THE UNIVERSITY OF HONG KONG

Human Research Ethics Committee

<u>Frequently Asked Questions (FAQ)</u>

1.   *Who should apply for ethical review?*

Staff members, research postgraduate, taught postgraduate and undergraduate students who are the Principal Investigator (PI) of a research project that involves human participants (including secondary data analysis) or vertebrate animal subjects must refer their research protocols for review and clearance by the appropriate ethics committee of the University.

2.   *I am not recording names or collecting new data from human participants.   Do I need to seek ethical clearance?*

Yes.   Any research project involving human participants, including the use of existing documents/records for secondary analysis of personal data, irrespective of whether or not the data are publicly available, whether or not the data originally collected are intended for research purposes and whether the personal data from existing documents/ records will be extracted for secondary analysis, should seek ethical clearance <u>prior to</u> collection or use of data.

Please note that exemption from ethical approval will only apply to anonymous surveys for improving teaching and learning (not for research) exclusively for the University's internal usage.

3.   *When should I submit my application for ethical clearance?*

There is no deadline for application for ethical clearance but you should submit your ethical application as early as possible to ensure that you fulfill your responsibility to obtain ethical approval <u>prior to</u> any data collection/analysis taking place.

4.   *To which University's ethical body should I submit my application for ethical approval?*

a)   *The Institutional Review Board of the University of Hong Kong/Hospital Authority Hong Kong West Cluster (HKU/HA HKW IRB, the "IRB")*

If a research project involves a Principal Investigator who is an academic/research staff member or student of the Faculties of Medicine or Dentistry or involves patients from any hospital, an application for ethical review should be sent to the IRB. Please refer to the <u>IRB website</u> for further details. The IRB will refer applications outside the scope of clinical studies to HREC for consideration.

b)   *The Human Research Ethics Committee (HREC)*

Staff members and students from non-clinical Faculties who are the PI of a research project (or the Co-I for a project that involves any data collection from human subjects in HKU or organized through or in the name of HKU and where the PI is not in HKU) that involves human subjects in research investigations

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should submit an application for ethical approval to the HREC. In some cases (such as when the human participants are hospital patients) ethical clearance is required from the IRB. In such cases, the HREC will refer the application to the IRB for consideration.

c)   *The Committee on the Use of Live Animals in Teaching and Research (CULATR)*

PIs of research protocols involving living animals should send their applications to the CULATR. Please refer to the CULATR's website for further details.

5.   *Where do I submit my application for ethical approval to the HREC?*

- For staff and research postgraduate (MPhil/PhD) students, please submit an online application via the Human Research Ethics Application System.

- For taught postgraduate students, please consult your Faculty. Complete either the HREC application form or the appropriate form for ethical review as advised by the Faculty and send it to the Faculty Office.

- For undergraduate students, please consult your Department/Faculty (if unitary). Complete the HREC application or the appropriate application forms for ethical review as advised by your Department with your Tutor/Supervisor as the Principal applicant, and send it to the Head of your Department/Dean of the Faculty.

Please refer to the flow chart on the procedures for applications for HREC ethical approval.

6.   *How long will the review process take?*

There are three types of review i.e. a full review by the HREC, a double review by at least two members of the HREC, or an expedited review by the Chairman of the HREC or his/her designate. (Please refer to the HREC's Operational Guidelines and Procedures to view the criteria for determining the type of review to be taken). The processing time from submission of application to notification of approval will normally take not more than 3 weeks, provided that the submitted application form is properly completed with all required documents attached.

7.   *How will I find out if my study has been approved?*

An email notification will be sent to the Principal Investigator as listed in the application. The formal approval letter can be downloaded from the Human Research Ethics Application System.

8.   *How will I find out the HREC reference number of my project?*

An HREC reference number will be assigned to each application once it is submitted to the Human Research Ethics Application System. Starting from April 1, 2015, PIs are required to include the HREC reference number in all materials sent to potential and actual participants.

9.   *Can I amend my proposal or research procedures after the Committee has reviewed and approved my study?*

Yes.   Please complete the Application for Amendment of an Approved Project (in

hardcopy) and attach a copy of any revised document(s).

10. *What can I do if I still need to collect or analyze data after the approved expiration date?*

You have to apply for extension of the ethical approval <u>prior to</u> the initially approved expiration date.   Please complete the Application for Amendment of an Approved Project and provide justifications in the application.

11. *Do I need to attend any interviews?*

Usually no, but you might be invited for an interview with the HREC if your application is in the full review category and the Committee would like to seek clarification on certain aspects of your proposal.

12. *Do I need to declare for any potential conflict of interests?*

Yes.   Any financial benefit to the investigators must be declared, as must any power relationship of the investigators over the participants (e.g. teacher/student, manager/staff) which might make participants feel obliged to participate.   There must be an explanation as to how this potential conflict will be addressed (e.g. for benefits, the benefit is declared, for teacher/student relationship, participation is not revealed to the investigator until after the exam results are determined).

13. *How should I differentiate compensation for participation from potential benefits to research participants?*

Compensation for participation does not count as potential benefits to research subjects. Normally compensation refers to how participants will be compensated for their time and can include non-monetary (participation credits, gifts/promotional items, etc.) and/or monetary (cash, gift cards, vouchers, etc.) remuneration.

14. *Am I required to obtain and document participants' consent?*

Yes.   It is essential to obtain participants' consent to participate in a research study. Prior to seeking their consent, they should be fully informed of what the study and their involvement are about so as to facilitate their decision on taking part in the study.   It is equally important to document participants' consent unless they are fully anonymous (i.e. you do not know who they are).   This can be done in the form of:

(i) written consent - participants to sign a written informed consent form;

(ii) online/email recorded consent – participants to indicate their consent through emails or by clicking "I agree" for online surveys; and

(iii) audio-recorded oral consent – where seeking written consent is not practical or too sensitive, participants to give a verbal consent to be audio-recorded.

15. *Other than procedures of the study, what is the most important information that I should include in the recruitment materials and informed consent form?*

All recruitment materials and consent forms must include a readily reachable contact of the PI or relevant personnel of the study for participants' enquiries about details of the study (normally a telephone number for studies conducted in Hong Kong, and an email address for overseas studies), the HREC's contact number for enquiries about

participants' rights and the HREC reference number assigned to each approved project as indicated in the letter of approval. Any deviation from the normal practice requires justifications when the application is submitted to the HREC. For surveys conducted by telephone and/or self-administered questionnaire, full contact   information of the HREC and also the PI concerned must be provided before data collection starts (but can be after selection of a respondent). PI will also be required to explain how long will the data containing personal identifiers be kept after publication of first paper, and whether personal identifiers will be removed for long term retention of the research data.

16. *How long can I retain the research data?*

The minimum retention period for research data and records is 3 years after publication or public release of the research to ensure that there are no problems with consent, fabrication and falsification. PIs are strongly advised to remove all personal identifiers for long term retention of their research data, in order to minimize privacy risks. No data with personal identifiers should be kept beyond 5 years after publication unless there is explicit written consent to retaining the data with personal identifiers preserved, such as in oral histories. Anonymised data and records should be retained for as long as they are of continuing value to the researcher and the wider research community.

17. *Will the project information be made available to the general public?*

To improve transparency of the ethics approval process and allow general public to search for research projects with ethical approval granted by the Committee, the project title/abbreviated project title provided by the PI in the application form, HREC reference number, ethical approval period, and name and department of the PI of all research projects approved by the HREC with effect from April 1, 2015 will be posted on a public website (http://www.rss.hku.hk/integrity/ethics-compliance/hrec-approved-projects) maintained by the Research Services until the expiry date of the ethical approval period.

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