

**Submission Highlights &
IRB Meeting Dates & Application Deadlines
HKU/HA HKW Institutional Review Board (HKU/HA HKW IRB)
2012**

I. Submission Highlights

- a. **FULL REVIEW** of Clinical Trial/Clinical Research

1 hard copy & 1 soft copy (by CD-R) of ALL documents including mainly:

1. Covering submission letter
2. Application form with **original signatures**. Signatures are not required in the soft copy.
3. Protocol
4. Investigator's brochure (if applicable)
5. Information sheet and consent form (English & Chinese)
6. PI's short CV
7. Other supporting documents, e.g. questionnaire, etc.
8. Certificate of insurance, if applicable
9. Declaration of support from other departments/services form, if applicable
10. Investigator's conflict of interest declaration form, if applicable

13 hardcopies of the following documents ONLY:

1. Application form with copied signatures
2. Information sheet and consent form (English & Chinese)

- b. **EXPEDITED REVIEW** (for criteria for expedited review, please refer to Section 9 of IRB Standard Operating Procedures)

3 hardcopies & 1 soft copy (by floppy disk /CD-R) of ALL documents, including mainly:

1. Covering submission letter
2. Application form with one of the 3 hard copies having the **original signatures**. Signatures are not required in the soft copy.
3. Protocol
4. Information sheet and consent form (English & Chinese)
5. PI's short CV
6. Other supporting documents, e.g. questionnaire, etc.
7. Declaration of support from other departments/services form, if applicable
8. Investigator's conflict of interest declaration form, if applicable

c. **Protocol amendment submission** (w.e.f. 1st January 2012)**1 hard copy & 1 soft copy (by floppy disk /CD-R) for the following documents :**

1. Protocol amendment form
2. All the amended study-related documents as a result of the proposed amendments, if any.

d. **Application fee**

The charging rates for company-sponsored clinical trial founded on a clinical trial agreement (CTA) are revised as follows:

(Including multi-cluster trials)	Full review	Expedited review
1. For each initial application	HK\$15,000 (or US\$2,013*)	HK\$15,000 (or US\$2,013*)
2. For each subsequent submission – major changes to the study protocol	HK\$12,000 (or US\$1,628*)	NA

* with bank charges

A cheque made payable to “Queen Mary Hospital” is required to be submitted together with the application documents. All charges are non-refundable.

e. **Endorsement of 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.

II. Submission address

The Secretary, HKU/HA HKW Institutional Review Board
Room 901, Administration Block, Queen Mary Hospital,
102, Pok Fu Lam Road,
Hong Kong.

III. Enquiries

- a. Mr. Chris YIP (Tel: 2255 4086) Email: yipcf@ha.org.hk
- b. Ms. Margaret WOO (Tel: 2255 3923) Email: woolw@ha.org.hk
- c. Ms. Mina WONG (Tel : 2255 4162) Email:wongkcm@ha.org.hk

IV. IRB Meeting Dates & Application Deadlines for Full-Review

- a. Please note that the following cut-off dates are scheduled ONLY for submissions requiring Full-Review. For those submissions which requires Expedited Review (refer to p.24 of IRB Standard Operating Procedures) are NOT Required to meet the following deadlines. Documents submissions for Expedited Review can be submitted at any time when documents have been prepared.
- b. Deadlines scheduled for document submissions for Full Review are stringently adhered to. Submissions can only be processed when all the required documents are submitted on or before the deadline.
- c. The IRB Office has the discretion to re-arrange the meeting date for the submitted applications when the total submissions exceeds the number (normally 5-6) that an IRB Panel can handle at any one meeting.

2012

Month		Dates of meeting (Tuesdays)			Cut-off dates for submission (Wednesday, unless stated)		
January	2012	10	Jan	2012	19 Dec 2011 (Monday) (4.30 p.m.)		
		31	Jan	2012	11	Jan	2012 (4.30 p.m.)
February	2012	14	Feb	2012	20 Jan 2012 (Friday) (4.30 p.m.)		
		28	Feb	2012	08	Feb	2012 (4.30 p.m.)
March	2012	13	Mar	2012	22	Feb	2012 (4.30 p.m.)
April	2012	10	Apr	2012	21	Mar	2012 (4.30 p.m.)
		17	April	2012	28 Mar 2012		(4.30 p.m.)
		24	Apr	2012	02 Apr 2012 (Monday) (4.30 p.m.)		
May	2012	08	May	2012	18	Apr	2012 (4.30 p.m.)
		22	May	2012	02	May	2012 (4.30 p.m.)
June	2012	05	Jun	2012	16	May	2012 (4.30 p.m.)
		19	Jun	2012	30	May	2012 (4.30 p.m.)
July	2012	03	Jul	2012	13	Jun	2012 (4.30 p.m.)
		24	Jul	2012	04	Jul	2012 (4.30 p.m.)
August	2012	14	Aug	2012	18	Jul	2012 (4.30 p.m.)
		21	Aug	2012	01	Aug	2012 (4.30 p.m.)
September	2012	04	Sep	2012	15	Aug	2012 (4.30 p.m.)
		18	Sep	2012	29	Aug	2012 (4.30 p.m.)
October	2012	09	Oct	2012	19	Sep	2012 (4.30 p.m.)
		30	Oct	2012	10	Oct	2012 (4.30 p.m.)
November	2012	06	Nov	2012	17	Oct	2012 (4.30 p.m.)
		20	Nov	2012	31	Oct	2012 (4.30 p.m.)
December	2012	04	Dec	2012	14	Nov	2012 (4.30 p.m.)
		18	Dec	2012	28	Nov	2012 (4.30 p.m.)

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