HONG KONG SHUE YAN UNIVERSITY

GUIDELINES FOR THE ETHICAL CONDUCT OF RESEARCH INVOLVING HUMAN PARTICIPANTS

These guidelines for the ethical conduct of research are designed to avoid harm to research participants and to preserve their dignity, rights and welfare. Respect for the rights of the individual imports two primary ethical principles: first, that subjects should enter research voluntarily and on the basis of sufficient information (informed consent) and, second, that persons with diminished autonomy (whether because of age or capacity) should be protected from harm (including through the obtaining of informed consent from other appropriate persons). Researchers must consider how risks to privacy, of stress or psychological or physical harm can be minimized and whether the risks are reasonable in relation to the anticipated benefits of the research.

Consistent with those objectives, these guidelines are designed to ensure that consistent ethical standards are applied to research involving human subjects. To that end, ethical clearance is normally required in relation to all research by staff or students that involves collecting new data from human participants and/or using pre-existing data[1], including:

- questionnaire surveys, including by telephone, post or internet;
- group or individual interviews;
- in-depth case studies of the target participants; and
- observation of human behaviour within or outside laboratory settings.

Such ethical clearance should normally be obtained prior to any data collection/analysis taking place.

The guidelines are based on six main principles:

1 ***Minimal Risk and Risk Proportionate to Research Benefit***

Research subjects should not be exposed to risks greater than minimal physical or emotional risk; that is, risks that are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or test. In addition, any risk must be evaluated in the context of the projected benefit of the research project and the risk should not be disproportionate to the benefits to be obtained.

2 ***Informed Consent***

The researcher must obtain either verbal or written informed consent of the research participants according to the following guidelines:

(a) Voluntary informed consent should normally be obtained from any participant who is able to give such consent.

(b) Research participants should be informed that they have the right to terminate their participation at any time and that refusal to participate or withdrawal of consent will not incur any penalty or loss of benefits to which the participant might otherwise be entitled.

(c) Where consent is withdrawn, any material gathered in relation to that person cannot

[1] Usage of pre-existing data refers to retrieving readily available data, irrespective of whether the data are publicly available, whether the data were originally collected for research purposes or whether the data are de-identified.).

be used and where, in relation to any audio or video recording, any material including a person who has refused or withdrawn consent must be deleted.

(d) Researchers should avoid conducting research or obtaining consent where a conflict of interest or duty arises. For example, a teacher should not normally seek consent from or interview his or her student until all grading in the relevant course is completed (one exception might be where the research is aimed at improving course quality).

(e) Research procedures should be explained to research participants prior to their participation using language that is readily understandable by the research participants.

(f) Normally there should be a record of the fact of having obtained informed consent. There must be an official English language version of any written record, as well as a version for the participants in the language in which the research will be conducted. The recording of consent can be implemented in different ways:

- Where research involves face-to-face interviews, direct observation or similar research methods, participants should be given an information sheet and be asked to sign a consent form. The consent form may be initialed if participants wish to preserve their anonymity. The purpose of the information sheet is to ensure that the consent is in fact 'informed'.
- For online surveys, the information sheet and acknowledgment of consent should be incorporated into the survey form.
- For telephone surveys, appropriate information should be given to participants to enable an informed oral consent to be given and, where possible and appropriate, they should be given the opportunity to access an online information sheet before proceeding with the telephone interview. Wherever possible, an audio recording of verbal consent should be made in order to provide a record.
- In the case of anonymous survey research which involves minimal risk, the survey form or advice should provide all relevant information to ensure that any consent is informed and include statements to the effect that no one will be able to associate the subjects' response with their identity, that participation is voluntary, and that completion of the survey signifies voluntary agreement to participate in the research project.

When it is not practical to obtain written or recorded consent in advance, the Human Research Ethics Committee may waive that requirement where the research involves only minimal risk to subjects, provided that the rights and welfare of the subjects will not be adversely affected. It remains that at least verbal informed consent should be obtained, whether directly or indirectly through a third party that is conducting the interview.

(g) The information sheet should set out the purposes of the research, the risks (including psychological distress), the benefits to the individual or to others, a statement that the participants are free to decline to participate, and significant factors that may be expected to influence their decision to participate, including the response burden and any limitations on ensuring confidentiality.

(h) In cases where a third party (e.g. spouse or other health care professional who are directly involved in the treatment and/or care of the potential participants) is involved or affected by the research, consent should also be obtained from them.

(i) In the case of school-based research involving secondary school children[2] i.e. Form 1 and above, if the research meets the requirements for an expedited review AND is anonymous, passive parental / guardian consent is sufficient (parents are informed, and while active consent is not required, the parents are given the opportunity to opt out of the research project). It remains that students should be clearly informed that their participation in the study is voluntary.

(j) Where the research takes place outside home and the school environment, parental consent is not normally required where:
- the subjects are aged 16 or above (on the basis that they are 'mature minors'), or
- the subjects are aged 12 or above and the research involves minimal risk.

(k) Parental consent is normally not required for research involving university students aged 16 or above on the grounds that they are mature minors and are treated as adults at university.

(l) Consent of a parent or legal guardian is needed for ALL other research (anonymous or non-anonymous) involving children, including primary school children.

(m) Users of existing documents or records containing personal data must complete the "Existing Data" section of the application form. This requires providing full details on the types of personal data to be used, and any appropriate informed consent forms or Personal Information Collection Statements from the original data collection process. It also requires an explanation of how this research is consistent with the purpose and use specified when the data were originally collected, as otherwise PIs must seek informed consent from participants again if they wish to use pre-existing data with personal identifiers for a new purpose.

(n) There is a need to seek consent before obtaining data in pilot studies on the grounds that the informed consent form could be tested and be refined for use in any subsequent study.

3 ***Undue Influence and Inducement to Participate***

(a) Research participants should be free from coercion of any kind and should not be pressurized to participate in any study.

(b) Subject to the following dot point, inducements, such as the provision of services or financial payments, are not permitted.

(c) Reasonable and proportionate payment for participation is permissible. However, details of all payments should be included in the Application to the Human Research Ethics Committee.

4 ***Vulnerable Research Participants***

(a) Vulnerable research participants are those who are either unable to give informed consent, or are captive participants who are less able to protect themselves, or participants who have engaged or are engaging in illegal activities

(b) Children should not be asked to be research participants if the required data could be obtained from adults.

(c) Interviewing young children should either be undertaken by a researcher with the presence of another adult or take place in areas where the researcher and child are not entirely alone to protect the researcher as well as the child.

(d) For research studies involving individuals who are not capable of giving informed consent because of their mental status (e.g. mental patients or individuals with

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[2] For the purposes of these Guidelines, 'child' means a person who has not reached the age of 18, within the meaning of the Hong Kong *Age of Majority Ordinance* (cap. 410).

cognitive disabilities), informed consent should be obtained from an appropriate person (e.g. legal guardian, an immediate relative, an attending physician). To the extent possible, consent should also be obtained from the participants themselves and on the basis of the fullest information that it is reasonable to provide in the circumstances. The same principles apply to elderly or acutely ill individuals who may not be able to make informed decisions regarding research participation.

(e) As far as possible care should be taken to avoid using as research participants people who are in a potentially dual or dependent relationship with the researcher (e.g. students, employees), as willingness to participate may be unduly influenced by power differences or by the expectations of advantageous benefits or penalties.

5 ***Research Involving Deception of Participants***

(a) The use of one-way mirrors must be clearly justified.

(b) Some research cannot effectively be carried out without some deception of the subjects as to the nature of the research. In circumstances where there is minimal risk, minor deception is permissible, providing that prior approval has been obtained from the Human Research Ethics Committee. In seeking that approval, the researcher must explain in detail why the research could not practicably be carried out without the deception, and why the deception will not adversely affect the well being of the participants in a significant way. All deception must be explained to participants as early as feasible, preferably at the conclusion of their participation, but in any case no later than at the conclusion of the research. At the time of that debriefing, the participant must be given the opportunity to withdraw from any involvement in the research project, in which event any record relating to their involvement must be destroyed.

6 ***Ensuring the Confidentiality and Security of Research and Personal Data***

(a) Surveys are either anonymous or non-anonymous, and effort must be made to protect the confidentiality of research data for both types of surveys.

(b) Whatever information is obtained in the course of research should under no circumstances be publicly disclosed in a fashion that would identify any specific person or organization (except with the participants' written consent or if subpoenaed by a court of law).

(c) Except in anonymous surveys or public/naturalistic observations, the researcher should outline to prospective research participants the purpose of the collection of the personal data and what measures the researcher will take to ensure confidentiality.

(d) For projects in which the private data collected about participants is not considered to be sensitive, participants should be informed that the researcher will take precautions to preserve the confidentiality of the research data and that all reports will be devoid of identifiers.

(e) When the researcher collects sensitive personal information about participants, the researcher should specify the precautions that will be taken in the storage, use and disposal of the information in order to protect their privacy and security.

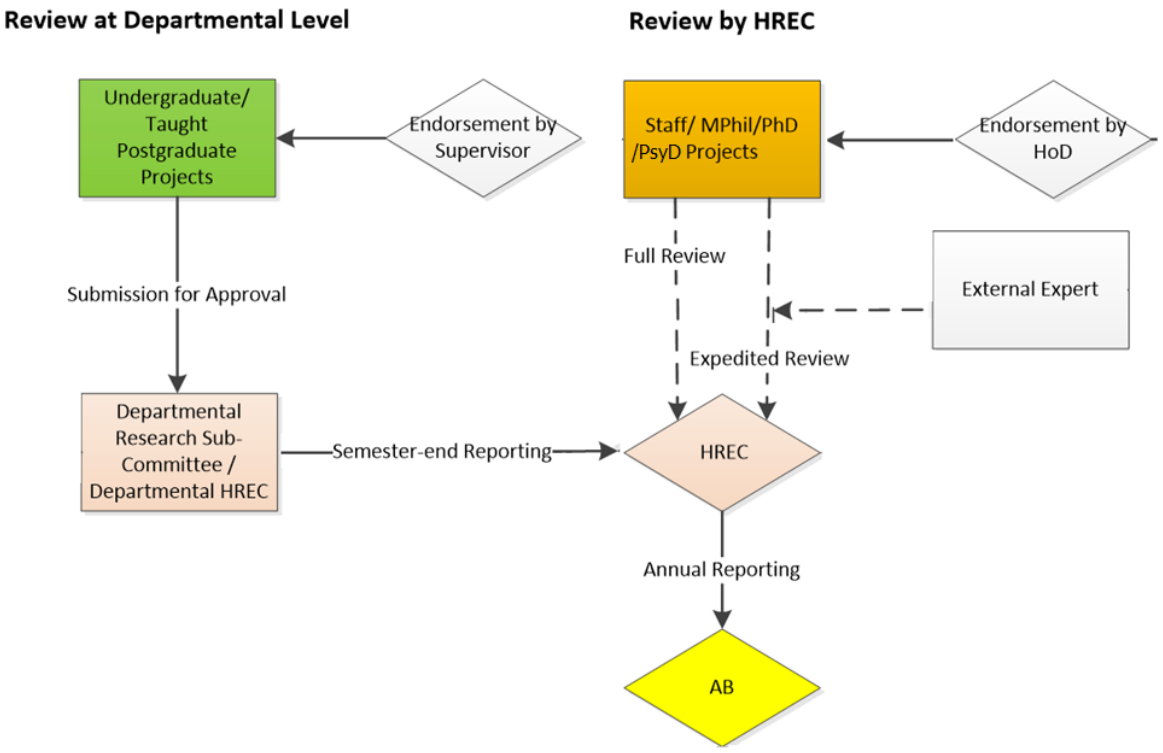
(f) Data containing personal identifiers may normally be kept for a maximum of 6 years. Researchers are strongly advised to remove all personal identifiers for long term retention of their research data, in order to minimize privacy risks. No data with personal identifiers should be kept beyond 6 years unless there is explicit written consent to retaining the data with personal identifiers preserved, such as in oral histories. For distribution of incentives such as cash coupon to participants, researchers should ensure that all personal data will be delinked.

Obligation to Comply with the Law

Researchers have an obligation to familiarize themselves with and observe legal requirements relevant to their research project. Non-observance of legal requirements can have consequences under the civil and criminal laws for both the researcher and the University. Research may be affected by diverse laws, including those in relation to data collection and dissemination, privacy, copyright, defamation, discrimination, and health and safety. In particular, researchers should be familiar with the Hong Kong *Personal Data (Privacy) Ordinance* (cap. 486) and with any applicable codes of practice. It should also be understood that generally research data is not privileged and may be subject to legal subpoena by the courts.

Procedures to Obtain Human Research Ethics Committee Approval

The university operates a two-tier review system, one for undergraduates and taught postgraduates, and another for staff and research/professional postgraduate students.



Review at Departmental Level

Applications from undergraduates and taught postgraduates will be considered only by the relevant Department, by the Project Supervisor in the first instance and reviewed and approved at departmental level. Approved cases will be signed by the Project Coordinator[3] or Programme Leader[4] and a prescribed Departmental Approval Form will be completed. A record of cases approved will be reported by individual departments to the Human Research Ethics Committee each semester. The relevant completed Departmental Approval Forms will be attached to that report.

[3] Coordinators of research-based or project-based courses, e.g., Research Thesis, Capstone Project, Dissertation, Graduate Seminar, etc.

[4] Head of Department or a designated staff appointed by Head of Department

At Departmental review level a checking mechanism will be in place to ensure that there is compliance with these guidelines, with particular reference to the obtaining of any necessary consents and the protection of the identity and personal details of any person the subject of research. Each Department will advise the Human Research Ethics Committee as to its review process and any amendments to that process.

Review by HREC

Applications from staff and research/professional postgraduate students are reviewed by HREC via expedited review or full review. Expedited review is conducted by Chair's discretion and/or 1-2 members designated by Chair subject to the number of projects accumulated within the approval period. Full review is to be conducted by full committee via a face-to-face meeting or by circulation whichever appropriate.

Researchers are required to complete the HREC application form and provide full project proposals at least 14 working days for determination of approval. Applicants are advised to submit their application in time to receive approval before their own submission deadlines.

(a) Expedited Review

In general, an expedited review is granted if none of the following is involved in a research project by staff or research/professional postgraduate students:

- Participants are unable to give informed consent.
- Deception of participants is involved.
- The study involves studying sensitive aspects of the participants' behaviour such as illegal conduct and sexual conduct.
- Disclosure of the observations on the participants will likely place the participants at risk of criminal or civil liability, or be damaging to the participants' financial standing, employability, or personal reputation.
- The study can induce more than minimal psychological stress to participants.
- Pain or discomfort that is higher than normally encountered in daily life is likely to result from participating in the research study.
- Prolonged and repetitive testing is involved.
- There is a conflict or potential conflict between these guidelines and any professional or other binding guidelines or codes of practice.

An expedited review is granted to research studies involving the collection or study of new or existing data, documents or records if:

- These sources are publicly available; or
- The participants cannot be identified in any published material and reasonable precautions are taken to preserve the confidentiality of the identity of individuals in the research data.

Researchers using existing data must complete the 'existing data' section of the application form.

(b) Full Review

Projects that fail to meet the requirements for an expedited review must go through a full review by the Human Research Ethics Committee at full committee meeting or by circulation whichever appropriate.

Validity of Approval

Ethical approval is time-limited, and will normally be granted for the duration of the project. Should any extension of ethical approval be required, the researcher has to apply for such extension well before the initially approved expiration date, and justifications for such extension must be provided in the application.

External Inputs

Two senior external research academics will be appointed to serve as advisors to the Committee on ethical issues and procedures, as well as to keep the University abreast of the latest developments on research ethics in the wider academic community. External advisors will be invited to:

- attend full committee meeting;
- comment on HREC annual report for submission to Academic Board; and
- review cases on an ad hoc basis as required.

In addition, further external or expert inputs in related disciplines will be sought in specialized projects on a case-by-case basis to ensure ethical integrity and minimize hazard/risk to participants, if necessary.

Amendments to HREC's Approved Study

All project team members have the responsibility to adhere to the study protocol and other related documents/materials approved by the HREC. No amendment or change to any approved study protocol and documents shall be implemented without the HREC's approval, except:

(1) if an amendment/change is only of an administrative or logistical nature (e.g., grammatical or editorial changes); or
(2) if approval of the change does not rest with HREC (e.g., project extension).
(*The Project Coordinator (PC)/Principal Investigator (PI) should notify the HREC Secretary (email: ro@hksyu.edu) of the change for update of record after the change was approved by the related approval authority*.)

In the event that any amendment or change needs to be made to any study documents/materials, the PC/PI should submit a request for amendment, and provide the list of amended items with justifications and revised documents for HREC's approval via the Secretary (email: ro@hksyu.edu). In principle, **approval from HREC must be sought prior to** the implementation of amendments that may:

(1) increase possible harm/risk to participants or affect overall risk-benefit assessment of study, e.g.,

(a) change in participant population, inclusion or exclusion criteria
(b) change in research procedures/data collection methods (e.g. increase in length of intervention or change in location where data to be collected)
(c) change in interview protocol/survey scale (e.g. collecting additional information about sensitive aspects of the participants' behavior)
(d) others

(2) affect the participants' willingness to engage in the project/experiment, e.g.,

(a) change in way of obtaining voluntary and informed consent of participants
(b) change to consent forms, the study-related information statements, etc.
(c) others

(3) increase the risk of personal information or participants' identities be disclosed, e.g.,

(a) change in recruitment strategies
(b) change in data management plan (e.g. change in storage, retention, destruction or personnel with access)
(c) change in data usage (e.g. the data collected in a project will become pre-existing data for another project, but that was not mentioned in original HREC application)
(d) others