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 personal data¹, 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.

Normally, ethical clearance is not required for:

- interviews or public observation of elected or appointed public officials or candidates for public office; nor
- surveys conducted for the purpose of market research, that do not involve the disclosure of any personal details by the participants or reveal the identity of any person.

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.

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¹ Usage of pre-existing data refers to retrieving readily available personal data from existing documents/records for secondary analysis, irrespective of whether or not the data are publicly available and whether or not the data originally collected were intentionally for research purposes.
2 Informed Consent

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

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

• 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.

• Where consent is withdrawn, any material gathered in relation to that person cannot 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.

• 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).

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

• Normally there should be a record of the fact of having obtained informed consent. There must be a version in the language in which the research will be conducted and a version of any written record, as well as an official English language version. 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.

• 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.

- 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.
- In the case of school-based research involving secondary school children\(^2\) i.e. Form 1 and above, if the research is anonymous, passive parental 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.
- Where the research takes place outside 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.
- Consent of a parent or legal guardian is needed for ALL other research (anonymous or non-anonymous) involving children, including primary school children.
- 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.
- 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
- Research participants should be free from coercion of any kind and should not be pressurized to participate in any study.
- Subject to the following dot point, inducements, such as the provision of services or financial payments, are not permitted.
- 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
- 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
- Children should not be asked to be research participants if the required data could be obtained from adults.

\(^2\) 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).
Interviewing children should either be undertaken by two researchers or take place in areas where the researcher and child are not entirely alone to protect the researcher as well as the child.

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 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.

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

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

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

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

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).

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.

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.

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.
• 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.

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 Master’s students and another for staff and postgraduate research students.

Review at Departmental Level

Applications from undergraduate and taught Master’s students 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 or Programme Leader 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.

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.

Full Review by HREC

Applications from staff and postgraduate research students must go through a full review by the Human Research Ethics Committee. These researchers are required to complete the HREC application form and provide full project proposals.

An annual report from the Committee will be considered by the Academic Board.

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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
Validity of Approval

Ethical approval is time-limited, and will normally be granted for one to two years in the first instance. 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 (Professor John Bacon-Shone (HKU) and Professor Alfred CHAN Cheung-ming (LN)) have been 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.

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.

Revised 17 June 2016
Revised: 18 January 2012
AB approved: 16 March 2012
Revised 4th November 2013
HONG KONG SHUE YAN UNIVERSITY  
Human Research Ethics Committee  

Application Form for Ethical Approval

Notes:
(1) Please read carefully the University’s Guidelines for Human Research Ethics, available at Moodle before completing this Form.
(2) The completed application form (of staff and of postgraduate research projects), together with all related documents, should be sent to the Secretary, HREC.
(3) Please note that ethical approval must be obtained prior to any data collection or analysis taking place.

Part A – Outline of Application

1. Research Proposal

<table>
<thead>
<tr>
<th>Study title:</th>
</tr>
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</table>

Data Collection Period: Please check and fill out the one that applies:
- □ Data collection/analysis will start as soon as ethical approval is obtained.
- □ From _________________________ to _________________________ (dd/mm/yyyy).

Note: Ethical approval MUST be obtained prior to any data collection or analysis taking place.

<table>
<thead>
<tr>
<th>Project Start / End Dates: From _______________________ to _______________________ (dd/mm/yyyy)</th>
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</table>

2. Principal Investigator (PI)

<table>
<thead>
<tr>
<th>Title:</th>
<th>Surname:</th>
<th>First name:</th>
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<tr>
<td>Position / Staff Grade:</td>
<td>Staff No.:</td>
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<tr>
<td>Contact - Tel:</td>
<td>Email:</td>
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</table>

For postgraduate research student PI only:

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<thead>
<tr>
<th>Programme / Year:</th>
<th>Student No.:</th>
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<tbody>
<tr>
<td>Name of Supervisor:</td>
<td>Supervisor Email:</td>
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3. Co-Investigators (Co-I), if any

<table>
<thead>
<tr>
<th>Name (Surname, First name)</th>
<th>Department / Institution, if not HKSYU</th>
<th>Position (For staff Co-I only)</th>
<th>Programme (For student Co-I only)</th>
<th>Email Address</th>
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4. Funding

<table>
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<tr>
<th>Funding source</th>
<th>Please check all that apply, and then specify the funding scheme below:</th>
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<tbody>
<tr>
<td>HKSYU RSDC</td>
<td></td>
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<tr>
<td>Research Grants Council</td>
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<tr>
<td>Other external grant</td>
<td></td>
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<tr>
<td>Contract Research</td>
<td></td>
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<tr>
<td>No funding</td>
<td></td>
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</table>
Part B – Proposal/Project Details

Please provide a summary in the sections below of the details of the project in layman terms. (Do not enter “see attached”.)

<table>
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<tr>
<th>5. Objectives of Study</th>
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<tbody>
<tr>
<td>(1)</td>
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<td>(2)</td>
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<tr>
<td>(3)</td>
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<td>(4)</td>
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<td>(5)</td>
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</table>

6. Hypothesis, if any

7. Elements of research methodology that involve human participants (not more than 1/2 page)

Part C – Data collection

8. Sources of data

Please check all that apply:

- □ New data to be collected from human participants
  - Experimental procedures / Treatment / Intervention
  - Focus group
  - Internet survey
  - Observation
  - Personal interviews
  - Self-administered questionnaire
  - Telephone survey
  - Others: please specify ___________________________

- □ Pre-existing data from human subjects

9. Study participants – for new data to be collected

(a) Recruitment and selection of participants
   (i) How will participants be recruited?

   (ii) Participant inclusion criteria (e.g. Hong Kong residents aged 18 years and above):

   Participant exclusion criteria (e.g. Non Cantonese speakers)

(b) Who will perform the data collection?

(c) Where will the data collection take place, and how long will it take?

(d) Possible benefits to participants:

10. Risk assessment – for new data to be collected from human participants

(a) Will the study involve intervention, such as action research / treatment of any type? Yes □ No □

   If “Yes”, please give details:

   ___________________________
(b) Will the study involve initial deception of the full context of the study to avoid bias?  
Yes [ ] No [ ]

If “Yes”, please provide details and attach the debriefing form:

(c) Before any attempts are made to minimize privacy risk (e.g. making the forms anonymous), is it possible that the study will involve greater than minimal privacy risks to research participants, either due to collection of sensitive data, such as political behaviour, illegal conduct, drug or alcohol use and sexual conduct?  
Yes [ ] No [ ]

(d) Is it possible that the duration of the procedures will induce greater than minimal stress, in particular, for children, given their age and capacity?  
Yes [ ] No [ ]

(e) Is it possible that the study will induce greater than minimal psychological stress/pain/discomfort?  
Yes [ ] No [ ]

(f) Is it possible that the study will expose participants to greater than minimal physical or medical risk?  
Yes [ ] No [ ]

Note: Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

If “Yes” to any of Questions (c) to (f), please state the precautions taken to minimize such stress/pain/discomfort/risk:

(g) Will photography or video-recording of participants be used during the study?  
Yes [ ] No [ ]

(h) Will audio-recording be used during the study?  
Yes [ ] No [ ]

If “Yes” to Questions (g) and/or (h), please provide details and justifications for the recording, and storage strategies:

(i) Will the study involve vulnerable participants who are unable to give informed consent, e.g. under the age of 18, mentally handicapped individuals?  
Yes [ ] No [ ]

If “Yes”, please specify details of the age group and/or vulnerability, and attach a Parent/Guardian Consent form:

(j) Is there any potential conflict of interest? (e.g. financial gain to the investigators, power over participants such as teacher/student relationship)  
Yes [ ] No [ ]

If “Yes”, please state details about the conflict of interest and state how that potential conflict will be addressed:

(k) Will this study involve matching different data sources (e.g. multiple questionnaires)? (NEW)  
Yes [ ] No [ ]

If “Yes”, please state explain what identifier will be used for matching:

11. Informed consent – for new data to be collected from human participants

- When conducting research where seeking written consent is not practical or too sensitive, audio-recorded oral consent or email recorded consent might be less of a privacy risk than written consent and can be considered as an alternative.

- The waiver of recorded informed consent is normally only applicable to newly collected data without personal identifiers.  In this case, PIs are required to clearly specify that they are recording data without personal
identifiers in their research grant proposals.

(a) How will you record informed consent? (Please check all boxes that apply)
   (i) Written consent  
   (ii) Audio-recorded consent  
   (iii) Online/Email recorded consent

If you will not record informed consent, please complete the following Questions (b) to (d) below and submit an information sheet.

(b) Please explain why the proposed study presents no more than minimal risk to the participants?

(c) Why does a waiver of recorded informed consent not adversely affect the rights and welfare of the participants?

(d) Do you know the identity of respondents?  
   Yes  
   No

Note: Knowing the identity of respondents is distinct from whether their identity is recorded.

If “Yes”, please explain why the study is not practicable with recorded informed consent.

12. Data Retention – for New Data to be Collected (NEW)

(a) How long will the data containing personal identifiers be kept after publication of the first paper arising from the research project?

(b) How long will the anonymized data be kept after publication of the first paper arising from the research project?

Note: Data retention, i.e. 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, must be addressed in the informed consent/assent forms. Please refer to paragraph 25 of the Operational Guidelines and Procedures for details.

13. Pre-existing data from human subjects

(c) What is the source of the original dataset?

(b) Are the original dataset in existing documents/records publicly available?  
   Yes  
   No

Note: “publicly available” means that the data can be accessed without an approval process.

If “No”, please specify the approving authority for access: (____________________)

(c) Were the original dataset originally collected for research purpose?  
   Yes  
   No

If “Yes”, please attach a copy of the Consent Form for the original collection of data.
If “No” please attach a copy of the Personal Information Collection Statement.

For ALL situations, please explain how this research is consistent with the purpose and use specified when the data were originally collected:

(d) Are the original dataset sensitive? (e.g. sexual preference, health status, criminal activity)  
   Yes  
   No

Please provide full details on types of personal data to be used:
(e) Do the original dataset contain any personal identifiers?  

Yes [ ]  No [ ]

If “No”, it means neither the researcher nor the source providing the data can identify a subject based upon the information provided with the data.

If “Yes”, is the personal identifier direct or indirect?  

Direct [ ]  Indirect [ ]

Direct identifier – e.g. name, address, ID card no., medical record no., etc.

Indirect identifier – e.g. assigned code that can make a subject reasonably identifiable.

If “Yes”, will you abstract/record any subject identifiers in the data extraction process?  

Yes [ ]  No [ ]  N/A [ ]

(f) Will any new data be collected from subjects, other than the data obtained from the original dataset?  

Yes [ ]  No [ ]

If “Yes”, please complete Questions 9 to 11.

Part D – Attachments

Please check the boxes as appropriate to indicate which of the following documents are enclosed to this application.

(1) Full research proposal including any questionnaire and/or interview script  

(2) Parent/Guardian Consent Form  

(3) Informed Consent Form  

(4) Consent script, for oral consent or email reply for consent  

(5) Deception: post debriefing consent form

Notes:

(i) Mandatory

(ii) Mandatory unless waiver has been applied for or no data collection is being undertaken.

Part E – Declaration

In making this application, I certify that I have read and understand the University’s Guidelines for Human Research Ethics, and I will comply with the ethical principles of these documents. I undertake not to proceed with data collection/analysis before I receive the letter of approval of this application. I will submit, as appropriate, any amendment(s) of an Approved Project, if there are significant changes to my research.

_________________________________________  _________________________  _________________
Name of Principal Investigator  Signature  Date

I/We hereby endorse this application with my approval and confirm that the investigator(s) are appropriately qualified in the research area involved to conduct the proposed research project, and am capable of undertaking this research study in a safe and ethical manner.

_________________________________________  _________________________  _________________
Name of Supervisor (for postgraduate research students only)  Signature  Date

_________________________________________  _________________________  _________________
Name  Signature  Date

Program Director / Head of Department

*Please delete as appropriate.

June 2016