 Quorum and Composition of Reviewers: The quorum for a Standard Panel review meeting is five (5) and the composition of the reviewers participating in a review meeting shall fulfill the minimum requirements as stipulated in Section 4.2.2.

7.4.3 Expert Advisors: The Chairman or Vice Chairman may, as he/she deems beneficial to the review of an application/submission, invite expert advisor(s) to participate in a review meeting or provide expert advice on an application/submission, provided that each expert advisor shall sign a statement of confidentiality. The expert advisor(s) shall not be eligible to vote for the application/submission.

7.4.4 Pre-meeting Review: For each application/submission assigned for full review by the Standard Panel, the Secretariat will, prior to the review meeting, send the application/submission (together with all the relevant documents) to the reviewers at least seven (7) calendar days before the review meeting for performing pre-meeting review. The Secretariat may, at its discretion, forward the reviewers' preliminary opinions, if any, to the principal investigator for consideration before the review meeting.

7.4.5 Investigator's Participation in a Meeting: The Chairman or Vice Chairman may, as he/she deems beneficial to the review of an application/submission, request a principal investigator (or his/her designee) to participate and/or present the application/submission in a review meeting.

7.4.6 Conduct of Meeting: The Chairman or Vice Chairman will use his/her endeavors to facilitate a balanced discussion among the participating reviewers in order to reach an ethically and scientifically satisfactory decision on each application/submission.

7.4.7 Scope of Considerations: In performing a review, the reviewers will evaluate and discuss the ethical and scientific aspects of the study for the purpose of protecting the rights, safety and well-being of human subjects, and in particular from six key dimensions including:

(a) research products/procedures;
(b) study design;
(c) study execution;

(d) subjects' rights;
(e) potential research biases; and
(f) potential liability management.

A list of common considerations corresponding to the six key dimensions is set out in Appendix E. The selected items are only provided for reference but should not be taken as an exhaustive checklist for performing a review.

7.4.8 Decision by Consensus: The Chairman or Vice Chairman will use his/her endeavors to facilitate the panel's decision on each application/submission by thorough discussion and unanimous consensus.

7.4.9 Decision by Voting: In the event that a unanimous consensus on an application/submission cannot be reached within a reasonable period of discussion, the Chairman or Vice Chairman may at his/her discretion call for resolution by voting. A reviewer may vote for or against an application/submission, or otherwise abstain from voting. A resolution shall be approved by majority vote of at least 75% of the reviewers who are eligible to vote for the application/submission. Any reviewer who has a conflict of interest or potential conflict of interest in an application/submission shall make a declaration and is not eligible to vote. The reviewer(s) dissenting and/or abstaining (together with the reason(s) for dissenting/abstaining) should be recorded in the minutes.

7.4.10 Types of Decisions: After reviewing an application/submission, the review panel will:

(a) approve the application/submission, if it is deemed fulfilling all the relevant requirements of the HKU-GHK IRB;
(b) disapprove the application/submission, if any fundamental inconsistency exists between the application/submission and the HKU-GHK IRB's requirements, and such inconsistency is deemed non-rectifiable;
(c) request the principal investigator to modify the application/submission or to provide clarification or further information about the application/submission; or
(d) give other opinion(s) or take other action(s) as it reasonably determines.

7.5 Expedited Review by Expedited Panel

7.5.1 Review Schedule: Expedited review of an application/submission shall be

performed by reviewer(s) in the Expedited Panel upon receipt of the application/submission by the Secretariat and assignment of the application/submission for expedited review by the HKU-GHK IRB as per Section 7.3.

7.5.2 Assignment of Reviewer(s): For each application/submission assigned for expedited review, the Secretariat will send the application/submission (together with all the relevant documents) to assigned reviewer(s) in the Expedited Panel for review.

7.5.3 Scope of Considerations: In performing an expedited review, the reviewer(s) will evaluate the study for the purpose of protecting the rights, safety and well-being of human subjects by taking into account the same ethical and scientific considerations as in a full review, and in particular the common considerations set out in Appendix E.

7.5.4 Decision by Consensus: If an expedited review of an application/submission is performed by more than one reviewer, the reviewers will use their endeavors to reach a decision on the application/submission by unanimous consensus. A decision by an expedited review may be tabled or endorsed in a full review meeting as the HKU-GHK IRB deems required.

7.5.5 Types of Decisions: After reviewing an application/submission, the reviewer(s) will:

(a) approve the application/submission, if it is deemed fulfilling all the relevant requirements of the HKU-GHK IRB;
(b) request the principal investigator to modify the application/submission or to provide clarification or further information about the application/submission;
(c) channel the application/submission for full review, if the reviewer(s) has/have a negative opinion on the application/submission and deem(s) a full review is needed; or
(d) give other opinion(s) or take other action(s) as the reviewer(s) reasonably determine(s).

Under no circumstances can an application/submission be disapproved only through an expedited review.

7.6 Notification and Documentation

7.6.1 Notification of Decisions: The decision on an application/submission will be notified to the principal investigator by the Chairman or Vice Chairman (or designee) in writing as soon as possible and within fourteen (14) calendar days after the decision is made. A sample notice for communicating decisions to principal investigators is set out in Appendix F for reference.

7.6.2 Documentation of Review: The Secretariat will be responsible for documenting and maintaining records for the review of each application/submission.

8. Progress Monitoring

8.1 Continuous Oversight

8.1.1 Modes of Continuous Oversight: The HKU-GHK IRB will perform continuous oversight of each approved clinical study, until its completion or early termination, by:

(a) regular progress monitoring;
(b) review of amendments and changes / new information;
(c) review of;
(d) review of deviations and compliance incidents;
(e) review of safety reports; and
(f) review of final report.

8.2 Regular Progress Monitoring

8.2.1 Frequency of Regular Continuing Review: The HKU-GHK IRB shall keep track of the updated status of each approved clinical study through regular continuing review once a year from the date of the initial approval and during the period of the study, or more frequently if deemed required by the HKU-GHK IRB considering the degree of risk of a study.

8.2.2 Progress Reporting: To facilitate the HKU-GHK IRB's continuing review, a principal investigator shall have the responsibility to submit a progress report on his/her study to the HKU-GHK IRB within one (1) month prior to each deadline for regular continuing review by using the HKU-GHK IRB's specified form.

8.2.3 Review of Progress Reports: Each progress report will be reviewed by reviewer(s) in the Expedited Panel through an expedited review process as

stipulated in Section 7.5. In the event that the reviewer(s) deem(s) any information in a progress report may be linked with a substantially higher degree of risk and a full review is required, the submission will be channeled for full review. In no circumstance a study can be terminated only by expedited review.

8.2.4 Failure to Submit Progress Report: In the event that a principal investigator fails to submit a progress report to the HKU-GHK IRB by the deadline for regular continuing review, the HKU-GHK IRB may:

(a) request for suspension of all subject recruitment activities and recruitment of additional subjects into the study; and/or
(b) refuse accepting any new application for initial review of clinical study submitted by the principal investigator and his/her participation in any new clinical study (whether as principal investigator, co-investigator/sub-investigator or otherwise); until the progress report is properly submitted and an acknowledgement is received from the HKU-GHK IRB.

8.3 Review of Amendments and Changes / New Information

8.3.1 Implementation of Amendments/Changes: No amendment or change to any approved study document/material shall be implemented without the HKU-GHK IRB's approval, except:

(a) where necessary to eliminate any immediate hazard to the subjects; or
(b) if an amendment/change is only of an administrative or logistical nature (e.g. correction of typo errors).

8.3.2 Application for Amendments/Changes: In the event that any amendment or change needs to be made to any study document/material, the principal investigator shall submit an application for study amendment(s)/change(s) to the HKU-GHK IRB by using the HKU-GHK IRB's specified form.

8.3.3 Reporting of New Information: A principal investigator has the responsibility to report to the HKU-GHK IRB, by using the HKU-GHK IRB's specified form, any new information that may adversely affect the rights, safety or well-being of the subjects or the proper conduct of his/her clinical study.

8.3.4 Review of Amendments/Changes / New Information: The Chairman or a Vice

Chairman (or designee) will perform a preliminary review of an application for study amendment(s)/change(s) / New Information and assess the possible change in the degree of risk arising from the proposed amendment(s)/change(s). An application for amendment(s)/change(s) or new information provided that is/are deemed adding no more than minimal additional risk to the subjects, and no special action will need to be taken, will be reviewed by reviewer(s) in the Expedited Panel through an expedited review process as stipulated in Section 7.5. In the event that the Chairman or Vice Chairman (or designee) deems the proposed amendment(s)/change(s) may incur more than minimal additional risk and a full review is required, the application will be channeled for full review.

8.4 Review of Deviations and Compliance Incidents

8.4.1 Reporting of Deviations/Incidents: A principal investigator has the responsibility to report to the HKU-GHK IRB, by using the HKU-GHK IRB's specified form, any deviation from the study protocol or compliance incident that has occurred during a study and may adversely affect the rights, safety or well-being of any subject, within thirty (30) calendar days from the first awareness of the deviation/incident by the principal investigator.

8.4.2 Review of Reports on Deviations/Incidents: The Chairman or a Vice Chairman (or designee) will perform a preliminary review of a report on a deviation/incident and assess if a full review or expedited review is required. If a reported deviation/incident is not deemed to have a substantial adverse effect to the rights, safety or well-being of any subject and no special action will need to be taken by the HKU-GHK IRB, the submission will be reviewed by reviewer(s) in the Expedited Panel through an expedited review process as stipulated in Section 7.5. In the event that the Chairman or Vice Chairman deems the deviation/incident may result in any substantial adverse effect to the rights, safety or well-being of any subject and special action(s) may need to be taken by the HKU-GHK IRB, the submission will be channeled for full review. In no circumstance a study can be terminated only by expedited review.

8.4.3 Rectification/Remedial/Modification Actions: The HKU-GHK IRB will have the right to:

(a) request the principal investigator to take appropriate rectification, remedial and/or modification action(s) with respect to the deviation/incident;

(b) request for suspension of further recruitment of subjects into the study until the required rectification/remedial/modification action(s) has/have been completed; and/or

(c) request for suspension or termination of the study if the required rectification/remedial/modification action(s) is/are not completed within a reasonable period of time, or if the deviation/incident is deemed by the HKU-GHK IRB seriously affecting the rights, safety or well-being of the subjects and the deviation/incident is not rectifiable/ remediable/ modifiable.

8.5 Notification of Decisions (in respect of sections 8.2 - 8.5)

8.5.1 Notification of Decisions: The decision on a submission will be notified to the principal investigator by the Chairman or Vice Chairman (or designee) in writing as soon as possible and within fourteen (14) calendar days after the decision is made. In case there is not any concern or comment, an acknowledgement of receipt of the submission will be issued to the principal investigator.

8.6 Review of Safety Reports

8.6.1 Safety Monitoring: Continuous safety monitoring is an important part in subject protection in clinical studies. An investigator has the responsibility to:

(a) monitor his/her subjects' safety by observing any safety event occurred in any of the subjects; and

(b) in the event of a multicentre clinical study, observe any significant safety event reported from any other study site.

8.6.2 Types of Safety Events: Considering the severity, foreseeability and causality with an investigational product/procedure, a safety event can be classified as:

(a) an adverse event ("**AE**"), which is an unfavorable or unintended sign, symptom, reaction or disease that is associated in time with participation in a clinical study or the use of an investigational product/procedure, whether or not the event is related to the study or the investigational product/procedure, or is expected;

(b) a serious adverse event ("**SAE**"), which is an AE that: (i) results in death; (ii) is life-threatening; (iii) requires inpatient hospitalization or prolongation of existing hospitalization; (iv) results in persistent or

significant disability or incapacity; (v) results in a congenital anomaly or birth defect; or (vi) in the professional medical judgment of an investigator, may seriously jeopardize a subject's health or may require medical intervention to prevent any of the events listed in (i) to (v) above; or

(c) an suspected unexpected serious adverse reaction ("**SUSAR**"), which is a SAE that is unexpected according to the available information and is suspected to be causally related to an investigational product/procedure.

8.6.3 Reporting of SAEs at Investigator's Study Site: The HKU-GHK IRB has the responsibility to protect subjects' safety through review of SAEs occurred on subjects recruited at the study sites under its jurisdiction. A principal investigator shall, during the period of a study, have the responsibility to report to the HKU-GHK IRB all SAEs observed from any subject recruited from his/her study site in accordance with the requirements set out in Appendix G by using the HKU-GHK IRB's specified form.

8.6.4 Reporting of SUSARs outside Investigator's Study Sites: The HKU-GHK IRB also has the responsibility to protect subjects' safety through review of SUSARs occurred outside study sites under its jurisdiction. A principal investigator shall, during the period of a study, have the responsibility to report to the HKU-GHK IRB all SUSARs reported from outside the principal investigator's study site in accordance with the requirements set out in Appendix G by using the HKU-GHK IRB's specified form.

8.6.5 Review of Safety Reports: A safety report will be reviewed by reviewer(s) in the Expedited Panel through an expedited review process as stipulated in Section 7.5. In the event that the reviewer(s) deem(s) a safety report has any significant implication on protection of subjects' safety, the report will be channeled for full review. In no circumstance a study can be terminated only by expedited review.

8.6.6 Notification of Decisions: The decision on a submission will be notified to the principal investigator by the Chairman or a Vice Chairman (or designee) in writing as soon as possible and within fourteen (14) calendar days after the decision is made. In case there is not any concern or comment on a safety report, an acknowledgement of receipt of the submission will be issued to the principal investigator.

8.6.7 Follow-up of SAEs: The principal investigator shall, with respect to each SAE

occurred at his/her study site and reported to the HKU-GHK IRB, have the responsibility to:

(a) provide further information about the SAE on the HKU-GHK IRB's request; and
(b) follow the SAE until resolution or conclusion of the event, and provide follow-up report(s) to the HKU-GHK IRB in due course.

8.7 Final Report

8.7.1 Final Report: The HKU-GHK IRB shall have the responsibility to follow each approved clinical study until its completion or early termination. A principal investigator shall have the responsibility to submit a final report on his/her study to the HKU-GHK IRB within two (2) months from the date of formal closure of the study by using the HKU-GHK IRB's specified form. The final report shall include a summary of study information, such as:

(a) the status of the study (e.g. completed or prematurely terminated);
(b) the numbers of subjects recruited in, withdrew from and completed the study;
(c) summary of serious adverse events;
(d) summary of complaints by subjects; and
(e) summary of significant updated information that may affect the safety of subjects.

8.7.2 Review of Final Report: Each final report will be reviewed by reviewer(s) in the Expedited Panel through an expedited review process as stipulated in Section 7.5. In the event that the reviewer(s) deem(s) any information in a final report may be linked with a substantially higher degree of risk and a full review is required, the submission will be channeled for full review.

8.7.3 Notification of Decisions: The decision on a submission will be notified to the principal investigator by the Chairman or a Vice Chairman (or designee) in writing as soon as possible and within fourteen (14) calendar days after the decision is made. In case there is not any concern or comment on a final report, an acknowledgement of receipt of the submission will be issued to the principal investigator.

8.7.4 Failure to Submit Final Report: In the event that a principal investigator fails to submit a final report to the HKU-GHK IRB by the deadline, the HKU-GHK

IRB may refuse accepting any new application for initial review of clinical study submitted by the principal investigator and his/her participation in any new clinical study (whether as principal investigator, co-investigator/sub-investigator or otherwise) until the final report is properly submitted and an acknowledgement is received from the HKU-GHK IRB.

9. Study Site Auditing

9.1 Purpose and Types of Audits by HKU-GHK IRB

9.1.1 Purpose of Audits: An audit by the HKU-GHK IRB is to determine whether the study concerned was conducted according to its study protocol, the Declaration of Helsinki, the ICH GCP (if applicable) and the HKU-GHK IRB's requirements, for the ultimate purpose of protecting the rights, safety and well-being of the subjects participated or participating in the study.

9.1.2 Types of Audits: The HKU-GHK IRB may perform two types of audits, including:

(a) routine audits; and
(b) for-cause audits.

9.1.3 Routine Audits: Routine audits may be performed as a general quality control measure for ensuring compliance in the conduct of a clinical study at a study site. The HKU-GHK IRB will select studies for routine audits by a risk-based approach by considering various risk factors. Examples include:

(a) studies involving special ethical concerns;
(b) studies involving special clinical risk; and
(c) studies involving a large number of subjects.

9.1.4 For-cause Audits: The HKU-GHK IRB may perform a for-cause audit in response to a particular compliance concern that may be triggered by:

(a) a complaint by a subject (or his/her family member or legally acceptable representative); or
(b) a report from the study's sponsor or a competent regulatory authority in respect of any compliance concern.

9.2 Follow-up of Audits

9.2.1 Follow-up on Audits: After completion of an audit, the HKU-GHK IRB will issue a written audit report to the principal investigator. The principal investigator will be required to:

(a) respond on any issue or finding highlighted in the audit report;
(b) take proper follow-up action(s) with respect to each issue or finding; and
(c) issue a follow-up report to the HKU-GHK IRB upon completion of all follow-up action(s).

10. Reevaluation Mechanism

10.1 Right to Request for Reevaluation

10.1.1 Investigators' Right to Request for Reevaluation: In the event that a principal investigator does not agree with the HKU-GHK IRB's decision(s)/opinion(s) with respect to his/her clinical study (e.g. disapproval of an initial application for a study), the principal investigator will have the right to make a written request for reevaluation within thirty (30) days from the date of the HKU-GHK IRB's written notification of its decision(s)/opinion(s), provided that sufficient justification(s) for the request can be made available to the HKU-GHK IRB for reevaluation.

10.2 Reevaluation Process

10.2.1 Initiation of Reevaluation: Any request for reevaluation shall be made in writing to the Chairman through the Secretariat. The principal investigator shall provide sufficient justification(s) for the request, with supporting documents or information as appropriate.

10.2.2 Reevaluation and Decisions: The HKU-GHK IRB will perform an independent review of the case by full review in accordance with the standards and requirements set out in this SOP, and will duly consider the rationale of the decision(s)/opinion(s) in the initial review and the justification for reevaluation by the principal investigator. The HKU-GHK IRB's decision after the reevaluation shall be final.

11. Review Fees

11.1 Determination of Review Fees

11.1.1 Determination of Review Fees: The fees for receipt of

applications/submissions and performance of ethics and scientific review and oversight shall be determined and may be adjusted from time to time by the ETRC.

11.1.2 Notification of Review Fees: The Secretariat will have the responsibility to maintain an updated fees schedule and provide the updated information to investigators on their request.

11.2 Payment of Review Fees

11.2.1 Payment Methods: All review fees shall be paid according to the instructions of the Secretariat, including, where relevant, the application fee.

11.2.2 No Refund: No refund of any fee so paid will be given in any circumstances, irrespective of the decisions/opinions of the HKU-GHK IRB, withdrawal of applications/submissions by principal investigators, refusal of applications/submissions by the HKU-GHK IRB or otherwise.

12. Records Management

12.1 Central Electronic Database

12.1.1 Central Database: A central database for the clinical studies reviewed by the HKU-GHK IRB is to be maintained by the HKU-GHK IRB. The database contains basic information about reviewed clinical studies (whether approved, disapproved, ongoing or closed). The Secretariat is responsible for maintaining an updated the database and making the data available to the ETRC and the Governing Body as required.

12.2 Records Retention

12.2.1 Retention of Essential Records: The HKU-GHK IRB shall retain all essential documents and records relating to ethics and scientific review and oversight of each clinical study.

12.2.2 Records Retention Period for Approved Studies: All essential HKU-GHK IRB records with respect to each approved clinical study shall be retained for a minimum period of three (3) years from the date of the final report to the HKU-GHK IRB or the date of termination of the study by the HKU-GHK IRB. Investigators shall control all study documents including but not limited to consent form, completed data collection sheet and interview notes in accordance with the proposed options delineated in the research application

forms.

12.2.3 Records Retention Period for Disapproved Studies: All essential HKU-GHK IRB records with respect to each disapproved clinical study shall be retained until the earlier of:

(a) the expiry of the 30-day period after the written notification of the HKU-GHK IRB's decision(s)/opinion(s) (to allow the principal investigator to make a request for reevaluation as per Section 10.1); and

(b) the conclusion of a reevaluation as per Section 10.2.

Reference

13.0 References

N.A

Appendix

14.0 Appendices

Appendix A: Examples of Medical Products, Clinical Procedures & Other

Appendix B: Organization Chart of the HKU-GHK IRB

Appendix C: Documents Required for an Application for Initial Review

Appendix D: Clinical Study Categorization Form

Appendix E: Common Considerations in HKU-GHK IRB Review

Appendix F: Sample Notice for Communicating HKU-GHK IRB's Decisions

Appendix G: Safety Events Reporting Requirements

Appendix A
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Examples of Medical Products, Clinical Procedures & Other Activities

Examples of Medical Products: Medical products may include:

(a) drugs (e.g. chemical drugs, biological drugs and vaccines);
(b) medical devices (e.g. implants, diagnostic kits and imaging machines);
(c) Chinese/herbal medicines (e.g. proprietary/traditional Chinese medicines);
(d) health/nutritional supplements;
(e) cell therapies (e.g. stem cells); and
(f) gene therapies (e.g. viral vectors).

Examples of Clinical Procedures: Clinical procedures may include:

(g) clinical examinations/assessments (e.g. venipuncture);
(h) surgical procedures (e.g. tumor resection);
(i) nursing procedures;
(j) physiotherapies;
(k) occupational therapies;
(l) psychotherapies;
(m) behavioral therapies;
(n) alternative therapies (e.g. acupuncture); and
(o) diagnostic imaging methods (e.g. X-ray examination).

Examples of Activities Not Defined as Clinical Studies: For the avoidance of doubt, clinical studies do not include:

(p) the use of medical products/procedures solely for the purpose of clinical care (e.g. emergency use of an unregistered drug with a patient in a life-threatening condition);
(q) evaluation of individual patients' medical records solely for the purpose of clinical care;
(r) investigation of clinical data for quality assurance purpose (e.g. clinical audits); and
(s) investigation on general statistical information relating to hospital services or disease patterns (e.g. number of hospital admissions per year, year-on-year change in the number of diabetic patients attending a specialist out-patient clinic); and
(t) provided that such activities are not intended to form a part of a research project or to derive a research publication

Appendix B
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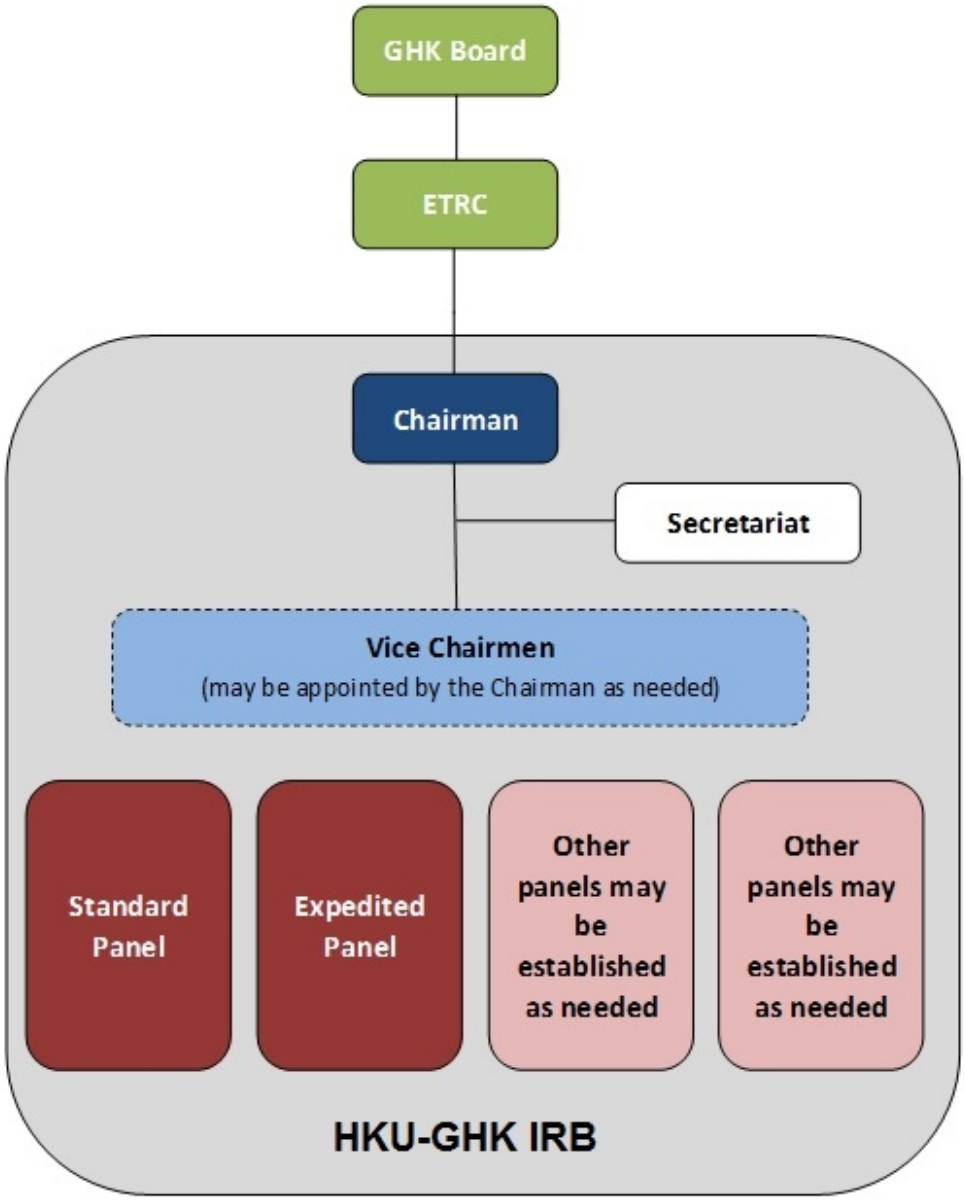
Organization Chart of the HKU-GHK IRB



ETRC	Education, Training and Research committee
GHK Board	Gleneagles Hospital Hong Kong
HKU-GHK IRB	University of Hong Kong – Gleneagles Hospital Hong Kong Institutional Review Board

Appendix C
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Documents Required for an Application for Initial Review

	Documents *(See notes overleaf)*	Languages	
		English	Chinese
1.	Submission letter for initial review	✓	---
2.	Clinical study protocol	✓	✶
3.	Completed and signed clinical research ethics review application form (refer to Hospital Policy - HP_GQSR_009, Appendix A)	✓	---
4.	Completed and signed Ethical Approval Checklist form (refer to Hospital Policy - HP_GQSR_009, Appendix B)	✓	---
5.	Informed consent form and/or subject information sheet	✶	✶
6.	Investigator's brochure	✶	✶
7.	Subject recruitment materials (e.g. subject recruitment advertisement or poster)	✶	✶
8.	Documents/materials for use by subjects in the study (e.g. subject-administered questionnaire)	✶	✶
9.	Principal investigator's curriculum vitae	✓	---
10.	Clinical study categorization form	✓	---
11.	Draft Clinical Trial Agreement		
12.	Investigator's conflicts of interest declaration form	✓	---
13.	Certificate of insurance for clinical study	✶	---
14.	A letter of indemnity for the standard indemnity agreement and procedure	✓	✶
15.	Crossed cheque/bank draft for payment of initial review application fee	---	---

✓ = mandatory ✶ = required if applicable

Remarks on the Documents Required for an Application for Initial Review

Documents	Remarks
1	A sample can be obtained from the HKU-GHK IRB's Secretariat.
2.	Incorporation of an investigator brochure with a clinical study protocol is acceptable
3	The form can be obtained from HP_GQSR_009. Also from the HKU-GHK IRB's Secretariat.
4.	The form can be obtained from HP_GQSR_009. Also from the HKU-GHK IRB's Secretariat.
5.	Informed consent form and subject information sheet may be combined into one document.
6.	Incorporation of an investigator brochure with a clinical study protocol is acceptable.
7, 8	The language(s) used in any subject recruitment material and/or other document/material for use by subjects will depend on the language(s) of the target subject population.
9.	The principal investigator's updated curriculum vitae must be submitted. The other study team members' curricula vitae may also be submitted at the principal investigator's discretion or on the HKU-GHK IRB's request.
10.	The form can be obtained from the HKU-GHK IRB's Secretariat.
12	All investigators participating in a clinical study shall provide their signed conflicts of interest declaration forms (which can be obtained from the HKU-GHK IRB's Secretariat). An investigator's potential conflicts of interest in a clinical study may include (i) any proprietary interest in the study and/or the investigational product(s)/procedure(s) (e.g. patent); (ii) any equity interest in an organization owning the rights to the study and/or the investigational product(s)/procedure(s) (e.g. stocks and options) , except for indirect ownership through collective investment schemes (e.g. mutual funds and mandatory provident funds) in which the investigator has no control over the investment strategy; (iii) any financial payment or valuable provided by an organization owning the rights to the study and/or the investigational product(s)/procedure(s) other than the costs for running a clinical study (e.g. donation); (iv) any financial arrangement linking to the outcomes of a clinical study (e.g. royalty fee); and (v) any decision-making or influential position in an organization owning the rights to the study and/or the investigational product(s)/procedure(s); and (vi) a direct family relationship with a person having any of the above interests (e.g. spouse).
13.	Any clinical study with higher than nominal clinical risk as determined by the HKU-GHK IRB may be required to be covered by appropriate insurance policy(ies) (e.g. no-fault clinical trial insurance), evidenced by certificate(s) of insurance. A certificate of insurance may be submitted to the HKU-GHK IRB separately from the application subject to the HKU-GHK IRB's permission, but in any event shall be prior to initiation of the clinical study.
15.	Application fee is only applicable to industry-sponsored clinical studies. Any crossed cheque or bank draft issued shall be denominated in Hong Kong dollars or U.S. dollars.

Appendix D
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Clinical Study Categorization Form

University of Hong Kong - Gleneagles Hong Kong Institutional Review Board

Clinical Study Categorization Form

Risk Group		Risk Factors *(See notes overleaf)*	Yes	No
Human Subjects	1	Recruitment of human subjects [***see notes of completion***]	☐ →2	☐ →B
Medical Products	2	Use of any medical product that is not needed or used for the Subjects' normal clinical care [***see notes of completion***]	☐ →3	☐ →8
	3	Each medical product used is registered or permitted to be marketed in Hong Kong	☐ →4	☐ →5
	4	Use of each medical product is within the labeled use in Hong Kong [***see notes of completion***]	☐ →8	☐ →5
	5	Any medical product used is a chemical or biological drug that is to be tested in humans for the first time	☐ →C	☐ →6
Study Designs	6	The study is a phase 1 clinical trial on a chemical or biological drug as designated on its study protocol	☐ →C	☐ →7
	7	The study only has human pharmacology, toxicity and/or safety (but not efficacy) of the chemical or biological drug as its primary objective(s) as specified on its study protocol	☐ →C	☐ →A
	8	Involvement of placebo, impeding access to available treatment, or withdrawal of ongoing treatment driven by the study protocol	☐ →A	☐ →9
Clinical Procedures	9	Involvement of any clinical procedure that is not needed or applied for the subjects' normal clinical care [***see notes of completion***]	☐ →10	☐ →11
	10	Each clinical procedure applied presents no more than minimal clinical risk to the subjects [***see notes of completion***]	☐ →11	☐ →A
Subject Assignment Methods	11	Subjects are assigned to different clinical intervention by randomization or other research specific methods (other than by the professional judgment of qualified medical professionals)	☐ →A	☐ →12
Subject Vulnerability	12	Involvement of vulnerable subjects [***see notes of completion***]	☐ →A	☐ →B

Channel A	**Full review by Standard Panel** (unless otherwise determined by the HKU-GHK IRB according to the HKU-GHK IRB's SOP)
Channel B	**Expedited review by Expedited Panel** (unless otherwise determined by the HKU-GHK IRB according to the HKU-GHK IRB's SOP or requested by the principal investigator for a full review)

Official Use Only

Categorization by HKU-GHK IRB: ☐ **Channel A** ☐ **Channel B**

Reason (if HKU-GHK IRB applies a different categorization):

Notes for Completion of the Clinical Study Categorization Form

Risk Factors	Remarks
1	Recruitment of human subjects means prospective recruitment of subjects into a clinical study, irrespective of the nature of the study. Retrospective research on human materials or human data that have already been collected may not require recruitment of human subject unless separate informed consent is required for some or all of the subjects in the circumstances.
2	Medical products may include (but not limited to): (a) drugs (e.g. chemical drugs, biological drugs and vaccines); (b) medical devices (e.g. implants, diagnostic kits and imaging machines) (c) Chinese/herbal medicines (e.g. proprietary/traditional Chinese medicines); (d) health/nutritional supplements; (e) cell therapies (e.g. stem cells); and (f) gene therapies (e.g. viral vectors).
4	Labeled use refers to the use a medical product in accordance with the conditions of registration in Hong Kong (e.g. indications, patient groups, formulations and dosages).
9	Clinical procedures include (but not limited to): (a) clinical examination/assessments (e.g. venipuncture) (b) surgical procedures (e.g. tumor resection); (c) nursing procedures; (d) physiotherapies; (e) occupational therapies; (f) psychotherapies; (g) behavioral therapies; (h) alternative therapies (e.g. acupuncture); and (i) imaging methods (e.g. X-ray examination).
10	Minimal clinical risk means the probability and magnitude of harm or discomfort anticipated to be caused to the human subjects are not greater than those ordinarily encountered in their daily life or normal clinical care (e.g. the clinical risk associated with a buccal swab, taking of a small quantity of blood by venipuncture, and a chest x-ray examination).
12	Vulnerable subjects are individuals whose willingness to participate in clinical studies may relatively easily be unduly influenced by biases or coercive factors, or who are incapable of giving free informed consent through a normal informed consent process, such as: (a) children or adolescent (of less than 18-year-old); (b) illiterates; (c) mentally incapacitated persons; (d) impoverished persons; (e) ethnic minority groups; (f) patients in emergency conditions; (g) prisoners; and (h) subordinates or students of investigators.

Appendix E
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Common Considerations in HKU-GHK IRB Review

Key Dimensions	Common Considerations
Research Products/Procedures	• Involvement of clinical interventions (e.g. medical products or clinical procedures) • Potential risks and related scientific rationale • Potential benefits and related scientific rationale
Study Design	• Significance of research questions • Correlation of study design and research questions • Use of randomization or other research specific subject assignment methods • Involvement of placebo, impeding access to available treatment, or withdrawal of ongoing treatment driven by study protocol • Statistical considerations
Study Execution	• Expertise and experience of investigators and study personnel • Training on the Declaration of Helsinki and ICH GCP • Study site facilities • Mechanism of ongoing safety monitoring and reporting • Medical emergency arrangements
Subjects' Rights	• Subject type and vulnerability • Involvement of healthy volunteers or subjects without the targeted diseases/conditions • Subject recruitment strategies • Informed consent documents and process • Protection of subjects' personal data • Payments to subjects
Potential Research Biases	• Conflicts of interest, potential conflicts of interest and declaration of interest • Public disclosure of study information (e.g. by registration with public clinical trial registries) • Publication plan
Potential Liability Management	• Insurance • Indemnity (for industry-sponsored clinical studies)

Appendix F
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Sample Notice for Communicating HKU-GHK IRB's Decisions

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

<HKU-GHK IRB ADDRESS>
Tel: <HKU-GHK IRB TEL> Fax: <HKU-GHK IRB FAX>

HKU-GHK IRB is an independent authority established by University of Hong Kong and Gleneagles Hospital Hong Kong and authorized to perform ethics and scientific review and oversight of clinical studies in accordance with its standard operating procedure and the principles of the Declaration of Helsinki and ICH Good Clinical Practice.

Date: <Date of Notice> HKU-GHK IRB Ref. No.: <Ref. No.>

To: <PI Name>
<PI Title & Department>
<PI Affiliated Institution>

This notice is issued by HKU-GHK IRB with respect to the application/submission by you, being the principal investigator of the following study at your study site:

- Study Protocol Title: <Title>
- Study Protocol No.: <No.>
- Lead Principal Investigator (if applicable): <Lead PI Name, or put "N/A"> *(for multicentre study and if different from the principal investigator of the following study site)*
- Study Site: <Study Site>

In accordance with our standard operating procedure, we have duly performed ethics and scientific review of your application/submission as detailed below:

- Nature of Your Application/Submission: ☐ Initial application ☐ Amendments/changes ☐ Others:
- Mode of Review: ☐ Full review ☐ Expedited review
- Date of Review/Decision: <Date of meeting/expedited review>
- Document(s) Reviewed: <List document(s), or put "See Schedule 1">
- Reviewer(s): <List reviewer(s), or put "See Schedule 2">

After due review by our reviewer(s), we hereby write to inform you of our decision on your application/submission as follows:

- Decision:
  - ☐ Application approved
  - ☐ Receipt of submission acknowledged without comment
  - ☐ Application disapproved (see opinion(s) below)
  - ☐ Others (see opinion(s) below)
- Opinion(s) (if applicable): <State opinion(s), or put "N/A" if not applicable>

- Regular Progress Report(s) Required: Every <No.> months from the date of initial approval and during the period of the study

You, being the principal investigator of the study at your study site, are reminded to comply with our requirements and to maintain communication with us during the period of the study by undertaking the principal investigator's responsibilities including (but not limited to):

- observing and complying with all applicable requirements under our standard operating procedure ("HKU-GHK IRB SOP"), the Declaration of Helsinki and the ICH GCP (if applicable);
- submitting regular progress report(s) at the required intervals (as specified above) in accordance with the requirements in the HKU-GHK IRB SOP;
- not implementing any amendment/change to any approved study document/material without our written approval, except where necessary to eliminate any immediate hazard to the subjects or if an amendment/change is only of an administrative or logistical nature;
- notifying us of any new information that may adversely affect the rights, safety or well-being of the subjects or the proper conduct of the study;
- reporting any deviation from the study protocol or compliance incident that has occurred during the study and may adversely affect the rights, safety or well-being of any subject in accordance with the requirements in the HKU-GHK IRB SOP;
- submitting safety reports on all SAEs observed at your study site or SUSARs reported from outside your study site in accordance with the requirements in the HKU-GHK IRB SOP; and
- submitting a final report in accordance with the requirements in the HKU-GHK IRB SOP upon completion or termination of the study at your study site.

In addition to the above, you are also reminded to observe and comply with other applicable regulatory and management requirements including (but not limited to):

- if required by Hong Kong laws or regulations, obtaining a certificate for clinical trial through the Hong Kong Department of Health and complying with the associated requirements; and
- obtaining the necessary consent from the management of your institution/department in accordance with the requirements of your institution/department.

Yours sincerely,
for and on behalf of
University of Hong Kong – Gleneagles Hospital Hong Kong Institutional Review Board

_____
<NAME OF CHAIRMAN/DESIGNEE>
<TITLE>

Attachments:

1. Schedule 1: Documents Reviewed with respect to the said application/submission
2. Schedule 2: List of Reviewers (including membership category) participated in reviewing the said application/submission and making the decision.

Appendix G
SOP_GQSR_011
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Safety Events Reporting Requirements

Origins of safety events:	• Local Site: SAEs observed from subjects of a principal investigator's own study site	• Other Site(s): SUSARs reported from outside a principal investigator's own study site, (e.g. SUSARs reported from another study site in the same multicentre clinical study, or from another clinical study involving the same investigational product/procedure)
Types of safety events that need to be reported to the HKU-GHK IRB:	• All SAEs	• All SUSARs
Reporting timeline:	• Fatal or life-threatening SAEs: Seven (7) calendar days from the first awareness of a SAE by the principal investigator • Other SAEs: Fifteen (15) calendar days from the first awareness of a SAE by the principal investigator	• Thirty (30) calendar days from the date of receipt of a SUSAR report by the principal investigator