

Submission Highlights & IRB Meeting Dates
HKU/HA HKW Institutional Review Board (HKU/HA HKW IRB)

2017/2018

I. APPLICATION PROCEDURES

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

All applicants have to upload your research ethics application through the new HA CRER Portal (<https://harec.ha.org.hk/Portal>) w.e.f. 29th November 2016.

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

1. Please read the Configuration, User Manuals and Quick Guide 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 (such as Investigator's Brochure, Protocol, Information Sheet and Consent Forms, Assessment Tools, Questionnaires, short CV, etc....., wherever applicable) 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 of All your documents and to obtain the required signatures and endorsements and then
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 Portal
10. We will inform you to send in the required no. 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 Consents, English & Chinese
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 with all Chinese documents in **“Full Traditional Chinese”** version :
 - a. Covering submission letter
 - b. Application form
 - c. Protocol (with Version No. and Date)
 - d. Investigator's brochure (if applicable)
 - e. Information sheet and consent form (English & Chinese) (with Version No. and Date)
 - f. PI's short CV
 - g. Other study-related documents, e.g. questionnaire, assessment tools, etc.
 - h. Certificate of insurance, if applicable

- i. Declaration of support from other departments/services form, if applicable

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 New HA CRER Portal **WILL NOT** apply to all types of post-approval activities of applications approved in/before 2016 (For easy identification of this category of submissions, their IRB Reference No. should be : UW 16-XXXX, UW 15-XXX, UW 14-XXX, UW 13-XXX, UW 12-XXX, and years for 2011, 2010.....etc) :

For all types of post-approval activities of approved applications, such as :

- a. Protocol amendments;
- b. Progress reports;
- c. SAE reports;
- d. Study-related documents reporting;
- 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).And you still need to use the forms provided on this webpage to perform the above-mentioned post-approval activities.*

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 scientific evaluation by Scientific Review Panel | Total Fees |
|----|--|--|--|-------------------------------|
| 1. | Phase 1 clinical trial | HK\$15,000 (initial application) (or US\$1,980*) | HK\$11,500 (or US\$1,526*) | HK\$26,500 (or US\$3,506*) |
| 2. | Other company-sponsored clinical trials | HK\$15,000 (initial application) (or US\$1,980*) | Not applicable | HK\$15,000 (or US\$1,980*) |
| 3. | Major changes to the study protocol of an IRB approved company-sponsored clinical trials | HK\$12,000 (or US\$1,590*) | | HK\$12,000 (or US\$1,590*) |

* 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 Affairs); or one of the Assistant Deans (Research Affairs) should the Associate Dean is also participating in the research concerned; and
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, Administration Block, Queen Mary Hospital,
102, Pok Fu Lam Road,
Hong Kong.

V. Enquiries

E-mail: hkwirb@ha.org.hk

FAX no. : 2255 4735

Secretariat

- a. Mr. Chris YIP (Tel: 2255 4086)
- b. Ms. Margaret WOO (Tel: 2255 3923)
- c. Ms. Julia TONG (Tel : 2255 6788)
- d. Ms. Minnie LAW (Tel : 2255 6789)
- e. 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 2017/2018

| Month | | Dates of meeting (Tuesday /Wednesday) | | | | Status of Submission Listing (as at Version Date) |
|--------------|------|--|------|------|-----------|--|
| October | 2017 | 10 | Oct | 2017 | Tuesday | Accepting submissions |
| | | 25 | Oct | 2017 | Wednesday | |
| November | 2017 | 07 | Nov | 2017 | Tuesday | |
| | | 22 | Nov | 2017 | Wednesday | |
| December | 2017 | 05 | Dec | 2017 | Tuesday | |
| | | 20 | Dec | 2017 | Wednesday | |
| January | 2018 | 9 | Jan | 2018 | Tuesday | |
| | | 24 | Jan | 2018 | Wednesday | |
| February | 2018 | 6 | Feb | 2018 | Tuesday | |
| | | 28 | Feb | 2018 | Wednesday | |
| March | 2018 | 13 | Mar | 2018 | Tuesday | |
| | | 28 | Mar | 2018 | Wednesday | |
| April | 2018 | 10 | Apr | 2018 | Tuesday | |
| | | 25 | Apr | 2018 | Wednesday | |
| May | 2018 | 8 | May | 2018 | Tuesday | |
| | | 30 | May | 2018 | Wednesday | |
| June | 2018 | 12 | Jun | 2018 | Tuesday | |
| | | 27 | Jun | 2018 | Wednesday | |
| July | 2018 | 10 | Jul | 2018 | Tuesday | |
| | | 25 | Jul | 2018 | Wednesday | |
| August | 2018 | 7 | Aug | 2018 | Tuesday | |
| | | 22 | Aug | 2018 | Wednesday | |
| September | 2018 | 4 | Sept | 2018 | Tuesday | |
| | | 19 | Sept | 2018 | Wednesday | |
| October | 2018 | 9 | Oct | 2018 | Tuesday | |
| | | 24 | Oct | 2018 | Wednesday | |
| November | 2018 | 6 | Nov | 2018 | Tuesday | |
| | | 21 | Nov | 2018 | Wednesday | |
| December | 2018 | 4 | Dec | 2018 | Tuesday | |
| | | 19 | Dec | 2018 | Wednesday | |

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