

Submission Highlights & IRB Meeting Dates
HKU/HA HKW Institutional Review Board (HKU/HA HKW IRB)
香港大學及醫管局港島西醫院聯網研究倫理委員會

2023

I. APPLICATION PROCEDURES

NEW Hospital Authority Clinical Research Ethics Review Portal

All applicants have to upload your research ethics application through the HA CRER Portal
(<https://hacrerportal.ha.org.hk/>).

- (A) **IMPORTANT STEPS** to take when using the HA CRER Portal for uploading
1. Please read the Configuration, User Manuals and Quick Guides provided on the webpage.
 2. If you already have an HA e-mail account (e.g. : xxxxx@ha.org.hk) or HKU e-mail account (e.g. xxxxx@hku.hk) then you can access to the Portal after signing up:
<https://hacrerportal.ha.org.hk/>
 3. If you do not have an HA e-mail account or HKU e-mail account, then you need to sign up a User Account first.
 4. Provide details in the Application Form on the Portal.
 5. Upload all the key documents (e.g. Investigator's Brochure, Protocol, Information Sheet and Consent Forms, Assessment Tools, Questionnaires, short CV, etc) by providing the key documents a specific Document Name with Version No. and Date (e.g. *Study Protocol, Version no.01 dated 2022.05.16*) on the Portal.
 6. **Submit** your application in the Portal.
 7. Print out hard copy for All documents and obtain the required signatures and endorsements.
 8. Send in **one hard-copy set** (with the required **"Original Signatures"**) to IRB for initial checking. Extra copies (depending on the type of review) may be required later as listed below.
 9. We will inform you if any changes are required, so that you could revise the documents on the Portal.
 10. The required number of copies of documents for :
 - (a) **Expedited Review: 2 hard copies** (with 1 copy having the required Original Signatures) for **ALL** types of documents; or
 - (b) **Full Review:** (i) **1 hard copy** with Original Signatures and ALL types of documents; (ii) **8 hard copies** of : Application Form (with copied signatures) and Informed Consent Forms (English & Chinese versions if applicable).
 11. Key documents for a submission should include the following:
 - (a) Research Submission
 - i. Covering submission letter
 - ii. Application form
 - iii. Protocol (with Version No. and Date)
 - iv. Investigator's brochure (applicable to clinical drug trials)
 - v. Information sheet and consent form (English & Chinese) (with Version No. and Date), (The IRB name in Chinese is 香港大學及醫管局港島西醫院聯網研究倫理委員會). (Chinese documents should be prepared in Traditional Chinese).
 - vi. Principal Investigator's short CV.
 - vii. Other study-related documents, e.g. questionnaire, assessment tools, etc.
 - viii. Certificate of insurance, if applicable
 - ix. Declaration of support from other departments/services form, if applicable

(b) Case Report Submission

- i. Application form
- ii. Abstract of Case Report
- iii. Journal's ethical requirement
- iv. Patient's Consent Form (if applicable)

For post-approval applications, please send in 1 hard copy with Original Signature and concerned document(s) to IRB, and then you can click “**Submit**” in HA CRER Portal directly. Portal application is only exempted for projects submitted via Old Portal or other means (please send in 1 hard copy with Original Signature and concerned document(s) and 1 soft copy (by CD-R/USB) of concerned document(s) to IRB).

II. Review Fees

	Type of Submission	Fee for research ethics review by IRB for company-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.	Phase 1 clinical trial	HK\$17,500 (initial application) (or US\$2,320*)		HK\$12,500 (or US\$1,670*)	HK\$30,000 (or US\$3,990*)
2.	Other company-sponsored clinical trials	HK\$17,500 (initial application) (or US\$2,320*)		Not applicable	HK\$17,500 (or US\$2,320*)
3.	Significant changes to the study protocol that require IRB to perform another Full Review		HK\$14,000 (or US\$1,865*)		HK\$14,000 (or US\$1,865*)
4.	Significant changes to the study protocol that require IRB to perform another Full Review and legal vetting of CTA		HK\$17,500 (or US\$2,320*)		HK\$17,500 (or US\$2,320*)

* with bank charges

A cheque made payable to “Hospital Authority - Queen Mary Hospital” is required to be submitted together with the application documents. All charges are non-refundable.

III. Endorsement on the application form by Chief of Service or Head of Department (or authorized representatives)

1. For HKU (Faculty of Medicine/Dentistry) staff, if the principal investigator / co-investigator is a Head of Department, the application form has to be endorsed by the Associate Dean (Research).
2. For HA staff, if the principal investigator /co-investigator is a Chief of Service, the application form has to be endorsed by the appropriate Hospital Chief Executive (HCE), or the appropriate Cluster Chief Executive (CCE) should the HCE is also participating in the research concerned.

IV. Submission address

The Secretary, HKU/HA HKW Institutional Review Board
Room 901, 9/F, Administration Block, Queen Mary Hospital,
102 Pok Fu Lam Road,
Hong Kong.

V. Enquiries

E-mail: hkwirb@ha.org.hk

Secretariat

- a. Ms. Jenny Ng (Tel: 2255 4086)
- b. Mr. Chris Yip (Tel: 2255 3144)
- c. Ms. Emily TSE (Tel: 2255 3923)
- d. Ms. Julia TONG (Tel: 2255 6788)
- e. Ms. Clara LEUNG (Tel: 2255 4162)
- f. Ms. Kelly LEE (Tel: 2255 6789)

VI. IRB Meeting Dates for Full-Review

IRB Secretariat would list the submission for a full-review only upon receiving all the required documents after necessary amendments 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 IRB Secretary directly.

Full-Review Meeting Dates-2023

Month	Dates of meeting (Tuesday /Wednesday)				Status of Submission Listing (as at Version Date)
June 2023	21	Jun	2023	Wednesday	Accepting submissions
July 2023	4	Jul	2023	Tuesday	
	19	Jul	2023	Wednesday	
August 2023	1	Aug	2023	Tuesday	
	16	Aug	2023	Wednesday	
September 2023	5	Sept	2023	Tuesday	
	20	Sept	2023	Wednesday	
October 2023	3	Oct	2023	Tuesday	
	18	Oct	2023	Wednesday	
November 2023	7	Nov	2023	Tuesday	
	22	Nov	2023	Wednesday	
December 2023	5	Dec	2023	Tuesday	
	20	Dec	2023	Wednesday	

- END -