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

(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)

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

<table>
<thead>
<tr>
<th>Type of Submission</th>
<th>Fee for research ethics review by IRB for company-sponsored trials founded on a clinical trial agreement (CTA) (Full Review or Expedited Review)</th>
<th>Fee for another Full-Review due to significant changes to the study protocol</th>
<th>Fee for scientific evaluation by Scientific Review Panel</th>
<th>Total Fees</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Phase 1 clinical trial</td>
<td>HK$17,500 (initial application) (or US$2,320*)</td>
<td>HK$12,500 (or US$1,670*)</td>
<td>HK$30,000 (or US$3,990*)</td>
<td>HK$17,500 (or US$2,320*)</td>
</tr>
<tr>
<td>2. Other company-sponsored clinical trials</td>
<td>HK$17,500 (initial application) (or US$2,320*)</td>
<td>Not applicable</td>
<td>HK$17,500 (or US$2,320*)</td>
<td>HK$17,500 (or US$2,320*)</td>
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<tr>
<td>3. Significant changes to the study protocol that require IRB to perform another Full Review</td>
<td>HK$14,000 (or US$1,865*)</td>
<td>HK$14,000 (or US$1,865*)</td>
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<td>HK$14,000 (or US$1,865*)</td>
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<tr>
<td>4. Significant changes to the study protocol that require IRB to perform another Full Review and legal vetting of CTA</td>
<td>HK$17,500 (or US$2,320*)</td>
<td>HK$17,500 (or US$2,320*)</td>
<td>HK$17,500 (or US$2,320*)</td>
<td>HK$17,500 (or US$2,320*)</td>
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* 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)
e. Ms. Angie Sin (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-2022

<table>
<thead>
<tr>
<th>Month</th>
<th>Dates of meeting (Tuesday /Wednesday)</th>
<th>Status of Submission Listing (as at Version Date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2022</td>
<td>10 May 2022 Tuesday</td>
<td>Accepting submissions</td>
</tr>
<tr>
<td></td>
<td>25 May 2022 Wednesday</td>
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<tr>
<td>June 2022</td>
<td>7 Jun 2022 Tuesday</td>
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<tr>
<td></td>
<td>22 Jun 2022 Wednesday</td>
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<tr>
<td>July 2022</td>
<td>5 Jul 2022 Tuesday</td>
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<tr>
<td></td>
<td>20 Jul 2022 Wednesday</td>
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<tr>
<td>August 2022</td>
<td>2 Aug 2022 Tuesday</td>
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<td></td>
<td>17 Aug 2022 Wednesday</td>
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<tr>
<td>September 2022</td>
<td>6 Sept 2022 Tuesday</td>
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<tr>
<td></td>
<td>21 Sept 2022 Wednesday</td>
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<tr>
<td>October 2022</td>
<td>11 Oct 2022 Tuesday</td>
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<td>26 Oct 2022 Wednesday</td>
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<td>November 2022</td>
<td>8 Nov 2022 Tuesday</td>
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<td></td>
<td>23 Nov 2022 Wednesday</td>
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<td>December 2022</td>
<td>6 Dec 2022 Tuesday</td>
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<td>21 Dec 2022 Wednesday</td>
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