THE UNIVERSITY OF HONG KONG

Human Research Ethics Committee

Frequently Asked Questions (FAQ)

1. *Who should apply for ethical review?*

   Staff members, students (including research postgraduate, taught postgraduate and undergraduate) and visitors of HKU 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 prior to 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. *My team is going to carry out data collection for my research that involves artefacts. Is the approval procedure similar to that for research project involving human participants?*

   Instead of submitting an online application via the Human Research Electronic Application System (HREAS), you are required to download the hard copy Application Form for Ethics Approval for Research Projects Involving Artefacts. The completed application form should be endorsed by the supervisor (for student PI) and head of department before sending to the Secretary, Human Research Ethics Committee (HREC), c/o Research Services, for processing.

4. *My research involves the study of cultural objects. How can I find out if the objects are classified as artefacts in the context of ethics approval?*

   Artefacts, for the purpose of ethical vetting, are defined as "objects which, on religious or secular grounds, are of importance for archaeology, prehistory, history, literature, art or science". There is a List of Cultural Properties / Cultural Objects under the Code of Practice for Ethical Vetting of Research Projects Involving Artefacts, which is adapted from that used by the UNESCO and UNIDROIT.

5. *I am studying in a very specialised area in artefacts. How will the HREC review my ethics application?*

   The review process will generally follow the ethics review of research projects involving human participants, but internal or external reviewers outside the Committee may be engaged if necessary.

6. *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 prior to any data collection/analysis taking place.

7. *To which University's ethics 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 IRB website 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 organised through or in the name of HKU and where the PI is not in HKU) that involves human subjects in research investigations 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.

8. *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 (HREAS).

- 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 either the HREC application form or the appropriate application form 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 (if unitary).

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

9. *Do I need to apply for ethics approval for using data from a previous research study?*

PIs using pre-existing data must complete the "Existing Data" section of the application form and have to explain how the purpose and use of the data in the current research are consistent with those specified when the data were originally collected, for otherwise, PIs must seek informed consent from participants again if they wish to use pre-existing data with personal identifiers for a new purpose.

10. *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 for details about 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 application form is properly completed with all required documents submitted.

11. *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, copying to the Co-PIs and supervisor of research student (if applicable). The formal approval letter can be downloaded from the Human Research Ethics Application System (HREAS).

12. *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 (HREAS). Starting from April 1, 2015, PIs are required to include the HREC reference number in all materials sent to potential and actual participants.

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

Yes. Please submit the Application for Amendment of an Approved Project. Starting from October 16, 2023, submission of amendments of approved projects (e.g. project extension, change of project scope, etc.) by staff and research postgraduate (RPg) students from all non-clinical Faculties should be made electronically via the Human Research Ethics Application System (HREAS).

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

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

15. *Do I need to attend any interview?*

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.

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

Yes. Any financial benefit to the investigators must be declared. Moreover, any power

relationship of the investigators over the participants (e.g. teacher/student, manager/staff) that might make participants feel obliged to participate, must also be declared. 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 examination results are determined).

17. *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.

18. *Due to limited budget, I can only offer a few vouchers to compensate the research participants for their time taken. Can I distribute the vouchers by way of lucky draw?*

PIs should be cautious of giving out compensation in the form of gaming or similar nature, including lucky draw. You are advised to refer to the following documents for further information about the need to apply for a Trade Promotion Competition License from the Office of the Licensing Authority of the Home Affairs Department under the Gambling Ordinance (Cap. 148):

How to apply for the Trade Promotion Competition Licence:
https://www.hadla.gov.hk/el/filemanager/common/docs/forms/TPC_How_to_apply_eng.pdf

Application Forms and Guide for Applicants:
https://www.hadla.gov.hk/el/filemanager/common/docs/forms/TPC_Application_Forms_Guide_eng.pdf

Enquiries about the application for a Trade Promotion Competition Licence:
Office of the Licensing Authority
Tel: (852) 2117 3916/ (852) 2117 3798
Email: hadlaenq@had.gov.hk.

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

Yes. It is essential to obtain participants' consent to participate in a 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.

20. *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 the data containing personal identifiers will be kept after publication of first paper, and whether personal identifiers will be removed for long-term retention of the research data.

21. *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 minimise 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.

22. *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, 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 (https://www.rss.hku.hk/integrity/ethics-compliance/hrec-approved-projects) maintained by the Research Services until the expiry date of the ethics approval period.

23. *I am required to submit documentary proof of ethics approval to support my grant application. How can I retrieve the record of my approval letter?*

You can do so by logging into the Human Research Ethics Application System (HREAS) and retrieve your approval letter via the following pathway:

For Approved Projects:
New Application > View Application Status > View/Download Approval Letter > Download

For Projects with amendments:
Project > View Application for Amendment Status > View/Download Approval Letter for Amendment > Download

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