

Submission Highlights

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

1. Application Procedures

All applications, excluding industry-sponsored studies, shall be submitted by email to ghkirb@gleneagles.hk. Key documents for a submission should include but not limited to the following:

- i. Covering submission letter
- ii. Research application form
- iii. Ethical approval checklist
- iv. Protocol (with Version No. and Date)
- v. 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)
- vi. Investigator's brochure, if applicable
- vii. CV of Principle Investigator (Signed and dated)
- viii. Other study-related documents, e.g. questionnaire, assessment tools, etc.
- ix. Certificate of insurance, if applicable
- x. Investigator's conflict of interest declaration form

Applications for **industry-sponsored studies** shall be submitted to the HKU Clinical Trials Centre (HKU-CTC).

2. Study Feasibility & Site Assessment

To ensure successful study implementation and multidisciplinary collaboration, the Research Office 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 Research Office 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	Fee for scientific evaluation by Scientific Review Panel	Total Fees
1.	Other Industry-sponsored clinical trials	HK\$25,000 (Initial application)		Not applicable	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

Ms Carol CHOW
In-patient Pharmacy, LG/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 a full-review only upon receiving all the required documents after necessary amendments and clearance from the Research Office well in advance, and would confirm with the Principal Investigators the date of the 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: ghkirb@gleneagles.hk

8. Secretariat

- a. Ms Catherine CHEUNG (Tel: 3153 9543)
- b. Mr Brian YEUNG (Tel: 3153 9520)
- c. Ms FOK See Kee (Tel: 3153 9546)

9. Research Office

- a. Ms Carol CHOW (Tel: 3153 9991)