THE EDUCATION UNIVERSITY OF HONG KONG

Human Research Ethics Committee (HREC) <u>Operational Guidelines and Procedures</u>

I. Ethical Review of Research Projects involving Human Participants and/or Human Data

- 1. Any research project conducted under the auspices of The Education University of Hong Kong (EdUHK) (irrespective of whether it is funded by the EdUHK/ other agencies or unfunded) must be conducted according to the highest standards of ethical research practice to safeguard the physical, emotional and intellectual well-being of the participants. It is a requirement of the EdUHK that all research projects involving research participants and/or human data (such as surveys, experiments, secondary data, archival data, data collected for one project and being used for another project etc) undergo independent ethical review in accordance with the EdUHK's *Guidelines on Ethics in Research*.
- 2. Principal Investigator* or Student Investigator should be aware of the basic ethical principles set out in the EdUHK's *Guidelines on Ethics in Research*.

The definition of research eligible for review by the HREC will be based on two criteria.

(a) Purpose of the project

- Research projects include all projects of research nature undertaken by staff, postgraduate, undergraduate and sub-degree students. Research is any creative or systematic work or investigation, including research development, testing and evaluation, designed to develop or contribute to the human stock of knowledge including knowledge of humankind, culture and society. A project is considered research if there will be public dissemination of findings for the purposes of advancing knowledge or solving problems;
- Retrospective applications to use information that has been collected for non-research
 purposes as research data for the purposes of new knowledge dissemination are not
 generally considered. Such applications would need to demonstrate that the proposed
 use of data is not inconsistent with the purposes for which the information was
 originally collected.

(b) Data of the project

- The project involves human participants, or human-produced data, that is not already part of the public domain.
- Research tends to involve certain level of risk to participants. Investigators should identify if there are any potential risks to participants arising from participation in the

project and/or from dissemination of findings, including risks to confidentiality, or risks of physical, emotional, psychological or social harms.

- 3. The following scenarios of data collection activities could be exempted from ethical review:
 - Literature review (published academic articles)
 - Meta-analysis of published research
 - Evaluation for improving teaching methods/ student learning
 - Writing a training manual using published information
 - Documenting a community issue using only public documents or information
 - Observations in public venues
 - Student evaluations of teaching
 - Course assignments for students with no purpose of increasing the stock of knowledge

II. Applicants and Approval Authority for Ethical Review

- 4. Staff members and students of the University, who are carrying out research project, must submit an application for ethical review if the research project involves human participants and/or human data in the investigations.
- 5. Depending on the type of research, the approval authority for an application for ethical review shall rest with the HREC/ Faculty-level research committees responsible for ethical review (i.e. Faculty Research and Higher Degrees Committee of FEHD; Faculty Research and Development Committee of FHM and Faculty Research Committee of FLASS) / Head of Department (HoD) of the Principal Supervisor of the Undergraduate (UG) student or HoD's designated delegate(s). Please refer to the following table with regard to the applicants, endorsement authority, and approval authority for ethical review for different types of research:

^{*} EdUHK staff as Co-I can submit the ethical review application to HREC in his/her capacity if s/he deems it necessary whenever the PI is not in a position to submit ethical review application or the PI is not EdUHK staff who has not obtained ethical approval from outside body/organization for his/her research.

Types of Research	Applicants for Ethical Review	Endorsement Authority for Ethical Review	Approval Authority for Ethical Review
Staff Research			
UGC/ RGC- related staff research and Internal Competitive Research Grant	Staff as Principal Investigator*		Human Research Ethics Committee (HREC)
Non-UGC/ RGC funded staff research	Staff as Principal Investigator*		Human Research Ethics Committee (HREC)
Other staff research in HKIEd (including non-funded research)	Staff as Principal Investigator*		Human Research Ethics Committee (HREC)
Student Research			
Research Postgraduate (RPg) (i.e. MPhil/ PhD) and Doctor of Education (EdD) student research	RPg/ EdD student as Student Investigator	Principal Supervisor	Human Research Ethics Committee (HREC)
Taught Postgraduate (TPg) (i.e. MA/ MEd/ PGDE) student research	TPg student as Student Investigator (Student Investigator and Principal Supervisor belong to the same Faculty)	Principal Supervisor	Head of Department (HoD)/ HoD's designated delegate(s)
	Cross-discipline TPg student as Student Investigator (Student Investigator and Principal Supervisor belong to different Faculties)	Principal Supervisor, Head of Department (HoD)/ HoD's designated delegate(s)	Faculty-level research committees responsible for ethical review (the mother Faculty of the TPg Student as final approver)
Undergraduate (UG) student research	UG student as Student Investigator	Principal Supervisor	Head of Department (HoD) of the Principal Supervisor or HoD's designated delegate(s)

^{*} EdUHK staff as Co-I can submit the ethical review application to HREC in his/her capacity if s/he deems it necessary whenever the PI is not in a position to submit ethical review application or the PI is not EdUHK staff who has not obtained ethical approval from outside body/organization for his/her research.

III. Procedures for Applications for Ethical Review

Staff Research

- 6. For UGC/RGC-related staff research and Internal Competitive Research Grant, applications for ethical review should be submitted to the Committee on Research and Development (CRD) via the CRD Secretary. The research proposals will be reviewed for their research merit by the usual process. The CRD will then forward to the HREC the ethical review applications of those UGC/RGC-related staff research/Internal Competitive Research Grant that are supported by the CRD or required to be revised for further consideration by the CRD. In case of applications for Internal Competitive Research Grant, funding will not be awarded unless ethical approval has been obtained from the HREC.
- For non-UGC/ RGC funded staff research and other staff research in EdUHK (including nonfunded research), applications for ethical review should be submitted to the HREC via the HREC Secretary.
- 8. The HREC will consider applications for ethical review against the EdUHKs *Guidelines on Ethics in Research*, how the research protects the rights of the participants and how all elements of the research will be conducted according to the highest standards of ethical behavior. The HREC may require additional information by an applicant or revisions to be made to a research proposal before ethical approval is given.
- 9. Upon receipt of an application for ethical review, a HREC member will be assigned to make a recommendation and comment on the application. The HREC Chairperson will then make a final decision on the application taking into account the HREC member's recommendation and comments. Meetings of HREC will be held at the call of the HREC Chairperson when necessary.

Student Research

- 10. Research postgraduate (RPg) (i.e. MPhil/ PhD) and Doctor of Education (EdD) students are required to submit their applications for ethical review, with endorsement of their Principal Supervisors, to the HREC for approval.
- 11. Taught Postgraduate (TPg) students (i.e. MA/ MEd/ PGDE), of which the Student Investigator and Principal Supervisor belong to the <u>same</u> Faculty, are required to submit their research projects for ethical review, with the endorsement of their Principal Supervisor and via him/ her, to that Supervisor's Head of Department (HoD) or the HoD's designated delegate(s) for approval.
- 12. Cross-discipline Taught Postgraduate (TPg) students (i.e. MA/ MEd/ PGDE), of which the Student Investigator and Principal Supervisor belong to <u>different</u> Faculties, are required to submit their applications for ethical review, with endorsement of both their Principal Supervisors and HoD/ HoD's designated delegate of their research projects, to the their mother Faculty Research Committee responsible for ethical review for approval.
- 13. Undergraduate (UG) students are required to submit their research projects for ethical review, with the endorsement of their Principal Supervisor and via him/ her, to that Supervisor's Head of Department (HoD) or the HoD's designated delegate(s) for approval.
- 14. For all Undergraduate and Taught Postgraduate research projects, appropriate informed consent must be obtained from the participating groups (schools, students, parents, etc). The approval

protocols for Undergraduate and Taught Postgraduate research projects are to be determined at the Faculty /Departmental level and reported to the HREC in the annual report to HREC by Faculties.

Outcome of Ethical Review

- 15. The relevant approval authority will notify the applicant in writing of the result of application normally within 4 weeks' time from receipt of his/ her completed application with all required documents. Research cannot begin until the protocol has been approved by the relevant approval authority.
- 16. For UGC/ RGC-related staff research and Internal Competitive Research Grant, the CRD Secretary will notify applicants of the results of their applications for ethical review.
- 17. For non-UGC/RGC funded staff research, other staff research in EdUHK (including non-funded research) and RPg/ EdD student research, the HREC Secretary will notify the applicants of the results of their applications for ethical review.
- 18. (a) For TPg student research, the HoD of the Principal Supervisor or HoD's designated delegate(s) will notify the applicants of the results of their applications for ethical review.
 - (b) For cross-discipline TPg student research, the Faculty-level research committees responsible for ethical review will notify the applicants of the results of their applications for ethical review.
- 19. For UG student research, the HoD of the Principal Supervisor or HoD's designated delegate(s) will notify the applicants of the results of their applications for ethical review.
- 20. The period of ethical approval is granted from the approved project start date to the project end date. If a project extension is applied for lasting more than 3 months, HREC should be contacted with information regarding the nature of and the reason for the extension. If any substantial changes have been made to the project, a new HREC application will be required.
- 21. The applicant will be responsible for informing the relevant approval authority in advance of any proposed substantive changes in the research proposal or procedures which may affect the validity of the ethical approval. The applicant will receive separate notification should a fresh approval be required.

Right to Appeal

- 22. The HoD or HoD's designated delegate(s) may refer special cases requiring advice to the Faculty-level research committees responsible for ethical review as appropriate. The Faculty-level research committees responsible for ethical review may further refer any unresolved issues to the HREC for consideration.
- 23. All applicants have a right to appeal and request that their applications be reviewed. Proposals reviewed by a departmental committee/officer may be referred to the Faculty HREC committee for consideration. Proposals reviewed by a Faculty committee/officer may be referred to the HREC committee for consideration. Where appropriate, proposals considered by the chairman of the HREC committee may be reviewed by the full committee. In all circumstances of appeal full documentation and argumentation must support the appeal. Frivolous appeals will not be considered. The decision of each of the committees of appeal are final.

Annual Report by Faculty-level Research Committees Responsible for Ethical Review

24. Each of the Faculty-level research committees responsible for ethical review is required to submit an annual report to the HREC in July each year. A template for the report can be downloaded from the following link: http://www.eduhk.hk/rdo/human.html

Delegation of Approval Authority for Ethical Review Applications

25. The Chairperson of the relevant approval authority may delegate a staff member of the Committee or responsible body to make decisions on ethical review applications on his/ her behalf under certain special circumstances, e.g. to consider applications requiring urgent attention during the absence of the Chairperson, and cases where there is potential conflict of interest if decisions are to be made by the Chairperson.

IV. Documents to be submitted by Applicants for Ethical Review

26. For Staff and RPg/EdD Student Applicants, applications for ethical review should be submitted through the online submission system.

For Taught Postgraduate (i.e. MA/ MEd/ PGDE) and Undergraduate Student Applicants, completed paper application form should be submitted to respective Departments where applicable.

An ethical review application should be submitted along with the following documents:

- A copy of the research proposal
- A sample of the bilingual consent form and information sheet to be distributed to potential research participants
- Draft informed consent form/ invitation letter/ approval letter for data collection site (e.g. school, hospital, NGO) (if applicable)
- Interview script (if applicable)
- Data collection form, including questionnaire and research protocol (if applicable)
- 27. The following reference documents and application form can be accessed from the link: http://www.eduhk.hk/rdo/human.html
 - Access link of Online Submission System (For Staff and RPg/EdD Student Applicants)
 - Application form for ethical review (For Taught Postgraduate (MA/ MEd/ PGDE) and Undergraduate Student Applicants)
 - EdUHK's Guidelines on Ethics in Research
 - Summary of the EdUHK's Guidelines on Ethics in Research
 - HREC Operational Guidelines and Procedures
 - An example of a consent form and information sheet

Use of Consent Form and Information Sheet

- 28. A sample of the consent form and information sheet, which will be distributed to potential research participants, should form part of an application for ethical review; otherwise, reasons for not using a consent form and information sheet should be provided by the applicant in the application form for consideration by the relevant approval authority.
- 29. For all research projects, appropriate informed consent must be obtained from the participating groups (schools/ data collection site, students, parents, etc) before data collection begins. The organization/ school should be aware of the research study and agree in writing to allow the

Project Investigator to run the study in the organization.

- 30. Consent forms and information sheets serve to document that informed consent has been obtained from research participants and to provide potential research participants with sufficient and clear information that allows them to make informed consent to participate in the study. Applicant may follow the suggested consent and information sheet format available on the HREC website. The following information should be included:
 - Name and contact information of the researcher
 - Title and aims of the project
 - Description of what participants will be asked to do and the time commitment required from the participants
 - Potential risks (if any) to the participants (e.g. discomforts, inconveniences expected) and how the risks will be mitigated
 - Potential benefits coming from the research (may be specific to the individual or to the Knowledge base of the field of study)
 - Statement that participation is voluntary
 - Statement that participant have a right to refuse to participate or withdraw at any time without negative consequences
 - How confidentiality/ anonymity/ privacy will be ensured
 - A description of how results will be disseminated
- 31. The following guidelines for obtaining consent should be adopted if the research participants are minors:
 - For children aged below 9, only the signature of their parents/guardians is required; completion of the task, after verbal explanation of its nature by the researcher, provides implied consent by the child; *
 - For children aged 9 to 15, signature of both the children and their parents/guardians is required; *
 - For adolescents aged 16 to 17, signature of the adolescents is required and consent from their parents/guardians is optional for studies involving minimal risk.
 - * For minimal risk research, you may ask for passive consent, that is, parents/guardians return the consent form only if they DO NOT wish their child to participate. For all other research, active consent, whereby parents/guardians indicate their child may participate, MUST be obtained.

Definition of Minimal Risk:

No undergraduate research on children should be more than minimal risk. In other words, the ethics proposal must not have any of the following elements [adopted from CUHK Survey Ethics Guidelines (expedited review section) http://tinyurl.com/brfrkjn]:

a. No excessive inducements to participate

If student-teacher relationship exists, teachers should take special care to emphasize to their own students that they are free to decline to participate, with no adverse consequences

- b. No deception, e.g. Purpose of study should be fully disclosed at beginning of the study)
- c. No "undue psychological stress" or "discomfort higher than a reasonable level"
- d. Questions should be asked in a way that will avoid discomfort for participants, e.g. Study on social exclusion among classmates: should avoid interviewing only students who are unpopular in the class (which may make them uncomfortable as they are obviously pointed out).
- e. No questions asked about "sensitive aspects of the participant's own behaviour such as illegal conduct, drug or alcohol use, and sexual conduct"
- f. To avoid problems if data were disclosed, fully anonymous surveys are advisable whenever

possible; or at least, "identifiable by codes known only to the researcher" (as stated in HREC's model consent form). That means: every participant will be given a Subject Number, and in the stored data files, participants will be identified by Subject Number only. Links between the Subject Number and identifiable information (such as name of participant) can be known by the researcher, but if stored in a file, should be stored separately from the data files to prevent accidental disclosure

- 32. Consent forms and information sheets should be written in simple language that is easily comprehensible by the potential research participants.
- 33. Consistency between the Chinese and English versions of a consent form and information sheet should be ensured by the applicant.
- 34. An example of a consent form and information sheet can be downloaded from the link: http://www.eduhk/rdo/human.html

V. Confidentiality and Storage of Data

- 35. Researchers should make every effort to protect the confidentiality of research data:
 - Researchers should under no circumstances publicly disclose information obtained in the course of a research project in a fashion that would identify any specific person or organization (except with the participants' written consent or if subpoenaed by a court).
 - Researchers should outline to prospective research participants the purpose of the collection of personal data and what methods the researcher would adopt to ensure confidentiality.
 - Research data should normally be kept confidentially for at least five years after completion of the project. Data containing personal identifiers may normally be kept for a maximum of 6 years after completion of the project.
 - Participants should be informed that the researcher will take precautions to preserve the
 confidentiality of the research data and that all reports of the research will be devoid of
 identifiers.
 - When the researcher collects sensitive human data and/or personal information about participants, the researcher should specify the precautions relating to the storage, use, and disposition of the materials. For example, data will be kept in locked files and only the researcher(s) will have access to them; data subjects will be identified by a code and therefore their personal identities will not be disclosed easily.
 - The researcher should give participants full information on the proposed management, use and disposition of photographs and audio or video recordings.
 - Researchers should familiarize themselves with the Personal Data and Privacy Ordinance, and ensure adherence when necessary.
- 36. It is advised that BEd Honours Project students should destroy video recordings which may identify research participants after project completion (i.e. after receiving their confirmed grade on their thesis).

VI. Deadline for Submission of Applications for Ethical Review

37. The deadline for applications for ethical review is in accordance with the respective regulations for different applications or proposals, where such ethical approval is required. For example, some funders require ethical approval of research proposals before the application for a research grant is considered. It is the responsibility of the Principal Investigator or Student Investigator to make sure that ethical approval has been obtained before any data collection takes place.

- Students should get ethical approval from relevant authorities in the University before starting any research activities in schools or other external organizations.
- 38. The processing time from submission of application to notification of approval will normally take not more than 4 weeks, provided that the submitted application form is complete with all required documents attached. Incomplete forms will be returned without review.
- 39. An application for ethical review, with a completed application form and all required documents, must, under normal circumstances, be submitted to the HREC at least four weeks before the expected date of receiving its ethical approval, including but not limited to the due date for submission of proposal for funding, commencement date of data collection, etc. HREC reserves the right to not process any application that does not adhere to this guideline. Exceptional cases may be considered on a case by case basis by the Chairperson of HREC.

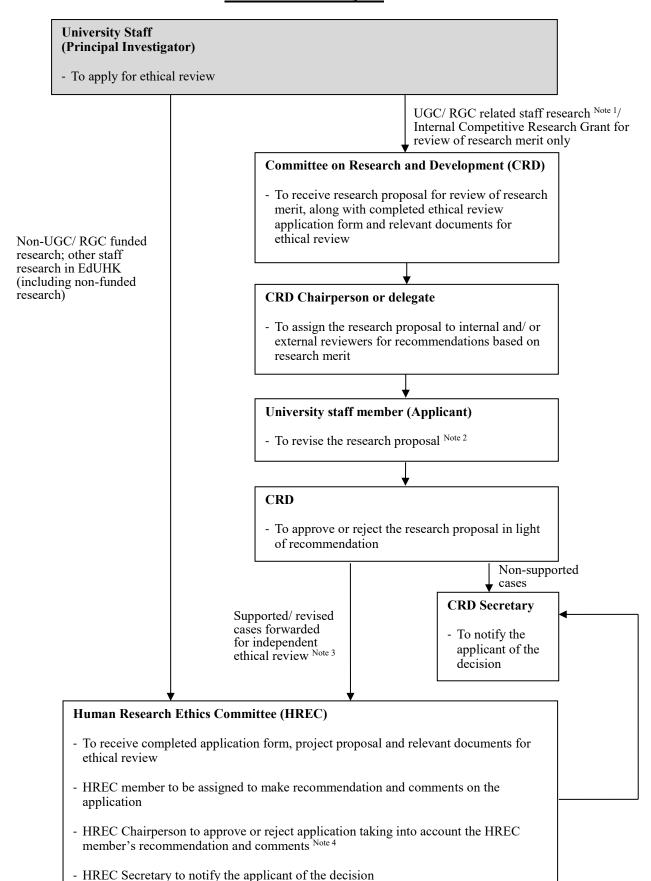
VII.Flowcharts

- 40. The following flowcharts (attached) provide an overview of the procedures for applications for ethical review:
 - Flow of Application for Ethical Review: Staff Research Projects (flowchart 1)
 - Flow of Application for Ethical Review: Research Postgraduate (RPg) (flowchart 2) (i.e. MPhil/ PhD)/ Doctor of Education (EdD) Student Research Projects
 - Flow of Application for Ethical Review: Taught Postgraduate (TPg) (flowchart 3) (i.e. MA/ MEd/ PGDE) Student Research Projects
 - Flow of Application for Ethical Review: Undergraduate (UG) Student (flowchart 4) Research Projects

VIII. Enquiries

41. Enquiries may be directed to Ms. Patsy Chung, HREC Secretary (tel. 2948 8120/ email: hrec@eduhk.hk).

Flow of Application for Ethical Review: <u>Staff Research Projects</u>



Notes:

- 1. These are research projects funded by the RGC General Research Fund, Public Policy Research Fund, Strategic Public Policy Research Fund, RGC Joint Research Schemes, Collaborative Research Fund, etc.
- 2. This applies to UGC/ RGC-related research only. For Internal Competitive Research Grant, reviewers' comments on the research proposal will only be passed to the University staff member concerned after the final decision is made by the CRD.
- 3. The CRD will forward to the HREC for independent review those ethical review applications of UGC/RGC-related research/ Internal Competitive Research Grant that are supported by the CRD or required to be revised for further consideration by the CRD.
- 4. The HREC Chairperson will make a final decision in light of the HREC member's recommendation and comments. If necessary, the HREC may require additional information or amendments to the research proposal before ethical approval is given.

(Flowchart 2)

Flow of Application for Ethical Review:

Research Postgraduate (RPg) (i.e. MPhil/ PhD)/ Doctor of Education (EdD) Student Research Projects

Research Postgraduate (RPg) (i.e. MPhil/ PhD)/ Doctor of Education (EdD) Student (Student Investigator)

- To apply for ethical review

Principal Supervisor

- To endorse the application before submission of the application to the Human Research Ethics Committee (HREC) for approval

Human Research Ethics Committee (HREC)

- To receive completed application form, project proposal and relevant documents for ethical review
- HREC member to be assigned to make recommendation and comments on the application
- HREC Chairperson to approve or reject application taking into account the HREC member's recommendation and comments*
- HREC Secretary to notify the applicant of the decision

Note:

* The HREC Chairperson will make a final decision in light of the HREC member's recommendation and comments. If necessary, the HREC may require additional information or amendments to the research proposal before ethical approval is given.

(Flowchart 3)

Flow of Application for Ethical Review:

Taught Postgraduate (TPg) (i.e. MA/ MEd/ PGDE) Student Research Projects

Taught Postgraduate (TPg) (i.e. MA/ MEd/ PGDE) Student (Student Investigator)

- To apply for ethical review

Principal Supervisor (PS)

- To endorse the application before submission of the application to Head of Department (HoD)/ HoD's delegate for endorsement

[Normal Applications – TPg student and the PS belong to the <u>SAME</u> Department]

Head of Department (HoD) of the PS or HoD's delegate(s)

- To approve or reject the application
- To notify the applicant of the decision
- To submit annual reports to the Human Research Ethics Committee (HREC) via Faculty-level research committees

[Cross-discipline Applications - TPg student and the PS belong to <u>DIFFERENT</u> Departments]

Head of Department (HoD) of the PS or HoD's delegate(s)

- To endorse the application before submission of the application to the mother Faculty of the TPg Student (i.e. Faculty-level research committee responsible for ethical review) for approval

Special cases/ Appeal cases/ Annual reports

Faculty-level research committees responsible for ethical review

- To consider special cases/ appeal cases

Faculty-level research committees responsible for ethical review

- To approve or reject the application
- To notify the applicant of the decision
- To consider special cases/ appeal cases
- To submit annual reports to the Human Research Ethics Committee (HREC)

Special cases/ Appeal cases/ Annual reports

Human Research Ethics Committee (HREC)

- To consider special cases/ appeal cases which cannot be resolved at the Faculty level
- To note the annual reports from the Faculty-level research committees responsible for ethical review

(Flowchart 4)

Flow of Application for Ethical Review: Undergraduate (UG) Student Research Projects

