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

## 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.
   *(Remark: Please state the primary affiliation of all investigators when filling in all parts of the Form, including the Team Member Form and Personal Particulars of Site Principal Investigator (PI).*
   *For HKU staff, please state Cluster as Others and Hospital/Institution as HKU.*
   *For HA staff, please state Cluster as HKWC and complete your primary affiliated hospital.)*
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 2024.01.15* ) 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).
    vi. All Investigators' short CVs.
    vii. All Investigators' Conflict of Interest Declaration Forms
    viii. Other study-related documents, e.g. questionnaire, assessment tools, etc.
    ix. Certificate of insurance, if applicable
    x. 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 (if applicable)** | **Total Fees** |
|---|---|---|---|---|---|
| 1. | Phase 1 clinical trial | HK$17,500 (initial application) (or US$2,320*) | | HK$20,000 (or US$2,548*) | HK$37,500 (or US$4,868*) |
| 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. Ms. Emily Tse (Tel: 2255 3923)
c. Ms. Julia Tong (Tel: 2255 6788)
d. Ms. Clara Leung (Tel: 2255 4162)
e. Ms. Heidi Chan (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 investigator the date of the full-review for the mandatory presentation by the principal investigator (or their co-investigators, if applied) in the meeting. IRB Secretariat may inform principal investigator to include a PowerPoint that summarizes the study if presentation is not mandatory. If you would like to check the updated status of listing for full-review meetings, please contact IRB Secretary directly.

# Full-Review Meeting Dates

# 2025

| Month | | Dates of meeting (Tuesday /Wednesday) | | | |
|---|---|---|---|---|---|
| January | 2025 | 7 | Jan | 2025 | Tuesday |
| | | 22 | Jan | 2025 | Wednesday |
| February | 2025 | 4 | Feb | 2025 | Tuesday |
| | | 19 | Feb | 2025 | Wednesday |
| March | 2025 | 4 | Mar | 2025 | Tuesday |
| | | 19 | Mar | 2025 | Wednesday |
| April | 2025 | 1 | Apr | 2025 | Tuesday |
| | | 16 | Apr | 2025 | Wednesday |
| May | 2025 | 7 | May | 2025 | Wednesday |
| | | 20 | May | 2025 | Tuesday |
| June | 2025 | 3 | Jun | 2025 | Tuesday |
| | | 18 | Jun | 2025 | Wednesday |
| July | 2025 | 8 | Jul | 2025 | Tuesday |
| | | 23 | Jul | 2025 | Wednesday |
| August | 2025 | 5 | Aug | 2025 | Tuesday |
| | | 20 | Aug | 2025 | Wednesday |
| September | 2025 | 2 | Sept | 2025 | Tuesday |
| | | 17 | Sept | 2025 | Wednesday |
| October | 2025 | 8 | Oct | 2025 | Wednesday |
| | | 21 | Oct | 2025 | Tuesday |
| November | 2025 | 4 | Nov | 2025 | Tuesday |
| | | 19 | Nov | 2025 | Wednesday |
| December | 2025 | 2 | Dec | 2025 | Tuesday |
| | | 17 | Dec | 2025 | Wednesday |

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