香港教育大學
The Education University of Hong Kong

A Brief Introduction to Research Ethics

Presented by Dr. Emma E. Buchtel, Sept 14, 2022
With thanks to Prof. Dennis M. McInerney's April 2013 HREC presentation

The Practical question: Process of Applying for Ethics review

Two goals:

- **The Practical question: Before you do research with human participants,** the project must be ethically approved. How to get through it?
- **The Ethical question**: What kinds of things are "ethical problems" in research? How do we fix them?

- This workshop aims to help you be aware of and solve possible ethical issues in research, helping you:
  - Know the basic rights of participants
  - Know how to SOLVE ethical risks (= to minimize risks for participants)
  - Know about the Ethics Review process & how to facilitate

What is the purpose of human research ethical review?

Why does research need to undergo review by a Research Ethics Committee?

It is not to "ensure" that the research is ethical– this is ultimately the researcher's responsibility.

REC provides *an outside, wider, experienced perspective* on:

- the potential negative implications/effects of the research for/on the participants,
- any unforeseen consequences of the research on participants or other associated parties, and
- Methods of reducing risk / increasing benefits to participants

Ethical review **helps protect** participants, but also the researchers / the Institute.

Also, if your data is collected without the approval of an Ethics Committee, *it cannot be used in a thesis or, generally, published in a reputable journal.*

The ethics application

- FORM: changes from time to time.
  - **Staff & Research Pg students (EdD / PhD / Mphil)**
    -> Online Application https://workflow.eduhk.hk/HREC/
  - **Taught PG students (MA / MEd / PGDE etc.) & Undergraduate students (BEd, etc.)**
    -> Currently: Printed Application Form
    - Download the most recent **forms** from the HREC
    -> Webpage: http://www.eduhk.hk/rdo/human.html
- To fill out the application, first READ the guidelines (BOTH):
  - "University's Guidelines on Ethics in Research" for general advice
  - "HREC Operational Guidelines and Procedures" (from *Procedures* page) for specific advice (e.g. types of consent required for different ages)

Time: A major issue!

- To apply for research ethics approval , you need to submit:
  - Application Form for Ethical Review, including open-ended sections describing research, protection of participants & data, etc.
  - Research proposal
  - Questionnaires, interview scripts
  - Consent forms to be given to participants / parents / school (organization)
- After ethics approval given: School/organization approval and parental consent may be required.
  - Signatures from school principal, parents, as well as participants…?

The application process: Flow

- Staff:
  - Submit your online application to the HREC
    - Can be drafted by another person first
  - RDO Staff will check for common problems (missing docs, etc.)
  - Application reviewed by a) an HREC member, and b) HREC chairperson
- Research Pg students (EdD / PhD / Mphil):
  - Seek endorsement from principal supervisor (PS) before online submission:
    1) draft an application at the Online System (save it but not submit) and save as a PDF file, then email .pdf to PS for PS' endorsement;
    2) then, *attach* an email reply from PS showing endorsement to the online application
  - Then, application reviewed by RDO staff & HREC as above
- Taught Pg students (MEd / PGDE etc.):
  - Forms submitted to thesis supervisor for his/her approval
  - Then, supervisor submits it to the HOD or HOD's delegate for ethical review & approval (FEHD: Faculty-level review board)
- Undergraduate students (BEd, etc.):
  - Submit to thesis supervisor for his/her approval
  - Then, supervisor submits it to the HOD / HOD's delegate for ethical review & approval

See "Flow of Application…" at https://www.eduhk.hk/human_hrec/view.php?secid=2551

Time: Solutions

- Please submit the Ethics application **more than a month** before you wish to begin the research
  - Students need to plan even more time, as both the supervisor and approving committees need to find time to review the application
- **Questionnaires / Interview scripts: submit the "best draft"**
  - Minor changes after the ethical approval *may be* OK (don't need separate approval) as long as experimental procedures will not change in *ethically important ways.*
  - For example:
    - do not **newly** ask any potentially sensitive information of the participants (e.g. drug use; sexual activity; etc.),
    - do not **newly** recruit children as participants,
    - do not introduce **new** recruitment procedures that could pressure potential participants to participate
    - do not **change** anonymity or confidentiality of data (e.g. newly deciding to take videotapes or other recordings)
- When planning your project, you may need to plan time to get organizational & parental consent

When reviewing TPg or UG ethics: Which of these do you focus on?

- **Research Merit:**
  - Important research questions, excellent methods
- **Research Integrity:**
  - Honesty, Accuracy, and Objectivity in evaluating and reporting evidence
- **Protection of Human Participants:**
  - Prioritizing rights of participants over your own self-interest
  - Right to informed consent; Right to refuse; Right to avoid harm; Right to know what will happen to their data.

Rules of thumb: RESIST improving their research; focus *on preventing harm while the student gets his/her learning experience*; try to have only 1 round of revisions (only ask for 2nd revision if new BIG problems become apparent)

A question for you:

Please ANNOTATE: which ones are NOT correct?

- **The Human Research Ethics Committee (HREC) has reviewed a study and determined that participating in the study will likely make the participants feel uncomfortable and embarrassed. Could the HREC allow the researchers to begin this study?**

a. No; if any aspects of research studies are harmful in any way, HRECs cannot allow them.
b. Yes; the HREC examines only whether participants will be in physical pain.
c. Yes; as long as participants are not overly harmed and the research has significant value.

Goal 2
General Ethical Issues
in doing Research with Human Participants

Ethical Research will *Balance* Risks and Benefits

All research should be designed:

- With a positive purpose in mind and be of benefit to individuals and society
- To avoid harm or risks to participants

- *But sometimes some risks are unavoidable!*
- Risks should be reduced as much as possible (try to make your research "Minimal Risk") and if risks are unavoidable, risks and benefits should be in balance.
  - E.g. if deception is necessary, are the benefits great enough to outweigh the deception?
- Benefits to participants can be increased, too

Risk : **Benefit** ratio
What are the benefits of your research?

- Doing your research WELL can benefit everyone
- **Research Merit:**
  - Important research questions, excellent methods
- **Research Integrity:**
  - Honesty, Accuracy, and Objectivity in evaluating and reporting evidence
  - https://grants.nih.gov/policy/research_integrity/what-is.htm
  - For example: If your results do NOT support your hypothesis, you report that, honestly, strictly, and with thoughtful analysis! (Students: It's TOTALLY FINE and YOU CAN STILL GET AN A.)

Minimal risk research means:

1	No excessive **inducements** to participate *(right to refuse)*	• E.g. personal pressure, or even too much $$$$.... • If student-teacher relationship exists, teachers should emphasize to their own students that they are free to NOT participate in the research, with no bad consequences
2	No **deception** (*right to know*)	• E.g. Purpose of study should be fully disclosed at beginning of the study
3	No "**undue psych. stress**" or "**discomfort** higher than a reasonable level" *(right to avoid negative outcomes)*	• Questions / methods will avoid embarrassment or discomfort for participants • No questions asked about "**sensitive** aspects of the participant's own behaviour such as **illegal conduct, drug or alcohol use, and sexual conduct**"
4	**Anonymous / Confidential** *(right to confidentiality of data)*	• Data should be fully anonymous (no names, student IDs etc.) whenever possible; or if not, then only "identifiable by codes known only to the researcher" (as stated in model consent form)

15

Risk : Benefit ratio
What are the risks of your research?

Aiming for minimal-risk means trying to NOT VIOLATE these basic research participant rights:

1	Right to refuse to participate	=	fully free to choose to NOT participate, without fear of consequences
2	Right to know what your research is about before consenting	=	Adequate information about research given to people who are competent to make decisions (leads to "informed consent")
3	Right to avoid negative outcomes and have positive outcomes	=	• to not feel social, mental, or physical discomfort, etc. • to benefit from the research as much as possible
4	Right to confidentiality of their data	=	participant data is anonymous, or individuating information hidden safely (confidential)

14

Risk : Benefit ratio

Aiming for *ethical* research also means BALANCING these rights with the needs for **Research Merit** (more discoveries with excellent methods)**.**

If your research is riskier on one, balance it with another, & vice versa.

1	Right to refuse to participate	=	fully free to choose to NOT participate, without fear of consequences
2	Right to know what your research is about before consenting	=	Adequate information about research given to people who are competent to make decisions (leads to "informed consent")
3	Right to avoid negative outcomes and have positive outcomes	=	• to not feel social, mental, or physical discomfort, etc. • to benefit from the research as much as possible
4	Right to confidentiality of their data	=	participant data is anonymous, or individuating information hidden safely (confidential)

16

How to solve potential ethical issues at all stages of research

1. Recruitment of participants
   - How will you find them without violating privacy? How will you ask them to participate without coercing them?
   - Compensation: How much will you be giving them? Is it too much?
2. Informed consent and Consent & Information Sheet
   - What do participants need to know so that they can give informed consent? Have you told them everything about compensation, method, risks & benefits, privacy?
   - Is parental/guardian consent needed? Etc.
3. Methodology: Care and protection of participants
   - Could the kinds of questions or activities cause discomfort, embarrassment, loss of reputation, etc? How can you minimize this?
4. Privacy and confidentiality of Data
   - How will you anonymize data? If your data will not be anonymous, what promises do you make about keeping it confidential?
   - How will you prevent data leakage, esp. individually identifying information? Or, will you publicly share data– if so, how to hide individually identifying information?

Examples of potential issues: Recruitment

- *Main concerns:* *Privacy / confidentiality (4), Right to refuse (1)*
- Does how you recruit particular populations make privacy an issue?
  - E.g. students with ADHD: Parents don't want you to know…
    - Possible solution: Ask teachers who already know the diagnosis to privately pass consent / information sheets to potential participants
- Are power relations existent and an issue?
  - E.g. recruiting one's own students; difficult to refuse you
    - Possible solution: Verbal assurance / explanation to participants that this is not a school assignment; they have the right to refuse to participate & can do so without consequence
    - Possible solution: Make refusal of participation as anonymous / hidden as possible.
- Are you tempting participants too much?
  - E.g. Paying poor participants a lot of money; difficult to refuse
    - Possible solution: Find evidence of what an appropriate payment for time is in that context

(Stage 1 / 4) Recruitment

Participants may worry:

How will you find me & persuade me to participate?

(Stage 2 / 4) Consent & Information sheets

Participants may worry:

Before I agree, tell me: what will I do, and why?

Examples of potential issues: Informed Consent

Main concern: *Right to know before consenting (2)*

Before starting a study, the participant should read an *Information Sheet* and sign a *Consent Form*.

The person signing should be giving *informed* consent: So that they understand **what** they will do and **why** the research is being done.

What should be included in information sheet?

- Participants need to know:
  - What is the **purpose** of your research?
  - What will they be asked to do as part of your research? (**Procedures**: What kinds of questions or activities? How long will it take?)
  - **Where** will the findings and data **go** later? (Journal? Conference? Etc) Will identifying information be shown?
  - How will their **data be stored**– will it be anonymous, etc.?
  - What are the **potential risks** of participating in your research?
  - What are the **potential benefits**? (e.g. is there payment? Or benefits to your academic field, in general?)
  - They also need to be REMINDED that they have the right to halt participation (**choose not to participate**) at any time

- Sample editable consent form templates, for participants, parents, and organizations, may be downloadable. But….

DO NOT BLINDLY USE THE TEMPLATE PROVIDED!!!

- …if it is not totally applicable…! (e.g. data anonymous, not confidential; addressed to children instead of parents; written in language participants wouldn't understand)
- Carefully consider if they are suitable for your purpose, and please EDIT.

Informed consent from whom?

But: Carefully consider **who** should be informed of an individual's participation

- Who would expect to be informed that the research is happening?
- What if participants are not able to give consent?

Informed consent: from whom?

- Who should be asked for consent, additionally or instead of the participant?
  - *Consider: Who **can** or **should** give "informed" consent: the participant, a parent/guardian, an organization?*
- If your participants are:
  - 5-year-olds in a kindergarten
  - EdUHK Students, 18 years old
  - Some other school's students, 18 years old
  - Adult cancer patients currently in the hospital
  - 16-year-olds
  - Autistic 16-year-olds
  - 16-year-olds, and you'll ask them to do something potentially harmful to them

(Stage 3 / 4) Methodology

Participants may worry:

Will I suffer if I do in this study??

EdUHK rules about who must give consent:

If taking place in a non-EdUHK site, find out if you need approval (e.g. generally required from school principals)

Age-specific rules: from the "HREC Operational Guidelines and Procedures:"

(i) For children aged below 9, only signature of their parents/guardians on consent form is required; completion of the task, after verbal explanation of its nature by the researcher, provides implied consent by the child;

(ii) For children aged 9 to 15, signature of both the children and their parents/guardians on consent form is required; and

(iii) For adolescents aged 16 to 17, signature of the adolescents on consent form would be required, while consent from their parents/guardians is optional for studies involving [only] minimal risk.

*If it is **more than** minimal risk, parental/guardian approval is required.*

Examples of potential issues: Methodology: Surveys

- *Main concern: Avoiding negative outcomes (3)*
- Be careful of your wording.
  - Is there possibility of questions being intrusive, inappropriate, offensive?
  - Are demographic details appropriate/necessary?
  - Are the topics under investigation/measurement appropriate to the participants?
    - Are there religious, social, gender, economic, or cultural issues that might make particular questions and demographic details inappropriate?

What kinds of questions would be inappropriate to ask:
University students in Mainland China?
Elementary school students in a class that you teach? Etc.

Examples of potential issues: Methodology: Experiments

Is it ethical if you do not reveal the existence of two conditions (in the consent form)?

- *Main concern: Right to know about research before consenting (2)*
- Is the deception absolutely necessary (for "research merit")?
- What can you do to minimize the negative effect?
  - Debriefing; Minimize the deception (don't actively deceive)

Is it ethical if you provide a presumably beneficial treatment to the experimental group but not to the control group?

- *Main concern: Right to avoid negative & have positive outcomes (3)*
- If unequal benefits accrue (e.g. educational benefits), what can you do to reduce unfariness?
  - Control group = waitlist group?
  - Note: For very strong benefits (e.g. lifesaving medical interventions), experiment may be ended as soon as benefits are evident, & provided to control group.

Examples of potential issues: Confidentiality/Data management

- *Main concern: Right to confidentiality of data (4)*
- Information about data storage should be *given* to participants, in their Information Sheet.
  - Participants should be told how long you will keep their data, and in what format (identifiable or not, etc.)
  - Personally identifiable data should be kept confidential, and ideally anonymous (= identifiable information destroyed)
  - Security issues related to data must be addressed:
    - How will you anonymize stored data?
      - Do you even NEED to collect non-anonymous data…?
    - Where will you store the data: office, password protected computer? Who can get access to the data? How long the data will be kept for?
  - More sensitive data = more sensitive data storage

(Stage 4 / 4) Data Confidentiality

Participants may worry:

Where will my personal data go-- who will know my answers?

Examples of potential issues: Confidentiality/Data management

- Especially if data is (initially) not anonymous, how could you help prevent that non-anonymous data from being "leaked" to outsiders? (Think about both on-paper and on-computer data)
  - Have identifiable data on a separate page from the rest of the survey; tear it off and make the connection with codes only
  - Have two separate data files on the computer, connection made with codes only
  - Computers (and, ideally, files) should be password-protected; only certain people should be able to see identifiable data

Benefits: How to increase them?

- *Main concern: Benefit vs. risks*
- You may think about, and tell REC about, the specific benefits that will come about from your research; either for participants directly, or for the world at large
  - Address the benefits in your research proposal (why this study is important to the field, why it is high-quality research, etc…)
  - Do you plan to publish your findings, so as to benefit… (who or what…?)
- Can you report your findings to your participants, so that they may personally benefit from them?
  - E.g. give participants a link to a webpage where you will eventually post the findings…? Collect email addresses to which you will eventually send a soft copy of the final report…?

Importance of Ethical Clearance

Ethical clearance will help to **PROTECT** the following parties:

- The participants
- The researcher himself/ herself
- The University

Final words

Declaration of Ethical Clearance

For any **thesis-like research** (that is not just a class project/exercise):

- Make sure that ethical approval has been obtained **BEFORE** contacting any participants!
- You **MUST NOT** proceed with any data collection until ethical clearance has been obtained. **This is both an international and UGC requirement.**

UGC 大學教育資助委員會 University Grants Committee

Research Ethics is all of these:

Increasing benefits

- **Research Merit:**
  - Important research questions, excellent methods
- **Research Integrity:**
  - Honesty, Accuracy, and Objectivity in evaluating and reporting evidence

Reducing risks

- **Protection of Human Participants:**
  - Prioritizing rights of participants over your own self-interest
    - Right to informed consent; Right to refuse; Right to avoid harm; Right to know what will happen to their data.

Thank you!

Emma Buchtel
buchtel@eduhk.hk