

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

2022

I. APPLICATION PROCEDURES

(A) **Hospital Authority (HA) Clinical Research Ethics Review (CRER) Portal**

All applicants have to upload your research ethics application through the HA CRER Portal

(<https://harec.ha.org.hk/Portal>).

(B) **IMPORTANT STEPS** to take when using the HA CRER Portal for uploading

1. Please read the Configuration, User Manuals and Quick Guides provided on this 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://harec.ha.org.hk/Portal>
3. If you do not have an HA e-mail account or HKU e-mail account, then you need to follow the steps in the **Applicant's User Manual** to access the Portal by signing up a User Account first.
4. Provide details in the Application Form on the Portal.
5. Attach 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 2016.11.29*).
6. Save your documents as **DRAFT** in the Portal (i.e. **DO NOT submit** it via Portal at this stage).
7. Print out one hard copy for All documents and to obtain the required signatures and endorsements.
8. Send in **one hard-copy set** (with the required **“Original Signatures”**) and **one soft copy (by CD-R) for ALL your documents** to IRB. For the CD-R, please save each type of documents one by one into the CD-R.
9. We will inform you if any changes are required, so that you could revise the documents directly in your **DRAFT** 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) and **1 soft copy (by Cd-R)** for **ALL** types of documents ;or
 - (b) **Full Review: 1 hard copy** with Original Signatures and **1 soft copy (by Cd-R)** for **ALL** types of documents and **10 hard copies** of : Application Form (with copied signatures) and Informed Consent Forms (English & Chinese versions if applicable).
11. We will inform you to carry out **“Submit”** on the Portal if the documents are in order.
12. 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

13. For post-approval applications, please send in 1 hard copy with Original Signature and 1 soft copy (by CD-R) of concerned document(s) to IRB, and then you can click "**Submit**" directly.

(C) **The HA CRER Portal WILL NOT apply to all types of post-approval activities of applications approved in/before 2016, as listed below:**

- a. Protocol amendments;
- b. Progress reports;
- c. Serious Adverse Event (SAE) reports;
- d. Notifications and reports;
- e. Final report

*Applicants are only required to submit **one hard copy (with Original Signature) and one soft copy (by CD-R)** of concerned documents to IRB for processing. **NO Portal uploading** is required for all these types of post-approval applications which fall within this category (i.e. your application was first approved in /before 2016).*

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. Mr. Chris YIP (Tel: 2255 4086)
- b. Ms. Emily TSE (Tel: 2255 3923)
- c. Ms. Julia TONG (Tel: 2255 6788)
- d. Ms. Clara LEUNG (Tel: 2255 4162)

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-2022

Month	Dates of meeting (Tuesday /Wednesday)				Status of Submission Listing (as at Version Date)
February 2022	23	Feb	2022	Wednesday	Accepting submissions
March 2022	8	Mar	2022	Tuesday	
	23	Mar	2022	Wednesday	
April 2022	12	Apr	2022	Tuesday	
	27	Apr	2022	Wednesday	
May 2022	10	May	2022	Tuesday	
	25	May	2022	Wednesday	
June 2022	7	Jun	2022	Tuesday	
	22	Jun	2022	Wednesday	
July 2022	5	Jul	2022	Tuesday	
	20	Jul	2022	Wednesday	
August 2022	2	Aug	2022	Tuesday	
	17	Aug	2022	Wednesday	
September 2022	6	Sept	2022	Tuesday	
	21	Sept	2022	Wednesday	
October 2022	11	Oct	2022	Tuesday	
	26	Oct	2022	Wednesday	
November 2022	8	Nov	2022	Tuesday	
	23	Nov	2022	Wednesday	
December 2022	6	Dec	2022	Tuesday	
	21	Dec	2022	Wednesday	

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