Section 6

Guidelines and Procedures for Ethical Review Regarding Human Research

I. Scope

1. The Research and Ethics Committee (REC) requires all research studies involving human participants as research subjects to obtain ethical approval. This requirement applies to all qualitative or quantitative research, with new data collected from human participants and/or by using pre-existing personal data, conducted on the Institute/College premises or at other off-campus locations, regardless of whether the studies are funded by internal or external resources or even unfunded. The ethical concern addressed here does not only safeguard the rights of the human participants, but also complies with relevant laws or legislation adopted in Hong Kong.

2. New data are often collected from human participants by means of:
   - questionnaire surveys, such as face-to-face, mail, telephone surveys, online surveys;
   - focus groups or one-on-one interviews;
   - case studies;
   - participant observations;
   - experiments or education tests; and
   - other data collection means including online/internet data collection methods.

3. The use of pre-existing personal data refers to the data collected from existing records of previous studies or projects containing personal data. According to the Personal Data (Privacy) Ordinance (PDPO) (Cap. 486), "personal data" means any data –
   (a) relating directly or indirectly to a living individual;
   (b) from which it is practicable for the identity of the individual to be directly or indirectly ascertained; and
   (c) in a form in which access to or processing of the data is practicable.

4. The meaning of "personal data" is in compliance with the PDPO regardless of:
   - whether the data are publicly or privately available;

- whether or not the data are designated for research purpose; and
- whether the data would be used for secondary analysis.

For example, using students' assignments, which were collected previously from a private source for non-research purposes, for research analysis indicates the usage of pre-existing personal data.

II. Who Should Apply for Ethical Review by the REC

5. All staff members and students of SFU/CBCC are subject to follow this set of guidelines and procedures for obtaining the ethical approval from the School/Department and/or the REC before they conduct their research studies or projects that involve human participants.

Teaching and Research Staff

6. Being the Principal Investigators ("PIs") of any research activities involving human participants as research subjects on the Institute/College premises or at other off-campus locations, the staff of SFU/CBCC should submit an ethical review application to the REC through the Dean of School/Head of Department.

7. Where a joint research study is proposed with the collaboration between local/overseas institutes or colleges, all investigators of the study are required to obtain ethical approval from their own institutions.

8. Where research is undertaken outside the jurisdiction of Hong Kong, investigators are under an obligation to comply with the laws, regulations and cultural practice of that particular jurisdiction as appropriate.

9. It should be noted that the ethical approval obtained from SFU/CBCC can never be substituted by the compliance with the ethical guidelines that are regarded as appropriate in the jurisdiction where the research is being undertaken.

Students

10. In the case of student projects involving human participants as research subjects on the Institute/College premises or at other off-campus locations, students of SFU/CBCC should obtain ethical approval. Unless in special cases, the Schools/Departments should have their own mechanism to ensure the ethical issues are handled properly for students.

11. Concerning the compliance of ethical review application, Student Project Leaders should consult their project supervisors if they are in doubt. The students should apply for ethical approval and the application should be firstly completed by the supervisors on behalf of the students or endorsed by the supervisors before being submitted to the Dean of School/Head of Department for approval. The School/Department should submit the summary of review outcomes to the REC annually.

12. If, in special cases, the Dean of School/Head of Department would like to seek for ethical approval from the REC, the supervisors should bear the responsibility for ensuring their students have obtained the ethical approval from the REC before the commencement of any data collection or analysis.

Exemption

13. Exemption from ethical approval may only apply to anonymous surveys which are for the improvement of teaching and learning but not for research purposes. In addition, they are exclusively for the internal usage of SFU/CBCC.

III. Ethical Guidelines for Research involving Human Participants

14. All data collection or analysis of the research projects must not be commenced unless a written approval has been granted by the REC. The following basic ethical principles are set out by the REC, and the PIs should be aware of them when designing and undertaking the research studies involving human participants as research subjects:

- risk assessment;
- informed consent;
- vulnerable participants;
- deception;
- privacy and confidentiality; and
- undue influence and inducement.

Risk Assessment

15. Concerning the protection of individual rights and interests of the participants, the PIs are under an obligation to undertake risk assessment before the commencement of research activities. For which, consideration should be given carefully if any possible risks and harms would be involved.

16. The PIs should avoid or minimize any possible physical and/or psychological pain/stress/discomfort which might be induced to the participants. Under normal situation, risks which are greater than minimal risks should not be posed to the participants.

17. Where there are risks, the PIs should inform the participants clearly about the following information:
    - which types and what degrees of the risks and harms
    - what kinds of measures for minimizing the risks
    - any remedial support to those at risk
    - how the collected data will be used and safely kept
    - when the collected data will be destroyed

Informed Consent

Informed Consent Process

18. An opportunity should be given to the participants when deciding what will or will not happen to them through the means of informed consent and there are two components:

    - an Information Sheet for providing sufficient information to the potential research

participants; and

- an Informed Consent Form for documenting the informed consent given by the potential research participants.

It is a basic rule of human research that both components shall be completed.

19. The PIs shall be attentive to the following instructions for obtaining appropriate informed consent from the participants:

- they should inform the participants how they may be affected by the study;
- they should give the participants sufficient information of the study and deliver it in a comprehensible way; and
- they should provide the participants sufficient opportunity to decide whether or not to participate and avoid using force, coercion, undue influence or inducement.

20. It is expected that the participants should be informed of the following before they give informed consent:

- they participate in the research study voluntarily;
- they are free to withdraw from the study at any time without negative consequences; and
- they have the opportunity to ask questions about the study and get the satisfactory answers.

Information Sheet

21. Participants should be provided an Information Sheet with sufficient information about the research studies. It should be written in a comprehensible manner with a language readily understandable by the participants. The following information is suggested to be included in the Information Sheet:

- purposes and procedures of the research;
- possible risks and harms to the research participants;
- potential benefits to the research participants or others;

- remedial support or compensation for the participants;
- voluntary participation and withdrawal without negative consequences;
- guarantee of privacy and confidentiality; and
- information and contact of the PI/research team.

The Information Sheet should be given to the participants together with the Informed Consent Form.

Informed Consent Form

22. To ensure that consent has been received, the PIs must obtain written consent from the participants when data is newly collected from them. Where the pre-existing personal data is used for a new purpose, consent from the participants should be sought again.

23. Not only does written consent serve as a means to obtain informed consent, but also online/email recorded response once it is acted in response after reading and understanding the Information Sheet provided beforehand.

24. Besides, audio-recorded oral consent could be considered as an alternative when written consent is impractical or too sensitive. For example, the respondents are illiterate or are afraid of privacy risk. In either case, a full justification should be submitted together with the Information Sheet and the application for seeking ethical approval from the REC.

25. The following are situations involving informed consent obtained other than the participants:

(a) Third Parties

Informed consent should be obtained from third parties if they are involved or affected by the research, for example, spouses and family members.

(b) Spouses or Immediate Relatives

Informed consent should be obtained from spouses or immediate relatives if the participants are incapable of giving informed consent, for example, mentally or physically handicapped persons, and acutely ill patients.

(c) Parents or Legal Guardians

Informed consent should be obtained from parents or legal guardians if the research involves children who are under the age of 18. If the PIs do not think parental consent is necessary, they have to provide a full justification.

- *For School-Based Research*

  Active parental consent should normally be required for school-based studies of primary school students; while passive parental consent should be sufficient for studies, which involve minimal risk, of secondary school students.

- *For Adolescent Research Outside School*

  Parental consent is normally not required for studies of adolescent aged 16 or above because they are regarded as "mature minors".

- *For Studies of University Students*

  Parental consent is normally not required for studies, which involve no greater than minimal risk, of university students because they should be capable of making their own decision.

26. A statement should be included in the Informed Consent Form to declare that the participant has read both the Information Sheet and the Informed Consent Form; in which, he or she understands both documents and agrees to participate in the research study.

27. Not only the participants are required to sign and date the Informed Consent Form, but also the one who collected it. For studies involving risks greater than minimal risk, a witness should also be invited to sign and date the Informed Consent Form.

Exemptions

28. Recorded informed consent should be normally obtained from the participants. For anonymous surveys, the PIs are strongly recommended to fulfill this requirement even though it could be optional.

29. This requirement, however, could still be waived if:
    - the new data collected are with no personal identifiers; AND
    - the research involves no greater than minimal risk to participants; AND
    - the research cannot possibly be conducted under the requirement.

30. If pre-existing personal data with personal identifiers are used for a new purpose, the PIs must obtain informed consent from participants again.

Vulnerable Participants

31. Vulnerable participants refer to those who are less capable of protecting themselves, or even are incapable of giving informed consent, or are in a special condition where careful consideration is required.

32. Justification is needed when vulnerable participants are involved in the research studies. When justifying the appropriateness, the PIs should look into the following variables:
    - nature and extent of risks and harms;
    - condition of that particular group involved; and
    - nature and level of expected benefits.

33. The PIs should make reference to the requirements for obtaining informed consent from vulnerable participants.

Deception

34. The PIs might provide misleading information or withhold some information from the participants. If in such exceptional cases, justification must be provided to the REC and the PIs must explain the following items in details:
    - reasons for impracticability without the deception;
    - proof of absence from any adverse effect to the well-being of the participants; and
    - research process including invitation, briefing and debriefing.

35. The PIs must explain the deception to their participants as early as practicable. Please note that it is more preferable to have it at the conclusion of their participation, but no later than the conclusion of the research.

Privacy and Confidentiality

Personal Data (Privacy) Ordinance (Cap. 486)

36. In compliance with the Personal Data (Privacy) Ordinance (PDPO) (Cap. 486), the PIs must guarantee the privacy and confidentiality of research data related to individual participants. For details of the ordinance, please refer to the Office of the Privacy Commissioner for Personal Data, Hong Kong at: https://www.pcpd.org.hk/english/data_privacy_law/ordinance_at_a_Glance/ordinance.html

37. No matter it is an anonymous or non-anonymous survey, the PIs are under a legal obligation to ensure the confidentiality of all the data collected, including written records, photographs, audio and video recordings.

38. When dealing with sensitive personal information, precautions relating to data storage, the use of data, and the disposition of research materials should be specified to the participants. Measures have to be taken to preserve such confidentiality during the research process.

Data Collection

39. When collecting data, the PIs should clearly indicate:
    - purpose for collecting the data; and
    - methods adopted for ensuring the confidentiality.

Data Storage

40. The collected information related to the participants should not be publicly disclosed in a way that they could be identified unless there is consent. Names, or personal identifiers, such as HKID no. and addresses which could lead to the identification of the participants, must be avoided in the research report.

41. After the completion of data collection, a maximum of five years is normally allowed for keeping data with personal identifiers. No personal data containing identifiers should be retained after five years unless there is written consent. For long term data retention, removal of all personal identifiers is strongly suggested to PIs in order to minimize privacy risk. Anonymized data are generally permitted to be kept for long term sharing.

42. The following measures are suggested to safeguard the privacy and confidentiality when accessing the collected data:

- raw data should be locked up in a cabinet and only the PIs or authorized persons could access;
- the PIs should save the electronic data in a protected file with password and authorization is needed to access the files;
- codes are used to identify the participants so that the personal identities would not be easily disclosed; and
- where research involving private sensitive data, the PIs are advised to use indirect identifiers and to preserve the direct identifiers from the data separately.

Undue Influence and Inducement

43. Participants should not be pressured or forced to participate in any research activities. They should be free from coercion or undue influence. Where there is a dependent or dual relationship between the investigator and the participant, such as teacher-student, employer-employee, and doctor-patient, careful consideration is required. The willingness of participation must not be unduly influenced by power differences.

44. Also, participants should not be adversely induced to participate in research by means of any incentive or financial reward. Any unreasonable financial payments, gifts or services provided to induce participation is ethically not permitted. If there is any payment to the participants, it should be indicated on the application form. Reimbursement of participants' expenses, such as travelling expenses, should be reasonable and commensurate with standard practice.

IV. Types of Reviews by the REC

45. Two types of review, which are expedited review and full review, are conducted by the REC for research involving human participants. An expedited review is eligible for studies involving no greater than minimal risk to human participants, while a full review is for those that do not meet the minimal requirements. For a full review, PIs are required to provide more details.

Expedited Review

46. Applicants have to ensure that the research studies have met the requirements before submitting their applications for expedited reviews. In general, expedited reviews are permitted if:

- studies would not involve vulnerable persons; AND
- no greater than minimal risk would be resulted.

47. All research protocols submitted to the REC will be considered, while projects involving minimal risk may be considered by the Chairperson or another experienced member of the Committee as recommended by the Chairperson. The submitted application may be decided as "approved", "conditionally approved", or a full review may be required.

Full Review

48. If the research studies do not meet the requirements for expedited reviews, the applicants should apply for full reviews.

V. Procedures to Obtain Ethical Approval

49. The PIs and the Student Project Leaders/Supervisors are responsible to ensure that the ethical approval has been obtained before the commencement of any data collection or analysis. Research grant applications may be declined because of the failure to obtain the required ethical approval.

Research Projects

50. For authorized schools and departments, the applicant should seek approval from their school/departmental-level research and ethics committee. To be an authorized school/department, the school/department should submit a proposal to the REC explaining their readiness in vetting applications for research ethics and safety approval. The REC will then consider the proposal and forward it, together with her recommendation, to the Academic Board for final decision.

51. For other schools and departments, the applicant should complete the application form before seeking endorsement from the Dean of School/Head of Department. Then the endorsed form should be submitted with relevant documents to the REC by the applicant. The REC will further consider the submitted research protocol.

52. Projects involving minimal risk would go through an expedited review, which may be considered by the Chairperson or another experienced member of the Committee as recommended by the Chairperson. Projects involving risk greater than minimal risk would go through a full review. The REC members will undertake a full review and discuss the applications at the meeting.

Student Projects

53. The students must consult their respective supervisors before filling in the application form. Either student or supervisor could complete the application form and it must be endorsed by both the Supervisor and the Dean of School/Head of Department. The application form with relevant documents should be submitted by the Supervisor to the School/Department for approval.

54. The Schools/Departments are responsible for the vetting of students' applications and should have their mechanism to ensure that ethical issues are handled properly for student projects. They should submit the summary of review outcomes to the REC annually. Only special cases of student projects would be reviewed by the REC. The responsibility for ensuring ethical approval has been obtained rests with the supervisor.

Documents to be Prepared and Submitted

55. Regarding the application for ethical approval, the applicants should prepare and submit the following items:
    - Completed Application Form
    - Research Proposal
    - Consent Form
    - Information Sheet
    - Questionnaire
    - Interview script
    - Other relevant documents (if applicable)

56. The applicants should submit the soft copies of the endorsed application with all other relevant documents to the REC or the School/Department. Absence of any required documents may render an approvable application "conditionally approved".

VI. Outcomes of the Review

56. The processing of application would normally be completed within three months from the date of submission. The results of application will be released in writing and applicants will receive a formal document indicating that the submitted application is "approved", "conditionally approved" or "not approved". The PIs are reminded not to begin any data collection or analysis unless ethical approval has been granted by the REC.

Approved

57. The REC will issue a formal document certifying ethical approval with an effective approval period to the PIs. The research study should be completed within the effective approval period.

58. An application for extension of ethical approval has to be raised by completing the Amendment Application Form if the PIs fail to complete the research before the end of the effective period.

59. Amendments to the research projects are allowed but it must be reported to the REC by completing the Amendment Application Form. In case the amendment involves major changes to the objectives and/or research methodology, the REC would require a new application for ethical review.

Conditionally Approved

60. The applicants would be notified the result with comments/recommendations made by the REC. An approval will be granted once the concerns of the REC are satisfactorily addressed with the provision of supporting documents. No data collection or data analysis could be begun until the REC confirms its approval.

Not Approved

61. Comments/recommendations from the REC will be specified in the notification. The research study could no longer be continued once the application is disapproved. The PIs may revise the research protocol and resubmit the application to the REC for reconsideration, or they may file an appeal to the REC.

VII. Amendment Application

62. The REC must be informed if there is any amendment to the research projects, including the application for extension of the project period, by completing the Amendment Form. PIs should submit the Amendment Form to the REC through the Dean of School/Head of Department. A new application should be made for review if any major change to the methodology is involved in the amendment.

VIII. Right to Appeal

63. All applicants are entitled the right to appeal. After the notification of the application results, the student applicants could request the REC via the Dean of School/Head of Department to further review the applications which are either not approved or conditionally approved. For research projects, the applicants could make such request to

the Research Appeals Committee appointed by the President via the RO. Request for appeal should be made within two months after the result notification and must be supported with reasons and/or documents.

IX. Enquiry

64. For enquiries, please contact:

- Research Office
  Email: ro@sfu.edu.hk