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 (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.
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. 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 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. Covering submission letter
    b. Application form
    c. Protocol (with Version No. and Date)
    d. Investigator's brochure (applicable to clinical drug trials)
    e. 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.
    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 HA CRER Portal **WILL NOT** apply to all types of post-approval activities of applications approved in/before 2016.

*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

<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$30,000 (or US$3,990*)</td>
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<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>
<td>HK$14,000 (or US$1,865*)</td>
<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>
</tr>
</tbody>
</table>

* 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.

Version Date: 17th November 2020
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. Sonnia WONG (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 2021

<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>January 2021</td>
<td>5 Jan 2021 Tuesday</td>
<td>Accepting submissions</td>
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<tr>
<td></td>
<td>20 Jan 2021 Wednesday</td>
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<tr>
<td>February 2021</td>
<td>2 Feb 2021 Tuesday</td>
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<tr>
<td></td>
<td>24 Feb 2021 Wednesday</td>
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</tr>
<tr>
<td>March 2021</td>
<td>9 Mar 2021 Tuesday</td>
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<tr>
<td></td>
<td>24 Mar 2021 Wednesday</td>
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<tr>
<td>April 2021</td>
<td>13 Apr 2021 Tuesday</td>
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<tr>
<td></td>
<td>28 Apr 2021 Wednesday</td>
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<tr>
<td>May 2021</td>
<td>11 May 2021 Tuesday</td>
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<tr>
<td></td>
<td>26 May 2021 Wednesday</td>
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<tr>
<td>June 2021</td>
<td>8 Jun 2021 Tuesday</td>
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<tr>
<td></td>
<td>23 Jun 2021 Wednesday</td>
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<tr>
<td>July 2021</td>
<td>6 Jul 2021 Tuesday</td>
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<td></td>
<td>21 Jul 2021 Wednesday</td>
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<tr>
<td>August 2021</td>
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<td></td>
<td>18 Aug 2021 Wednesday</td>
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<tr>
<td>September 2021</td>
<td>7 Sept 2021 Tuesday</td>
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<td>29 Sept 2021 Wednesday</td>
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<tr>
<td>October 2021</td>
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<td>27 Oct 2021 Wednesday</td>
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<tr>
<td>November 2021</td>
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<tr>
<td></td>
<td>24 Nov 2021 Wednesday</td>
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<tr>
<td>December 2021</td>
<td>7 Dec 2021 Tuesday</td>
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<td>22 Dec 2021 Wednesday</td>
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