**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

# 2021/2022

## 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. Julia TONG (Tel : 2255 6788)
c. Ms. Minnie LAW (Tel : 2255 6789)
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-2021/2022

| Month | | Dates of meeting (Tuesday /Wednesday) | | | | Status of Submission Listing ( as at Version Date ) |
|---|---|---|---|---|---|---|
| November | 2021 | 24 | Nov | 2021 | Wednesday | Accepting submissions |
| December | 2021 | 7 | Dec | 2021 | Tuesday | |
| | | 22 | Dec | 2021 | Wednesday | |
| January | 2022 | 4 | Jan | 2022 | Tuesday | |
| | | 19 | Jan | 2022 | Wednesday | |
| February | 2022 | 8 | Feb | 2022 | Tuesday | |
| | | 23 | Feb | 2022 | Wednesday | |
| 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 | |

**- END -**