Gleneagles Hospital
HONG KONG
港怡醫院

Submission Highlights
HKU-GHK Institutional Review Board (HKU-GHK IRB)

1. Application Procedures

Soft copies of all applications shall be submitted by email to ghkirb@gleneagles.hk. Key documents for submission should include but not limited to the following:

i. Covering submission letter, listing all submitted documents
ii. Clinical Research Ethics Review Application Form
iii. Protocol (with Version No. and Date)
iv. Information sheet and consent form (English & Chinese) (with Version No. and Date), if applicable
(The IRB name in Chinese is 香港大學及港怡醫院研究倫理委員會)
(Chinese documents should be prepared in Traditional Chinese)
v. Investigator's brochure, if applicable
vi. Curriculum Vitae of Principal Investigator and Co-Investigators (Signed and dated)
vii. Other study-related documents, e.g. questionnaire, assessment tools, etc.
viii. Certificate of insurance, if applicable
ix. Investigator's conflict of interest declaration form

Hard copies of both **industry-sponsored studies** and **investigator-initiated studies** shall be submitted to the Gleneagles Clinical Trials Centre (GHK CTC).

2. Preliminary Assessment

To ensure successful study implementation and multidisciplinary collaboration, the GHK CTC/ HKU-GHK IRB Secretariat would vet the submission prior to listing for full-review, based on but not limited to the following, where applicable:

i. Site feasibility (including study nature, available equipment and manpower, risks, etc.)
ii. Logistic arrangement (including drug/laboratory processing, storage, shipment, etc.)
iii. Staff training and awareness

Applicants may wish to consult the GHK CTC/HKU-GHK IRB Secretariat on the aforementioned prior to formal submission if need be. Please provide the protocol, investigator's brochure, drug/laboratory manual, and any documents that may deem necessary.

3. Fees & Charges

An initial review application fee of **HK$25,000** will be charged for industry-sponsored studies.

	Type of submission	**Fee for research ethics review by IRB for industry-sponsored trials founded on a clinical trial agreement (CTA) (Full Review or Expedited Review)**	**Fee for another Full Review due to significant changes to the study protocol**	**Total Fees**
1.	Other Industry-sponsored clinical trials	HK$25,000 (Initial application)		HK$25,000
2.	Significant changes to the study protocol that require IRB to perform another Full Review		HK$25,000	HK$25,000
3.	Significant changes to the study protocol that require IRB to perform another Full Review and legal vetting of CTA		HK$25,000	HK$25,000

4. Payment Instruction

All cheques shall be made payable to "**GHK Hospital Limited**" and mailed to the below-listed submission address. All charges are non-refundable.

5. Submission Address

Gleneagles Clinical Trials Centre (GHK CTC)
1/F, Gleneagles Hospital Hong Kong
1 Nam Fung Path, Wong Chuk Hang, Hong Kong

6. IRB Meeting for Full Review

IRB Secretariat would list the submission for full-review only upon receiving all required documents after necessary amendments and clearance from the GHK CTC/HKU-GHK IRB Secretariat well in advance, and would confirm with the Principal Investigators the date of full-review for their mandatory personal presentation in the meeting. If you would like to check the updated status of listing for full-review meetings, please contact the IRB Secretariat directly.

7. Enquiries

Email:

ghkctc@gleneagles.hk (GHK CTC)

ghkirb@gleneagles.hk (HKU-GHK IRB Secretariat)

8. HKU-GHK IRB Secretariat

Mr. Chris YIP (Tel: 3153 9775)

9. GHK CTC

Ms. Carol CHOW (Tel: 3153 9991)