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) for 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 (w.e.f. 1st October 2017)

<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$42,500 (or US$5,990*)</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$35,000 (or US$4,620*)</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$42,000 (or US$5,530*)</td>
</tr>
<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$42,000 (or US$5,530*)</td>
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</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.
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.
<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>February 2018</td>
<td>6 Feb 2018      Tuesday</td>
<td>Accepting submissions</td>
</tr>
<tr>
<td>March 2018</td>
<td>13 Mar 2018     Tuesday</td>
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<tr>
<td></td>
<td>28 Mar 2018     Wednesday</td>
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<tr>
<td>April 2018</td>
<td>10 Apr 2018     Tuesday</td>
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<td></td>
<td>25 Apr 2018     Wednesday</td>
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<tr>
<td>May 2018</td>
<td>8 May 2018      Tuesday</td>
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<td></td>
<td>30 May 2018     Wednesday</td>
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<tr>
<td>June 2018</td>
<td>12 Jun 2018     Tuesday</td>
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<td></td>
<td>27 Jun 2018     Wednesday</td>
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<tr>
<td>July 2018</td>
<td>10 Jul 2018     Tuesday</td>
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<td></td>
<td>25 Jul 2018     Wednesday</td>
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<tr>
<td>August 2018</td>
<td>7 Aug 2018      Tuesday</td>
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<td>22 Aug 2018     Wednesday</td>
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<tr>
<td>September 2018</td>
<td>4 Sept 2018   Tuesday</td>
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<td>19 Sept 2018    Wednesday</td>
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<tr>
<td>October 2018</td>
<td>9 Oct 2018      Tuesday</td>
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<td>24 Oct 2018     Wednesday</td>
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<tr>
<td></td>
<td>21 Nov 2018     Wednesday</td>
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</tr>
<tr>
<td>December 2018</td>
<td>4 Dec 2018      Tuesday</td>
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<tr>
<td></td>
<td>19 Dec 2018     Wednesday</td>
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