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# Research Involving Human Subjects
# School of Graduate Studies
# Student Guide on Ethical Conduct

## Overview

The University of Toronto requires that all graduate student and faculty research involving human subjects be reviewed and approved by the relevant institutional Research Ethics Boards (REBs) before work can begin. Although research methodologies differ, the fundamental ethical issues and principles in research involving human subjects are common across all disciplines. The standards that must be met are set out in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), and can be reviewed at http://www.pre.ethics.gc.ca/english/pdf/TCPS%20June2003_E.pdf. This "living" document outlines the guidelines for research involving human subjects in Canada and is the creation of the three major Canada research councils (CIHR, NSERC, SSHRC).

In compliance with the TCPS, the University of Toronto has five Research Ethics Boards (REBs) that meet monthly to review ethical protocols from faculty members and graduate students of the departments that they serve. At present, the University has two Health Sciences, Education, HIV/AIDS and Social Sciences & Humanities REBs. The Ethics Review Office is part of the Office of the Vice-President, Research and Associate Provost, and functions to assist researchers through the ethical review process and to provide administrative support to the REBs. We also serve as an educational resource for faculty and students in learning the why's and how's of research ethics and ethics review.

Every researcher conducting research involving human subjects has the obligation to be familiar with the Tri-Council Policy Statement as well as the University of Toronto policies on research. Researchers are encouraged to take the TCPS On-line Tutorial, found at http://www.pre.ethics.gc.ca/english/tutorial/. Graduate students engaged in human subjects research are responsible for the ethical conduct of the projects, as are their supervisors. It is vital that both parties are aware of what these responsibilities entail. Graduate students engaged in human subjects research off campus must obtain ethics approval from the University of Toronto REB and, if required from the institution or site where their research will be conducted. Generally, graduate students are not covered by risk management insurance outside of the University unless the REB of the University has vetted their research. Hence the University of Toronto requires REB approval of all human research conducted by its students.

Graduate students who are engaged in human subject research at one of the nine fully affiliated teaching hospitals/research institutes must obtain approval first from the hospital REB and then from the University of Toronto REB.[1] Under some circumstances the university review will be expedited.

[1] The nine teaching hospitals/research institutes that are fully affiliated with the University of Toronto include: Baycrest Center for Geriatric Care; Bloorview MacMillan Childrens Center; Center for Addiction and Mental Health; Hospital for Sick Children; Mount Sinai Hospital; Sunnybrook and Women's Health Science Center; St. Michael's Hospital; The Toronto Rehabilitation Institute; University Health Network.

It is mandatory that all projects involving human subjects receive ethical approval **before** commencing any research activities, including recruitment, pre-screening or pilot trials. The ethical process for each protocol is slightly different (dependent on ethical issues inherent to research methodology, subject population, research question, etc.) and may take several weeks to months for final approval. Clarification and revisions to original submissions are common, and are handled as quickly and efficiently as possible. Understanding the issues and receiving proper guidance and supervision in the crafting of both the research study and the ethical protocol can minimize turn-around time.

**What Principles Guide Ethical Conduct?**

Although methodologies differ, ethical conduct of human subject research, of any kind, relies on the following guiding principles, outlined in the Tri-Council Policy Statement:

- respect for human dignity
- respect for free and informed consent
- respect for vulnerable persons
- respect for privacy and confidentiality
- respect for justice and inclusiveness
- balancing harms and benefits
- minimizing harm
- maximizing benefit

**What Research Requires Ethics Review?**

As stated in the TCPS, Article 1.1:

a) All research that involves living human subjects* requires review and approval by an REB (Research Ethics Board) before the research is started, except as stipulated below.

b) Research involving human remains, cadavers, tissues, biological fluids, embryos or foetuses shall also be reviewed by the REB.

c) Research about a living individual involved in the public arena, or about an artist, based exclusively on publicly available information, documents, records, works, performances, archival materials or third-party interviews, is not required to undergo ethics review. Such research only requires ethics review if the subject is approached directly for interviews or for access to private papers, and then only to ensure that such approaches are conducted according to professional protocols;

d) Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review. Performance reviews or studies that contain an element of research in addition to assessment may be subject to review.

***** Research involving human subjects must be reviewed whether or not the research is funded and/or whether the research is funded internally or by an external sponsor.

**What must be reviewed?**

Research involving human subjects includes:

- Obtaining data about a living individual through intervention or interaction with the individual, or the obtaining of private personal information about the individual.
- Secondary use of data (i.e. information collected for purposes other than the proposed research) that contains identifying information about a living individual, or data linkage through which living individuals may become identifiable.
- Naturalistic observation, except the observation of individuals in contexts in which it can be expected that the participants are seeking public visibility.

**What may not require review?**

- Research involving only the use of published or publicly available information or materials, performances or archival materials.
- Secondary use of data that contains no identifying information.

**Before submitting your protocol for ethics review**

The following prerequisites for ethics review of University of Toronto graduate student protocols must be in place:

- A supervisor who has an appropriate School of Graduate Studies faculty appointment at the time of the ethics review protocol submission and for the duration of the research activity.
- In the case of thesis research, it is required that the supervisory committee has been established, convened at least once, and has approved the thesis proposal. Members of the committee and the dates on which the committee has met must be recorded on ROSI. The date of approval of the thesis proposal must be recorded on the ethics protocol cover sheet.
- The student must be registered in a University of Toronto graduate program at the time of the ethics review submission and must be registered in the graduate program for the duration of the research activity involving human subjects.

If any of these conditions change, the student must inform the Ethics Review Office; the protocol could be suspended pending resolution.

**What does all this mean to graduate students and faculty researchers?**

- Every researcher using human subjects has the obligation to be familiar with the University of Toronto policies on research.
- Ethics approval must be received from all relevant Research Ethics Boards (University, affiliated hospital, school board, and/or other institution) **before** the research commences. Students must seek ethics approval for a new project, or if they are joining an ongoing project they must be certain that their research has already received ethics approval and that they are named on the proposal. This applies to student research as part of a graduate

course or degree requirement, thesis research, and/or as part of research conducted by any student or faculty member at the University of Toronto whether or not the research is funded.

- Faculty or graduate students intending to conduct interviews, administer/distribute questionnaires, or in any way systematically gather any personal information from individuals must seek ethics approval.
- Ethics approval is required for all research involving secondary use of data (or information collected for purposes other than the proposed research) if the data contains information through which individuals can be identified.
- Ethics approval is required for all research involving naturalistic observation except when the observation is of participants in political rallies, demonstrations, or public meetings or performances in which it can be expected that participants are seeking public visibility.
- Student research involving human subjects must be "sponsored" or supervised by a faculty member. The faculty sponsor or supervisor must sign the application and oversee the research.
- Graduate students performing research in one of the hospitals fully affiliated with the University of Toronto should submit protocols to both the University REB and REB of that hospital. It is preferred that submission to the hospital REB is done first, with the approved protocol and approval letter then submitted to the University. In most circumstances (but not all) the protocol can then be reviewed through the expedited process.
- Approval can be granted only if the subject participating in the research has been given an opportunity for fair and informed consent and it is clear that the result of the research will not identify the individual unless the individual prefers and consents to be identified.

**How does one obtain approval?**

The Ethics web site is located at http://www.rir.utoronto.ca/ethics_home.html and provides all the information and resource materials needed to submit an ethics protocol for review to one of the University of Toronto REBs.

Graduate students engaged in research in one of the nine fully affiliated teaching hospitals should submit to the hospital's REB for ethics review **first**. The approved protocol should then be submitted with a University of Toronto cover sheet, appendices and approval letter to the University. This second review is usually conducted under the expedited process, but can be brought to the full board, at the discretion of the Chair of the REB. Research may not be started until approval is received by **all** relevant REBs.

Graduate students who are engaged in human subject research off-campus and outside one of the nine fully affiliated teaching hospitals must obtain full review and approval from both the University of Toronto REB and the other institutional REB prior to commencing the research. Approval at the off-campus institutional REB does not guarantee approval by the University of Toronto REB.

OISE/UT students should submit a Statement of Intent and Ethical Review Protocol to the appropriate OISE/UT Ethical Review Departmental Coordinator, who will conduct a pre-review prior to submission to the Education Research Ethics Board.

The opinion of the Ethics Review Office should be sought whenever there is any doubt about the applicability of this policy to a particular research project. The Ethics Review Office is

located in Simcoe Hall, Room 10A, or may be reached at ethics.review@utoronto.ca or by calling the Information Assistant at 416-946-3273.

**What is the REB looking for?**

- All sections of the protocol are complete, concise and comprehensible.
- The design of the research project is capable of addressing the question(s) being asked in the research.
- The research is formulated from a participant-centred perspective, ensuring that all guiding ethical principles are followed, including:
    - Respect for human dignity
    - Free and informed consent, voluntariness
    - Protection of vulnerable persons
    - Privacy and confidentiality
    - Respect for justice and inclusiveness
    - Minimum harm and maximum benefits to participants

**Roles and responsibilities of the student investigator**

The student investigator has the following responsibilities:

- Inform him/herself and adhere to the relevant University and federal policies governing the ethical conduct of research and the use of human subjects.
- Submit his/her research plans for ethics review.
- Receive ethics approval **before** engaging in research activities that involve human subjects.
- Report adverse events, apparent (or potential) conflicts of interest or observed non-compliance with ethical conduct guidelines that arise during the course of an approved research project.
- Report any deviation from the project as originally approved to the respective REB for approval **prior to** its implementation.
- Ensure that any research, which he/she collaborates on in the course of his/her studies, has received ethics approval.

**Roles and responsibilities of the faculty "sponsor" or supervisor**

The Faculty "Sponsor" or Supervisor has the following responsibilities:

- Ensure that the ethics review application, and the proposed research project is compliant with those federal and University policies that govern research involving human participants.
- Ensure that any activity (or change) in which students require ethics review approval will receive appropriate review and approval prior to commencement of the activity.
- Provide the necessary supervision to the student investigator to ensure that all procedures performed under the research project will be conducted in accordance those federal and University policies that govern research involving human subjects.
- Ensure reporting of adverse events, apparent conflicts (or potential conflicts) or interest or non-compliance with ethical conduct guidelines that arise during the course of an approved research project.

- Professors responsible for courses involving any activity in which students obtain personal information from human subjects must ensure that that the activity has received review and approval.

**Once Approval Has Been Granted What Happens?**

Obtaining ethics approval is not the end of a researcher's responsibility:

If there are any changes to the research project after it has been approved, an amendment must be submitted to and approved by the REB before the revised research project can continue. Any adverse events (e.g., subject injuries or adverse drug reactions) must be reported to the REB.

An Annual Renewal is required each year (or shorter, at the discretion of the REB) before the anniversary date of the approval until the fifth year, or study completion, whichever is earlier. If complete, a Study Completion form is required. Otherwise, a new protocol is required on the fifth year of the protocol (after 4 renewals).

More detailed information on the requirements, forms and procedures are available on the Human Subjects section of the Ethics website at http://www.library.utoronto.ca/rir/ethics_home.htm.

The annual supervisory committee report on the progress of a doctoral or a master's student should include a statement of confirmation that the research has received, and continues to conform to, the ethics approval.

**What are the General Points to Keep in Mind?**

- Human subjects and their private information do not belong to the investigator.
- No person shall be an "unwilling or unwitting" participant in research.
- The participant has the right to say "no" at any time and request removal of their data (whenever possible).
- The scientific value of the research does not in any way trump the rights of the participants.
- Approval must be obtained before any interaction with human subjects begins, including recruitment.
- Informed Consent is a process and not simply the act of signing a form.
- Any changes to the approved protocol that alter the intent, content or procedure of the research must be approved before they are implemented