GUIDELINES AND PRACTICES MANUAL FOR RESEARCH INVOLVING HUMAN SUBJECTS

Committee on Human Subjects in Research
Vice-President, Research and Associate Provost
Ethics Review Office

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Chapter 1: Preamble and Introduction

1.1 Guidance

The University of Toronto Guidelines and Practices Manual for Research Involving Human Subjects was developed to communicate policies, guidelines and practices relevant to research ethics review and ethical conduct in research involving human subjects at the University of Toronto. It is a document that is complementary to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS – found at http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm). The policies, practices and guidelines discussed in this Manual are to be used as guiding documents, together with the TCPS, for researchers to consult when planning, designing and executing studies, and for reviewers when evaluating ethics protocols and continuing review. Ethical issues should not be thought to be solved through literal interpretation of the documents within the Manual, as many issues are complex and require balancing different ethical and scholarly principles, along with points of practicality. Through the use of the TCPS and Manual, it is expected that researchers will plan and conduct studies that incorporate best practices with respect to human subject participation. As a collegial process, feedback from researchers on their experiences using these guidelines will further refine REB deliberations and the documents themselves. As regional, national and international policies change, this Manual will evolve as well.

1.2 Importance of Research to the University

The University of Toronto, founded as King's College in 1827, is a large and complex institution, occupying three campuses – St. George, Scarborough and Mississauga – within 2 cities. The University is fully affiliated with nine teaching hospitals in Toronto, and is fully or partially affiliated with several other institutions. Faculty members and students conduct research in every discipline and methodology throughout Canada and around the world. The University of Toronto is Canada's most important research institution and has gained an international reputation for its research. The University is committed to maintaining this reputation, and to building upon it.

The University of Toronto is dedicated to fostering an academic community in which the learning and scholarship of every member may flourish, with vigilant protection for individual human rights, and a resolute commitment to the principles of equal opportunity, equity and justice. Within the university context, human rights include the rights of freedom of speech, academic freedom, and freedom of research. These entail the right to raise deeply disturbing questions and provocative challenges to the cherished beliefs of society at large and of the University itself.

Along with these rights come responsibilities. Researchers that engage in human subject research must do so ethically, and protect the rights of all participants involved. Essential to human subject research is the principle of Respect for Human Dignity. Persons may not be treated solely as a means to an end, because doing so fails to respect their intrinsic human dignity and thus impoverishes all of humanity. The welfare and integrity of the individual must be paramount. To conduct ethical research involving human subjects, University of Toronto
researchers at all levels of study and across all disciplines must work in compliance with research ethics policies and guidelines at institutional, provincial, national and international levels. This requires, at a minimum, that all research receives ethics approval prior to its commencement, and that it maintains approval, through continuing review, until its conclusion.

The purpose of this manual is to provide information, guidance and best practices to all parties engaged in human subject research. Knowledge and regulations are constantly evolving, and so will the policies and practices incorporated. Researchers should consult this document throughout the design and execution of their research projects.

1.3 History of Research Ethics Policies at the University and Affiliated Hospitals

Ethical research has always been the standard at the University of Toronto. The Ethics Review Office was established almost 40 years ago, and through the years has evolved with the field of research ethics.

Throughout the 1960s and early 1970s, ethical policies followed the Nuremberg Code (1947), which focused on voluntariness in research, and the Declaration of Helsinki (1964), which was written by the World Medical Association and adopted by research institutions around the world, including the University of Toronto. The University created protocol submission procedures, outlined in the University’s Handbook on the Use of Human Subjects (1975) and established the Human Subjects Review Committee, a body whose members reviewed and approved protocols individually, then met to ratify protocols and discuss ethical issues in order to develop policy.

In 1979, the Department of Health and Human Services (U.S.) released The Belmont Report, a document outlining ethics review requirements to fulfill the ethical principles of Respect for Persons, Beneficence and Autonomy. Professor Bernard Dickens, Chairman of the Human Subjects Review Committee, at that time, created the Guidelines on the Use of Human Subjects (1979). Currently, 25 years since the development of this document, it continues to serve as a useful reference for researchers.

In 1987, the Medical Research Council of Canada (MRC) published Guidelines on Research Involving Human Subjects. This document specified the requirements of ethics review, including evaluation of scientific merit and risk-benefit analysis, review of methods to maintain voluntariness and informed consent, and protection of privacy and confidentiality. Adoption of these guidelines gave rise to the establishment of the five subject-based Ethics Review Committees at the University of Toronto. These were Oncology I and II, Cardiology, Education and HIV/AIDS. Each committee met monthly to review ethical protocols for research that was to be conducted at the University, or one (or more) of the affiliated teaching hospitals.

Throughout the mid 1990s, the three granting councils, MRC, now called the Canadian Institutes of Health Research, the Social Sciences and Humanities Research Council (SSHRC) and the Natural Sciences and Engineering Research Council (NSERC) worked together to produce a document that would express their continuing commitment to the people of Canada, to promote the ethical conduct of research involving human subjects. The culmination of their efforts resulted in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS, 1998). This document firmly set the guidelines for ethics review and ethical
conduct of research in Canada. The policy outlined the requirements and composition of the Research Ethics Board (REB), at least one per institution, and led to the formation of separate REBs in the affiliated teaching hospitals. As a result, research which took place in the hospitals no longer required ethics review by the University, and protocols were no longer submitted here. This led to a major shift in the types of studies that were seen at the University, and resulted in a change in the 5 ethics review committees, now referred to as REBs. The HIV/AIDS REB remained, and was joined with 4 discipline/department specific REBs: Health Sciences I and II, Social Sciences and Humanities, and Education. The boards meet monthly to review all protocols that are above minimal risk, and ratify expedited protocols which have met the minimal risk criteria. They also discuss research ethics issues that are important to achieving best practices in ethics review.

The University of Toronto has put into place the necessary policies to establish compliance with the TCPS, and is working to develop policies and practices to exceed the minimum standard and to be on the forefront of best practices in research ethics and ethics review. The Human Subjects Review Committee has been replaced with the Committee on Human Subjects in Research (CHSR), an advisory body to the Vice-President, Research and Associate Provost. Since its creation in 2003, the CHSR and its executive has been meeting regularly to discuss the ethics issues brought forward by the REBs, researchers and the Ethics Review Office, to develop policies and advice to the Vice-President.

1.4 Promoting a Culture of Research Ethics at the University

It is a goal of the University to promote high quality research. Research can only be of high quality when it is conducted with high ethical standards. In order to achieve this goal, the University of Toronto is committed to a culture of research ethics and integrity. Research ethics and ethics review cannot be viewed as an obstacle to conducting research. Ethics is an integral part of the research endeavour, and should be valued throughout the process of research, from initial planning of a study to the dissemination of results.

There are several ways to promote a culture of research ethics at the University of Toronto that extend beyond the ethics protocol. REB review is a collegial process, and as such requires representation from all departments for which it serves. Hence it is important that faculty researchers involved in human subject research participate in this crucial research activity through service on a Research Ethics Board. Some researchers may find research ethics workshops and conferences interesting and worthwhile, and may wish to join the (Canadian) National Council on Ethics in Human Research (NCEHR) or the (American) Applied Research Ethics National Association. Most importantly, faculty members must bring research ethics into the classroom and the laboratory. It is vital that graduate and undergraduate students who engage in human subject research, and/or intend on doing so in the future understand the importance of ethics review and ethical conduct. Research ethics should be a mandatory component of any research methods course. The Ethics Review Office provides materials and lectures that can be incorporated into such classes, as well as offers workshops and consultation services.

Through use of the guidelines included in this manual, following of best practices, and maintaining a connection with research ethics at the University and beyond, researchers can
continue to foster the high quality research on which our reputation is built. Moreover, we can continue this tradition into the future.
Chapter 2: Principles of Research Ethics

The fundamental principles of research ethics transcend disciplines and methodologies. They should be kept in mind regardless of the nature of the research, or how minimal the risk may appear to be. At the University of Toronto, we strive to uphold the most stringent standards for these principles for all research.

The following is a brief outline of key research ethics principles, and will require supplementation from other sources. For further explanation of these principles, please see the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm), on which this text is based.

**Respect for Human Dignity**
Respecting the dignity of research subjects is a key component of ethics throughout the research process. To maintain respect for human dignity, research must respect the autonomy of the individual, and therefore protect the multiple and interdependent interests of the person, including physical, psychological, social and cultural. Respecting dignity also entails ensuring that subjects are not treated in a way that they may find embarrassing, upsetting or uncomfortable.

**Free and Informed Consent**
The voluntary and knowing agreement of the subject to participate in the research is a cornerstone of modern research ethics. Maintaining valid informed consent means more than obtaining a signature on a page. It is a continuous process of disclosure and education that involves ongoing communication, trust and fidelity between researchers and human subjects.

**Respect for Vulnerable Persons**
Respect for dignity entails high ethical obligations towards those who are relatively disempowered or have diminished decision-making capacity. Researchers must be aware of the power dynamic involved in any research, but particularly with those who are vulnerable because of cognitive or other deficits, or situational factors. Ethical obligations to vulnerable individuals in the research enterprise will often dictate special procedures to protect their interests.

**Respect for Privacy and Confidentiality**
Protecting subjects’ privacy and confidentiality are fundamental to ensuring their dignity. Researchers must not collect personal information about subjects unless required for the research, and should be particularly sensitive to information that may be embarrassing or harmful to the subject if disclosed. Further, research data and other personal information must be carefully protected from release without consent, or other legal justification. Subjects must be clearly warned about the circumstances in which their information is required to be disclosed to others.

**Respect for Justice and Inclusiveness**
Procedural justice requires that the ethics review process have fair methods, standards and procedures for reviewing research protocols, and that the process be effectively independent. Justice also requires a fair distribution of benefits and burdens of research. No segment of the population should be unfairly burdened with the risks and inconveniences of research. At the same time, justice also requires that researchers’ neither neglect nor discriminate against
individuals or groups seeking to take part in research or who may benefit from advances in research.

Balancing Harms and Benefits
The analysis, balance and distribution of risks and potential benefits are critical to the ethics of human research. Research ethics requires a positive balance, where the foreseeable risks should not outweigh anticipated benefits. Risk-benefit analysis thus affects the welfare and rights of research subjects, the informed assumption of risks and the potential for benefit, and the ethical justifications for competing research paths. Because research involves advancing the frontiers of knowledge, its undertaking often involves uncertainty about the precise magnitude and kind of benefits or harms that may attend proposed research. These realities and the principle of respect for human dignity impose obligations to ensure the scientific validity, appropriate design and ethical conduct of research.

Minimizing Harms
A principle directly related to harms-benefits analysis is non-maleficence, or the duty to avoid, prevent or minimize harms to others. Research subjects must not be subjected to unnecessary risks of harm, and their participation in research must be essential to achieving scientifically and socially important aims that cannot be realized without the participation of human subjects. In addition, the principle of minimizing harm requires that the research involve the smallest number of human subjects needed to ensure scientifically valid data.

Maximizing Benefits
The ethical principle of beneficence imposes a duty to benefit others and, in research ethics, a duty to maximize net benefits. The principle has particular relevance for researchers in applied professions. Researchers must seek to design and conduct studies that may yield important new information and that maximize the likelihood of benefit for participants.
Chapter 3: Governance

All research involving human subjects that is to be conducted at or under the auspices of the University of Toronto must be in compliance with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS), a policy created and regulated by the three federal granting councils: the Canadian Institutes for Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC). The University has a reporting relationship with these councils through a memorandum of understanding and is responsible for ensuring that all research is properly reviewed and conducted within the guidelines of the TCPS.

Until June 2006, the University had 5 Research Ethics Boards (REB) that are responsible for the ethical reviews of all research protocols involving human subjects. [As of July 2006, the HIV/AIDS REB has been disbanded, with a plan to transition to a Research Advisory Network (HRAN). More details are available on the ERO website and will be incorporated into the 2nd edition of the Manual.] Delegated review – expedited and departmental – may be conducted by (a) member(s) of the REB, or a departmental/joint-departmental/divisional/faculty Ethics Review Committee (ERC). However, the final approval is given by the respective REB.

The REBs report to the Committee on Human Subjects in Research, which is an advisory committee to the Vice-President, Research and Associate Provost. The VP, RAP in turn reports to the Governing Council. The Ethics Review Office (ERO), within the Office of the VP, RAP, is mandated to facilitate research ethics and ethics review policies and procedures to maintain compliance with the TCPS and with federal, provincial and University policies. This includes proportionate and continuing review of all human subject research. The ERO also works to educate and inform researchers of the policies and procedures necessary to follow.

At the present time, there is no Canadian regulatory body to oversee ethics review at the University of Toronto. However, the National Committee on Ethics in Human Research (NCEHR) is working towards the creation of a Canadian accreditation system, different than, but hopefully equivalent to the American system run by the Association for Accreditation of Human Research Protection Programs (AAHRPP). In the near future, a mandatory or voluntary system may be developed for governance, oversight and accountability over ethics review policies and procedures at the national level.

The University of Toronto is bound, through a Memorandum of Understanding (MOU) with the three federal granting councils, to uphold the guidelines outlined in the TCPS. This is the primary document used by the University’s REBs and delegates in their review of research involving human subjects. The University also holds a Federal-wide Assurance with the Office of Human Research Protection, the office within the Department of Health and Human Services (HHS) in the United States ensuring compliance with federal regulations based upon the *Belmont Report*. As a Canadian institution, we are expected to follow our national guidelines (TCPS), which are consistent with the ethical principles within the *Belmont Report*. This assurance enables our researchers to apply for and retain funding from the National Institutes of Health (NIH) and other American federal grants.

All applicable provincial and national regulations are taken into account during REB review, including the new Ontario privacy laws: Personal Health Information Protection Act (PHIPA) and
Freedom of Information and Protection of Privacy Act (FIPPA). It is also the responsibility of the REB to determine whether international research undergoing ethics review is compliant with the laws of that country, taking into account the ethical legitimacy of those laws with respect to human rights.

University of Toronto REBs take into consideration other existing guidelines when reviewing protocols, including the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use – Good Clinical Practice (ICH-GCP), the United Nations General Assembly Special Session on HIV/AIDS (UNGASS) Declaration of Commitment on HIV/AIDS, and the Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects. On the rare occasion that a practice from one of these guidelines comes into conflict with TCPS or Canadian regulations, the latter takes precedence.
Chapter 4: Responsibilities for the Conduct of Research

All research involving human subjects conducted at or under the auspices of the University of Toronto, must be reviewed and approved by the appropriate University of Toronto Research Ethics Board or its delegate prior to the commencement of the activity. The purpose of this section is to determine which activities constitute research, and by which process, if any, should they undergo research ethics review.

4.1 Definitions

4.1.1 Research

The current definition of research, according to TCPS is the involvement of a “systematic investigation to establish facts, principles or generalizable knowledge”. Many researchers and reviewers alike disagree with this narrow definition, preferring to expand the definition of research to include more encompassing statements. ProGroup, a working committee of the Interagency Advisory Panel on Research Ethics (PRE), released a discussion paper entitled Refinements to the Proportionate Approach to Research Ethics Review in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS), which proposed further expansion of the definition of research to include:

- Traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline; and
- Contribution or addition to a body of knowledge, or obtaining or confirming knowledge, which includes the expectation that the knowledge will be disseminated. (ProGroup 2005)

At present, the comments received in response to this paper have been submitted to PRE for analysis.

See Section 7.1 for further explanation on the definition of “research”.

4.1.2 Researcher

A researcher, at the University of Toronto, is defined as any person who conducts or advances research as connected with the University and/or conducts research using University resources, including space, materials, equipment or human resources. University of Toronto researchers may include academic staff, non-academic staff, post-doctoral fellows, graduate or undergraduate students and volunteers.

All researchers engaged in research involving humans are expected to follow University policies and guidelines, as well as provincial, federal and international regulations. Principal investigators and faculty supervisors have additional responsibilities including proper training and oversight of researchers working under their guidance.
4.2 Responsibilities of Researchers

University of Toronto researchers have primary responsibility for ensuring that their research is carried out in an ethical manner, and that the protection of the rights and welfare of human research participants is maintained throughout the project and beyond.

Researchers must be familiar with and comply with all University of Toronto research policies, as well as all relevant provincial, national and international policies and regulations. All human subject research projects that require ethics review, as per Article 1.1 of the TCPS, must be submitted for review by a University of Toronto Research Ethics Board or delegate (see guidelines for Ethics Review of Course-based Undergraduate Research), and receive ethics approval prior to commencement of the research activity. Researchers must maintain approval throughout the research activity, by following the practices of Continuing Review, which includes submitting an Annual Renewal form before the expiry date, and submitting a Study Completion Report at the conclusion of the project. Any significant change to the protocol must be reported, through submission of an Amendment Form.

All researchers who conduct research under the supervision of others bear personal responsibility for the ethical conduct of research involving human subjects. The Principal Investigator also has the responsibility of ensuring that members of the research team comply with the relevant policies and regulations. Principal Investigators should ensure that all members of the research team are aware of these policies and regulations, and that all individuals under their supervision have the training, education and competence needed to carry out their responsibilities in an ethical manner.

Researchers must report to the REB, through the Ethics Review Office (ERO) any apparent or potential conflict of interest or observed non-compliance with ethical conduct guidelines that arise during the course of an approved research project. Researchers must seek approval from the REB before a revised research project can continue under the financial guidelines of the sponsor and the University. Any adverse event must be reported to the REB, through the ERO.

4.3 Responsibilities of Faculty Members as Supervisors of Student Researchers

“Faculty Supervisor” refers to all academic staff who supervise student researchers at every level of study, including course instructors who assign research projects as part of a course requirement.

The role of the Faculty Supervisor is to oversee, mentor, train and educate student researchers under his/her supervision. In this role, it is the Faculty Supervisor’s responsibility to oversee all aspects of the student’s research, from evaluating scholarly merit to conduct of the research and dissemination of results.

The Faculty Supervisor must ensure that the ethics review application and the proposed research project is compliant with all relevant University, provincial, national and international policies and regulations that govern research involving human subjects. Any research activity (or change) in which students require ethics review approval must receive appropriate review
and approval prior to commencement of the activity. The Faculty Supervisor is responsible for reviewing the scholarly merit of the research project and the ethics protocol prior to its submission.

The Faculty Supervisor must provide the necessary supervision to the student researcher to ensure that all procedures performed under the research project will be conducted in accordance with University, provincial, national and international policies and regulations that govern research involving human subjects. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor. The Faculty Supervisor must also ensure that if any adverse events, apparent conflicts (or potential conflicts) of interest or non-compliance with ethical conduct guidelines arise during the course of an approved research project, that the REB, through the Ethics Review Office, has been notified.

4.4 Responsibilities of Student Researchers

Student Researchers, at all levels of study, assume primary responsibility for the ethical conduct of their research involving human subjects. They must ensure that the level of risk that is inherent to their projects is reasonable taking time frame of project, research experience, and expertise into account.

Student Researchers must be knowledgeable of and adhere to the relevant University, provincial and national policies and regulations governing the ethical conduct of research and the use of human subjects. The research proposal must be properly evaluated for scholarly merit, compliance with ethics policies and regulations, and written quality. Where relevant, thesis committees must approve the research proposal prior to submission for ethics review.

Student Researchers must receive ethics approval, through the REB or delegate process prior to engaging in research activities that involve human subjects, and must maintain approval throughout the research activity, by following the practices of Continuing Review, which includes submitting an Annual Renewal form before the expiry date, and submitting a Study Completion Report at the conclusion of the project. Any significant change to the protocol must be reported, through submission of an Amendment Form.

If a student research project is part of a larger study, the student researcher must ensure that the study has received ethics approval. If the research project is to be conducted off site, additional steps, including permission and supervision may be required. It is the responsibility of the Student Researcher to make sure that all required steps are taken prior to commencement of the research activity.

Student Researchers must report to the REB (through the ERO), or delegate, any apparent or potential conflict of interest or observed non-compliance with ethical conduct guidelines that arise during the course of an approved research project. Researchers must seek approval from the REB or delegate before a revised research project can continue under the financial guidelines of the sponsor and the University. Similarly, any adverse event must be reported.

More details can be found in Section 7.7.
4.5 Responsibilities of the Administration

The Ethics Review Office, as a unit within the Office of the Vice-President, Research and Associate Provost (OVP-RAP) is responsible for the implementation of the University’s policies on research involving human subjects. The OVP-RAP must provide for the appropriate administrative oversight and the necessary resources to ensure that the University’s policies, guidelines, practices and procedures are being adhered to and are in compliance with all relevant provincial, national and international policies and regulations in the ethical conduct of research involving human subjects.

Academic Administrators such as Principals, Deans, Academic Directors and Departmental Chairs, have a responsibility for oversight of the ethical conduct of research carried out within their jurisdictions. They have a responsibility to be aware of ongoing research and a duty to promote a culture of research ethics and ethical conduct of research involving humans. This includes being involved in the recruitment process of REB members when asked, and encouraging ongoing research ethics education and training opportunities for researchers.

Academic Administrators (or delegate) must sign ethics review protocol applications prior to their submission to the Ethics Review Office or REB delegate process. The Academic Administrator’s signature on an ethics protocol submission confirms that he/she is aware of the proposed activity, will allocate space and other resources required, and will provide administrative support to the research activity. The signature also means that the department, faculty or division will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national or international policies and regulations that govern research involving human participants.
Chapter 5: Integrity in Research

5.1 Preamble

Integrity in research is fundamental to maintaining the ethical principles upon which human participant protection is based. It is also required to preserve the appreciation, respect and trust society has for the research enterprise as a whole. Integrity in research must touch every part of the research cycle. Maintaining integrity involves resolving real or perceived conflicts of interest in funding or involvement in a study; receiving appropriate ethics approvals prior to the commencement of the study; ethical conduct throughout the project; and refraining from such activities as falsification or fabrication of data or deliberate omission or misleading of research findings. Integrity in research may also extend to reflecting the rights and obligations of researchers, and of society, including maintaining academic freedom and human rights. Only through integrity in research can public trust be maintained, and the symbiotic relationship between researchers and the public continue.

The University of Toronto remains committed to the highest standards of integrity in research. Policies and guidelines continue to be reviewed, revised and developed to reflect the various components associated with research integrity, and the handling of allegations of misconduct. Contained in this chapter are links to current University policies, as well as related national and international policies.

5.2 Relevant Policies and Guidelines

University of Toronto

Policy on Ethical Conduct in Research http://www.utoronto.ca/govcncl/pap/policies/ethicalr.html


Policy for Safety in Field Research http://www.utoronto.ca/govcncl/pap/policies/safefr.html

Policy on Conflict of Interest – Academic Staff http://www.utoronto.ca/govcncl/pap/policies/conacad.html

Conflict of Interest, Policy on – Librarians http://www.utoronto.ca/govcncl/pap/policies/library.html
Copyright Policy [http://www.utoronto.ca/govcncl/pap/policies/copyright.html]

Publication Policy [http://www.utoronto.ca/govcncl/pap/policies/pubs.html]


**National**

Tri-Council Policy Statement: Integrity in Research and Scholarship
[http://www.nserc.ca/professors_e.asp?nav=profnav&lbi=p9]

Framework for Tri-Council of Institutional Policies Dealing with Integrity in Research
[http://www.nserc.ca/institution/framework_e.htm]

Conflict of Interest/Conflict of Commitment – An Issues Paper
[http://www.nserc.ca/institution/coi/ch11_e.htm]

**International**

US Federal Research Misconduct Policies
[http://ori.dhhs.gov/policies/fed_research_misconduct.shtml]
[http://ori.dhhs.gov/policies/federal_policies.shtml]

Other international polices and documents
[http://ori.dhhs.gov/international/websites/index.shtml]
Chapter 6: Research Ethics Boards and Committees: Authority, Mandate and Membership

6.1 Office of the Vice-President, Research and Associate Provost

The Vice-President, Research and Associate Provost (RAP), is responsible for maintaining a research environment at the University of Toronto that is among the best in the world. This includes putting in place the mechanisms to ensure that all research involving human subjects conducted under the auspices of the University of Toronto is done so at the highest standards of ethics and integrity. The Ethics Review Office (ERO), as part of RAP, is responsible for providing the support and resources necessary to uphold these standards through compliance with University, provincial, national and international policies, regulations and guidelines. The ERO works with researchers to maintain human subject protection throughout the research enterprise; from ethics protocol submission through to study completion. The ERO works with the Committee on Human Subjects in Research (CHSR) in the development of policies, guidelines and procedures and facilitates the ethics review process conducted by the University of Toronto’s five Research Ethics Boards (REBs), and provides continuing oversight of REB-approved research projects. Finally, the ERO provides educational programs for faculty members, students and REB members about ethics review and research ethics from general principles to discipline-specific best practices.

6.2 Committee on Human Subjects in Research (CHSR) – Terms of Reference

1. The University of Toronto Committee on Human Subjects in Research shall advise the Vice-President (Research) and Associate Provost on policy and procedures with respect to the use of human subjects in research.

2. The Committee shall also serve as an appeals board for decisions of the Research Ethics Boards established by the University. When serving in that capacity, the membership of the Committee may be augmented so as to conform to the requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998), as amended from time to time.

3. The Chair, Vice-Chair and members of the Committee shall be appointed by the Vice-President – Research and Associate Provost, normally for terms of three years, with possibility of renewal. The membership shall include:

- Past Chair;
- Chairs of all University of Toronto Research Ethics Boards;
- Member of the Joint Centre for Bioethics;
- Vice-Provost (Faculty);
- At least one Chair of a Research Ethics Board of a teaching hospital affiliated with the University;
• Active researchers drawn from the humanities, the social sciences, the physical sciences and the life sciences;
• A member knowledgeable in law;
• A “community member” as defined by the Tri-Council Policy Statement;
• Director, Ethics Review Office, who shall serve as Secretary to the Committee.

4. When the membership is augmented for the purpose of hearing an appeal, the terms of new members appointed for that purpose may be for shorter periods of time, to be determined by the Vice-President.

5. The Committee shall meet at least two times a year, or more often at the discretion of the Chair. Minutes of the Committee’s meeting shall be taken, and a copy sent to the Vice-President.

6. The Committee’s responsibilities shall include, but not be limited to:

• providing guidance to the University’s Research Ethics Boards on the interpretation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as amended from time to time;
• recommending to the Vice-President the promulgation of University guidelines on particular aspects of the use of human subjects in research;
• advising the Vice-President on appointments to the University’s Research Ethics Boards;
• recommending to the Vice-President ways of better educating faculty, students and staff regarding the ethical use of human subjects in research;
• at the request of the Vice-President, evaluating the effectiveness of the University’s procedures for ethics review of research involving human subjects and recommending appropriate changes;
• serving as an appeals board for decisions by the University’s Research Ethics Boards, in accordance with the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, as amended from time to time;
• other responsibilities, at the discretion of the Vice-President.

7. The quorum for regular meetings of the Committee shall be 50% of the members. When serving as an appeals board, however, the Committee’s membership must conform to the requirements of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans.

8. The Chair shall approve the agenda for each meeting of the Committee, preside over the meetings of the Committee, advise the Vice-President on new appointments to the Committee and, as appropriate, represent the University, internally and externally, at meetings relating to the ethical conduct in research involving human subjects. In the absence of the Chair, the Vice-Chair shall assume these responsibilities.
9. An Executive Committee – composed of the Chair, the immediate Past Chair, the Chairs of the University REBs and the Director, Ethics Review Office – shall meet at the discretion of the Chair to deal with operational issues, plan for meetings of the full Committee and conduct any other business brought to it by the Chair.

6.3 University of Toronto Research Ethics Boards – Terms of Reference

6.3.1 Preamble

The establishment of our current Research Ethics Board system began shortly after the acceptance of the TCPS. Each REB was formed to fulfill the requirements of the TCPS in terms of composition of members, mandate and process.

Although all of the University of Toronto REBs have started at relatively the same place, as time progresses, each continues to evolve with experience, discipline and membership to become distinct. This enables each board to meet its own goals of due diligence and due process. In this context it is important to understand that the terms of reference for each REB are somewhat different. However, the levels of professionalism and dedication are the same. Each board continues to serve the University research community to the highest ethical standards.

6.3.2 Reporting Relationship of Research Ethics Boards

The University of Toronto Research Ethics Boards report to the Vice-President, Research and Associate Provost, through the Committee on Human Subjects in Research.

6.3.3 Mandate

Research is an essential component of the University’s mission statement. The University recognizes that special considerations exist when conducting research involving human subjects.

The University of Toronto REBs have been established to approve, reject, propose modifications to or terminate any proposed or ongoing research involving human subjects which is conducted within or by members of the University of Toronto. The REBs ensure that all research carried out by investigators meets the highest ethical standards as per Tri-Council Policy Statement, and that safeguards are developed which provide ongoing protection to those who serve as research subjects.
6.3.4 Membership and Quorum

Each REB will consist of at least 10-12 members, and will comply with Article 1.3 of TCPS, which states:

The REB shall consist of at least five members, including both men and women, of whom:

(a) At least two members have broad expertise in the methods or in the areas of research that are covered by the REB;

(b) At least one member is knowledgeable in ethics;

(c) For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and

(d) At least one member has no affiliation with the institution, but is recruited from the community served by the institution.

The REB composition as written in Article 1.3 defines quorum for any University of Toronto REB meeting.

As per Article 1.12, in situations where REB members may have a personal interest in the research under review (e.g. as a researcher, the student's supervisor or may have a financial interest) conflict of interest principles require that the member not be present when the REB is deliberating or making decisions. The REB member may disclose and explain the conflict of interest and offer evidence to the REB provided that the conflict is fully explained to the REB and the researcher has the right to hear evidence and to offer a rebuttal.

Terms of membership are 1-3 years with the possibility of one renewal. Membership is staggered to ensure appropriate balance and maintain continuity. Members are expected to attend all meetings with all protocols for discussion adequately read and evaluated. Members may be asked to review expedited protocols and to act as primary or secondary reviewer on full-REB protocols.

All members are expected to review and evaluate protocols within the guidelines of the TCPS and other relevant guidelines, policies and regulations. They are also required to maintain a strict level of confidentiality regarding protocol information, reviews and decisions. Differences of ideas and interpretations are important in the ethics review process. However, it is expected that members will be respectful of each other and the process throughout their deliberations.

REB members are expected to stay current in their knowledge of ethical guidelines, policies and best practices. It is the ERO’s responsibility to offer educational opportunities to members, including conferences, the REB Annual Retreat, workshops and lectures. It is the responsibility of REB members to engage in these educational initiatives, when possible.
6.3.5 Decision Process

All REB meetings are held face-to-face and decisions are made by consensus.

After review, individual proposals are referred back to the primary investigator with comments and/or suggestions for revision. Investigators may be invited to the meeting to respond to questions about their proposals, but are not present during the decision process. Investigators who are members of the REB will leave the room during considerations of their proposal or any proposal in which they have an interest. Members are expected to disclose any apparent conflicts of interest to the Chair.

No protocols or protocol amendments may be initiated without prior written approval by the respective REB.

Further details on REB review can be found in Chapter 9. Terms of Reference for each REB can be found in Appendix I.

6.3.6 Record Keeping

As stated in Article 1.8 of the TCPS,

Minutes of all REB meetings shall be prepared and maintained by the REB. The minutes shall clearly document the REB’s decisions and any dissents and the reasons for them. In order to assist internal and external audits or research monitoring, and to facilitate reconsideration or appeals, the minutes must be accessible to authorized representatives of the institution, researchers and funding agencies.

At the University of Toronto, the Ethics Review Coordinators take minutes of all REB meetings, as part of their supportive function of the REB. These minutes are approved by the Chair of the REB prior to dissemination to the researcher. The minutes are circulated among the entire REB prior to the next meeting, with members invited to request revisions or clarifications of the minutes, as required.

Only authorized representatives can access REB minutes. These include ERO staff, members of the respective REB and researchers named in the protocol. Under certain conditions other individuals may be granted access to the minutes. This requires written permission by the respective REB Chair, or the Director, ERO. Where appropriate, identifiers not related to the specific inquiry, may be removed.

6.4 Delegated Ethics Review

As per the TCPS, all human subject research conducted at the University is required to undergo ethics review by the University. This includes undergraduate research. Provisions in the TCPS, outlined in Article 1.4, allow the institution to delegate this responsibility to the departments/faculties. Such arrangements are beneficial for both the University and departments, as it reduces the burden on the REBs, and empowers the departments to establish procedures and guidelines that are discipline-specific and pedagogically relevant.
Over the years, this delegated ethics review of undergraduate student research has varied across the University. With the goal of reaching consistency of ethics review process throughout the institution, the Ethics Review Office began the formal process of establishing a Delegated Ethics Review process in Spring 2005. With close involvement of the Committee on Human Subjects in Research (CHSR), guidelines for Ethics Review of Undergraduate Research Involving Human Subjects were created, and approved. The main points of the guidelines are risk relative to research experience, responsibility, and supervision.

Delegated Ethics Review Committees (DERCs) have begun registering with the ERO and submitting their DERC-specific Terms of Reference. The template Terms of Reference can be found in Appendix I.

6.5 Recruitment of Research Ethics Board Members

The ethics review process, at its best, is efficient, effective and educational for members of the Research Ethics Board and researchers alike. It is a collegial process, and one that is based on the ability to marry expertise in research ethics with understanding of the research discipline. A fair and knowledgeable REB can exist only when its composition is reflective of the areas of research which it reviews. Moreover, the ethics review process can run efficiently only when the responsibility of membership is assumed by the researchers for which it serves.

In order to facilitate the process, as well as to help promote a culture of research ethics across the University, recruitment of new REB members must remain a top priority. Academic administrators including the Vice-President, Research and Associate Provost, the Deans, Associate and Vice-Deans, Research and Departmental Chairs must all be involved in maintaining REB membership.
Chapter 7: Requirements for Research Ethics Review

7.1 Research Requiring Review

The current definition of research, according to TCPS is the involvement of a “systematic investigation to establish facts, principles or generalizable knowledge”. Many researchers and reviewers alike disagree with this narrow definition, preferring to expand the definition of research to include more encompassing statements:

- Traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline; and
- Contribution or addition to a body of knowledge, or obtaining or confirming knowledge, which includes the expectation that the knowledge will be disseminated. (ProGroup 2005)

All research involving human subjects, conducted at or under the auspices of the University of Toronto must be reviewed and approved by the appropriate University of Toronto REB or delegate thereof. The University is required to follow the guidelines outlined by the TCPS, which states in Article 1.1 that:

(a) All research that involves living human subjects requires review and approval by an REB in accordance with this Policy Statement, 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 and to Article 2.3 of this Policy.

(d) Quality assurance studies, performance reviews or testing within normal educational requirements should also not be subject to REB review.

The Common Rule, 45 CFR 46 (§46.102(f) - U.S.) is helpful in further defining human subject:

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains:

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.
Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

A further elaboration on the scope of research requiring review can be found in Appendix 1 of the TCPS:

Scope of Research Requiring Ethics Review

- Whether the research is funded or not;
- Whether the funding is internal or external;
- Whether the subjects are from inside or outside the institution;
- Whether the subjects are paid or unpaid;
- Whether the research is conducted inside or outside Canada;
- Whether the research is conducted inside or outside the institution;
- Whether the research is conducted by staff or by students;
- Whether the research is conducted in person or remotely (e.g. by mail, electronic mail, fax or telephone);
- Whether the research is to be published or not;
- Whether the focus of the research is the subjects;
- Whether the research is observational, experimental, correlational or descriptive;
- Whether a similar project has been approved elsewhere or not;
- Whether the research is a pilot study or a fully developed project;
- Whether the research is to acquire basic or applied knowledge; and
- Whether the research is primarily for teaching or training purposes or whether the primary purpose is the acquisition of knowledge.
7.2 Principles to Determine Exemptions from Research Ethics Review

7.2.1 Preamble

As stated above, according to the Tri-Council Policy Statement (TCPS), the mandate of a Research Ethics Board (REB) is to provide Research Ethics Review (RER) for all research involving human subjects, as defined in Article 1.1. It is not within the mandate of the REB to review research activities outside of this definition. Items c) and d) of this article give some guidance as to the types of activities which may be exempt: research based on publicly available data or individuals in the public arena, research-like activities that fall into the areas of quality assurance or performance reviews and non-research activities such as testing within normal educational requirements.

Even with these instructions, in many instances it is still difficult to determine which activities do not constitute research involving human subjects, and therefore do not require RER. Therefore, the purpose of this document is to provide guidance to facilitate the determination of whether an activity, possessing qualities of research, requires RER or may be exempt. Both principles must be taken into consideration when making this determination.

7.2.2 Principles

1. Intention/purpose of the activity and how the data shall be used

   The current definition of research, according to TCPS is the involvement of a “systematic investigation to establish facts, principles or generalizable knowledge”. Many researchers and reviewers alike disagree with this narrow definition, preferring to expand the definition of research to include more encompassing statements:

   - Traditional or emergent methodologies and techniques that are accepted as characteristic of the specific discipline; and
   - Contribution or addition to a body of knowledge, or obtaining or confirming knowledge, which includes the expectation that the knowledge will be disseminated. (ProGroup 2005 – See Section 4.1.1 for further explanation on ProGroup.)

   From either definition, some activities can quickly be ruled out as not involving research. However, for many others, making a firm determination is somewhat unrealistic, as the activities possess attributes common with research. They may:

   - Employ or include research tools, methods and data collections practices.
   - Be funded by the same agencies as research, and undertaken by persons or organizations that are primarily concerned with research.

   In such situations, it may be more useful to evaluate the intention or purpose of the activity in order to determine whether or not it requires RER. Although not perfect, the following exemption categories may be useful:
Quality Assurance, Performance Review: Activities that are inherent in the mandate of an organization or are required by law. The primary intent of conducting these types of activities is to assess how the organization/department/program’s is doing, to better serve its clients/students. Typically, final reports remain internal to the organization. However, findings may be relevant to other stakeholders (e.g. similar organizations, departments or programs).

Reflective Practice / Professional Development: Reflective Practice has been defined as “Examining one’s situation, behavior, practices, effectiveness, and accomplishments by asking: What am I doing and why? The self-evaluation that follows involves active, persistent, and careful consideration, speculation, and contemplation of the practitioner’s beliefs and knowledge and leads to professional development, growth, and greater understanding of self and the profession.”  Reflective Practice / Professional development may involve research-like activities where others (e.g. students, colleagues and supervisors) are engaged in order to solicit information that can be used for self-evaluation and growth, provided no information about these other individuals is made public or identifiable.

Standard Professional Practice*: Research-like activities that take place within acceptable standard practice of the respective profession. Typically, professional ethics codes cover these activities. An example of such an activity is evaluating the benefits of a change in teaching method in the professional setting, where the change is recognized within standard practice. The testing of activities that are novel, or used differently than is accepted as part of standard professional practice, or is conducted outside of the professional setting is research.

(*Not including those defined as research)

2. Does it Involve Human Subjects?
In many cases, this question is easy to answer: a literature review obviously does not involve human subjects, a clinical trial does. However, in other situations, human beings may be engaged with a research project, but their role may not be that of a research participant or subject, and therefore the research may not require RER. They may serve as collaborators, or members of the research team or steering committee. Human data may be used for secondary analysis, which is aggregated and anonymous. Students in a class may be asked for feedback to enable their teacher to reflect on his/her professional practice.

Determining whether or not the type of relationship is that of researcher – subject/participant is key to understanding whether the research does involve human subjects, and thereby requires RER. Professional courtesy and professional ethics should not be confused with the requirement for RER.

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7.2.3 Process for Exemptions

1. Development of Divisional Guidelines
The Delegated Ethics Review Committees (DERC) and departments/divisions should work together with the Ethics Review Office to develop a priori guidelines for activities that may be exempt from RER. Such guidelines will assist researchers in differentiating between activities that require REB review and those that do not. Guidelines will facilitate consistency and reduce ad hoc decision-making on the part of the REBs.

2. Evaluation of Exemption Requests
The ERO will develop an evaluation form to determine whether an activity may be exempt from RER. If the determination is that indeed the activity is exempt from RER, this form should be submitted to the respective DERC or the ERO (for departments not affiliated with a DERC). It is within the jurisdiction of the DERC or ERO to further investigate if the evaluation seems erroneous. If RER is required, a protocol should be submitted as per normal procedure.

In its Annual Report, the DERC will report to the ERO the number and types of research-like activities that were exempted over the course of the year.

Although an activity may be exempt from RER, it is expected that it is conducted ethically and professionally. This may require oversight by the department and/or consultation with ethics codes or experts.

7.3 Projects for which the Researcher is acting as a Consultant

Ethics Review through a University of Toronto REB or DERC is a service of the University. As such, it is available to all faculty members and students who conduct research as part of their University responsibility or course of study.

It is understood that many faculty members and students may conduct research as private, paid consultants outside of their University responsibilities. Some of these arrangements do involve the University, either through funding agreements, recruitment or conduct of the research activity. These projects should go through the standard ethics review process at the University, and ethics approval must be granted prior to commencement of the research activity.

Arrangements made between researchers as consultants and outside companies that do not involve the University in any way – no recruitment or research activities are to be conducted at this institution, and funds will not be administered here – are not eligible for ethics review at the University of Toronto.

In these cases, it is the responsibility of the consultant or company to seek ethics review from an alternate source. This may be an REB affiliated with the company, or with the researcher. There are at least two independent/private REBs in the Greater Toronto Area that will conduct ethics review, for a fee. The ERO can provide contact names and numbers for these REBs.
In the situation that both University REB and independent REB review are required, the University of Toronto REB should be the lead reviewer. Protocols will not be reviewed through the expedited process based on an approval from an independent REB.

7.4 Research Conducted Off-Campus or Involving Other Sites

According to the Article 1.14 of the TCPS:

Research to be performed outside the jurisdiction or country of the institution which employs the researcher shall undergo prospective ethics review both (a) by the REB within the researcher's institution; and (b) by the REB, where such exists, with the legal responsibility and equivalent ethical and procedural safeguards in the country or jurisdiction where the research is to be done.

7.4.1 Research Involving an Affiliated Teaching Hospital

It is the goal of the University of Toronto and the University-affiliated teaching hospitals to work together as partners to support the research endeavours of their faculty, staff and students. As required by the *Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS)*, each institution has its own research ethics board(s) (REB(s)) to review studies that involve its facilities in one capacity or another. However, in the spirit of partnership, the University and affiliated teaching hospitals continue to work together to streamline ethics review as much as possible, in order to facilitate the process.

Research that occurs solely at a University-affiliated hospital needs only to be reviewed at the hospital, and, similarly, research that occurs solely at the University needs only to be reviewed at the University. However, in some circumstances, hospital-based human subject research may involve the University in some capacity, including administration of funds, student involvement and/or transfer of data or biological samples.

Over the last two years, a subcommittee of the Committee on Human Subjects in Research has worked to develop procedures to streamline ethics review procedures for research where the subject-researcher interaction takes place solely at the hospital, but for which the University is involved in a related aspect of the project.

Three sources of regulations have been taken into account in determining the minimum procedure required by the University. These are:

**Federal Granting Councils:**
Memorandum of Understanding
*Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*

**Privacy legislation:**
Freedom of Information and Protection of Privacy Act (FIPPA)
Personal Health Information and Privacy Act (PHIPA)
Procedures

Table 7.1 illustrates the new procedures for handling these types of studies. It is the responsibility of the Principal Investigator (or Faculty Supervisor) to ensure that procedures are followed appropriately. If the University plays more than one role in the project, the most stringent of the procedures must be followed. Please contact the Ethics Review Office at 416-946-3273 with any questions or concerns.
Table 7.1 Processes to be taken by PIs for hospital-based human subjects research, where the University plays a role*

<table>
<thead>
<tr>
<th>University's Role</th>
<th>Process to be undertaken by Principal Investigator</th>
<th>University's next steps</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Administration of funds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) New fund</td>
<td>Copy of approval letter sent to UT Research Services</td>
<td>Funds are released</td>
</tr>
<tr>
<td>b) Annual renewal/ Study Completion</td>
<td>Copy of approval letter sent to UT Research Services</td>
<td>Funds are maintained</td>
</tr>
<tr>
<td>2. Student research</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) Graduate student</td>
<td>Copy of approved TAHSN protocol and approval letter and University of Toronto Cover Sheet submitted to UT Ethics Review Office</td>
<td>Administrative review</td>
</tr>
<tr>
<td>b) Undergraduate student</td>
<td>Copy of approval letter sent to respective Delegated Ethics Review Committee</td>
<td>No action required</td>
</tr>
<tr>
<td>3. Storage or Analysis of Personal information (data)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) de-identified</td>
<td>Copy of approved TAHSN protocol and approval letter and University of Toronto Cover Sheet submitted to UT Ethics Review Office</td>
<td>Administrative review will determine that the University activities are compliant with FIPPA(^2)</td>
</tr>
<tr>
<td>b) identifiable</td>
<td>2 copies of conditionally-approved TAHSN protocol and approval letter submitted to UT Ethics Review Office***</td>
<td>Protocol will undergo REB review, normally through expedited process</td>
</tr>
<tr>
<td>4. Storage or Analysis of Biological samples</td>
<td></td>
<td></td>
</tr>
<tr>
<td>a) no access to identifiers**</td>
<td>PI contacts UT Research Services</td>
<td>Material Transfer Agreement created</td>
</tr>
<tr>
<td>b) access to identifiers**</td>
<td>2 copies of conditionally-approved TAHSN protocol, approval letter and University of Toronto Cover Sheet submitted to UT Ethics Review Office***</td>
<td>Protocol will undergo REB review, normally under expedited process, as required by FIPPA and PHIPA(^3)</td>
</tr>
</tbody>
</table>

* Please note: this role does NOT involve intervention or interaction with human subjects. ANY research involving human subjects interaction or intervention at the University MUST receive REB review and approval from a University of Toronto REB prior to commencement.

1 There are two provincial acts of legislation governing privacy in Ontario. The Freedom of Information and Protection of Privacy Act (FIPPA) only applies to government institutions, which include public universities, but not hospitals. Therefore the University must have a process by which personal information is determined to be protected. This may be through an administrative review by a Research Ethics Officer, or REB review by a University of Toronto REB.

2 Under the Personal Health Information Privacy Act (PHIPA), a hospital is defined as a Health Information Custodian (HIC), whereas a university, normally, is not. Use and storage of personal health information requires both the permission of the HIC (usually through a Privacy Officer), and ethics approval by the REB.
**at the University**

*** For research that requires approval by both the hospital and the University, it is imperative that the principal investigator receives approval from both institutions prior to starting the research.

### 7.4.2 Research Involving the Toronto District School Board

All research involving the TDSB, whether participants are teachers, staff, students or parents, must be reviewed and approved by its External Research Review Committee after receiving University of Toronto REB approval. The mandate of this committee is to facilitate the conduct of educational research while ensuring that the educational process is safeguarded for all projects.

It is important that researchers who intend on involving the TDSB understand the criteria that the External Research Review Committee consider when deciding whether the research project should be approved, as these differ in some respects to those of University of Toronto REBs. They include the relevance of the study to education, the methodology and scholarship, and the protection of staff and students in terms of time and demands. Protocols that do receive University of Toronto REB approval may not necessarily receive approval from the External Research Review Committee. Furthermore, this committee only meets 8 times throughout the school year (October to May or June), and gives undergraduate projects a low priority.

For these reason, researchers are encouraged to read the Guidelines for Conducting Research in the Toronto District School Board prior to writing their University of Toronto ethics proposal.

Keep in mind, the school Principal has the right to refuse his/her school’s involvement in an approved project. Administrative approval is required prior to starting the research (see Administrative Consent, section 7.10).

Guidelines and application forms can be founded by searching for the External Research Application on the TDSB website at www.tdsb.on.ca.

### 7.4.3 Research Involving Other Institutions

Research involving human subjects conducted by University of Toronto researchers in other institutions must be reviewed and approved by the appropriate University REB prior to the commencement of the research activity. It is also required that the research be vetted and approved through the proper mechanisms of the host institution, unless there is a good reason not to do so (see Article 2.1 commentary in the TCPS). This may involve review by an REB, an ethics committee, research committee, or process by which administrative consent is acquired by an authorizing official. It is the responsibility of the researcher to determine what is required by the host institution and obtain approval before beginning the research activity.
7.4.4 Fieldwork Research

Research involving human subjects conducted in the field, whether in Canada or in foreign countries, must be reviewed and approved by the appropriate University of Toronto REB and host REB or equivalent before the research may begin. Final approval cannot be given by the University REB until evidence of approval by the host REB is submitted. In countries where there is no ethics review process, a letter from a reputable source, verifying that the research proposed is culturally acceptable should be submitted. If outside knowledge of the research to take place may put the safety of the researcher at risk, a statement to this effect in the protocol submission should suffice. Please consult the University’s Policy for Safety in Field Research.

7.4.5 Review of Multi-Centre Research

This section applies to research that involves the University of Toronto as one of two or more research sites, where the other sites are not affiliated to the University.

Section 1.13G of the TCPS discusses the complexities that arise in multi-centered research. While principles of institutional accountability require that each local REB reviews the protocol, doing so may result in different, sometimes contradictory decisions.

In order to avoid this, researchers who are submitting protocols involving multiple REBs are asked to identify one institution as the “host” site. Once the host site’s REB has approved the protocol, the researcher should then submit copies of the approved protocol and informed consent documents, approval letter, and REB comments through the host review process. A cover letter distinguishing between core elements of the research, and elements that can be altered to comply with local requirements should be provided. Whenever appropriate, The University of Toronto REB will review an approved protocol through the expedited review process. ERO staff may also communicate with counterparts at the other sites to facilitate coordination of the ethics review process.

7.5 Research Conducted by Status-Only and Adjunct Faculty Appointments

Status-Only and Adjunct faculty members entitled to conduct research assume the same responsibilities as all University of Toronto researchers. Those who supervise graduate students as part of their appointments are expected to follow the same policies and guidelines as University of Toronto faculty supervisors. Please see Chapter 4, Section 4.1.
7.6 Research Conducted by Post-Doctoral Fellows and Visiting Professors

Post-doctoral Fellows and Visiting Professors conducting research at the University of Toronto must assume a faculty member to “sponsor” his/her research. The Faculty Sponsor’s responsibilities are the same as those of a Faculty Supervisor overseeing a graduate student’s project. Please see Chapter 4, Section 4.2.

7.7 Student Research

All human subject research that is part of a student’s degree or course requirement must undergo ethics review by a University of Toronto REB (graduate) or Delegated Ethics Review Committee (undergraduate course). If the research project will be conducted off-site, please see Section 7.3. The responsibilities of the student and the faculty supervisor are outlined in Chapter 4, Sections 4.2, 4.3 and 4.4.

7.7.1 Graduate Thesis-based Research

For thesis-based research, see Research Involving Human Subjects: School of Graduate Studies Student Guide on Ethical Conduct, available online at http://www.sgs.utoronto.ca/gradadmin/policies/index.asp.

7.7.2 Graduate Non-Thesis-based and Undergraduate Research

Small projects and experiential learning that involve human subjects are a valuable part of a student's research experience. For many, they provide a first glance into the world of research, to understand how studies develop, from first thought to final report. For others, they provide a foundation, and may be a starting point for a thesis project later on, or even a career in research. It is therefore vital that student research projects are designed and conducted with the same level of professionalism as graduate thesis and faculty research. Similarly, ethics review of these projects must adhere to the principles outlined in the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS). This document can be found at http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm. It is the responsibility of both student researcher and supervisor/instructor to understand and follow the federal and University of Toronto policies governing research involving human subjects, to submit a proper ethics protocol.

Research Conduct

Student researchers assume primary responsibility for the ethical conduct of their research involving human subjects. It is therefore important that projects they design and carry out are at a level of risk for which they are competent. It is strongly recommended that for all but
experienced student researchers, projects involve minimal risk to subjects. Definitions and criteria can be found in Section 8.3 of this manual. Final decision as to whether a project is at an appropriate risk level for student research resides with the REB or DERC to which the protocol is submitted.

A student researcher must:
- 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 protocol 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 they collaborate on in the course of their studies has received ethics approval.
- If research is to be conducted off-site, seek and obtain permission and supervision, as required. Documentation may be required for ethics approval by the REB.

**Supervision**

It is the responsibility of the supervisor/instructor to oversee all aspects of the student’s research, from evaluating scholarly merit to conduct of the research and dissemination of results. A supervisor must:
- Ensure that the ethics review application and the proposed research project is compliant with those federal and University policies that govern research involving human subjects.
- 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 with those federal and University policies that govern research involving human subjects.
- Ensure reporting of adverse events, apparent conflicts (or potential conflicts) of interest or non-compliance with ethical conduct guidelines that arise during the course of an approved research project.

Please see Section 4.3 for further information on Faculty Supervisor responsibilities.

**Education and Training**

All students should be knowledgeable of the TCPS and the principles upon which it is written. Therefore, it is highly recommended that they complete the online tutorial that is offered by the Inter-agency Panel on Research Ethics (PRE). The course takes approximately two hours to complete, and issues a certificate upon completion. It can be found at [http://www.pre.ethics.gc.ca/english/tutorial](http://www.pre.ethics.gc.ca/english/tutorial).

The Ethics Review Office offers workshops to students and their faculty supervisors/instructors at the beginning of each term. Students and supervisors are encouraged to attend these workshops, along with lectures that are given in departments, upon request.
Research Ethics Review

All graduate research must be reviewed by the respective REB, as written in the TCPS.

For undergraduate research, the Delegated Ethics Review Committee (DERC) system has been put in place, as per Article 1.4 of TCPS:

An institution may decide that ethics review of research that is carried out by undergraduate students as part of their course work may be delegated to a departmental level process that complies with this Policy Statement. The institution should set out criteria for determining which categories of research proposal are suitable for consideration through this means, and establish such procedural issues as to who will be responsible for implementing and overseeing the approval mechanisms. As with other levels of review, proper accountability demands appropriate record keeping. Departmental level review should not be used for research in which an undergraduate student is carrying out research that is part of a faculty member’s own research program. Such research should be reviewed by the regular institutional REB procedures.

The University of Toronto has established several Delegated Ethics Review Committees (DERCs) at the divisional or departmental level dedicated to research ethics review of undergraduate course-based protocols for student-initiated projects and course templates. The DERC general terms of reference appears in Appendix I of the manual. The DERC is run independently of the Ethics Review Office, but has a reporting relationship with it. Students should contact the Research Administrator or faculty supervisor/instructor to be aware of where to submit, deadlines, et cetera. If the project is part of a faculty member’s larger study, review of the faculty’s study by the respective Research Ethics Board is required. If the study has already received ethics approval, no further review is required.

If the department has not set up such a committee, or the DERC feels that the protocol is outside of its jurisdiction – because of a complex or high-risk component – the protocol may then be reviewed by the respective REB. Details of where to submit, how to submit, deadlines and other information can be found on the website.

Whether reviewed by the DERC or REB, the same level of professionalism is expected of the protocol submission. Incomplete or poorly-composed protocols may be returned without review. It is expected that the supervisor's signature on the submission form means that the supervisor/instructor has overseen the research design and creation of the protocol, and approves of the submission. The signature also means that the supervisor/instructor, like the student investigator, assumes responsibility of the research conduct and will strictly adhere to the approved protocol.
7.8 Other Guidelines Documents

7.8.1 Ethical Guidelines on Interviewing Public Personalities

This section offers guidelines on the preparation of ethical protocols involving the use of public personalities in research, particularly through interviews. It is based on the spirit of the principles included in the Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans (1998). These guidelines were prepared by a sub-committee in political science, chaired by Professor Jacques Bertrand and were approved by the Social Sciences and Humanities Research Ethics Board on August 19, 2003.

Overall principles

1. Research in the social sciences often involves individual interviews of public personalities. These are individuals who are interviewed because of the roles they play or positions they hold in government, public or private organizations, the media, the arts, public campaigns, or even public demonstrations.

2. Research involving public personalities should follow the general ethical principles included in the Tri-Council Policy Statement. Among the most relevant for this type of research, they include:
   a. The right to privacy and confidentiality
   b. Respect for free and informed consent

3. Research involving public personalities should recognize two particular dimensions:
   a. The degree to which individuals are in the “public eye”: Some individuals may be official representatives of public organizations, politicians, journalists, heads of organizations, frequently quoted in the media, or used to speaking in public. However, other public personalities may include mid-level or even lower level officials of public organizations, such as government departments, non-governmental organizations, businesses. These individuals may be less familiar with interviews and therefore require that researchers take greater care to obtain free and informed consent and respect the right to confidentiality.
   b. Degree of vulnerability: it is generally recognized that public personalities, by virtue of their position or their work within public organizations, are exposed to public scrutiny and criticism. In some contexts, individuals pursue their public activities with high degree of personal risk. In authoritarian settings, for example, members of opposition groups may expose their views publicly, knowing that they might be persecuted or even killed. More often, the degree of risk in exposing their views may entail retribution from superiors, criticism from peers, loss of employment, or damage to reputation. The greater the risk to individuals, the more researchers should take care to ensure free and informed consent, and to respect the right to confidentiality.

4. Research on public policy can often be critical of organizations or individuals who are interviewed. Such research entails, at times, that researchers might not fully share with public personalities the use of interview material or the full purpose of the study. Researchers should weigh the necessity of such concealment against the potential harm to interviewees. They should be particularly careful to avoid harming individuals beyond their public roles.
Preparing protocols

In preparing protocols, researchers should reflect on the general principles of the Tri-Council statement and how they can best be implemented in the context of interviewing public personalities. Preparation of a protocol places the burden on the researcher to clearly explain the reasons for choosing a particular kind of process for obtaining informed consent and for respecting the right to privacy. Researchers should build a convincing case for any proposed process, taking into account the ethical principles of the Tri-Council Statement, the guidelines for public personalities, the type of research and the particular context of the research. Protocols should provide ample and clear information on these processes. The researcher must demonstrate that they have weighed potential risks against the benefits of the research, and considered the particularities of the context in assessing particular means of ensuring ethical standards.

1. When seeking consent for interviews, researchers should normally seek to obtain written consent. However, given the time constraints of public personalities, the sensitivities of some political contexts, and some other circumstances, the researcher can propose alternative means of seeking consent. Such consent may be obtained verbally or at the time of scheduling an interview (via an introduction letter, e-mail or fax, for example). Ethical protocols should specify the reasons for seeking an alternative consent process. These should be weighed against the potential risks to the individuals interviewed and the degree of the public nature of their positions, as specified in point 3 above. Researchers using verbal consent or an alternative consent process should provide sample consent scripts or letters in their protocols.

2. The less individuals’ positions entail a public or representative role, or the less they are familiar with interviews and voicing their positions publicly, the more researchers should seek to obtain written informed consent and clarify confidentiality processes. For example, it might be acceptable to develop a protocol with a minimal requirement for consent and guarantees of confidentiality when interviewing politicians, heads of organizations, public relations officers of corporations, journalists, or academics, who would be used to interviews and would be most likely to know how to protect themselves or their organizations. Such assumptions would be less true for members of organizations who play less of a public role and may never be called upon to represent their organization.

3. The most detailed consent scripts or letters contain information about the nature of the research, the researcher’s identity, the participant’s role, the right to confidentiality, the right to terminate the interview at any given time, use of audio-tapes, risks and benefits of the research (See Checklist for informed consent documents, available from Research Services and through the web-page below). It may not be appropriate, feasible, or necessary to include all of the above requirements to obtain informed consent from public personalities for interviews. Researchers should justify the level of detail required for consent in relation to the context of their research, if they must exclude some of the above requirements.

4. The right to confidentiality is usually stated at the time of seeking consent for an interview. Agreements on confidentiality may vary. They might include complete anonymity of the interviewee and no direct quotes; permission to use some quotes while keeping the identity anonymous; permission to identify the individual in publications and to use direct quotes. The less individuals are used to interviews or to playing a public role, the more researchers should ensure that permission has been adequately obtained to publish interview materials, share them with other researchers or other people, or identify the individuals. Protocols should be clear
about the ways to guarantee that the interviewee has fully consented to the publication of her/his name or use of direct quotes.

5. Researchers should provide more guarantees of confidentiality and a more detailed consent process when planning interviews with public personalities who may expose themselves to potential retribution from their superiors or governmental authorities.

6. In authoritarian contexts, or under conditions of political instability, the personal risk to public personalities can be much higher than in democratic contexts. Researchers should take additional precautions to ensure that informed consent is obtained and confidentiality requirements are met. In these cases, researchers may wish to include a consent process in their protocols that more explicitly addresses the means by which consent will be obtained to quote individuals or publish their names. In cases where the interview can cause a very high personal risk to public personalities, the researcher should justify the importance of conducting these interviews for the success of the research project.

7.8.2 Guidelines for Ethical Conduct in Participant Observation

This section was drafted by Professors Gavin Smith, Katharine Rankin, and Jacques Bertrand from the Social Sciences and Humanities REB. It is designed to serve two purposes. First it serves to help researchers think about some of the ethical issues that might arise while doing studies that involve Participant Observation. Second the guidelines should aid applicants in preparing protocols in a way that will provide the REB with the information they need to make an informed judgement on the ethical issues involved in this component of the research programme.

Participant Observation Described

Participant Observation is usually just one part of a cluster of other non-experimental, inductive, field-based research strategies. These guidelines refer only to the Participant Observation component.

In Participant Observation the researcher is, to a greater or lesser extent, immersed in the day-to-day activities of the people being studied. The objective is usually to record conduct under the widest range of possible settings. In this way, participant observation differs from 'naturalistic observation', as discussed in the Tri-Council Policy Statement (TCPS) because the latter does not involve interaction between researcher and researched. Insofar as information is often the result of dialogical interaction between the researcher and the informants, participant observation covers a wide range of ethical issues that are complex and often unpredictable. Because most participant observation involves long term presence among the people being studied, the informed consent process should be dynamic and continuous. Starting with the project design it should continue throughout the participant observation period by way of dialogue with those studied.

Participant Observation was historically associated with a form of research in which the researcher resides for extended periods of time in a small community. These guidelines, however, refer also to Participant Observation in a wide variety of settings, and over longer and shorter periods of time; for example, participant observation can transpire in institutions, class
rooms and markets, or it may involve traveling with migrants, or interacting with specific categories of people.

**Overall Principles**

The range of issues:
Among the issues that throw up special challenges for Participant Observation, especially as it is practiced in social/cultural anthropology and cognate disciplines, are:

- The often long term nature of the interface between researcher and the subjects of study;
- The wide range of relationships involved, such as status differences between the two parties, power differences and educational differences, as well as degrees of formality;
- The variety of settings, from close interpersonal interactions to observation of public meetings and actual participation in social events.
- In many cases, the research will be taking place in settings that are unfamiliar to the researcher, making her/his presentation of self and interaction with others especially sensitive. While ethical issues are often raised in the context of cultural differences the same kinds of issues may arise when research transpires in familiar settings. Power differentials rooted in gender, class, health and so on also require similar sensitivity.
- The ethical codes of the groups under study may well be different from those of the researcher’s home country/home institution. They may also be different from the ethical principles followed by the host government, non-governmental organizations in the area, or funding agencies for the research.

In addressing these issues, researchers should:
- be as aware as possible that the researcher practicing Participant Observation does not have just one role – that of the researcher – but performs a variety of statuses and roles;
- be especially sensitive to differences of age, gender, class, health, and culture that may raise ethical issues during the course of Participant Observation;
- be aware of potential clashes in ethical principles, and give primary ethical considerations to the people being studied or being effected by the study. In some instances, researchers may have to make exception to this principle.

**Stages in the research programme**

Researchers are encouraged to think through the changing ethical challenges through the various stages of the research programme, from issues prior to fieldwork, entering the field-site, the changing nature of interactions as the fieldwork proceeds, the responsibilities that arise as one leaves the field and, finally, ethical issues arising from writing up Participant Observation based research. Precisely because it is difficult to anticipate every ethical issue, researchers engaged in long term Participant Observation need to interrogate themselves continuously about the ethical issues arising as the research setting undergoes change.

**Technical Recording**

While there are a vast range of informal interactions, encounters, observations and ‘participations’ involved in this form of research, with the various ethical issues that thereby arise, it is to be noted that more ‘technical’ practices produce their own particular ethical concerns. These include mapping, filming, video-taping, photographing and tape-recording.
Confidentiality

As with ethics more generally so too with confidentiality, the most important issue is not so much to do with one or another setting, but with taking extreme care overall and as one crosses from one setting to another. The confidentiality of the Participant Observer’s knowledge must be made explicit to each informant as well as to the larger group of people that provide the setting of the research. But in many cultural settings it will be important that the Participant Observer’s discretion is also conveyed implicitly and over time. Researchers need to be aware too that confidentiality refers to information gathered in any of the components of their research programme, not just that gathered through Participant Observation. (This can include land-holding records, court cases, information gathered from archives, interviews, and so on.)

The distinction between informal and more technical interfaces applies here too. Specific information gathered about health, intimate relations and beliefs, or even economic data, can be especially sensitive and may require additional reassurances to informants and those closely connected to them.

Informed Consent

Even in the context of Participant Observation, informed consent remains one of the most important ethical principles. There are numerous issues that arise in the context of seeking informed consent during Participant Observation. Is it feasible to receive formal informed consent from every participant in a group with which one interacts? At what point is informed consent required, given the numerous roles and statuses the researcher adopts? Can one receive “collective” consent by approaching group leaders or spokespersons? There are no easy answers to these questions. They vary by setting and by the nature of the research. However, the researcher should seek the highest standards in applying the principle of informed consent when using Participant Observation. In so doing, the researcher should:

• Ensure that participants are aware of the researcher’s identity and purpose among the group;
• Disclose and disseminate as broadly as possible through general announcements or other more informal means the researcher’s purpose, research topic, and data gathering method. Participants should be aware that any of their interactions with the researcher may constitute some form of data gathering.
• Seek permission from group leaders or spokespersons, where appropriate, but especially if they can help to broadcast to a community the researcher’s identity, purpose, method. However, researchers should also be careful to avoid situations where such public endorsements/announcements to the community can create pressure to participate. Participants should remain free to avoid all interaction with the researcher.
• As much as possible, the researcher should obtain informed consent from each individual participant with whom the researcher will be interacting. It is especially important to remain aware that some participants might not be fully informed despite general announcements in public. As the researcher gains awareness of the level of information individual participants have about the researcher’s identity, purpose and method, he/she should make every possible effort to disclose such information individually.
Preparing the Protocol

In preparing protocols, researchers should reflect on the general principles of the Tri-Council Statement and how they can best be implemented in the context of Participant Observation. The task is to reassure a fellow scholar in the social sciences and humanities—but possibly one not familiar with this form of research—that one has thought out and resolved as many ethical issues as can reasonably be anticipated. The researcher should clearly explain the reasons for choosing a particular kind of process for obtaining informed consent and for respecting confidentiality. Of course, in addition to the Tri-Council Statement, the researcher can take into account these guidelines on Participant Observation and the particularities of the context when communicating research methods and means of ensuring ethical standards. Protocols should provide ample and clear information on these processes and demonstrate that the researcher has weighed potential harms against the benefits of the research.

1. Methodology: Researchers should fully explain the setting(s) for Participant Observation, what potential interactions are involved, how data will be gathered, the kinds of issues that might be discussed more formally, and detail as much as possible the anticipated process. It is fine to acknowledge the limitations of predicting ahead of time what will happen during the course of the research, but details that can be anticipated should be stated.

2. Participants: Describe who the people are, and reflect on potential ethical issues that may arise in the context of the research. It is acceptable to disregard issues of sample size and ‘inclusion/exclusion criteria’ unless these are relevant to your methods. The researcher should also explain how s/he plans to enter the field and make people more familiar with his/her presence and the nature of the research project.

3. Potential harms: the researcher should expand as much as possible on the extent and variety of potential harm to participants.

4. Privacy and confidentiality: The researcher should provide information about how he/she will safeguard data once recorded and treat sensitive information. If one intends to quote or name anyone in publications/work, explicit consent must be sought from participants, or they should be made explicitly aware, on an individual basis, that they might be quoted.

5. Informed consent: While the Tri-Council Policy Statement upholds the principle of written consent as superior to verbal consent, there are many settings in which verbal consent is more appropriate. In many cases involving Participant Observation researchers would not find it feasible or desirable to seek written informed consent by all participants. In such cases, verbal consent will be required. In any case, the researcher should elaborate on the appropriateness of a particular informed consent process for the setting/group studied by Participant Observation, and should include means of informing the community/group/individuals of the researcher’s identity, purpose, topic of research and method; appropriateness of seeking consent from group leaders or spokespersons; informal/formal means of obtaining informed consent, relative to what is appropriate in the given setting. It is important to clearly explain ethical dilemmas that might arise, or limitations to ideal procedures in given contexts.
7.9 Administrative Consent for Research at the University

Several divisions and departments within the University of Toronto have policies and procedures regarding recruitment of their student or staff populations into studies. These policies typically require administrative consent by the local research committee or department head. It is the responsibility of the researcher to ensure that these policies and procedures are followed. They include:

Guidelines and Procedures Regarding Access to University of Toronto Faculty, Students and Staff as Research Subjects [New – July 2006]
http://www.provost.utoronto.ca/English/Guidelines-and-Procedures-Regarding-Access-to-University-of-Toronto-Faculty-Students-and-Staff-as-Research-Subjects.html

Principles and Responsibilities Regarding Access to Professional Program Students and Residents as Research Subjects

Principles and Procedures Governing the Use of the PSY100 Subject Pool
http://www.psych.utoronto.ca/~psy100/research/
Chapter 8: Procedures for Research Ethics Review

8.1 Procedures for Protocol Writing

8.1.1 University of Toronto Ethics Review Protocol Submission Form

As Canada’s most research-intensive university, it is important to recognize the diversity of research conducted at the University of Toronto and by its researchers, in terms of discipline, method, location and participant population.

No single form can adequately address all relevant issues nor utilize all relevant terminology for all projects. Three University of Toronto Ethics Review Protocol Submission Forms have been created to cover the basic ethical questions required by the REBs for informed review. The basic protocol forms are separated according to user: one for faculty members, the other for supervised or sponsored researchers, including graduate students, post-doctoral fellows and non-faculty researchers. A Graduate Course Template Form is also available, which is meant for course instructors to fill out, in order to receive blanket ethics approval of human subjects research that will be conducted as part of a graduate course assignment. It is well understood by both the ERO and REBs that not all questions will be applicable to all research, nor will all terms be relevant. The ERO continues to evaluate and revise the forms in response to the needs of its researchers.

In order to facilitate the research ethics review process for research that is conducted primarily at the affiliated teaching hospitals, the current practice is to accept the hospital REB-approved Toronto Academic Health Sciences Network (TAHSN) Human Subjects Research Application form protocol submission form with the University of Toronto Cover Sheet. This form may also be appropriate for clinical trials that are University- or community-based.

The newly revamped University of Toronto Ethics Review Protocol Submission Forms will become available shortly. They have been written to better suit non-biomedical research, and have replaced the former form and cover sheet. It is anticipated that the by asking more targeted questions, the new forms will facilitate protocol writing as well as REB review (Appendix IIa, IIb and IIc – see Section 8.1.3).

8.1.2 Instructions for University of Toronto Ethics Review Protocol Submission Forms – Faculty and Supervised or Sponsored Researchers

The goal of the Ethics Review Office is to facilitate the research ethics review process for all researchers and Research Ethics Boards. There is a broad range of research activities and disciplines that must undergo the research ethics review process, and we recognize that one form cannot ask questions completely appropriate for all research. For those questions that are not appropriate, please answer N/A.

For research that is reviewed at one or more affiliated teaching hospitals, or for research that is clinical in nature, it may be more appropriate to use the TAHSN form, found at
Section A – General Information

1. Title of the Research Project
   For funded research, please ensure that the title is the same as that of the grant application. Where more than one ethics protocol is required to cover the research of a specific project, please use the title plus subtitle or other form of identification.

2. Investigator Information
   The Principal Investigator is the researcher who assumes primary responsibility for conduct of the research. This may not be the same researcher who serves as PI on the grant, nor the PI on the overarching project, if it is multi-centered. In the case of graduate student research, if the project will serve as the thesis or degree-fulfilling requirement, the graduate student will normally be the PI.

   Post-doctoral fellows and Visiting Professors may serve as PI on the ethics protocol. However, in these cases, a faculty member must sign as the “Faculty Sponsor” of the project. The Faculty Sponsor, like the Faculty Supervisor, takes responsibility for ensuring that the PI conducts the research project ethically, in accordance with the REB-approved protocol.

   Undergraduate course-based research should be reviewed by the appropriate Delegated Ethics Review Committee. Please see your department or faculty Undergraduate Coordinator to determine what this process entails.

3. University of Toronto Research Ethics Board
   REBs are normally responsible for specific departments within the University, with the exception of the HIV/AIDS REB. This board reviews all research that involves HIV/AIDS. In situations where the research proposed may fit better with an REB not responsible for the researcher’s department, the Ethics Review Office may choose to re-assign that REB for its review.

4. Type of Review
   Full REB review is the default process. In some situations an expedited review process may be appropriate. Please consult with our guidelines regarding Criteria for Expedited Review. The final decision of review process is at the discretion of the ERO and the REB. A justification why the protocol should be reviewed through the expedited process is also required. The justification should include potential risk to participants – physical, emotional/psychological and social/legal through method and/or type of data, as well as vulnerability of the population.

5. Location of research
   Community within the GTA would include school boards (e.g. Toronto District School Board, Peel, Durham, York Region, etc.), medical clinics not affiliated with a hospital, COTA, etc. Research in the community may require administrative consent and/or ethics review by another board or committee. It is the responsibility of the researcher to make sure that all necessary processes required are followed, and that all approvals are obtained prior to the commencement of the research activity.

   Field research outside of Canada normally requires ethics review by a board or committee within that jurisdiction. Please see http://www.hhs.gov/ohrp/international/ to determine what
process is in place in the country where the research is to take place. In cases where there is no ethics review process, a letter by a relevant body (e.g. NGO, University) stating that there is no ethics review process that covers the participants but that the research is culturally and ethically acceptable is required. In situations where authorities’ knowledge of the research to be conducted could potentially put the researcher and/or the participants in danger, it may be preferable not to seek administrative consent. Please explain these circumstances in the protocol submission form. Please refer to the University’s policy on Safety in Field Research at http://www.utoronto.ca/safety/Policies/fieldres.htm.

6. Other Research Ethics Board Approval
Please list other REBs that have or will need to review the protocol.

7. Funding of the Project
For projects that require funding in order to commence, it may be beneficial to postdate ethics approval to the day that the funds are released. This is a new service that the ERO is offering.

It is common for one protocol to cover several grants. Please make sure to include all agency and known funding information that the protocol will be covering.

It is also common for one grant to fund several research projects, each of which is/will be covered by a separate ethics protocol. Please provide the number of protocols they anticipate will be submitted in order to cover the entire funded research activity, and to specify that this is # X of total number.

If funding changes (e.g. addition of sponsor, deletion of sponsor, change of sponsor) during the course of research, an amendment should be submitted to the ERO to state this.

Scholarships and fellowships are not relevant to this section unless there is a research allowance component that involves human subjects.

8. Project Start and End Dates
Project start and end dates can be interpreted in several ways. In some traditions, engagement with the participant group may start before the beginning of data collection, and end significantly later than the end of data collection. Therefore, the start date should refer to the beginning of a formal recruitment process, or, in the case where there is no formal process, the commencement of the informed consent process and data collection. Completion of a study can be defined as the point in which data analysis has been completed in order to answer the original research question(s).

9. Scholarly Review
Please see our guidelines on Scholarly Review.

10. Conflict of Interest
Please refer to the University of Toronto’s Policy on Conflict of Interest Academic Staff (http://www.utoronto.ca/govcncl/pap/policies/conacad.html) and Publication Policy (http://www.utoronto.ca/govcncl/pap/policies/pubs.html).
Section B – Summary of the Proposed Research

11. Rationale
This section should be clear, concise, and provide just enough information to give the reviewers an understanding of why the research is being proposed, and what research has been done in this area. It should be assumed that the REB is familiar with the discipline, but may not be knowledgeable of the specific research area being proposed. In general lengthy literature and thesis proposals are not appropriate.

12. Methods
This section should include all methods to be used in the study, with respect to human participants and biological materials. When complex, tables, figures and timelines may be useful. It is not necessary to describe standard tests or procedures (e.g. DNA analysis, MRI scans, Beck’s Depression Inventory, etc.). It is the responsibility of the researcher to obtain the proper permission to use certain standard instruments in their research. If this is necessary, please ensure that this is done before using any such instruments in your research.

Please include copies of non-standard tests, interview schedules, etc.

For naturalistic or participant observation, describe the setting, kinds of information and interactive and observational procedures that you anticipate using.

13. Participants/Informants or Data Subjects
This information should help the REB to establish not only who the participants/informants will be, but what potential vulnerabilities, if any, they may have. For personal information, this section should provide details on how the information will be extracted or collected and what it will contain. The degree of identifiability should also be discussed (e.g. names, postal codes or parts thereof, OHIP numbers, etc.).

14. Experience
Research with human participants can only be conducted ethically when the researcher team’s abilities are equal to the needs and expectations of the participant. Therefore, if the research is to involve methods that pose greater than minimal risk, collection of sensitive data, and/or a vulnerable population, a brief description of the research team’s experiences and/or ability to conduct the research is required. If the researcher is a student, the degree of supervision, by the faculty supervisor and/or on-site supervisor should be included.

15. Recruitment
It is understood by the REBs that methods of recruitment differ by discipline, with some not having any formal recruitment whatsoever. If there are any extenuating circumstances as to why a certain method (formal or informal) is to be used, please include this in the description. It is understandable that in some cases potential participants will be known to the researcher prior to the submission of the protocol.

16. Compensation
If compensation is offered, it should not provide undue influence in an individual’s decision to participate in the research, nor should it be a simple token; participants should be duly compensated for time spent participating in the study. When participants represent a particular profession, compensation per time spent may be appropriate. Justification for the amount of compensation to be offered to participants should be provided.
It is expected that whenever possible, participants who withdraw will receive partial compensation.

**17. Possible Risks**
In order to assist researchers in evaluating possible risks of harm for participants, these have been separated into types of risk: physical, psychological/emotional, and social, including legal. Deception may pose additional risks, and may require consideration as to what the debriefing process should include. Deception should, whenever possible, be through omission (leaving details out), not commission (providing false descriptions).

If the research does involve greater than minimal risk, it is important for the researcher to contemplate the best way to manage or minimize it.

**18. Possible Benefits**
Whenever possible, benefits should be first felt by the participants in the study. “Society” may refer to the community in which the research was conducted, Canada, Western society, etc. The term is used vaguely here for the researcher to explain benefits applicable to his/her research.

It is important that possible benefits listed are realistic. If there is no benefit to the participant, this should be expressed.

**19. The Consent Process**
While the default, according to the TCPS, is written consent, the REBs understand that many disciplines and cultures do not accept written consent as appropriate. It is the quality of the consent process, not the format that is most important.

Informed consent is an on-going process that starts with the researcher’s first contact with the individual and continues through study completion/subject withdrawal, and beyond. Any verbal exchange about the study, the written informed consent form and any other written documentation given to participants should provide adequate information for the participant to make an informed decision about his/her participation.

Please see our website for best practices and examples of consent forms.

**20. Consent by an authorized party**
In Canada, there is no definitive age below which parental/guardian consent is required in order to participate in research. Whenever children (under 18 years of age) are to be included as participants, the researcher must consider the risk of the research, the maturity level of the children, and any potential risks versus benefits associated with parental knowledge of the research (e.g. research looking at drug use in youth).

Adolescents that do not live with their parents can consent for themselves. Similarly, university students are considered to be adults, whether or not they live out of the home.

If an adult participant is not competent to formally consent, a surrogate decision maker can do so. However, the research should be explained to the participant, and given the opportunity to provide assent or dissent.
Assent from children should also be obtained, as even very young children can be made to understand simple explanations of what the research involves and determine whether they want to participate or not.

21. Debriefing
Deception is considered a risk, as it can negatively impact on a participant’s feelings of trust in the study, in the researcher, and in research. Therefore, whenever deception is to be used, it is important that debriefing be done so as to provide the participant with an opportunity for real informed consent. The participant should also be re-consented, or asked whether they wish to have data withdrawn, after debriefing.

It is important that participants have access to study findings. For some populations, it may not be appropriate for dissemination of results to only be accessible in a scholarly journal article format. Please describe the format by which participants can access findings (newsletter, copy of thesis material, etc.), and how they will be notified of this.

22. Participant withdrawal
What actions constitute withdrawal should be listed. This may include actions of non-compliance by the participant, leading the researcher to withdraw the participant from the study. If participants cannot withdraw after a certain point for any reason (e.g. de-linking of data), this should be explained.

Section E – Confidentiality and Privacy
23. Confidentiality of data
Ways to ensure confidentiality include:
Use pseudonyms and/or linkages, labels, etc.
Minimize access to data – who may access it?
Storage – where? How will data be secured? How long will data be retained?
When will data be destroyed?

24. Privacy Regulations
Please see relevant regulations, including:

Personal Health Information Protection Act (PHIPA):
http://www.e-laws.gov.on.ca/DBLaws/Statutes/English/04p03_e.htm

Personal Information Protection and Electronic Documents Act (PIPEDA):
http://www.privcom.gc.ca/legislation/02_06_01_e.asp

and Health Insurance Portability and Accountability Act (HIPAA):
http://www.hhs.gov/ocr/hipaa/privacy.html

Patriot Act (US): http://www.epic.org/privacy/terrorism/hr3162.html

Clinical Trial Registration: http://www.icmje.org/clin_trialup.htm
Section F – Continuing Review of Ongoing Research

The Continuing Review program at the University of Toronto is conducted in compliance with the TCPS, Article 1.13 and the Tri-Council Memorandum of Understanding, Schedule 2, Article 2.1d. Quoting from the TCPS, Article 1.13:

a. Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.

b. As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.

c. Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.

In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk that is referred to in Article 1.13 (b), in addition to annual review (Article 1.13 (c)) include:

- formal review of the free and informed consent process,
- establishment of a safety monitoring committee,
- periodic review by a third party of the documents generated by the study,
- review of reports of adverse events,
- review of patients’ charts, or
- a random audit of the free and informed consent process.

Other models of a continuing ethics review may be designed by researchers and REBs to fit particular circumstances.

Taking Question #17 into account, the researcher is asked to evaluate the risk level of his/her research on a tri-partite (low-medium-high scale), taking into account the vulnerability of the group, the intrusiveness and/or invasiveness of the method and the sensitivity of the data. Each of the three risk levels is associated with a more rigorous program of Continuing Review.

Level 1: All protocols extending beyond one year require annual renewal in the form of a brief summary report commenting on:

- any changes to the protocol, forms, or personnel (e.g., status as students or employees)
- number of participants currently in the study, or who have completed the study, or who withdrew (including their reasons for withdrawing)
- any ethical concerns arising
- researchers should submit a Study Completion Report when data analysis has been completed in order to answer the original research question(s)

Level 2: In addition to being subject to Level 1 review, mid- and high-risk protocols have a small chance of receiving a routine site visit, including review of:

- REB’s file documenting the approval process
- researcher’s consent files documenting participant consent and eligibility
**Level 3:** in addition to being subject to Level 1 review, and having a small chance of being subject to Level 2 review, high-risk protocols have a small chance of receiving a routine site visit, including review of:

- researcher’s data files documenting adherence to or deviation from protocol, reporting of adverse/unanticipated events, and data quality; this may include audio or video recordings, electronic or paper records, field notes, etc.
- under unusual circumstances, continuing review may also include direct contact with the research process (i.e., observing the consent or study procedures) if the researcher has received permission from the participant to do so, and the ERO and relevant REB determine that the risks to participants do not outweigh the benefits. Under similar circumstances, continuing review may also include contacting participants during or after participation (e.g., by phone, or by appending relevant questions to study protocols); relevant questions may include how they were recruited, who they interacted with and in what capacity, whether they were given an opportunity to ask questions, whether they felt pressure to participate or continue, whether they are satisfied with their experience as a participant, and whether they have any other questions or comments. Such procedures, however, are not expected to be the norm.

The Risk Matrix and explanation/justification will be taken into account when determining which category of Continuing Review the research will fall under (Level 1, 2 or 3). The University of Toronto REB will make the final decision of the risk level, and, in cooperation with the ERO, will determine the program of Continuing Review that will be followed. This determination will be communicated to the researcher in the ethics approval letter.

**Section G - Signatures**

<table>
<thead>
<tr>
<th>Principal Investigator</th>
<th>Requires signatures from:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Faculty researcher including Status-Only and Adjunct appointments</td>
<td>Principal Investigator and Departmental Chair/Dean (or designate)</td>
</tr>
<tr>
<td>Post-Doctoral Fellow or Visiting Professor</td>
<td>PI, Faculty Sponsor and Departmental Chair/Dean (or designate)</td>
</tr>
<tr>
<td>Graduate Student</td>
<td>PI, Faculty Supervisor and Departmental Chair/Dean (or designate)</td>
</tr>
</tbody>
</table>

**8.1.3 Course Templates**

Instructors who intend on assigning research as part of a graduate level course requirement may consider using a **Graduate Course Template Ethics Protocol Form** (Appendix IIc). The purpose of this form is to apply for ethics approval of a general format for research to be used by all students whose research will be covered by the template, and its ethics approval. For a template to be appropriate, all activities within the approval should carry the same level of risk as stated in the template (or lower), and should fall within the general description provided. It is then the responsibility of the course instructor to review the individual student projects to ensure that they are being planned and conducted within the parameters covered by the approved course template.
Students within the course who propose projects that fall outside of template parameters, because of level of risk (i.e. greater risk), method or other reasons, will need to submit a project-based ethics protocol for review. It is at the instructor’s discretion to allow students to propose projects that require separate ethics review, or to advise or mandate students to remain within the guidelines of the course template.

Student projects within an approved course template will have ethics approval valid for one year. Projects are then closed, unless the ERO is told beforehand that the project will be ongoing and an Annual Renewal form is submitted and approved. The course template may also be renewed through the Annual Renewal process up to 4 times, for continuing ethics approval of up to 5 years. A new course template must then be submitted for review.

8.1.4 Undergraduate Ethics Review Protocol Submission Form Templates

To assist the Delegated Ethics Review Committees, the ERO has put together templates for their Undergraduate Ethics Review Protocol Submissions Forms. There are two types:

1. **Course Template** (Appendix III) – for Course Instructors to use to obtain umbrella ethics approval over all student projects within a course. All projects should fit within the parameters described in the protocol submission form, with particular attention paid to risk level (see Section 8.1.3).
2. **Student Initiated Projects** (Appendix IV) – for undergraduate students undertaking independent projects that cannot fall under a course template

Each DERC may revise these templates as required. Students and Course Instructors are asked to contact their DERC or the ERO (for departments without a DERC) to obtain copies of the respective forms.
8.2 Procedures for Protocol Submissions

Ethics protocols are reviewed by one of four University of Toronto REBs, based on the departmental or faculty affiliation of the principal investigator. As of July 2006, all HIV/AIDS protocols should be submitted to the REB associated with the department or faculty. A representative from the HIV/AIDS RAC will be contacted by the ERO to conduct a simultaneous review.

<table>
<thead>
<tr>
<th>REB</th>
<th>Department/Faculty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health Sciences I</td>
<td>Nursing, Pharmaceutical Sciences, Social Work, Physical Education &amp; Health, Dentistry, Public Health Sciences, Health Policy Management &amp; Evaluation, Occupational Therapy</td>
</tr>
<tr>
<td>Health Sciences II</td>
<td>Anaesthesia, Biomedical Communications, Centre for Health Promotion, Family &amp; Community Medicine, Immunology, Institute of Medical Sciences, Laboratory Medicine &amp; Pathobiology, Medical Genetics and Microbiology, Medical Biophysics, Medical Imaging, Medicine, Nutritional Sciences, Obstetrics &amp; Gynecology, Ophthalmology and Vision Sciences, Otolaryngology, Paediatrics, Pharmacology, Physical Therapy, Physiology, Psychiatry, Radiation Oncology, Speech Language Pathology, Surgery, Graduate Department of Rehabilitation Science</td>
</tr>
<tr>
<td>Education REB</td>
<td>All OISE/UT research, from the following departments: Adult Education &amp; Counselling Psychology, Curriculum, Teaching &amp; Learning, Human Development &amp; Applied Psychology, Sociology &amp; Equity Studies in Education, Theory and Policy Studies in Education</td>
</tr>
<tr>
<td>Social Sciences &amp; Humanities REB</td>
<td>All departments within Social Sciences &amp; Humanities and Applied Science &amp; Engineering</td>
</tr>
</tbody>
</table>

There are two processes for research ethics review, full REB review, and expedited review. Full REB review is the default process, which involves discussion of the ethics protocol by the REB at one of the monthly meetings. Expedited review involves a REB member or subcommittee, and can only be applied to research that poses no greater than minimal risk to participants. Deadlines for submissions, numbers of copies required and other information can be found on the ERO website, at www.research.utoronto.ca. Criteria required to be met for expedited review is in the following section.

8.3 Criteria for Expedited Review

The most fundamental criterion of whether an ethical protocol submission may be reviewed through the expedited process is that of risk. It is essential that only studies which are deemed to be of minimal risk are reviewed through this process. The definition of minimal risk is:

“The probability and magnitude of possible harms implied by participation in the research can reasonably be expected by participants to be no greater than those encountered by the subject in those aspects of his or her everyday life that relate to the research, or during the performance of routine physical or psychological examinations or tests.”
Several factors must be taken into account when evaluating the risk of a research study. Some of these are obvious and methodologically-determined, while others require much reflection, and may depend on the subject population or what the implications of the research could entail.

The expedited review process may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, insurability, reputation, or may be stigmatizing.

**Types of Risks to Consider**

*Physical risk:* Risk of harm through bodily contact or administration of any substance.

*Psychological/emotional risk:* Risk of feeling uncomfortable, embarrassed, anxious or upset.

*Social risk:* Risk of loss of status, privacy, and/or reputation, legal or financial risk.

**Types of Research that MAY be expedited**

- Annual renewals of research studies that originally qualified for expedited review and/or have had no adverse events or ethical problems arisen.

- Studies which have received previous approval by another institutional REB.

- Minor amendments to previously approved research where the changes to the study protocol or consent documents do not result in increased risk to participants.

- Chart reviews.

- Collection of blood samples by finger stick, heel stick, ear stick or venipuncture as follows:
  - from healthy, non-pregnant adults who weigh at least 50 kg. Amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - from other adults, considering the age, weight, and health of the subject, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. Amounts drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week*.

- Prospective collection of biological samples for research purposes by non-invasive means, in adults*.

- Research involving materials that have been collected, or will be collected solely for non-research purposes*.
• Collection of data from voice, video, digital or image recordings made for research purposes*±.

• Research on individual or group characteristics or behaviour or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies*±.

*provided that identification of subjects would not lead to personal risk, whether legal, psychological, or social, as prescribed above.

±It is not to be assumed that most or all research utilizing these methods can or will be expedited. The default process is full review, and justification for expedited review cannot be based on method of collection. Attention must be paid to how these methods will be used in order to maintain minimal risk of harm to participants.

**Types of Research that MAY NOT be Expedited**

• Research involving genetic testing that may cause psychological or social risk to individuals, the subject population or to their community in the present or future.

• Research involving testing for additional diseases or markers not yet determined that may cause psychological or social risk to individuals, the subject population or to their community in the present or future.

• Research involving the generation of databanks (of specimens) or databases (of populations) where potential future research is unknown.

**Special Considerations for Research Populations**

Any research involving physical intervention or collection of biological samples, whether by invasive or non-invasive means, in children cannot be expedited, unless it is part of a required medical procedure and carries no additional risk.
8.4 Amendments

An amendment is defined as a written description of (a) change(s) to, or formal clarification of an ongoing currently approved protocol. Amendments may be minor (e.g. administrative changes) or major (e.g. addition of study method). Changes that alter the overall purpose or objective of a study may require a new protocol submission.

Amendments may include (but are not limited to) changes to:

- Title
- Recruitment - number of subjects (if significant), recruitment methods, recruitment materials
- Research personnel who may interact with participants and/or who may have access to personal data, e.g. PI, Co-I, students or study coordinators
- Location of recruitment or research activity
- Study duration or method
- Privacy of information
- Confidentiality of subjects
- Data storage, retention or destruction
- Informed consent - forms, procedures, new findings or information
- Sponsorship
- Compensation
- Conflicts of interest
- Any change to protocol that alters the risk to participants, regardless if risk is increased or decreased

Amendments may be submitted to the ERO through the Amendment Request Form (Appendix V). Minor amendments, reflecting administrative changes are handled by the ERO. Major amendments are typically reviewed through the expedited process, unless they propose a significant increase in risk, and are then submitted for full REB review. Revised procedures may not be implemented until they have received ethics approval.
8.5 Adverse and Unanticipated Events

8.5.1 Definitions

Adverse Event (AE) is any unfavourable or unintended occurrence or a change in current health status (including mental, emotional or psychological) in a subject participating in a research study. An AE may also be referred to as Adverse Reaction, Adverse Experience or Side Effect.

Serious Adverse Event (SAE) or reaction is any untoward occurrence that:
- Results in death,
- Is life-threatening (an event in which the study subject was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe),
- Requires patient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/capacity, or
- Is a congenital anomaly/birth defect. An occurrence is also considered an SAE if it represents other significant hazards or potentially serious harm to research subjects or others, in the opinion of the researcher.

Unanticipated Event is any unfavourable or unintended occurrence during the course of a research study which may have real or potential implications on participants.

Causality is the relationship between an adverse event and the test agent or intervention in terms defined by the protocol (i.e. unrelated, likely related, possibly related, probably related, related).

Related to the Research Intervention if there is a reasonable possibility that the reaction or event may have been caused by the research intervention (i.e. a causal relationship between the reaction and research intervention cannot be ruled out by the researcher).

8.5.2 Reporting

Faculty investigators and supervisors must immediately report any adverse effects (undesirable and unintended, although not necessarily unexpected events) arising out of the research. Please submit the Adverse/Unanticipated Event Report Form (Appendix VI) to the ERO within 30 days of being notified of the event or reaction. Follow-up may be conducted by the ERO and the respective REB. For multi-site trials, please include all relevant reporting documentation.
8.6 Annual Renewal and Study Completion

As stated in Article 1.13 of the TCPS:

Ongoing research shall be subject to continuing ethics review. Continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.

Therefore, at the minimum, researchers wanting to continue with a project beyond the expiry date of their current ethics approval (normally valid for one year, dependent on the REB's evaluation of risk level) are required to submit an Annual Renewal of Ethics Approval Application (Appendix VII). This may be done up to 4 times, for a total of 5 years of approval of a protocol. If the study is to continue beyond 5 years, a re-review of the full protocol, through a full REB or expedited review (based on level of risk), must be conducted. A study is considered to be ongoing until data analysis is complete. A Study Completion Report (Appendix VIII) must be submitted once the study is closed.

Please see Section 9.3 for full details on Continuing Review.
Chapter 9: Review of Research

9.1 Research Ethics Review and Appeals

The Committee on Human Subjects in Research (CHSR) advises the Vice-President (Research) & Associate Provost on policies, procedures and issues relating to the use of human subjects in research at the University of Toronto. The Committee also serves as an appeals board for decisions made by the Research Ethics Boards (REB) established by the University to review proposals to use human subjects in research.

Research ethics review at the University is based on peer-review and collegial relations amongst researchers. Much care and consideration is taken by REB to evaluate ethics protocols in compliance with *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS)* and in accordance with the ethical principles of which it is founded. REB members, administrators and support staff work with researchers to enable human studies research, while maintaining its highest standards of ethical conduct.

Because of this common goal, it is expected that when conflicts arise around the ethical review of a protocol, a researcher and his/her respective REB shall make all reasonable attempts to come to a workable solution for the research to be approved. Only once an impasse has been reached and proven insurmountable, should an appeal to the CHSR be made.

This document explains the mechanics of the ethical review process of the University, as well as the guidelines of its appeal process.

9.1.1 Research Ethics Review

The University review ethics protocols through one of two processes: expedited review or full REB review. The decision of which process is to be used is based on the risk of harm to the research participant. Only studies that fall within the limits of *minimal risk* are considered for expedited review, and the final decision resides with the REB Chair or designate. Details of what constitute minimal risk, and types of studies that may be reviewed through the expedited process can be found in Chapter 9, Section 9.3.

**Expedited Review**

- Conducted by single reviewer who may be Chair, Vice-chair or member of the REB.
- Sometimes a secondary reviewer will be added, if a second opinion is required.
- If the reviewer(s) feel(s) that the protocol does not meet the criteria for expedited review, he/she/they may bring the protocol to the full REB.
- If the protocol is not acceptable as-is, the investigator will receive comments and/or questions to address.
- Revisions and/or responses are received and the reviewer(s) re-evaluate(s) the protocol on the basis of the adequacy of the changes made and/or responses provided. If issues still remain, a second set of comments are given, and the process continues. If after two cycles
of revisions an ethical issue cannot be resolved, the protocol may be sent to the full REB for review.

**Full Review**

- Review is conducted by full REB, and is often led by a primary reviewer.
- The full REB is engaged in discussion about the protocol, with minutes taken by the ERO.
- Occasionally, protocols are sent to an additional external reviewer with scientific or legal expertise, to evaluate or clarify risk.
- Decisions are made by consensus of the REB, in compliance with the TCPS.
- If the protocol is not acceptable as-is, the investigator will receive comments and/or questions to address. The REB decides to whom the revised protocol should go – to the full REB, or a subset thereof, depending on the ethical complexity of the issues.
- Revisions and/or responses are received and the reviewer(s) re-evaluate(s) the protocol on the basis of the responses provided.
- If issues still remain, a second set of comments are given, and the process continues. If the protocol has gone back to the full REB for re-review and needs further changes, the REB decides to whom the re-revised protocol should go.
- The process may continue for normally up to 2 rounds of substantive issues. If at this point a resolution is not apparent, the investigator, at the discretion of the REB, may be asked to consult with a member of the REB and/or be invited to attend a meeting to find ethically acceptable alternatives.
- Only the full REB may reject the protocol, with the reasons clearly articulated to the investigator.
- As per TCPS Article 1.10, “Researchers have the right to request, and REBs have an obligation to provide, reconsideration of decisions affecting a research project”.

**9.1.2 Appeals**

Appeals will be dealt with according to the following Guidelines:

- Decisions of any Research Ethics Board established by the University may be appealed. Appeals may be made only by the affected researcher(s), and not by third parties. Grounds for appeal include procedural irregularities, bias and interpretation of the TCPS.

- Decisions of any Research Ethics Board established by an affiliated teaching hospital shall be subject to the “Letter of Agreement on the Appeals Process,” approved by the Toronto Academic Health Sciences Council (TAHSC) Research Committee’s Working Group on Human Subjects in Research.

- Appeals should be in writing, include all relevant documentation and present both the grounds for the appeal and the desired remedy. They should initially be directed to the Chair of the Committee on Human Subjects in Research, who will determine whether there is sufficient basis in fact or circumstance for the case to be heard by the Committee. The Chair’s decision shall be final and not subject to appeal.

- Appeals will be heard by a Sub-Committee of no more than seven members of the Committee, selected by the Chair. The Sub-Committee’s composition must meet the
requirements of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects* for quorum which includes:

At least five members, including both men and women, of whom:

(a) At least two members have broad expertise in the methods or in the areas of research that are covered by the REB;

(b) At least one member is knowledgeable in ethics;

(c) For biomedical research, at least one member is knowledgeable in the relevant law; this is advisable but not mandatory for other areas of research; and

(d) At least one member has no affiliation with the institution, but is recruited from the community served by the institution.

- In addition, neither the Chair of the REB involved in the appeal nor the Vice-Provost (Faculty) shall participate. As provided in the Committee’s Terms of Reference, additional members may be added to ensure that the Committee has the necessary expertise.

- The appellant shall be required to present a written statement outlining the complaint, along with copies of relevant documents. This statement will be sent to the Chair of the REB in question, who will present a written response. Both statements and the documentation will be given to all members of the Sub-Committee. The Sub-Committee may ask both the appellant and the REB Chair to appear before the Sub-Committee to present verbal arguments and answer questions. If the appellant is a student, his/her supervisor will also be asked to appear.

- After hearing from both sides, the Sub-Committee shall decide whether to reject or accept the appeal. If the appeal is accepted, the Sub-Committee shall determine what action should be taken. The Sub-Committee’s decision is not subject to further appeal.

- Appeals should normally be filed within a month of the REB’s decision. They should normally be heard by the Sub-Committee within 60 days of receipt of the complaint. The Sub-Committee’s decision and the reasons for it should normally be delivered to the parties within two weeks of the decision.

- Normally, documents and statements relating to the appeal will be treated as confidential. The Sub-Committee shall, however, inform the full Committee and the Vice-President (Research) & Associate Provost of the general nature of the appeal and the action taken.
9.2 Scholarly Review as Part of Research Ethics Review

According to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) research is defined as “a systematic investigation to establish facts, principles or generalizable knowledge.” Following this definition, research must involve:

- A valid scholarly motivation
- A sound design
- Methods recognized and validated by the given discipline

These requirements are especially important when research involves human subjects, as the foundation of ethical research is good research. It is therefore within the scope of the Research Ethics Board’s mandate to concern itself with the scholarly review of a study. The requirement of an external review process will differ with regard to the customs of the discipline. For all protocols, we trust and ensure that REB reviewers are well matched with the studies that they review, and are therefore able to evaluate scholarly merit as needed.

The REB will follow, at a minimum, the requirements of the TCPS, Article 1.5:

Scholarly Review as Part of Ethics Review

(a) The REB shall satisfy itself that the design of a research project that poses more than minimal risk is capable of addressing the questions being asked in the research.
(b) The extent of the review for scholarly standards that is required for biomedical research that does not involve more than minimal risk will vary accordingly to the research being carried out.
(c) Research in the humanities and the social sciences which poses, at most, minimal risks shall not normally be required by the REB to be peer reviewed.
(d) Certain types of research, particularly in the social sciences and the humanities, may legitimately have a negative effect on public figures in politics, business, labour, the arts or other walks of life, or on an organization. Such research should not be blocked through the use of harms/benefits analysis or because of the potentially negative nature of the findings. The safeguard for those in the public arena is through public debate and discourse, and, in extremis, through action in the courts for libel.

The requirement for scholarly merit is not reserved for faculty level research, as it is expected that student researchers are taught research methodology and proper design of studies. However, in the case of course-based research, pedagogical goals may substitute for scholarly motivation. Whether the purpose of the research is to conduct a novel investigation, or to learn how to do research, adequate faculty supervision is always required.

Regardless of level of risk, the REB expects a reasonable level of scholarly merit for all studies, and it is within the REB’s jurisdiction to comment on study design. It is at the discretion of the REB to request additional processes, including the turning back of protocols for external scholarly review (e.g. peer, departmental) where deemed necessary. Research deemed “minimal risk” will generally not be expected to receive scholarly review external to the REB.
9.3 Review of Multi-Centred Research

Section 1G of the TCPS speaks to an issue that causes much difficulty in review of research: multi-centred REB review. Each institution involved in the research endeavour is accountable for its undertaking and execution (as stated in the TCPS, Article 1.2), and therefore must ensure that it receives proper research ethics review.

In some circumstances, arrangements between institutions have been created to allow for only one review to take place, or for one institution to take the lead (full review), with other institutions expediting the review on the basis of approval from the lead institution. Both types of arrangements have been made for University research involving the affiliated teaching hospitals, depending on the level of involvement of the University in the project (see Section 7.4.1).

To facilitate review of multi-centred research involving non-affiliated institutions, researchers are asked to distinguish between core elements of the research – which cannot be altered without invalidating the pooling of data from participating institutions – and elements that are due to local customs and may therefore change (e.g. specific wording on consent forms). Protocols that have already received approval from the lead institution (that is not the University of Toronto) may be reviewed through the expedited process when submitted with a copy of the approval letter and other approved documentation. REB comments should also be submitted, to facilitate the review process.

9.4 Continuing Review

9.4.1 Preamble

The mandate of the Ethics Review Office (ERO) and the Research Ethics Boards (REBs) is to protect human research participants; this is part of a larger collective responsibility and common interest shared by all stakeholders including researchers, the university, and research granting councils, to maintain the highest ethical and scholarly standards in research. One aspect of this commitment is to maintain a rigorous program of continuing review of ongoing research.

The University of Toronto’s approach to continuing review is intended to be in keeping with the spirit of the Tri-council policy statement: Ethical conduct for research involving humans, Article 1.13 and the Tri-council Memorandum of Understanding, Schedule 2, Article 2.1d. Quoting from the TCPS, Article 1.13:

a. Ongoing research shall be subject to continuing ethics review. The rigour of the review should be in accordance with a proportionate approach to ethics assessment.

b. As part of each research proposal submitted for REB review, the researcher shall propose to the REB the continuing review process deemed appropriate for that project.

c. Normally, continuing review should consist of at least the submission of a succinct annual status report to the REB. The REB shall be promptly notified when the project concludes.
Beyond scrutinizing reports, the REB itself should not normally carry out the continuing ethics review, except in specific cases where the REB believes that it is best suited to intervene. For research posing significant risks, the REB should receive reports on the progress of the research project at intervals to be predetermined. These reports should include an assessment of how closely the researcher and the research team have complied with the ethical safeguards initially proposed.

In accordance with the principle of proportionate review, research that exposes subjects to minimal risk or less requires only a minimal review process. The continuing review of research exceeding the threshold of minimal risk that is referred to in Article 1.13 (b), in addition to annual review (Article 1.13 (c)) might include:

• formal review of the free and informed consent process,
• establishment of a safety monitoring committee,
• periodic review by a third party of the documents generated by the study,
• review of reports of adverse events,
• review of patients' charts, or
• a random audit of the free and informed consent process.

Other models of a continuing ethics review may be designed by researchers and REBs to fit particular circumstances.

The process of a continuing ethics review should be understood as a collective responsibility, to be carried out with a common interest in maintaining the highest ethical and scientific standards. Research institutions should strive to educate researchers on the process of a continuing ethics review through workshops, seminars and other educational opportunities.

(Text available at http://www.pre.ethics.gc.ca/english/policystatement/section1.cfm#1F)

At the University of Toronto, researchers should submit—and the ERO should review—an annual renewal or study completion form for all studies extending beyond one year. This should be repeated to a maximum of five years, after which a new protocol should be submitted for review.

The ERO should also work with the REBs to undertake a modest number of site visits to research teams’ facilities each year, with particular focus on those projects that involve the highest risk to research participants. Such site visits may be undertaken for a variety of reasons: as part of the routine program (described below), by request of a researcher for educational purposes, to help a researcher prepare for an external audit, or for cause (e.g., in response to complaints from research participants). In general, the ERO should undertake a variety of educational outreach initiatives (e.g., orientations, workshops, seminars) to help ensure back-and-forth flow of relevant information among researchers, the ERO, and the REBs. Site visits should be conducted with respect for the privacy and confidentiality of all parties, with the active involvement of researchers. Site visits should normally be undertaken by the Research Ethics Officers, who should be understood as operating on behalf of the REB that has jurisdiction over the research, as part of their role in the ERO, which administers the participant protection program at the University.
9.4.2 Continuing Review at the University of Toronto

Continuing review is a generic term that covers a range of possible procedures that should be undertaken in a manner proportionate to the level of risk inherent in the research ethics protocol. Three levels of continuing review procedures may be invoked depending on whether a project is low, medium, or high risk:

- **Level 1**: All protocols extending beyond one year require annual renewal in the form of a brief summary report (see Appendix 1) commenting on:
  - any changes to the protocol, forms, or personnel (e.g., status as students or employees)
  - number of participants currently in the study, or who have completed the study, or who withdrew (including their reasons for withdrawing)
  - any ethical concerns arising
  - researchers should submit a study completion report (Appendix 2) when data analysis has been completed in order to answer the original research question(s).

- **Level 2**: in addition to being subject to Level 1 review, mid- and high-risk protocols have a small chance of receiving a routine site visit, including review of:
  - REB's file documenting the approval process
  - researcher's consent files documenting participant consent and eligibility

- **Level 3**: in addition to being subject to Level 1 review, and having a small chance of being subject to Level 2 review, high-risk protocols have a small chance of receiving a routine site visit, including review of:
  - researcher's data files documenting adherence to or deviation from protocol, reporting of adverse/unexpected events, and data quality; this may include audio or video recordings, electronic or paper records, field notes, etc.
  - under unusual circumstances, continuing review may also include direct contact with the research process (i.e., observing the consent or study procedures) if the researcher has received permission from the participant to do so, and the ERO and relevant REB determine that the risks to participants do not outweigh the benefits. Under similar circumstances, continuing review may also include contacting participants during or after participation (e.g., by phone, or by appending relevant questions to study protocols); relevant questions may include how they were recruited, who they interacted with and in what capacity, whether they were given an opportunity to ask questions, whether they felt pressure to participate or continue, whether they are satisfied with their experience as a participant, and whether they have any other questions or comments. Such procedures, however, are not expected to be the norm.

In general, routine site visits should be undertaken in a collegial spirit, with an emphasis on the shared mission of excellence in research ethics and scholarship.

Researchers should be given advanced notice of a routine site visit (see Appendix 3), together with a description of the ongoing review procedures to be conducted (see Appendix 4).

The lead faculty investigator should attend a meeting at the beginning and end of the site visit; they should also provide adequate space to conduct the review, and allow unimpeded access to any required documentation.

In the case of research with an off-campus component—e.g., in the field, in host settings such as clinical or community organizations, in collaborating institutions, in home offices—researchers, the ERO, and the relevant REB Chair should work together to determine how best
to evaluate research participant protection as reflected in the content and management of research records.

The length of a site visit should be proportional to the risk level and complexity of the project under continuing review.

9.4.3 Determining the Level of Continuing Review

To help determine the appropriate level of continuing review for a project, researchers submitting a new protocol should propose the risk level of the project. To do this, researchers should provide a brief statement that specifies:

- The groups they intend to work with, assessing any pre-existing vulnerabilities associated with these groups. Group vulnerability may relate to pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status.
- The methods they intend to use and types of data they intend to collect, assessing the probability and magnitude of harms participants may experience as a result of conducting the research. Research risk may relate to physiological or health issues such as clinical diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, and socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of duty to report, subpoena, or breach of confidentiality).
- These factors should be summarized with over-all assessments of low, medium, or high group vulnerability and low, medium or high research risk.

The researcher’s statement will therefore locate the proposed study on a 3 x 3 continuing review matrix that specifies the level of continuing review—i.e., Level 1, 2, or 3—appropriate to each cell (see Table 9.1).

Table 9.1. Level of continuing review by group vulnerability and research risk.

<table>
<thead>
<tr>
<th>GROUP VULNERABILITY</th>
<th>RESEARCH RISK</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Low</td>
</tr>
<tr>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>Medium</td>
<td>1</td>
</tr>
<tr>
<td>High</td>
<td>2</td>
</tr>
</tbody>
</table>

The continuing review matrix should be understood as a broad heuristic to help researchers frame risk factors for standard research ethics issues such as free and informed consent, privacy and confidentiality, and inclusion-exclusion criteria, as well as any special considerations such as relevant professional qualifications of the research team members. In general, if a relatively large proportion of protocols from a particular discipline involve high risk to participants and receive full REB review, whereas a relatively large proportion of protocols from a different discipline involve low risk to participants and receive expedited review, this should be reflected in the relative distributions for the two disciplines in the continuing review matrix. Researchers should not assume, however, that a protocol involving, say, physiological measures carries inherently higher risk than a protocol involving naturalistic observations, given that one might conduct relatively innocuous electroencephalograms with normal adults, and one
might conduct highly charged observations of a marginalized group involved in criminal activities.

The relevant REB will take the researchers' assessments of group vulnerability and research risk into account to make the final decision regarding which level of continuing review would be appropriate for a protocol. This decision will be indicated in the letter approving the protocol.

9.4.4 Determining which Sites are Visited

To determine which research teams actually receive routine site visits in any given year, a modest number of protocols should be randomly selected from a database on the basis of continuing review level (i.e., 1, 2, or 3); additional practical factors may then be taken into account, such as where particular projects are in the data collection cycle, and which departments and methods have recently received visits.

As mentioned in the preamble, continuing review site visits may be initiated not only as part of the routine program, but also by request of a researcher for educational purposes, or to help a researcher prepare for an external audit. Site visits may also be initiated for cause. Continuing review for cause may be triggered by a variety of incidents including but not necessarily limited to: complaints from research participants or host institutions, whistle blowing by members of the research team, or irregularities observed at lower levels of continuing review, including annual renewals.

Additional comments regarding annual renewals: Annual renewals may be either expedited or drawn to the attention of the REB Chair, depending on: the initial level of review of the protocol (i.e., expedited versus full REB) and the seriousness of ethical issues arising. Any project that extends to 5 years should be resubmitted as a new protocol, and protocols that no longer require annual renewal should be closed with a study completion form. Researchers who allow the lapse of an annual renewal—or study completion, accordingly—or who fail to respond to feedback regarding a proposed amendment or adverse/unanticipated event, may be informed that their funding has been frozen, that other proposals will not be reviewed, or that they have triggered a higher level of continuing review.

9.4.5 Additional Comments regarding Annual Renewals

Annual renewals may be either expedited or drawn to the attention of the REB Chair, depending on: the initial level of review of the protocol (i.e., expedited versus full REB) and the seriousness of ethical issues arising. Any project that extends to 5 years should be resubmitted as a new protocol, and protocols that no longer require annual renewal should be closed with a study completion form. Researchers who allow the lapse of an annual renewal—or study completion, accordingly—or who fail to respond to feedback regarding a proposed amendment or adverse/unanticipated event, may be informed that their funding has been frozen, that other proposals will not be reviewed, or that they have triggered a higher level of continuing review.
9.4.6 Reporting

Continuing review reports should highlight strengths, as well as opportunities for improvement arising from discrepancies between actual practice and written policies, guidelines, and accepted best practices. Such information should help to inform the ERO and REBs of actual practice, and should feed into a larger proactive effort to provide researchers with updates, guidelines, and other research ethics educational opportunities.

A draft copy of the continuing review report should be given to the researcher with opportunity for feedback, before final copies of the report are given to the researcher and the REB Chair.

Any observations pertaining to the REB file—as opposed to the researcher’s conduct of the project—should be understood as a quality assurance issue, and should be flagged for the chair of the relevant REB and, if appropriate, the director of the ERO.

The REB should decide what additional actions, if any, to take as a result of a final continuing review report. This could include follow-up continuing review procedures, or escalation to an ad hoc research misconduct investigation committee. Other actions could include initiating review and change of relevant University of Toronto policies or procedures.

The researcher, the REB and the ERO should be aware of which irregularities, if any, they have a duty to report (e.g., to external funding bodies, or to affiliated or collaborating institutions).

9.4.7 Related points

Researchers should be prepared to explain to participants—in consent forms or scripts or responses to questions—that in addition to the research student, supervisor, and other members of the research team having access to the data, there is a small chance that the University of Toronto might check a researcher’s activities for quality assurance purposes, and that this would be done to the extent required by regulations, in manner that maintains confidentiality.

Researchers should also be prepared to provide participants with contact information (e.g., telephone, e-mail) not just for the student and supervisor—i.e., if participants have questions about the research, but also for the ERO—i.e., if participants have questions about their rights as a research participant.

9.4.8 References

Tri-council policy statement: Ethical conduct for research involving humans, Article 1.13: http://www.pre.ethics.gc.ca/eng/policystatement/section1.cfm#1F
Tri-council memorandum of understanding, schedule 2, Article 2.1d: http://www.nserc.ca/institution/mou_sch2_e.htm
9.5 Conflicts of Interest

All researchers conducting research at or under the auspices of the University of Toronto must comply with the University's Policy on Conflict of Interest – Academic Staff or Librarian, as well as Provost's guidelines on Conflict of Interest and Close Personal Relations.

Actual or potential conflicts of interest must be disclosed in the ethics protocol submission. The REB evaluates the information provided with respect to University policies and guidelines, as well as those of the relevant granting council. A decision is reached as to whether the conflict is real or perceived, manageable or problematic. The REB will propose a plan to the researcher to manage or remove the conflict, which may range from disclosure to potential participants to abandoning one of the researcher's interests, which is causing the apparent conflict. The researcher can then follow the advice of the REB, or respond as to why this solution is problematic and offer another suggestion. An unresolved or unresolvable conflict of interest may be a cause for an REB rejection of a protocol. Not disclosing a potential conflict of interest to the REB may be viewed and investigated as Non-Compliance or Protocol Violation (See Section 9.6) and/or Research Misconduct (see Chapter 5).

9.6 Non-Compliance

Research involving human subjects at or under the auspices of the University of Toronto requires that an approved ethics protocol, obtained prior to its commencement. Every researcher is expected to understand the policies and regulations governing research at the University. Any allegation of noncompliance will be taken seriously.

Noncompliance may include:
- Conducting research involving human subjects without a protocol and/or without ethics approval
- Allowing ethics approval to expire without renewal or study completion
- Not complying with the Continuing Review program assigned to the protocol
- Conducting research not covered by the approved protocol, or contradictory to the protocol, otherwise known as Protocol Violation

Non-compliance is a research integrity issue, and can result in an investigation of research misconduct. Please see Chapter 5: Integrity in Research for policies and guidelines that address research integrity and allegations of research misconduct.
10.1 Preamble

“Free and informed consent lies at the heart of ethical research involving human subjects. It encompasses a process that begins with the initial contact and carries through to the end of the involvement of research subjects in the project. The process of free and informed consent refers to the dialogue, information sharing and general process through which prospective subjects choose to participate in research involving themselves.” (Tri-Council Policy Statement, Section 2A)

Free and Informed Consent is the hallmark of modern research ethics. All ethical codes from Nuremberg to Belmont and Tri-Council Policy Statement are built upon the principle of respect for persons and their autonomy. To uphold this principle, enabling a potential subject to make a free and informed decision whether to participate in research, or not, requires the fulfillment of three essential components:

- Voluntariness
- Information
- Competence

While these components are universally accepted, how they are met is dependent on a variety of conditions: research discipline, methodology, characteristics of the research population, and the cultural environment. Therefore, to help researchers and REB members in promoting best practices, guidelines have been developed for general conditions for informed consent, and specialized ones for specific research conditions.

10.2 Basic Requirements

Section 2 of TCPS is devoted to requirements for free and informed consent with respect to the three essential components stated above, and provides some guidance for circumstances where informed consent is not required or practicable. The text discussed in this section focuses on the basic requirements, as stated in the TCPS. Some of the material may not be applicable to all research, particularly in the social sciences and humanities. References to other relevant guidelines can be found at the end of this chapter.

TCPS, Article 2.1

(a) Research governed by this Policy may begin only if 1) prospective subjects or authorized third parties have been given the opportunity to give free and informed consent about participation, and 2) their free and informed consent has been given and is maintained throughout their participation in the research.

(b) Evidence of free and informed consent by the subject or authorized third party should ordinarily be obtained in writing. Where written consent is culturally
acceptable, or where there are good reasons for not recording consent in writing, the procedures used to seek free and informed consent shall be documented.

(c) The REB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent, provided that the REB finds and documents that:

i. The research involves no more than minimal risk to the subjects;

ii. The waiver or alteration is unlikely to adversely affect the rights and welfare of the subjects;

iii. The research could not practicably be carried out without the waiver or alteration;

iv. Whenever possible and appropriate, the subjects will be provided with additional pertinent information after participation; and

v. The waived or altered consent does not involve a therapeutic intervention.

(d) In studies including randomization and blinding in clinical trials, neither the research subject nor those responsible for their care know which treatment the subjects are receiving before the project commences. Such research is not regarded as a waiver or alteration of the requirement for consent if subjects are informed of the probability of being randomly assigned to one arm of the study or another.

Voluntariness

TCPS, Article 2.2

Free and informed consent must be voluntarily given, without manipulation, undue influence or coercion.

Information

TCPS, Article 2.4

Researchers shall provide, to prospective subjects or authorized third parties, full and frank disclosure of all information relevant to free and informed consent. Throughout the free and informed consent process, the researcher must ensure that prospective subjects are given adequate opportunities to discuss and contemplate their participation. Subject to the exception in Article 2.1(c), at the commencement of the free and informed consent process, researchers or their qualified designated representatives shall provide prospective subjects with the following:

(a) Information that the individual is being invited to participate in a research project;
(b) A comprehensible statement of the research purpose, the identity of the researcher, the expected duration and nature of participation, and a description of research procedures;

(c) A comprehensible description of reasonably foreseeable harms and benefits that may arise from research participation, as well as the likely consequences of non-action, particularly in research related to treatment, or where invasive methodologies are involved, or where there is a potential for physical or psychological harm;

(d) An assurance that prospective subjects are free not to participate, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue to participate; and

(e) The possibility of commercialization of research findings, and the presence of any apparent or actual or potential conflict of interest on the part of researchers, their institutions or sponsors.

Competence

“Competence refers to the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand the information presented, to appreciate the potential consequences of a decision, and to provide free and informed consent. This ability may vary according to the choice being made, the circumstances surrounding the decision, or the time in question. Competence to participate in research, then, is not an all-or-nothing condition. It does not require prospective subjects to have the capacity to make every kind of decision. It requires that they be competent to make an informed decision about participation in particular research. Competence is neither a global condition nor a static one; it may be temporary or permanent.” (TCPS, Section 2E.)

TCPS, Article 2.5

Subject to applicable legal requirements, individuals who are not legally competent shall only be asked to become research subjects when:

(a) The research question can only be addressed using individuals within the identified group(s); and

(b) Free and informed consent will be sought from their authorized representative(s); and

(c) The research does not expose them to more than minimal risks without the potential for direct benefits for them.
10.3 Best Practices in Informed Consent

10.3.1 General Conditions

This section has been developed in consultation with the Informed Consent Working Group (ICWG), a subcommittee of the Committee on Human Subjects in Research. The ICWG is made up of researchers, REB members and administrators, ethicists and legal representatives. Its mandate is to develop guidelines and best practices for informed consent to advance human subject protections in research.

When considering best practices in informed consent, it is important for researchers and REB members to understand that the informed consent process – information exchange and thoughtful decision making – is of primary importance. Informed consent documentation – letters, forms and scripts – is secondary, and should augment the process.

A successful informed consent process includes 4 components:

1. A competent information provider
   - Members of the research team responsible for conducting informed consent process must have experience and/or training with the participant population. They must also be well versed in the study protocol and the REB-approved ethics protocol, and should be able to predict questions that will normally arise through the informed consent process.
   - Although it is recognized that the information provider has an interest in recruiting participants to the study, this must be balanced by the interest to respect the individual’s right to free and informed decision-making. The information provider must ensure that no actual, potential or apparent conflicts of interest arise in the recruitment of any individual to the study.
   - Good communication skills are essential.
   - Other skills, specific to the type of research and potential vulnerabilities of the participant population may be required or desired.

2. A clear exchange of relevant information
   - All information that would be needed for a reasonable person to make an informed decision to participate in the research study, or not, must be provided.
   - Typically, an information sheet or informed consent form will include all details. However, it is important that any difficult or complex parts of the research are discussed slowly with the potential participant, and that the information provider is reasonably confident that the individual understands all of the information needed to make an educated decision.
   - Areas of information provided typically include:
     - Introductory information about the study and who is conducting it.
     - Why this individual is being invited to participate, and in what circumstances s/he may need to be excluded.
     - The voluntary nature of research - can say no, can withdraw without consequence.
     - Research procedures, duration and time involvement.
     - Reasonably foreseeable risks, harms or inconveniences.
     - Risks with low probability of occurrence, but high magnitude of harm.
     - Reasonably expected benefits, if any, to the participant; or that no direct benefits are expected.
- Compensation or reimbursement.
- Privacy of participants’ information and confidentiality of their involvement.
- How the researchers may use the results. This may include debriefing and/or providing a summary of results to participants.
- Any apparent, actual or potential conflicts of interests of the researcher or team
- Contact information – who to call for further information regarding the study and regarding the rights of research participants.

3. Thoughtful decision-making
   - The potential participant must be given the time and access to the information provider or to other members of the research team, that is required for her/him to fully understand what the research involves (research procedures), and its implications on her/his daily life (reasonably foreseeable risks).
   - The information provider must ensure that the potential participant understands what s/he is consenting to. This may require that:
     - The language used to explain the study, whether written or verbal, is in lay/plain terms, preferably at a grade 6 reading level, or is appropriate for the participant population.
     - For participants for whom the study is not in their first language, ongoing communication support (e.g. translation “navigator”) is provided throughout the study.
     - The potential participant is asked to explain what he/she understands from the information provided. (e.g. “What do think is going to happen to you during the course of the study?”)
     - Measures of competence are used, by an experienced individual.
     - A substitute decision maker is involved.
   - If the decision to participate seems to be made in haste, contrary to what the information provider would have reasonably expected, or with “unconditional/complete trust” of the researcher, more discussion is needed to ensure that the positive decision is appropriate.

4. Ongoing communication with the participant
   - The informed consent process begins with first contact and continues until the end of the of participant involvement. Participants should be periodically asked whether they have any questions or concerns with the research study. For complex or multi-part studies, re-consent (verbal or written) may be necessary. The information provider should be available to revisit any aspect of the study or consent process as needed.
   - Although participants may withdraw their participation at any time, withdrawal of collected data may not be possible beyond a certain point. This information should be made clear throughout the informed consent process.
10.3.2 Observational Research

Naturalistic Observation

Article 2.3

REB review is normally required for research involving naturalistic observation. However, research involving observation of participants in, for example, political rallies, demonstrations or public meetings should not require REB review since it can be expected that the participants are seeking public visibility.

Although REB review is normally required, informed consent is not required for naturalistic observation, for reasons expressed in Article 2.1c (see above). Naturalistic observation research that would violate any component of that article would likely be rejected by the REB, on ethical grounds.

Participant Observation

Please see Section 7.8.2, Guidelines for Ethical Conduct in Participant Observation.

10.3.3 Research in Emergency Situations

Article 2.8

Subject to all applicable legislative and regulatory requirements, research involving emergency health situations shall be conducted only if it addresses the emergency needs of individuals involved, and then only in accordance with criteria established in advance of such research by the REB. The REB may allow research that involves health emergencies to be carried out without the free and informed consent of the subject or his or her authorized third party if ALL the following apply:

(a) A serious threat to the prospective subject requires immediate intervention; and

(b) Either no standard efficacious care exists or the research offers a real possibility of direct benefit to the subject in comparison with standard care; and

(c) Either the risk of harm is not greater than that involved in standard efficacious care, or it is clearly justified by the direct benefits to the subject; and

(d) The prospective subject is unconscious or lacks capacity to understand risks, methods and purposes of the research; and
(e) Third-party authorization cannot be secured in sufficient time, despite diligent and documented efforts to do so; and

(f) No relevant prior directive by the subject is known to exist.

When a previously incapacitated subject regains capacity, or when an authorized third party is found, free and informed consent shall be sought promptly for continuation in the project and for subsequent examinations or tests related to the study.

10.3.4 Research Involving Incompetent Individuals

Article 2.6

For research involving incompetent individuals, the REB shall ensure that, as a minimum, the following conditions are met:

(a) The researcher shall show how the free and informed consent will be sought from the authorized third party, and how the subjects’ best interests will be protected.

(b) The authorized third party may not be the researcher or any other member of the research team.

(c) The continued free and informed consent of an appropriately authorized third party will be required to continue the participation of a legally incompetent subject in research, so long as the subject remains incompetent.

(d) When a subject who was entered into a research project through third-party authorization becomes competent during the project, his or her informed consent shall be sought as a condition of continuing participation.

Article 2.7

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject’s dissent will preclude his or her participation.
10.3.5 Implied Consent

Implied consent is a sometimes used in circumstances where the research risk is low, and the researcher does not physically interact with the participant. This tool is common in survey research: internet- or paper-based. In these circumstances, not requiring written consent may provide more protection to research participants, by allowing them to remain anonymous.

In no circumstances should implied consent mean “no consent”. The informed consent process must remain intact – information is provided to the participant, typically through an information letter covering the survey. Participants may choose to participate, or not. Those who have chosen to participate, thereby taking the survey, have the same rights as any participant who has signed a consent form. Any restrictions to withdrawal must be outlined in the information letter.

10.3.6 Best Practices to be Developed

Below is a list of areas of informed consent for which the ICWG will be working on in the next few months to develop best practices.

- Assent and consent for research with children and students
- Informed consent in situations where the research subjects are incapacitated
- Deception, non-disclosure of information and debriefing
- Research in situations where consent is not practicable or not required
- Administrative consent
- Informed consent in community-based and cross-cultural research
- Informed consent in aboriginal research
- Oral consent

10.4 Models of Informed Consent

There are a variety of models of informed consent processes. The research team must decide which model serves their research and participant population best, in consultation with the REB. Some examples are:

1. Group information session – The information provider meets with a group of prospective participants to go over the details of the research study and answer any preliminary questions. An information letter and informed consent form may be distributed prior to the provider speaking, and any questions may be handled at the end of the presentation. The actual consent to participate typically (though not always) occurs afterwards, in a one-to-one interaction.
2. One-on-one information session/informed consent – The information provider meets with the prospective participant to go over the details of the research study and answer any questions. The prospective participant may choose to decide to participate or not at that meeting, or may wish to take the consent form home for further thought or discussion.

3. Informed consent for research that does not involve direct interaction – For research where the research team never interacts directly with participants, it is important that adequate, comprehensible information is provided to prospective participants. In some cases, e.g. survey (paper-based or internet) research, participating in the research implies consent. In other cases, signed consent forms are required, as determined by the research team and the REB. In all situations the information letter should include contact information for the information provider, research team and research ethics representative, in case of any questions. It may also be useful for a Frequently Asked Questions section to be created.

4. Informed consent in the context of participant observation – The researcher should:

- Ensure that participants are aware of the researcher’s identity and purpose among the group;
- Disclose and disseminate as broadly as possible through general announcements or other more informal means the researcher’s purpose, research topic, and data gathering method. Participants should be aware that any of their interactions with the researcher may constitute some form of data gathering.
- Seek permission from group leaders or spokespersons, where appropriate, but especially if they can help to broadcast to a community the researcher’s identity, purpose, method. However, researchers should also be careful to avoid situations where such public endorsements/announcements to the community can create pressure to participate. Participants should remain free to avoid all interaction with the researcher.

As much as possible, the researcher should obtain informed consent from each individual participant with whom the researcher will be interacting. It is especially important to remain aware that some participants might not be fully informed despite general announcements in public. As the researcher gains awareness of the level of information individual participants have about the researcher’s identity, purpose and method, he/she should make every possible effort to disclose such information individually.
Appendices
Appendix I – Research Ethics Boards and Committees Terms of Reference

Health Sciences I Research Ethics Board

NAME OF BOARD
Health Sciences I Research Ethics Board

REPORTING RELATIONSHIP
The REB will report to the Vice-President, Research and Associate Provost, University of Toronto, through the Committee on Human Subjects in Research.

MANDATE
Research is an essential component of the University’s mission statement. The University recognizes that special considerations exist when conducting research involving human subjects.

The Health Sciences I Research Ethics Board has been established to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within or by members of, the University of Toronto in the departments listed below. The Health Sciences I Research Ethics Board has been established:

1. To review studies from faculty and graduate students in:
   Dentistry
   Pharmaceutical Sciences
   Social Work
   Nursing
   Physical Education & Health
   Public Health Sciences
   Health Policy Management & Evaluation

2. To ensure that all research carried out by investigators associated with this board meets the highest ethical standards as per the Tri-Council Policy Statement.

3. To ensure that safeguards are developed which provide ongoing protection to those who serve as research subjects.

MEMBERSHIP
The REB will consist of at least 12 members and will include, but not be limited to, one representative from each of the following departments:
Dentistry
Pharmaceutical Sciences
Social Work
Nursing
Physical Education & Health
Public Health Sciences
Health Policy Management & Evaluation

The membership will include at least two community members, at least one member knowledgeable in ethics and one member knowledgeable in the relevant law, including the Personal Health Information Protection Act, who has no affiliation with the University of Toronto.

The term of membership is 1 – 2 years with the possibility of renewal. Members are appointed by the Vice-President, Research and Associate Provost.

FUNCTIONS AND RESPONSIBILITIES

1. To assure that all health-related research protocols presented to the REB receive appropriate ethical and scientific review.

2. To assure that records of ethical and scientific reviews of projects are available on a need-to-know basis following written request, through the Ethics Review Office in accordance with procedures set up by the University.

3. To monitor the ethical conduct of research by:
   • providing for frequent and/or rigorous monitoring in specific cases as determined in an initial review
   • requiring researchers to report to the Health Sciences I REB in a timely fashion any significant deviations from the approved protocol. That is, any deviation:
     1) which would lead to an increase in risk or a decrease in benefit to human subjects and/or
     2) any unanticipated developments within the research prior to implementation
   • requiring researchers to report to the Health Sciences I REB in a timely fashion adverse occurrences associated with their studies in accordance with procedures set up by the University
   • requiring at least annual reconsideration of all approved protocols: requiring researchers submit at least an annual report with the annual renewal form
   • a full re-review of each study should occur after 5 years

4. To participate in education through
   • ensuring that all members of the REB are provided with a basic understanding of the principles involved in research ethics review
   • including an educational component as part of the regular REB meetings from time-to-time in order to keep members informed of new developments in the area of research ethics
   • acting as a resource to researchers on issues of ethics

5. To suspend research under situations of undue risk to the study subjects.
6. To ensure that any matter that requires further action will be brought to the attention of Vice-President, Research and Associate Provost, and the Chair of the Committee on Human Subjects in Research.

**FREQUENCY OF MEETINGS**
The Board will meet face-to-face approximately monthly.

**QUORUM**
Quorum for a meeting will consist of not fewer than 5 members, which comprise at least 1 community member, 1 person with research ethics background, 1 person with knowledge in the relevant law and 2 other academics.

**DECISION PROCESS**
Decisions will be by consensus.

After review, individual proposals will be referred back to the primary investigator with comments and/or suggestions for revision. Investigators may be invited to the meeting to respond to questions about their proposals, but will not be present during the decision process. Investigators who are members of the REB will leave the room during the consideration of their proposal or any proposal in which they have an interest. Members are expected to disclose any apparent conflicts-of-interest to the Chair.

No protocols or protocol amendments may be initiated without prior written approval of the Health Sciences I REB.

**EXPEDITED REVIEW**
Research that fits within the guidelines of *Criteria for Expedited Review* may be reviewed through the expedited process.

**APPEAL**
Appeals of REB decisions are possible, in accordance with the University’s *Guidelines for Ethical Review and Appeals*.

**ADMINISTRATION**
Staff support and record keeping will be provided by the Ethics Review Office.
Health Sciences II Research Ethics Board

NAME OF BOARD
Health Sciences II Research Ethics Board

REPORTING RELATIONSHIP
The REB will report to the Vice-President, Research and Associate Provost, University of Toronto, through the Committee on Human Subjects in Research.

MANDATE
Research is an essential component of the University’s mission statement. The University of Toronto recognizes that special considerations exist when conducting research involving human subjects.

The Health Sciences II Research Ethics Board has been established to approve, reject, propose modifications to, or terminate any proposed or ongoing research involving human subjects which is conducted within or by members of, the University of Toronto in the departments listed below. The Health Sciences II Research Ethics Board has been established:

1. To review studies from faculty and graduate students in the following departments:
   - Anaesthesia, Biomedical Communications, Centre for Health Promotion, Family & Community Medicine, Graduate Department of Rehabilitation Sciences, Immunology, Institute of Medical Sciences, Laboratory Medicine & Pathobiology, Medical Biophysics, Medical Imaging, Medicine, Nutritional Sciences, Obstetrics & Gynecology, Occupational Therapy, Ophthalmology & Vision Sciences, Otolaryngology, Paediatrics, Pharmacology, Physical Therapy, Physiology, Psychiatry, Radiation Oncology, Speech Language Pathology and Surgery

2. To ensure that all research carried out by investigators associated with this Board meets the highest ethical standards as per the Tri-Council Policy Statement.

3. To ensure that safeguards are developed which provide ongoing protection to those who serve as research subjects.
MEMBERSHIP
The REB will consist of at least 12 members and will include, but not be limited to, one representative from each of following the Departments:

- Anesthesia
- Nutritional Sciences
- Physical Therapy
- Centre for Health Promotion
- Obstetrics and Gynecology
- Physiology
- Family & Community Medicine
- Occupational Therapy
- Speech & Language Pathology
- Laboratory Medicine & Pathobiology
- Surgery
- Medical Genetics and Microbiology
- Otolaryngology
- Biomedical Communications
- Medical Imaging
- Medicine
- Pharmacology
- Ophthalmology and Vision Sciences

The membership will include at least two community members, at least one member knowledgeable in ethics and one member knowledgeable in the relevant law, including the Personal Health Information Protection Act, who has no affiliation with the University of Toronto.

The term of membership is 1 – 2 years with the possibility of renewal. Members are appointed by the Vice-President, Research and Associate Provost.

FUNCTION AND RESPONSIBILITIES
1. To assure that all health-related protocols presented to the REB receive appropriate ethical and scientific review.
2. To assure that records of ethical and scientific reviews of projects are available on a need-to-know basis following written request, through the Ethics Review Office in accordance with procedures set up by the University.
3. To monitor the ethical conduct of research by:
   - Providing for frequent and/or rigorous monitoring in specific cases as determined in an initial review.
   - Requiring researchers to report to the Health Sciences II REB in a timely fashion any significant deviations from the approved protocol. That is, any deviation:
     1. which would lead to an increase in risk or a decrease in benefit to human subjects and/or
     2. any unanticipated developments within the research prior to implementation.
   - Requiring researchers to report to the Health Sciences II REB in a timely fashion adverse occurrences associated with their studies in accordance with procedures set up by the University.
   - Requiring at least annual reconsideration of all approved protocols: requiring researchers submit at least an annual report with the annual renewal form.
   - A full re-review of each study should occur after 5 years.
4. To participate in education through:
   - Ensuring that all members of the REB are provided with a basic understanding of the principles involved in research ethics review.
   - Including an educational component as part of the regular REB meetings from time-to-time in order to keep members informed of new developments in the area of research ethics.
   - Acting as a resource to researchers on issues of ethics.

5. To suspend research under situations of undue risk to the study subjects.

6. To ensure that any matter that requires further action will be brought to the attention of Vice-president, Research and Associate Provost, and the Chair of the Committee on Human Subjects in Research.

**FREQUENCY OF MEETINGS**
The Board will meet face-to-face approximately once monthly.

**QUORUM**
Quorum for a meeting will consist of not fewer than 5 members, which comprise at least 1 community member, 1 person with research ethics background, 1 person with knowledge in the relevant law and 2 other academics.

**DECISION PROCESS**
Decisions will be reached by consensus.

After review, individual proposals will be referred back to the primary investigator with comments and/or suggestions for revision. Investigators may be invited to the meeting to respond to questions about their proposals, but will not be present during the decision process. Investigators who are members of the REB will leave the room during the consideration of their proposal or any proposal in which they have an interest. Members are expected to disclose any apparent conflicts-of-interest to the Chair.

No protocols or protocol amendments may be initiated without prior written approval of the Health Sciences II REB.

**EXPEDITED REVIEW**
Research that fits within the guidelines of *Criteria for Expedited Review* may be reviewed through the expedited process.

**APPEAL**
Appeals of REB decisions are possible, in accordance with the University’s *Guidelines for Ethical Review and Appeals*. 

ADMINISTRATION
Staff support and record keeping will be provided by the Ethics Review Office.

HIV/AIDS Research Ethics Board

NAME OF BOARD
University of Toronto HIV/AIDS Research Ethics Board

REPORTING RELATIONSHIP
The HIV/AIDS Research Ethics Board (REB) will report to the Committee on Human Subjects in Research (CHSR), and the Committee on Human Subjects in Research will report to the Vice-President, Research & Associate Provost, University of Toronto.

MANDATE
The HIV/AIDS Research Ethics Board has been established to ensure that HIV/AIDS research that involves humans is conducted in accordance with the highest ethical standards. The Committee will:

• review HIV/AIDS related protocols from faculty and graduate students from across all University of Toronto departments. The REB will review protocols from undergraduate students if they do not meet the criteria for expedited review.

• ensure that all research protocols submitted to and approved by the REB meet the ethical standards and practices described in the Tri-Council Policy Statement.

FUNCTIONS AND RESPONSIBILITIES
1. To ensure that all HIV/AIDS related protocols presented to the REB receive appropriate ethical review. Such review may include an assessment of the validity of the research methodology proposed.

2. To monitor the ethical conduct of research by:

• requiring researchers to report to the HIV/AIDS REB in a timely fashion:
  a) any significant deviations (i.e., any deviation which would lead to an increase in risk or a decrease in benefit) from the approved protocol, as well as any changes to the consent procedures in an approved protocol.
  b) any adverse occurrences associated with their approved protocols, in accordance with procedures set up by the University.
• providing for frequent and/or rigorous monitoring in specific cases as determined in an initial review, once continuing review mechanisms are in place.

3. To suspend or withdraw approval for any project which no longer complies with the approved research protocol or where the research ceases to be ethically acceptable.

4. To ensure that any matter that requires further action will be brought to the attention of the Committee on Human Subjects in Research and the Vice-President, Research & Associate Provost.
5. To facilitate education of members of the REB by:
   • ensuring that they are provided with a basic understanding of the principles involved in research ethics review.
   • including an educational component as part of the regular REB meetings from time to time in order to keep members informed of new developments in the area of research ethics.

6. To educate the University community on ethical issues related to research involving humans and to act as a resource to researchers on issues of ethics.

7. To advise and supervise Delegated Ethics Review Committees (departmental, interdepartmental and/or Faculty committees) which assess and approve undergraduate student research and to advise units in the setting up of subject pools.

MEMBERSHIP
The REB will consist of between five and fifteen members who are knowledgeable about HIV/AIDS research. The REB should also have at least one community member for each five academic members, and at least one individual with expertise in research ethics and one with expertise in legal matters. The term of membership is two years with the possibility of renewal. Members are appointed by the Vice-President, Research and Associate Provost.

QUORUM
Quorum for a meeting will consist of not fewer than 5 members, which comprise at least 1 community member, 1 person with research ethics background, 1 person with knowledge in the relevant law and 2 other academics.

FREQUENCY OF MEETINGS
The HIV/AIDS REB will meet face-to-face approximately monthly. Dates are established twice a year and are made available to the University community. Any member of the REB who fails to attend more than two consecutive meetings of the REB, not having the leave of the REB or of the Chair acting on its behalf, shall be deemed to have resigned his or her membership of the REB.

DECISION PROCESS
Decisions made by the REB will be made by consensus and if consensus cannot be reached the matter will be brought forward to the CHSR.

After review, individual protocols will be returned to the primary investigator with comments and/or suggestions for revision. Investigators will be invited to the meeting to respond to questions about their protocols, but will not be present during the decision process. Investigators who are members of the REB will leave the room during the consideration of their protocol or any protocol in which they have an interest. Members are expected to disclose any apparent conflicts-of-interest to the Chair.

No research may be initiated without prior written approval of the protocol or protocol amendment by the HIV/AIDS REB.
EXPEDITED REVIEW
Research that fits within the guidelines of Criteria for Expedited Review may be reviewed through the expedited process.

APPEAL
Appeals of REB decisions are possible, in accordance with the University's Guidelines for Ethical Review and Appeals.

ADMINISTRATION
Staff support and record keeping will be provided by the Ethics Review Office.
Education Research Ethics Board

NAME OF BOARD
University of Toronto Education Research Ethics Board

REPORTING RELATIONSHIP
The Education Research Ethics Board (REB) will report to the Committee on Human Subjects in Research (CHSR), and the Committee on Human Subjects in Research will report to the Vice-President, Research & Associate Provost, University of Toronto.

MANDATE
The Education Research Ethics Board has been established to ensure that research in education that involves humans is conducted in accordance with the highest ethical standards. The REB will:

• review protocols from faculty and graduate students at the Ontario Institute for Studies in Education of the University of Toronto (OISE/UT). The REB will review protocols from undergraduate students if they do not meet the criteria for expedited review.

• ensure that all research protocols submitted to and approved by the REB meet the ethical standards and practices described in the Tri-Council Policy Statement.

FUNCTIONS AND RESPONSIBILITIES
1. To monitor the ethical conduct of research by:
   • requiring researchers to report to the Education Research Ethics Board in a timely fashion:
     a) any significant deviations (i.e., any deviation which would lead to an increase in risk or a decrease in benefit) from the approved protocol, as well as any changes to the consent procedures in an approved protocol.
     b) any adverse occurrences associated with their approved protocols, in accordance with procedures set up by the University.
   • providing continuing review in the form of annual renewal of ethics approval, as well as frequent and/or rigorous monitoring in specific cases as determined in an initial review, once the mechanisms for continuing review are in place.

2. To suspend or withdraw approval for any project which no longer complies with the approved research protocol or where the research ceases to be ethically acceptable, once the mechanisms are in place.

3. To ensure that any matter that requires further action will be brought to the attention of the Committee on Human Subjects in Research and the Vice-President, Research & Associate Provost.

4. To facilitate education of members of the REB by:
• ensuring that they are provided with a basic understanding of the principles involved in research ethics review.
• including an educational component as part of the regular Committee meetings from time to time in order to keep members informed of new developments in the area of research ethics.

5. To educate the University community on ethical issues related to research involving humans and to act as a resource to researchers on issues of ethics.

6. To advise and supervise Delegated Ethics Review Committees (departmental, interdepartmental and/or Faculty committees) which assess and approve undergraduate student research.

MEMBERSHIP
The REB will consist of between five and fifteen members and should include, but not be limited to, one representative from each of these Departments: Adult Education and Counselling Psychology, Curriculum, Teaching and Learning, Human Development and Applied Psychology, Sociology and Equity Studies in Education, and Theory and Policy Studies in Education. The REB should also have a community member for each five academic members, and at least one individual with expertise in research ethics and one with expertise in legal matters. The term of membership is two years with the possibility of renewal. Members are appointed by the Vice-President, Research and Associate Provost.

QUORUM
Quorum for a meeting will consist of five members and will include at least one community member, one person with research ethics background, and three other members of academic departments.

FREQUENCY OF MEETINGS
The Education REB will meet face-to-face approximately monthly. Dates are established twice a year and are made available to the University community. Any member of the REB who fails to attend more than two consecutive meetings of the REB, not having the leave of the REB or of the Chair acting on its behalf, or good reason as deemed by the committee, shall be deemed to have resigned his or her membership of the REB.

DECISION PROCESS
Decisions made by the REB will be made by consensus and if consensus cannot be reached the matter will be brought forward to the CHSR.

After review, individual protocols will be returned to the primary investigator with comments and/or suggestions for revision. Investigators may be invited to the meeting to respond to questions about their protocols, but will not be present during the decision process. Investigators who are members of the REB will leave the room during the consideration of their protocol or any protocol in which they have an interest. Members are expected to disclose any apparent conflicts-of-interest to the Chair.

No research may be initiated without prior written approval of the protocol or protocol amendment by the Education Research Ethics Board.
EXPEDITED REVIEW
Research that fits within the guidelines of Criteria for Expedited Review may be reviewed through the expedited process.

APPEAL
Appeals of REB decisions are possible, in accordance with the University’s Guidelines for Ethical Review and Appeals.

ADMINISTRATION
Staff support and record keeping will be provided by the Ethics Review Office.
Social Sciences and Humanities REB

NAME OF BOARD
University of Toronto Social Sciences and Humanities Research Ethics Board (SSH REB)

REPORTING RELATIONSHIP
The Social Sciences and Humanities Research Ethics Board will report to the Committee on Human Subjects in Research, and the Committee on Human Subjects in Research will report to the Vice-President, Research & Associate Provost, University of Toronto.

MANDATE
The Social Sciences and Humanities Research Ethics Board has been established to ensure that research in the humanities and social sciences that involves humans is conducted in accordance with the highest ethical standards. The SSH REB will:

• review protocols from faculty and graduate students in social sciences and humanities disciplines at the three University of Toronto campuses at St. George, Mississauga, and Scarborough. The REB will review protocols from undergraduate students if they do not meet the criteria for expedited review.

• ensure that all research protocols submitted to and approved by the REB meet the ethical standards and practices described in the Tri-Council Policy Statement. In order to be in compliance with the TCPS, a protocol for research involving humans must be submitted to the ERU and approved by the REB before the research can be conducted; therefore, the REB cannot grant retrospective approval. Researchers must obtain written notification of approval before they can conduct research involving humans.

FUNCTIONS AND RESPONSIBILITIES
1. To ensure that all research protocols emanating from faculty and graduate students in social sciences and humanities disciplines at the three University of Toronto campuses at St. George, Mississauga, and Scarborough presented to the REB receive appropriate ethical review. Such review may include an assessment of the validity of the research methodology proposed.

2. To monitor the ethical conduct of research by:

• requiring researchers to report to the Social Sciences and Humanities Research Ethics Board in a timely fashion:
  a) any significant deviations (i.e., any deviation which would lead to an increase in risk or a decrease in benefit) from the approved protocol, as well as any changes to the consent procedures in an approved protocol.
  b) any adverse occurrences associated with their (approved) protocols, in accordance with procedures set up by the University.

• providing for frequent and/or rigorous monitoring in specific cases as determined in an initial review.
3. To suspend or withdraw approval for any project which no longer complies with the approved research protocol or where the research ceases to be ethically acceptable.

4. To ensure that any matter that requires further action will be brought to the attention of the Committee on Human Subjects in Research and the Vice-President, Research & Associate Provost.

5. To facilitate education of members of the REB by:
   • ensuring that they are provided with a basic understanding of the principles involved in research ethics review.
   • including an educational component as part of the regular REB meetings from time to time in order to keep members informed of new developments in the area of research ethics.

6. To educate the University community on ethical issues related to research involving humans and to act as a resource to researchers on issues of ethics.

7. To advise and supervise Student Research Ethics Committees (departmental, interdepartmental and/or Faculty committees) which assess and approve undergraduate student research and to advise units in the setting up of subject pools.

MEMBERSHIP
The Committee will consist of between five and fifteen members and should include, but not be limited to, one representative from each of these Departments: Psychology, Sociology, Anthropology and Political Science. The Committee should also have a community member for each five academic members, and at least one individual with expertise in research ethics and one with expertise in legal matters. The term of membership is three years with the possibility of renewal. Members are appointed by the Vice-President, Research and Associate Provost.

QUORUM
Quorum for a meeting will consist of five members and will include at least one community member, one person with research ethics background, and three other members of academic departments.

FREQUENCY OF MEETINGS
The Social Sciences and Humanities Research Ethics Board will meet face-to-face approximately once per month. Dates to meet are established at the end of each semester for the next semester and are made available to the University community through the Ethics website. Any member of the SSH REB who fails to attend more than two consecutive meetings of the SSH REB, not having the leave of the SSH REB or of the Chair acting on its behalf, or good reason, as deemed by the SSH REB, shall be deemed to have resigned his or her membership of the SSH REB.

DECISION PROCESS
Decisions made by the SSH REB will be made by consensus and if consensus cannot be reached the matter will be brought forward to the CHSR.
After review, individual protocols will be returned to the primary investigator with comments and/or suggestions for revision. Investigators may be invited to the meeting to respond to questions about their protocols, but will not be present during the decision process. Investigators who are members of the REB will leave the room during the consideration of their protocol or any protocol in which they have an interest. Members are expected to disclose any apparent conflicts-of-interest to the Chair.

No research may be initiated without prior written approval of the protocol or protocol amendment by the Social Sciences and Humanities Research Ethics Board.

**EXPEDITED REVIEW**
Research that fits within the guidelines of Criteria for Expedited Review may be reviewed through the expedited process.

**APPEAL**
Appeals of REB decisions are possible, in accordance with the University’s Guidelines for Ethical Review and Appeals.

**ADMINISTRATION**
Staff support and record keeping will be provided by the Ethics Review Office.
Delegated Ethics Review Committee – Terms of Reference (Template)

**NAME**  
(Departmental/Joint Departmental/Faculty/Divisional*) Ethics Review Committee (ERC)

*Will use Delegated to denote any of these types of ERC.

**REPORTING RELATIONSHIP**  
The (Delegated) Ethics Review Committee will report to the respective Research Ethics Board, through the Ethics Review Office, and the Committee on Human Subjects in Research will report to the Vice-President, Research & Associate Provost, University of Toronto.

**MANDATE**  
The (Delegated) Ethics Review Committee has been established to ensure that undergraduate research in the (Department of X) that involves humans is conducted in accordance with the highest ethical standards. The (Delegated) ERC will:

- Review protocols from undergraduate students in (department) at the University of Toronto.
- Review undergraduate course templates.
- Review undergraduate research-like and experiential learning activities.
- Ensure that all research and experiential learning protocols submitted to and approved by the ERC meet the ethical standards and practices described in the Tri-Council Policy Statement. In order to be in compliance with the TCPS, a protocol for research involving humans must be submitted to and approved by the ERC before the research can be conducted; therefore, the ERC cannot grant retrospective approval.

**FUNCTIONS AND RESPONSIBILITIES**

1. To monitor the ethical conduct of research by:
   - Requiring undergraduate student researchers to report to the (Delegated) ERC in a timely fashion:
     a) any significant deviations (i.e., any deviation which would lead to an increase in risk or a decrease in benefit) from the approved protocol, as well as any changes to the consent procedures in an approved protocol.
     b) any adverse occurrences associated with their (approved) protocols, in accordance with procedures set up by the University.
   - Providing for frequent and/or rigorous monitoring in specific cases as determined in an initial review

2. To suspend or withdraw approval for any project which no longer complies with the approved research protocol or where the research ceases to be ethically acceptable.

3. To manage risk of undergraduate research activities by upholding requirements for risk proportionate to student experience and pedagogical goals.
4. To ensure that any matter that requires further action will be brought to the attention of the Committee on Human Subjects in Research and the Vice-President, Research & Associate Provost.

5. To advise and educate undergraduate student researchers and course instructors in the development of research projects and protocols.

**MEMBERSHIP**
The Committee will consist of between five and ten members from the (department of X). The Committee should also have a community member and at least one individual with expertise in research ethics and at least one with expertise in legal matters. The term of membership is one year with the possibility of renewal. Members are appointed by the Departmental Chair/Vice-Dean/Undergraduate Coordinator.

**QUORUM**
Quorum for a meeting will consist of five members and will include at least one community member, one person with research ethics background, and three other members of (department of X).

**FREQUENCY OF MEETINGS**
The (Delegated) ERC will meet as required.

**DECISION PROCESS**
Decisions made by the (Delegated) ERC will be made by consensus whenever possible. If a decision cannot be reached the matter will be brought forward to the respective Research Ethics Board.

After review, individual protocols will be returned to the primary investigator with comments and/or suggestions for revision. Investigators may be invited to the meeting to respond to questions about their protocols, but will not be present during the decision process. Members are expected to disclose any apparent conflicts-of-interest to the Chair.

No research may be initiated without prior written approval of the protocol or protocol amendment by the (Delegated) ERC.

**APPEAL**
Appeals of ERC decisions are possible, in accordance with Tri-Council Policy. Appeals will be made to the Committee on Human Subjects in Research, University of Toronto.

**EXPEDITED REVIEW**
Protocols which meet the expedited review criteria may be reviewed by the Chair, the Vice Chair, a designate or a subcommittee. In such cases, the ERC will be notified of approvals at its next meeting, and the record of such reviews will be noted in the meeting minutes. Studies that may be eligible for expedited review must pose minimal risk to participants.

**ADMINISTRATION**
Records will be kept according to requirements by the Ethics Review Office. These include minutes of meetings, case files, and spreadsheets detailing investigator, supervisor, protocol title, course, whether the application is for an individual protocol or template, expedited or full review, approval date and any comments. Reports of protocols that have been reviewed,
approved or rejected will be given to the Ethics Review Office at the end of each academic year, and distributed to the respective REB for approval.
## SECTION A – GENERAL INFORMATION

### 1. Title of Research Project

___________________________________________________________________________________
___________________________________________________________________________________

### 2. Investigator Information

**PRINCIPAL INVESTIGATOR:**

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<th>Title</th>
<th>Name</th>
<th>Department</th>
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**Mailing Address**

Phone________________ Fax________________ Email________________

**CO-INVESTIGATORS:**

Are co-investigators involved? Yes ☐ No ☐

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<th>Title</th>
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**Mailing Address**

Phone________________ Fax________________ Email________________

### 3. University of Toronto Research Ethics Board

☐ Health Sciences I ☐ Health Sciences II ☐ Education ☐ Social Science and Humanities

Please consult [http://www.research.utoronto.ca/ethics/eh_forms.html](http://www.research.utoronto.ca/ethics/eh_forms.html) to determine which Research Ethics Board your proposal should be submitted to.

### 4. Type of Review

☐ Full Review ☐ Expedited Review

Certain minimal risk research may qualify for Expedited Review. Please consult [http://www.research.utoronto.ca/ethics/eh_when_exp.html](http://www.research.utoronto.ca/ethics/eh_when_exp.html) to determine whether your study meets the criteria for expedited review. Please note that the final decision is at the discretion of the Ethics Review Office and the REB.
If submitted for expedited review, please include a brief justification (max. 100 words) including risk to participants. Please consult with Section C #17 for risks involved in the study, and the Risk Matrix (Section F). Only research with Review Type=1 may be reviewed through the expedited process.

5. Location(s) where the research will be conducted:
University of Toronto ☐
Affiliated teaching hospital ☐ _________________ specify site(s)
School board or community agency ☐ _________________ specify site(s)
Community within the GTA ☐ _________________ specify site(s)
International ☐ _________________ specify site(s)
Other ☐ _________________ specify site(s)

If the research is to be conducted at a site requiring administrative approval/consent (e.g. in a school), please include all draft administrative consent letters. It is the responsibility of the researcher to determine what other means of approval are required, and to obtain approval prior to starting the project.

6. Other Research Ethics Board Approval(s)
(a) Does the research involve another institution or site? Yes ☐ No ☐
(b) Has any other REB approved this project? Yes ☐ No ☐
(c) If YES, please provide a copy of the approval letter upon submission of this application.
(d) If NO, will any other REB be asked for approval?
   Yes ☐ _________________ (please specify which REB) No ☐

7. Funding of the Project
(a) Please check one:
   Funded ☐
       Agency: _____________ Fund #: __________
       Agency: _____________ Fund #: __________
   Applied for funding ☐
       Agency: _____________ Submission date: __________
       Agency: _____________ Submission date: __________

If one protocol is to cover more than one grant, please include all fund numbers.

Unfunded ☐

(b) If waiting for funding, do you wish to postdate ethics approval to the release of funds?
   Yes ☐ No ☐
(c) For funded research, will more than one protocol be submitted to cover all research funded by the respective grant?  
Yes ☐ If yes, this is # ___ of ___ No ☐

8. Project Start and End Dates  
Estimated start date for this project: _______________  
Estimated completion date for this project: _______________

9. Scholarly Review  
Please check one:
☐ The research has undergone scholarly review prior to this submission for ethical review  
________________________ (specify review committee)  
☐ The research will undergo scholarly review prior to funding  
________________________ (specify review committee)  
☐ The research will not undergo scholarly review apart from this ethics review

10. Conflict of Interests  
(a) Will the researcher(s), members of the research team, and/or their partners or immediate family members:
   (i) Receive any personal benefits (e.g. financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection to this study?  Yes ☐ No ☐
   (ii) If Yes, please describe the benefits below. (Do not include conference and travel expense coverage, or other benefits which are standard to the conduct of research.)

(b) Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that has been placed on the investigator(s). This includes controls placed by sponsor, advisory or steering committee.

(c) Where relevant, please explain any pre-existing relationship between the researcher(s) and the researched (e.g. instructor-student; manager-employee; minister-congregant).

SECTION B – SUMMARY OF THE PROPOSED RESEARCH
Please include a list of appendices for all additional materials submitted.

11. Rationale
Describe the purpose and background rationale for the proposed project, and, if relevant, the hypotheses/research questions to be examined.

12. Methods
Please describe all formal and informal procedures to be used, settings and types of information to be involved.

Attach a copy of all questionnaires, interview guides or other non-standard test instruments.
13. Participants or Data Subjects
Describe the participants that will be recruited, or the subjects about whom personal information will be collected. Where active recruitment is required, please describe inclusion and exclusion criteria. Where the research involves extraction or collection of personal information, please describe from whom the information will be obtained and what it will include.
14. Experience
For projects that involve collection of sensitive data, methods that pose greater than minimal risk to participants, or involves a vulnerable population, please provide a brief description of the researcher's/research team’s experience with this type of research.

| Financial | Yes □ | No □ |
| In-kind   | Yes □ | No □ |
| Other     | Yes □ | No □ |

15. Recruitment
Where there is formal recruitment, please describe how and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g. living in a community, visiting on a bi-weekly basis, attending organized functions).

Attach a copy of any posters, advertisements, flyers, letters, or telephone scripts to be used for recruitment.

16. Compensation
(a) Will participants receive compensation for participation?

(b) If Yes, please provide details.
(c) Where there is a withdrawal clause in the research procedure, if participants choose to withdraw, how will you deal with compensation?

SECTION C –DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

17. Possible Risks
1. Indicate if the participants as individuals or as part of an identifiable group or community might experience any of the following risks by being part of this research project:

(a) Physical risks (including any bodily contact or administration of any substance)? Yes □ No □

(b) Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious or upset)? Yes □ No □

(c) Social risks (including possible loss of status, privacy and/or reputation)? Yes □ No □

(d) Is there any deception involved? (See Debriefing, #21) Yes □ No □

2. If you answered Yes to any of the above, please explain the risks, and describe how they will be managed and/or minimized.

18. Possible Benefits
Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific/scholarly community or society that would justify involvement of participants in this study.

SECTION D – THE INFORMED CONSENT PROCESS
19. The Consent Process
Describe the process that the investigator(s) will be using to obtain informed consent. If there will be no written consent form, please explain (e.g., discipline, cultural appropriateness, etc.). Please note, it is the quality of the consent, not the format that is important. If the research involves extraction or collection of personal information from a data subject, please describe how consent from the individuals or authorization from the custodian will be obtained.

For information about the required elements in the information letter and consent form, please refer to http://www.research.utoronto.ca/ethics/eh_best.html.

Where applicable, please attach a copy of the Information Letter/Consent Form, the content of any telephone script, letters of administrative consent or authorization and/or any other material which will be used in the informed consent process.

20. Consent by an authorized party
If the participants are children, or are not competent to consent, describe the proposed alternate source of consent, including any permission/information letter to be provided to the person(s) providing the alternate consent as well as the assent process for participants.

21. Debriefing
(a) If deception will be used in the research study, please explain what information/feedback will be provided to participants after participation in the project.
Please provide a copy of the written debriefing form, if applicable.

(b) How will participants be informed of study results?

22. Participant withdrawal
(a) Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.

(b) Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

(c) If participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain.

SECTION E –CONFIDENTIALITY AND PRIVACY

23. (a) Will the data be treated as confidential? Yes □ No □
(b) Describe the procedures to be used to ensure anonymity of participants or informants, where applicable, or the confidentiality of data during the conduct of research and dissemination of results.

(c) Explain how written records, video/audio tapes and questionnaires will be secured, how long they will be retained, and provide details of their final disposal or storage.

(d) If participant anonymity or confidentiality is not appropriate to this research project, please explain.

24. Privacy Regulations
For research involving extraction or collection of personal information, provincial, national and/or international laws may apply. My signature as Principal Investigator, in Section G of this protocol form, confirms that I understand and will comply with all relevant laws governing the collection and use of personal information in research.
SECTION F – CONTINUING REVIEW OF ONGOING RESEARCH

RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY AND RESEARCH RISK - circle one:

<table>
<thead>
<tr>
<th>Group Vulnerability</th>
<th>Research Risk</th>
</tr>
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<tbody>
<tr>
<td></td>
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</tr>
<tr>
<td>High</td>
<td>2</td>
</tr>
</tbody>
</table>

Briefly explain/justify the level of risk and group vulnerability reported above (max 100 words):

Please note, the final determination of Review Type and program of Continuing Review will be made by the University of Toronto REB and the Ethics Review Office.

SECTION G – SIGNATURES

All researchers and their respective Departmental Chair/Dean or designate must sign below:

As the Principal Investigator on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national and international policies and regulations that govern research involving human participants. Any deviation from the project as originally approved will be submitted to the Research Ethics Board for approval prior to its implementation.

Signature of Principal Investigator: ___________________________ Date: ______

As the Departmental Chair/Dean, my signature confirms that I am aware of the proposed activity. My administrative unit will follow guidelines and procedures which ensure compliance with all relevant University, provincial, national or international policies and regulations that govern research involving human subjects. My signature also reflects the willingness of the department, faculty or division to administer the research funds, if there are any, in accordance with University, regulatory agency and sponsor agency policies.

Name of Departmental Chair/Dean (or designate): ___________________________

Signature: ___________________________ Date: ______
ETHICS REVIEW PROTOCOL SUBMISSION FORM – SUPERVISED AND SPONSORED RESEARCHERS
(For use by graduate students, post-docs and visiting professors and researchers)

SECTION A – GENERAL INFORMATION

1. Title of Research Project
___________________________________________________________________________________
___________________________________________________________________________________

2. Investigator Information
INVESTIGATOR:

Title ______ Name__________________________________________
Department__________________________________________________
Mailing Address_______________________________________________
Phone________________ Fax________________ Email__________________

Level of Project
Faculty Research ☐ Personnel Number _________________________
Post-Doctoral Research ☐ Personnel Number _______________________
Student Research: Doctoral ☐ Masters ☐ Student Number ______________

FACULTY SUPERVISOR/SPONSOR:

Name________________________________________________________
Department__________________________________________________
Mailing Address_______________________________________________
Phone________________ Fax________________ Email__________________

CO-INVESTIGATORS:
Are co-investigators involved? Yes ☐ No ☐

Title ______ Name__________________________________________ Personnel Number: _______________________
Department__________________________________________________
Mailing Address_______________________________________________
Phone________________ Fax________________ Email__________________

Title ______ Name__________________________________________ Personnel Number: _______________________
Department__________________________________________________
Mailing Address_______________________________________________
Phone________________ Fax________________ Email__________________

3. University of Toronto Research Ethics Board
Health Sciences I  ☐ Health Sciences II  ☐ Education  ☐ Social Science and Humanities
Please consult http://www.research.utoronto.ca/ethics/eh_forms.html to determine which Research Ethics Board your proposal should be submitted to.

4. Type of Review
☐ Full Review  ☐ Expedited Review
Certain minimal risk research may qualify for Expedited Review. Please consult http://www.research.utoronto.ca/ethics/eh_when_exp.html to determine whether your study meets the criteria for expedited review. Please note that the final decision is at the discretion of the Ethics Review Office and the REB.

If submitted for expedited review, please include a brief justification (max. 100 words) including risk to participants. Please consult with Section C #17 for risks involved in the study, and the Risk Matrix (Section F). Only research with Review Type=1 may be reviewed through the expedited process.

5. Location(s) where the research will be conducted:
University of Toronto  ☐
Affiliated teaching hospital  ☐ _______________ specify site(s)
School board or community agency  ☐ _______________ specify site(s)
Community within the GTA  ☐ _______________ specify site(s)
International  ☐ _______________________________ specify site(s)
Other  ☐ ________________________________ specify site(s)

If the research is to be conducted at a site requiring administrative approval/consent (e.g. in a school), please include all draft administrative consent letters. It is the responsibility of the researcher to determine what other means of approval are required, and to obtain approval prior to starting the project.

6. Other Research Ethics Board Approval(s)
(a) Does the research involve another institution or site? Yes ☐ No ☐
(b) Has any other REB approved this project? Yes ☐ No ☐
(c) If YES, please provide a copy of the approval letter upon submission of this application.
(d) If NO, will any other REB be asked for approval?
Yes ☐ ______________________ (please specify which REB)  No ☐

7. Funding of the Project
(a) Please check one:
Funded □ Agency: _____________ Fund #: __________
Agency: _____________ Fund #: __________

Applied for funding □ Agency: ____________ Submission date: _____________
Agency: _____________ Submission date: _____________

If one protocol is to cover more than one grant, please include all fund numbers.

Unfunded □

(b) If waiting for funding, do you wish to postdate ethics approval to the release of funds?
Yes □ No □

(c) For funded research, will more than one protocol be submitted to cover all research funded by the respective grant?
Yes □ If yes, this is # ___ of ___ No □

8. Project Start and End Dates
Estimated start date for this project: ______________
Estimated completion date for this project: ____________

9. Scholarly Review
Please check one:
□ The research has been approved by a thesis committee (required for thesis research)
□ The research has undergone scholarly review prior to this submission for ethical review
□ The research will undergo scholarly review prior to funding
□ The research will not undergo scholarly review apart from this ethics review

10. Conflict of Interests
(a) Will the researcher(s), members of the research team, and/or their partners or immediate family members:
   (i) Receive any personal benefits (e.g. financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection to this study? Yes □ No □
   (ii) If Yes, please describe the benefits below. (Do not include conference and travel expense coverage, or other benefits which are standard to the conduct of research.)

(b) Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that has been placed on the investigator(s). This includes controls placed by sponsor, advisory or steering committee.
(c) Where relevant, please explain any pre-existing relationship between the researcher(s) and the researched (e.g. instructor-student; manager-employee; minister-congregant).

SECTION B – SUMMARY OF THE PROPOSED RESEARCH

Please include a list of appendices for all additional materials submitted.

11. Rationale
Describe the purpose and background rationale for the proposed project, and, if relevant, the hypotheses/research questions to be examined.

12. Methods
Please describe all formal and informal procedures to be used, settings and types of information to be involved.

Attach a copy of all questionnaires, interview guides or other non-standard test instruments.
13. Participants or Data Subjects
Describe the participants that will be recruited, or the subjects about whom personal information will be collected. Where active recruitment is required, please describe inclusion and exclusion criteria. Where
the research involves extraction or collection of personal information, please describe from whom the information will be obtained and what it will include.

14. Experience
For projects that involve collection of sensitive data, methods that pose greater than minimal risk to participants, or involves a vulnerable population, please provide a brief description of the researcher’s/research team’s experience with this type of research.

15. Recruitment
Where there is formal recruitment, please describe how and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g. living in a community, visiting on a bi-weekly basis, attending organized functions).

Attach a copy of any posters, advertisements, flyers, letters, or telephone scripts to be used for recruitment.
16. Compensation
(a) Will participants receive compensation for participation?

- Financial: Yes ☐ No ☐
- In-kind: Yes ☐ No ☐
- Other: Yes ☐ No ☐

(b) If Yes, please provide details.

(c) Where there is a withdrawal clause in the research procedure, if participants choose to withdraw, how will you deal with compensation?

SECTION C –DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH

17. Possible Risks
1. Indicate if the participants as individuals or as part of an identifiable group or community might experience any of the following risks by being part of this research project:

(a) Physical risks (including any bodily contact or administration of any substance)? Yes ☐ No ☐

(b) Psychological/emotional risks (feeling uncomfortable, embarrassed, anxious or upset)? Yes ☐ No ☐

(c) Social risks (including possible loss of status, privacy and/or reputation)? Yes ☐ No ☐

(d) Is there any deception involved? (See Debriefing, #21) Yes ☐ No ☐

2. If you answered Yes to any of the above, please explain the risks, and describe how they will be managed and/or minimized.
18. Possible Benefits
Discuss any potential direct benefits to the participants from their involvement in the project. Comment on the (potential) benefits to the scientific/scholarly community or society that would justify involvement of participants in this study.

SECTION D – THE INFORMED CONSENT PROCESS

19. The Consent Process
Describe the process that the investigator(s) will be using to obtain informed consent. If there will be no written consent form, please explain (e.g. discipline, cultural appropriateness, etc.). Please note, it is the quality of the consent, not the format that is important. If the research involves extraction or collection of personal information from a data subject, please describe how consent from the individuals or authorization from the custodian will be obtained.

For information about the required elements in the information letter and consent form, please refer to http://www.research.utoronto.ca/ethics/eh_best.html.

Where applicable, please attach a copy of the Information Letter/Consent Form, the content of any telephone script, letters of administrative consent or authorization and/or any other material which will be used in the informed consent process.
20. Consent by an authorized party
If the participants are children, or are not competent to consent, describe the proposed alternate source of consent, including any permission/information letter to be provided to the person(s) providing the alternate consent as well as the assent process for participants.

21. Debriefing
(a) If deception will be used in the research study, please explain what information/feedback will be provided to participants after participation in the project.

Please provide a copy of the written debriefing form, if applicable.

(b) How will participants be informed of study results?

22. Participant withdrawal
(a) Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.
(b) Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

(c) If participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain.

SECTION E – CONFIDENTIALITY AND PRIVACY

23. (a) Will the data be treated as confidential? Yes □ No □

(b) Describe the procedures to be used to ensure anonymity of participants or informants, where applicable, or the confidentiality of data during the conduct of research and dissemination of results.

(c) Explain how written records, video/audio tapes and questionnaires will be secured, how long they will be retained, and provide details of their final disposal or storage.

(d) If participant anonymity or confidentiality is not appropriate to this research project, please explain.
24. Privacy Regulations
For research involving extraction or collection of personal information, provincial, national and/or international laws may apply. My signature as Principal Investigator, in Section G of this protocol form, confirms that I understand and will comply with all relevant laws governing the collection and use of personal information in research.

SECTION F – CONTINUING REVIEW OF ONGOING RESEARCH

RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY AND RESEARCH RISK - circle one:

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</tr>
<tr>
<td></td>
<td>High</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

Briefly explain/justify the level of risk and group vulnerability reported above (max 100 words):

Please note, the final determination of Review Type and program of Continuing Review will be made by the University of Toronto REB and the Ethics Review Office.
SECTION G – SIGNATURES

All researchers and their respective Departmental Chair/Dean or designate must sign below:

As the **Investigator** on this project, my signature confirms that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national and international policies and regulations that govern research involving human participants. Any deviation from the project as originally approved will be submitted to the Research Ethics Board for approval prior to its implementation.

For **student researchers**, my signature confirms that I am a registered student in good standing with the University of Toronto. My project has been reviewed and approved by my advisory committee (where applicable). If my status as a student changes, I will inform the Ethics Review Office.

Signature of Investigator: ___________________________ Date: ____________

For **Graduate Students** the signature of the Faculty Supervisor is required. For **Post-Doctoral Fellows and Visiting Professors or Researchers**, the signature of the Faculty Sponsor is required.

As the **Faculty Supervisor** of this project, my signature confirms that I have reviewed and approve the scientific merit of the research project and this ethics protocol submission. I will provide the necessary supervision to the student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with relevant University, provincial, national or international policies and regulations that govern research involving human subjects. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

As the **Faculty Sponsor** for this project, my signature confirms that I have reviewed and approve of the research project and will assume responsibility, as the University representative, for this research project. I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national or international policies and regulations that govern research involving human participants.

Name of Faculty Supervisor/Sponsor: ___________________________

Signature: ___________________________ Date: ______________

As the **Departmental Chair/Dean**, my signature confirms that I am aware of the proposed activity. My administrative unit will follow guidelines and procedures which ensure compliance with all relevant University, provincial, national or international policies and regulations that govern research involving human subjects. My signature also reflects the willingness of the department, faculty or division to administer the research funds, if there are any, in accordance with University, regulatory agency and sponsor agency policies.

Name of Departmental Chair/Dean (or designate): ___________________________

Signature: ___________________________ Date: ______________
The purpose of a Course Template is to set the parameters of the assignment(s) that involve(s) human subjects. The Course Instructor is responsible for setting the parameters, through the use of the Graduate Course Template Ethics Review Protocol Form, and reviewing each student’s individual proposal to ensure its academic merit and adherence to the parameters set out in the template. The Course Instructor is also responsible for providing the necessary supervision to each student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with all relevant University, provincial and national policies and regulations that govern research involving human participants. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

RESEARCH ETHICS BOARD to review this template:

Health Sciences I    Health Sciences II    Education    Social Sciences & Humanities

COURSE INSTRUCTOR:

Name ___________________________ Personnel Number __________
Department ____________________________________________
Mailing Address _________________________________________
Phone __________ Fax __________ Email ______________________

COURSE:

Course Title _____________________________ Number of Students in Course __________
Course Code ____________________________
Course Start Date _______________________

Student projects are marked Complete at the end of the academic year. If a student wishes to continue a project beyond the end of the academic year, please inform the respective Ethics Review Coordinator.

Course Instructors who wish to maintain approval of a Course Template for greater than one year may submit an Annual Renewal form up to 4 times (for ongoing ethics approval of up to 5 years).
MINIMAL RISK AND EXPEDITED REVIEW:
Risk to participants should be proportionate to student experience and pedagogical goals, with appropriate levels of responsibility and supervision. Typically, graduate non-thesis research should involve low to no risk to participants. For research involving participants from vulnerable populations, greater oversight and team qualifications are required.

To evaluate risk for this protocol, consider:
- Group vulnerability—i.e., any pre-existing vulnerabilities associated with proposed participant groups, e.g., relating to pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status.
- Research risk—i.e., the probability and magnitude of harms participants may experience as a result of the proposed methods to be used and types of data to be collected, e.g., relating to physiological or health issues such as clinical diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, and socio-economic or legal ramifications such as stigma, loss of employment, deportation, or criminal investigation (e.g., in the event of duty to report intent to cause serious harm, subpoena, or breach of confidentiality).

RISK MATRIX: Review Type by Group Vulnerability and Research Risk – Circle one or more cells as appropriate.

<table>
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</tr>
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<td>Medium</td>
<td>Expedited</td>
</tr>
<tr>
<td>High</td>
<td>Full</td>
</tr>
</tbody>
</table>

Briefly explain (max. 100 words) the group vulnerability and research risk:
HOST SITES:
Indicate the location(s) where the research will be conducted:

University of Toronto  □
Affiliated teaching hospital  □ ______________________________ (specify site(s))
Community within the GTA  □ ______________________________ (specify site(s))
Other  □ ______________________________ (specify site(s))

If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a school), please include all draft administrative consent letters. It is the responsibility of the Course Instructor to determine what other means of approval are required, and to obtain approval prior to starting the project.

Other Research Ethics Board Approval:
(a) Does the research involve another institution or site?  Yes  □  No  □
(b) Has any other REB approved this project?  Yes  □  No  □
(c) If Yes, please provide a copy of the approval letter upon submission of this application.  Yes  □  No  □
(d) If No, will any other REB be asked for approval?  Yes  □  No  □
   If Yes, please specify which REB __________________

BACKGROUND, PURPOSE, AND OBJECTIVES:
Briefly describe the pedagogical goal of the assignment.
METHODS AND DATA:

- Please provide a general description of the methods that will be used in the student projects i.e. formal interviews, or tests, naturalistic or participant observation, secondary analysis of previously collected data etc.
- Please provide a general description of the settings in which the student projects will take place.
- If the assignment involves using specialized methods with participants, describe the students’ relevant experience (e.g. prerequisite courses or training) or the nature of direct supervision they may receive.

PARTICIPANTS, INFORMANTS, OR DATA SUBJECTS:

Describe, in general terms, the individuals or groups whose personal information is to be used as part of the assignment (e.g. 1st year university students, teachers, doctors or other professionals). If the assignment involves working with a vulnerable population, describe the students’ relevant experience or the nature of direct supervision they may receive.
RECRUITMENT:
- Where there is formal recruitment, please describe, in general terms, how and from where the participants will be recruited.
- Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, etc.)
- Where relevant, please explain any non-research relationship between the students and the research participants (e.g., teacher-student, manager-employee, clinician-patient).

It is advised that the Course Instructor prepares templates for student posters, advertisements, flyers, letters, or telephone scripts to be used for recruitment. Please attach a copy of each template to each Course Template submission.

RISKS:
Indicate if participants in student projects covered by this Course Template might experience any of the following risks:

(a) Physical (e.g., bodily contact, administration of any substance)?  Yes □ No □
(b) Psychological/emotional (e.g., feeling embarrassed, anxious, upset)?  Yes □ No □
(c) Social (e.g., possible loss of status, privacy, reputation)?  Yes □ No □
(d) Is there any deception involved (see “Debriefing”, below)?  Yes □ No □
(e) Are risks to participants greater than in their everyday life?  Yes □ No □

If you answered Yes to any of the above, please explain the risks, and describe how they will be managed, and how they are proportionate to student experience and pedagogical goals.

BENEFITS:
Discuss any potential direct benefits to the participants from their involvement in the student projects.

**COMPENSATION:**
It is recommended that graduate course assignments do not involve remuneration for participants. Describe the course policy with regard to compensation; if some form of compensation is to occur, explain the reasoning behind it. (See note on courtesy copies, under “Debriefing”, below)

**CONSENT PROCESS:**
Describe the process that the instructor and/or students will use to obtain informed consent. If there will be no written consent form, please explain (e.g., if culturally inappropriate). If the research involves extraction or collection of personal information from a data subject, please describe how consent from the individuals or authorization from the custodian will be obtained. For information about the required elements in the information letter and consent form, please refer to: [http://www.research.utoronto.ca/ethics/eh_u_inf.html](http://www.research.utoronto.ca/ethics/eh_u_inf.html)

It is advised that the Course Instructor prepares templates for the student consent forms. Please attach a copy of each template to each Course Template submission.

If the participants are children, or are not competent to consent, describe the proposed alternate source of consent, including templates of any permission/information letters to be provided to the person(s) providing the alternate consent as well as the assent process for...
Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.

Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

If the participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain.
PRIVACY AND CONFIDENTIALITY:
Will the data be treated as confidential? Yes ☐ No ☐

If Yes, please describe the procedures that students will use to protect confidentiality during the conduct of research and in preparation of the final report.

Explain how students will store written records, video/audio tapes and questionnaires (e.g., password protected computer, double locked office and filing cabinet), and provide details of their final disposal or retention schedule.

If No—i.e., confidentiality is not appropriate in the context of this assignment—please explain (e.g., participants are key informants with established reputations in their field).
DEBRIEFING:
Explain what information will be provided to the participants after participation in the project, and in what form (e.g. research summary). If deception will be used in the research study, please explain what information will be provided to the participants after participation in the project—if applicable, attach a copy of the written debriefing form.

Please note that all copies of the students’ final reports—e.g., for circulation as courtesy copies, or future writing samples—must clearly indicate on the cover page the instructor, course number, and department or program at the University of Toronto that the report was prepared for.

REPORT TO THE RESEARCH ETHICS BOARD:
If relevant, the course instructor should provide the Research Ethics Board that reviewed the template with a list of titles of students’ projects, once they have been chosen.

SIGNATURES:
As the Course Instructor of this template course assignment, my signature confirms that I will review each student proposal to ensure its academic merit and adherence to the template. I will provide the necessary supervision to each student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with University, provincial and national policies and regulations that govern research involving human participants. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

Name of Course Instructor: _________________________
Signature: ___________________________ Date: ____________

As the Graduate Chair/Dean, my signature confirms that I am aware of the proposed activity. My administrative unit will follow guidelines and procedures which ensure compliance with all relevant University, provincial, national or international policies and regulations that govern research involving human subjects. My signature also reflects the willingness of the department, faculty or division to administer the research funds, if there are any, in accordance with University, regulatory agency and sponsor agency policies.

Name of Graduate Chair/Dean: _________________________
Signature: ___________________________ Date: ____________
UNDERGRADUATE ETHICS REVIEW PROTOCOL SUBMISSION FORM
COURSE TEMPLATE

DELEGATED ETHICS REVIEW COMMITTEE reviewing this template: ____________

COURSE INSTRUCTOR:
Name __________________________ Personnel Number ______________
Department _______________________
Mailing Address _____________________
Phone __________________ Fax __________ Email ___________________

COURSE:
Course Title __________________________ Number of Students in Course ___________
Course Code _______________ (Students’ projects will be considered completed once
the course is over. Instructors who wish to use the same course template again, however,
may submit an annual renewal form.)

MINIMAL RISK AND EXPEDITED REVIEW:
Risk to participants should be proportionate to student experience and pedagogical goals,
with appropriate levels of responsibility and supervision. Typically, undergraduate research
should involve minimal risk, which means that the probability and magnitude of harm due to
participation in the research is no greater than that encountered by participants in their
everyday lives. Assessing risk may to some degree be affected by discipline-specific
considerations—e.g., forensics, medicine, and nursing may involve work with participants in
clinical settings, with attendant requirements for oversight and team qualifications.
Departments will likely want to work with the Ethics Review Office (ERO) to decide how best
to handle different levels of risk. Additional on-line resources may also be helpful, including:

• www.research.utoronto.ca/ethics_home.html
• www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
• www.pre.ethics.gc.ca/english/tutorial/

To evaluate risk for this protocol, consider:
• Group vulnerability—i.e., any pre-existing vulnerabilities associated with proposed
  participant groups, e.g., relating to pre-existing physiological or health conditions,
  cognitive or emotional factors, and socio-economic or legal status.
• Research risk—i.e., the probability and magnitude of harms participants may
  experience as a result of the proposed methods to be used and types of data to be
  collected, e.g., relating to physiological or health issues such as clinical diagnoses or
  side effects, cognitive or emotional factors such as stress or anxiety during data
  collection, and socio-economic or legal ramifications such as stigma, loss of
  employment, deportation, or criminal investigation (e.g., in the event of duty to report
  intent to cause serious harm, subpoena, or breach of confidentiality).

Please provide over-all assessments of group vulnerability and research risk (i.e., low,
medium, high) and locate the protocol in the matrix, below.
**RISK MATRIX: Review Type by Group Vulnerability and Research Risk--circle one:**

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<td>High</td>
<td>Full</td>
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<td></td>
<td>Full</td>
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<td></td>
<td>Full</td>
</tr>
</tbody>
</table>

Briefly explain (max. 100 words) the group vulnerability and research risk, and explain any exceptional circumstances (e.g., student experience) justifying greater than minimal risk:

**CO-INVESTIGATORS:**  
Are co-investigators involved? Yes ☐ No ☐  
If YES, provide the name(s) and contact information on a separate sheet.

**HOST SITES:**  
Indicate the location(s) where the research will be conducted:  
University of Toronto ☐  
Affiliated teaching hospital ☐ ___________________________ (specify site(s))  
Community within the GTA ☐ ___________________________ (specify site(s))  
Other ☐ ___________________________ (specify site(s))  

N.B. If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a school), please include all draft administrative consent letters. It is the responsibility of the researcher to determine what other means of approval are required, and to obtain approval prior to starting the project.

Other Research Ethics Board Approval:  
(a) Does the research involve another institution or site? Yes ☐ No ☐  
(b) Has any other REB approved this project? Yes ☐ No ☐  
(c) If YES, please provide a copy of the approval letter upon submission of this application.  
(d) If No, will any other REB be asked for approval? Yes ☐ No ☐  
   If YES, please specify which REB ___________________________
BACKGROUND, PURPOSE, AND OBJECTIVES:
Briefly describe the pedagogical goal of the assignment.

METHODS AND DATA:

• If the research takes place in a controlled environment (e.g. clinic, laboratory, formal interview or tests), describe sequentially, and in detail, all procedures in which research participants will be involved.

• If the research involves naturalistic or participant observation, please describe the setting, the types of interactive and observational procedures to be used, and the kinds of information to be collected.

• If the research involves secondary analysis of previously collected data, describe the original source of the data and measures that have been taken to protect data subjects’ identities.

• If the assignment involves using specialized methods with participants, describe the students’ relevant past experience, or the nature of any supervision they may receive.

N.B. Attach a copy of all questionnaires, interview guides or other test instruments.
PARTICIPANTS, INFORMANTS, OR DATA SUBJECTS:
Describe the individuals whose personal information is to be used as part of the assignment (i.e., in terms of inclusion and exclusion criteria, especially where active recruitment is involved). If the assignment involves working with a vulnerable population, describe the students’ relevant past experience, or the nature of any supervision they may receive.
RECRUITMENT:
Where there is formal recruitment, please describe how and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, etc.) Where relevant, please explain any non-research relationship between the students and the research participants (e.g., teacher-student, manager-employee, nurse-patient).

N.B. Attach a copy of any posters, advertisements, flyers, letters, or telephone scripts to be used for recruitment.

RISKS:
Indicate if the participants might experience any of the following risks:

(a) Physical (e.g., bodily contact, administration of any substance)? Yes ☐ No ☐

(b) Psychological/emotional (e.g., feeling embarrassed, anxious, upset)? Yes ☐ No ☐

(c) Social (e.g., possible loss of status, privacy, reputation)? Yes ☐ No ☐

(d) Is there any deception involved (see “Debriefing”, below)? Yes ☐ No ☐

(e) Are risks to participants greater than in their everyday life? Yes ☐ No ☐

If you answered Yes to any of the above, please explain the risks, and describe how they will be managed, and how they are proportionate to student experience and pedagogical goals.
**BENEFITS:**
Discuss any potential direct benefits to the participants from their involvement in the project. Comment on potential benefits to the students, the scholarly community, or society that would justify involvement of participants in this study. (See the note on courtesy copies of final reports in the “Debriefing” section, below)

**COMPENSATION:**
The ERO recommends that undergraduate course template assignments not involve any reimbursements or remuneration for participants. Describe the course policy with regard to compensation; if some form of compensation is to occur, explain the reasoning behind it. (See note on courtesy copies, under “Debriefing”, below)

**CONSENT PROCESS:**
Describe the process that the instructor and/or students will use to obtain informed consent. Please note, it is the quality of the consent not the format that is important: if there will be no written consent form, please explain (e.g., if culturally inappropriate). If the research involves extraction or collection of personal information from a data subject, please describe how consent from the individuals or authorization from the custodian will be obtained. For information about the required elements in the information letter and consent form, please refer to: [www.research.utoronto.ca/ethics_icrequir.html](http://www.research.utoronto.ca/ethics_icrequir.html)

N.B. Where applicable, please attach a copy of the Information Letter/Consent Form, the content of any telephone script, letters of administrative consent or authorization and/or any other material which will be used in the informed consent process.
If the participants are minors, or are not competent to consent, describe the proposed alternate source of consent, including any permission/information letter to be provided to the person(s) providing the alternate consent as well as the assent process for participants.

Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.

Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

If the participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain.

**PRIVACY AND CONFIDENTIALITY:**

Will the data be treated as confidential?  
Yes □  No □

If **Yes**, please describe the procedures to be used to protect confidentiality during the conduct of research and in preparation of the final report.
Explain how written records, video/audio tapes and questionnaires will be stored (e.g., password protected computer, double locked office and filing cabinet), and provide details of their final disposal or retention schedule.

If No—i.e., confidentiality is not appropriate in the context of this assignment—please explain (e.g., participants are key informants with established reputations in their field).

DEBRIEFING:
Explain what information (e.g., research summary) will be provided to the participants after participation in the project. If deception will be used in the research study, please explain what information will be provided to the participants after participation in the project—if applicable, attach a copy of the written debriefing form.

N.B. Please note that all copies of the students’ final reports—e.g., for circulation as courtesy copies, or future writing samples—must clearly indicate on the cover page the instructor, course number, and department or program at the University of Toronto that the report was prepared for.

REPORT TO THE DELEGATED ETHICS REVIEW COMMITTEE:
If relevant, the course instructor should provide the Delegated Ethics Review Committee that reviewed the template with a list of titles of students’ projects, once they have been chosen.
SIGNATURES:

As the **Course Instructor** of this template course assignment, my signature testifies that I will review each student proposal to ensure its academic merit and adherence to the template. I will provide the necessary supervision to each student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with University, provincial and national policies and regulations that govern research involving human participants. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

Signature of Course Instructor: ____________________________ Date: ______________

As the **Undergraduate Coordinator**, my signature testifies that I am aware of the proposed activity, and understand that the level of risk inherent to the project should be managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Instructor and/or On-site Supervisor.

Signature of Undergraduate Coordinator: ____________________________ Date: ______________

As the **Departmental Chair/Dean**, my signature testifies that I am aware of the proposed activity, will allocate space and other resources required, and will provide administrative support to the activity. My department, faculty or division will oversee the conduct of research involving human participants to ensure compliance with University, provincial and national policies and regulations.

Signature of Departmental Chair/Dean: ____________________________ Date: ______________
UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

UNDERGRADUATE ETHICS REVIEW PROTOCOL SUBMISSION FORM
STUDENT-INITIATED PROJECT

DELEGATED ETHICS REVIEW COMMITTEE reviewing this project: ________________

FACULTY SUPERVISOR:
Name ___________________________ Personnel Number ____________
Department ______________________________________________________
Mailing Address _________________________________________________
Phone ___________________ Fax ___________________ Email __________

PRINCIPAL INVESTIGATOR (UNDERGRADUATE STUDENT):
Name ___________________________ Student Number ____________
Department ______________________________________________________
Mailing Address _________________________________________________
Phone ___________________ Fax ___________________ Email __________

COURSE:
Course Title __________________________ Course Code _____________
Course Year ____________________________________________________
(The student’s project will be considered completed once the course is over. It is possible, however, to submit an annual renewal form if the project continues beyond the course.)

MINIMAL RISK AND EXPEDITED REVIEW:
Risk to participants should be proportionate to student experience and pedagogical goals, with appropriate levels of responsibility and supervision. Typically, undergraduate research should involve minimal risk, which means that the probability and magnitude of harm due to participation in the research is no greater than that encountered by participants in their everyday lives. Assessing risk may to some degree be affected by discipline-specific considerations—e.g., forensics, medicine, and nursing may involve work with participants in clinical settings, with attendant requirements for oversight and team qualifications. Departments will likely want to work with the Ethics Review Office (ERO) to decide how best to handle different levels of risk. Additional on-line resources may also be helpful, including:

- www.research.utoronto.ca/ethics_home.html
- www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm
- www.pre.ethics.gc.ca/english/tutorial/

To evaluate risk for this protocol, consider:
- Group vulnerability—i.e., any pre-existing vulnerabilities associated with proposed participant groups, e.g., relating to pre-existing physiological or health conditions, cognitive or emotional factors, and socio-economic or legal status.
- Research risk—i.e., the probability and magnitude of harms participants may experience as a result of the proposed methods to be used and types of data to be collected, e.g., relating to physiological or health issues such as clinical diagnoses or side effects, cognitive or emotional factors such as stress or anxiety during data collection, and socio-economic or legal ramifications such as stigma, loss of
employment, deportation, or criminal investigation (e.g., in the event of duty to report intent to cause serious harm, subpoena, or breach of confidentiality).
Please provide over-all assessments of group vulnerability and research risk (i.e., low, medium, high) and locate the protocol in the matrix, below.

**RISK MATRIX: Review Type by Group Vulnerability and Research Risk—circle one:**

<table>
<thead>
<tr>
<th>Group vulnerability</th>
<th>Research Risk</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>Expedited</td>
<td></td>
<td>Expedited</td>
<td>Full</td>
</tr>
<tr>
<td>Medium</td>
<td>Expedited</td>
<td></td>
<td>Full</td>
<td>Full</td>
</tr>
<tr>
<td>High</td>
<td>Full</td>
<td>Full</td>
<td>Full</td>
<td>Full</td>
</tr>
</tbody>
</table>

Briefly explain (max. 100 words) the group vulnerability and research risk, and explain any exceptional circumstances (e.g., student experience) justifying greater than minimal risk:

**CO-INVESTIGATORS:**
Are co-investigators involved? Yes ☐ No ☐
If YES, provide the name(s) and contact information on a separate sheet.

**HOST SITES:**
Indicate the location(s) where the research will be conducted:
University of Toronto ☐
Affiliated teaching hospital ☐ _______________________________ (specify site(s))
Community within the GTA ☐ _______________________________ (specify site(s))
Other ☐ _______________________________ (specify site(s))

N.B. If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a school), please include all draft administrative consent letters. It is the responsibility of the researcher to determine what other means of approval are required, and to obtain approval prior to starting the project.

Other Research Ethics Board Approval:
(a) Does the research involve another institution or site? Yes ☐ No ☐
(b) Has any other REB approved this project? Yes ☐ No ☐
(c) If YES, please provide a copy of the approval letter upon submission of this application.
(d) If NO, will any other REB be asked for approval? Yes ☐ No ☐
   If YES, please specify which REB _______________________________
BACKGROUND, PURPOSE, AND OBJECTIVES:
Briefly describe the pedagogical goal and scholarly motivation for the project.

METHODS AND DATA:
• If the research takes place in a controlled environment (e.g. clinic, laboratory, formal interview or tests), describe sequentially, and in detail, all procedures in which research participants will be involved.
• If the research involves naturalistic or participant observation, please describe the setting, the types of interactive and observational procedures to be used, and the kinds of information to be collected.
• If the research involves secondary analysis of previously collected data, describe the original source of the data and measures that have been taken to protect data subjects’ identities.
• If the project involves using specialized methods with participants, describe the student’s relevant past experience, or the nature of any supervision they may receive.

N.B. Attach a copy of all questionnaires, interview guides or other test instruments.
PARTICIPANTS, INFORMANTS, OR DATA SUBJECTS:
Describe the individuals whose personal information is to be used as part of the assignment (i.e., in terms of inclusion and exclusion criteria, especially where active recruitment is involved). If the assignment involves working with a vulnerable population, describe the student’s relevant past experience, or the nature of any supervision they may receive.

RECRUITMENT:
Where there is formal recruitment, please describe how and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion
of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, etc.) Where relevant, please explain any non-research relationship between the student and the research participants (e.g., teacher-student, manager-employee, nurse-patient).

**N.B. Attach a copy of any posters, advertisements, flyers, letters, or telephone scripts to be used for recruitment.**

<table>
<thead>
<tr>
<th><strong>RISKS:</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicate if the participants might experience any of the following risks:</td>
<td></td>
</tr>
<tr>
<td>(a) Physical (e.g., bodily contact, administration of any substance)?</td>
<td>Yes No</td>
</tr>
<tr>
<td>(b) Psychological/emotional (e.g., feeling embarrassed, anxious, upset)?</td>
<td>Yes No</td>
</tr>
<tr>
<td>(c) Social (e.g., possible loss of status, privacy, reputation)?</td>
<td>Yes No</td>
</tr>
<tr>
<td>(d) Is there any deception involved (see “Debriefing”, below)?</td>
<td>Yes No</td>
</tr>
<tr>
<td>(e) Are risks to participants greater than in their everyday life?</td>
<td>Yes No</td>
</tr>
</tbody>
</table>

If you answered **Yes** to any of the above, please explain the risks, and describe how they will be managed, and how they are proportionate to student experience and pedagogical goals.

**BENEFITS:**
Discuss any potential direct benefits to the participants from their involvement in the project. Comment on potential benefits to the student, the scholarly community, or society that would justify involvement of participants in this study. (See the note on courtesy copies of final reports in the “Debriefing” section, below)
COMPENSATION:
Will participants receive compensation for participation? Yes □ No □

- Financial Yes □ No □
- In-kind Yes □ No □
- Other Yes □ No □

(b) If Yes, please provide details.

(c) Where there is a withdrawal clause in the research procedure, if participants choose to withdraw, how will you deal with compensation?

CONSENT PROCESS:
Describe the process that the student will use to obtain informed consent. Please note, it is the quality of the consent not the format that is important: if there will be no written consent form, please explain (e.g., if culturally inappropriate). If the research involves extraction or collection of personal information from a data subject, please describe how consent from the individuals or authorization from the custodian will be obtained. For information about the required elements in the information letter and consent form, please refer to: www.research.utoronto.ca/ethics_irequire.html

N.B. Where applicable, please attach a copy of the Information Letter/Consent Form, the content of any telephone script, letters of administrative consent or authorization and/or any other material which will be used in the informed consent process.
If the participants are minors, or are not competent to consent, describe the proposed alternate source of consent, including any permission/information letter to be provided to the person(s) providing the alternate consent as well as the assent process for participants.

Where applicable, please describe how the participants will be informed of their right to withdraw from the project. Outline the procedures which will be followed to allow them to exercise this right.

Indicate what will be done with the participant’s data and any consequences which withdrawal may have on the participant.

If the participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain.

**PRIVACY AND CONFIDENTIALITY:**
Will the data be treated as confidential?  

Yes [ ]   No [ ]

If Yes, please describe the procedures to be used to protect confidentiality during the conduct of research and in preparation of the final report.
Explain how written records, video/audio tapes and questionnaires will be stored (e.g., password protected computer, double locked office and filing cabinet), and provide details of their final disposal or retention schedule.

If No—i.e., confidentiality is not appropriate in the context of this assignment—please explain (e.g., participants are key informants with established reputations in their field).

DEBRIEFING:
Explain what information (e.g., research summary) will be provided to the participants after participation in the project. If deception will be used in the research study, please explain what information will be provided to the participants after participation in the project—if applicable, attach a copy of the written debriefing form.

N.B. Please note that all copies of the students’ final reports—e.g., for circulation as courtesy copies, or future writing samples—must clearly indicate on the cover page the instructor, course number, and department or program at the University of Toronto that the report was prepared for.
SIGNATURES:

As the Principal Investigator on this project, my signature testifies that I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial and national policies and regulations that govern research involving human participants. Any deviation from the project as originally approved will be submitted to the Research Ethics Board for approval prior to its implementation.

Signature of Principal Investigator: ____________________________ Date: ______________
(Undergraduate Student)

As the Faculty Supervisor on this project, my signature testifies that I have reviewed and approve the scholarly merit of the research project and this ethics protocol submission. I will provide the necessary supervision to the student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with University, provincial and national policies and regulations that govern research involving human subjects. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

Signature of Faculty Supervisor: ____________________________ Date: ______________

As the Undergraduate Coordinator, my signature testifies that I am aware of the proposed activity, and understand that the level of risk inherent to the project should be managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

Signature of Undergraduate Coordinator: ____________________________ Date: ______________

As the Departmental Chair/Dean, my signature testifies that I am aware of the proposed activity, will allocate space and other resources required, and will provide administrative support to the research activity. My department, faculty or division will oversee the conduct of research involving human subjects to ensure compliance with University, provincial and national policies and regulations. My signature also reflects the willingness of the department, faculty or division to administer the research funds, if there are any, in accordance with University, regulatory agency and sponsor agency policies.

Signature of Departmental Chair/Dean: ____________________________ Date: ______________
AMENDMENT REQUEST FORM

This form is to be submitted with amendments to previously approved protocols. Revised procedures should not be implemented until ethics approval has been received.

PRINCIPAL/PRIMARY INVESTIGATOR:
Please indicate the level of research: Faculty o Post-Doctoral o Doctoral o Master’s o Undergrad. o

Name_________________________________________________________
Department_____________________________________________________
Mailing Address_________________________________________________________ Postal Code________________________
Phone________________________________ Fax________________________ Email________________________

Student Number __________________________

FACULTY SUPERVISOR/SPONSOR: (if applicable)
Name_________________________________________________________
Department_____________________________________________________
Mailing Address_________________________________________________________ Postal Code________________________
Phone________________________________ Fax________________________ Email________________________

PROJECT TITLE: __________________________________________________________
________________________________________________________________________
Protocol reference number: __________

Date of most recent approval:_________

o Check here if you believe this submission qualifies for expedited review.
http://www.research.utoronto.ca/ethics_ercriteria.html

1. Please describe the proposed study amendment or modification with rationale. Please specify if it is a minor (e.g. administrative change) or major (e.g. addition of study method) change. Please use extra pages as required.
2. Will the proposed amendment change the overall purpose or objective of the study?  
   - Yes  - No  
   If Yes, a new protocol may be requested by the REB.

3. Will the proposed amendment affect the vulnerability of the participant group or the research risk?  
   - Yes  - No  
   If Yes, please indicate the new overall risk level on the Risk Matrix:

**RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY AND RESEARCH RISK - circle one:**

<table>
<thead>
<tr>
<th>Group Vulnerability</th>
<th>Research Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
<td>High</td>
</tr>
<tr>
<td>Low</td>
<td>1</td>
</tr>
<tr>
<td>Medium</td>
<td>1</td>
</tr>
<tr>
<td>High</td>
<td>2</td>
</tr>
</tbody>
</table>

4. What follow-up action do you recommend for study participants who are already enrolled in the study?  
   - Inform study participants  
   - Revise consent/assent forms (please attach a copy with the changes)  
   - Other (please describe) _______________________________
   - No action required

5. Attach revised protocol and materials to this form with changes highlighted (e.g. bold, italicize, underline).

6. Submit the appropriate number of signed copies to the Ethics Review Office (please see http://www.research.utoronto.ca/ethics_hscommittees.html to determine the number of copies required).

**My signature certifies that the above information is correct and that no unapproved procedures will be used in this study.**

Signature of Principal/Primary Investigator: __________________________ Date: __________

   AND (if applicable)

Signature of Faculty Supervisor/Sponsor: __________________________ Date: __________
Appendix VI

UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

ADVERSE/UNANTICIPATED EVENT REPORT FORM

An Adverse Event is any unfavorable change in current health status (including mental, emotional or psychological) in a subject participating in a research study. This change may or may not be causally related to the study protocol.

An Unanticipated Event is any unfavourable or unintended occurrence during the course of a research study which may have real or potential implications on participants.

This form is to be used to report:
• Any unanticipated event relevant to a research ethics protocol (e.g., health-related event, breach of confidentiality, protocol violation, participant complaint).
• Any Adverse Event or Adverse Drug Reaction in relation to a University of Toronto REB-approved protocol. Please include the sponsor’s reports where available.

Principal Investigator:__________________________________________

Faculty Supervisor or Faculty Sponsor: ____________________________

Protocol Title:___________________________________________________

U of T Protocol Reference #___________

University of Toronto Research Ethics Board
☐ Health Sciences I    ☐ Health Sciences II    ☐ HIV/AIDS    ☐ Education    ☐ Social Science and Humanities

Date of event:______________

LOCATION
1. Did the event occur at the University of Toronto? YES o    NO o
   If YES, specify precise location of event (building, room #, etc.) __________________________

2. Did the event occur at a University of Toronto-Affiliated Teaching Hospital or research institution? YES o    NO o
   If YES, specify the University-affiliated institution __________________________
   Has the University-affiliated institution been informed of the event? YES o    NO o
3. If the event occurred off-site, specify the location where the event occurred: ________________

Has anyone from the site been notified? YES o (who) ____________________ NO o

**DESCRIPTION OF ADVERSE/UNANTICIPATED EVENT**

4. What action (if any) has been taken, or will be taken, by the research site, and by whom?

5. What action (if any) has been taken, or will be taken, by the research team?
STATEMENT OF PRINCIPAL INVESTIGATOR
I am aware of and understand the circumstances and/or information related to the adverse/unanticipated event referred to on this form. I have assessed the significance of this event with respect to participants involved in this research and as a result, I believe that:

The study should continue without change to the protocol:  YES o  NO o

The study should continue without change to the consent form:  YES o  NO o

If you answered NO to either question, please enclose the revised protocol and/or consent form, in sufficient copies, for review by the appropriate Research Ethics Board.

SIGNATURES

Principal Investigator: ___________________________ Date: ________________

AND (if applicable)

Faculty Supervisor/Faculty Sponsor: _______________ Date: ________________
UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost
Ethics Review Office

ANNUAL RENEWAL OF ETHICS APPROVAL APPLICATION

PRINCIPAL INVESTIGATOR:
Please indicate the level of research, Faculty o  Post-Doctoral o  Doctoral o  Master’s o  Undergrad o

Name______________________________
Department________________________
Mailing Address______________________Postal Code____________
Phone__________________Fax____________Email__________________

Student Number____________________

FACULTY SUPERVISOR/SPONSOR: (if applicable)
Name______________________________
Department________________________
Mailing Address______________________Postal Code____________
Phone__________________Fax____________Email__________________

PROJECT TITLE: ________________________________

Protocol Reference #: _____________  Original Approval Date: ________________
Previous Reference #: _____________  Previous Renewal Date: ________________

Please answer the following questions:

1. What is the funding status of this project?

   o Funding ongoing
     Agency: ________________  Fund #: ____________  Funding Period: ________________
     o Year 1  o Year 2  o Year 3  o Year 4  o Other

   o Application pending
     Agency: ________________  Submission date: ________________

   o Unfunded
2. Have there been any changes to the study protocol or consent form documents since the most recent approval?  
   - NO  
   - YES

   If YES, please submit an Amendment Request Form with your application. Revised procedures may not be used until approved.

3. Have there been any changes in research personnel who interact with participants and/or have access to personal data?  
   - NO  
   - YES

   If YES, please list former/new personnel and position:


4. What is the current status of the study?
   - Human subjects are currently being recruited/participating.
     Provide start and end dates:____________________
   - Human subjects will be recruited/participate.
     Provide start and end dates:____________________
   - Human subject involvement has been completed.
     The study is closed. (Please complete the Study Completion Report)

5. How many subjects are currently in the study?  ________

6. How many subjects have completed the study?  ________

7. Did any subjects withdraw?  
   - No  
   - YES

   If YES, please describe circumstances below, use additional page(s) if necessary.


8. Since receiving original ethics approval, have any ethical concerns (minor or major) arisen?  
   - No  
   - YES

   If YES, please describe concerns in detail, use additional page(s) if necessary.


9. Have any adverse or unanticipated events occurred?  o No  o YES

If YES, please submit an Adverse/Unanticipated Event Report Form as soon as possible.

10. Provide a brief summary of study progress, and results. Use additional page(s) if necessary.

My signature certifies that the above information is correct and that no unapproved procedures will be used on this study.

Signature of Principal Investigator: ________________  Date: ________________

AND (if applicable)

Signature of Faculty Supervisor/Sponsor: ________________  Date: ________________
Study completion is defined as the point at which the primary objectives of the project have been met and/or data analysis has ended.

PRINCIPAL INVESTIGATOR:
Please indicate the level of research, Faculty o Post-Doctoral o Ph.D. o Masters o Undergrad o

Name _____________________________ Department _____________________________
Mailing Address ________________________________________________________________
Phone __________ Fax __________ Email ____________________________________________

FACULTY SUPERVISOR/SPONSOR: (if applicable)
Name _____________________________ Department _____________________________
Mailing Address ________________________________________________________________
Phone __________ Fax __________ Email ____________________________________________

PROJECT TITLE:

____________________________________________________________________________

Protocol Reference #: __________ Original Approval Date: __________
Previous Reference #: __________ Previous Renewal Date: __________

Completion/Closure date: ________________

Please answer the following questions:

1. How many human subjects were proposed for the study? ______

2. How many human subjects enrolled? ______

3. How many human subjects withdrew after enrollment? ______

   Please describe circumstances (use additional page(s) if necessary).

4. How many human subjects completed the study? ______

5. Since receiving original ethics approval, have any ethical concerns arisen?
   oNo o YES (please describe in detail, use additional page(s) if necessary)

6. Have any adverse or unanticipated events occurred during the course of the research project?
   oNo o YES
   If YES, please submit an Adverse/Unanticipated Event Report Form.

7. During the study, did any unforeseen circumstances arise?
8. Please describe how data will be stored and/or destroyed. If research using the collected data (i.e. secondary data analysis) is likely in the future, please describe how data will be kept private and secure.

9. Please describe how results will be disseminated to participants. If they will not be disseminated, please explain why.

My signature certifies that the above information is correct and that no additional procedures will be conducted without ethics approval. Proper safeguards to confidentiality and security of data will be maintained until all data are destroyed.

Signature of Principal Investigator: ____________________________ Date: ____________

AND (if applicable)

Signature of Faculty Supervisor/Sponsor: ____________________________ Date: ____________
Date

Principle Investigator’s Name
Department

Dear Prof. ,

RE: Protocol [# , title]

As part of the University of Toronto’s commitment to maintaining the highest ethical and scholarly standards in research, and in keeping with the standards laid out in the Tri-council policy Statement: Ethical conduct in research involving humans, Article 1.13, “Continuing review of ongoing research”, the Ethics Review Office, the Committee on Human Subjects in Research, and the five Research Ethics Boards, have undertaken a plan to conduct a modest number of site visits to research teams’ facilities each year. Site visits may be initiated as part of the routine program, by request of a researcher for educational purposes, to help a researcher prepare for an external audit, or for cause (e.g., in response to complaints from research participants). The above-named protocol has been selected for a [routine, researcher-requested, for-cause] site visit. All site visits will be conducted with respect for the privacy and confidentiality of all parties, with the active involvement of researchers. Please find attached the checklist to be used during the site visit, noting that this study has been chosen for a Level [2 or 3] site visit.

I will be contacting you to arrange this visit, to occur some time within the next four to six weeks. In the meantime, please do not hesitate to contact me if you have any questions regarding the site visit process.

Sincerely,

Dean Sharpe, Ph.D.
Ethics Review Officer and Monitor, Social Sciences and Humanities
Ethics Review Office

Continuing Review Site Visit Report:

Date of Site Visit:
Report Date:

Dean Sharpe and Jill Parsons
Research Ethics Officers
University of Toronto
Preamble:

PI Background:

Research Program:

Protocol Number and Title:

Protocol Selection:

☐ Random Selection
☐ Voluntary (Pilot Site Visits)
☐ Researcher Requested
☐ “For Cause”
☐ Other: ________________________________

Note on Protocol Selection:
Level 2
Pre-Consultation:

Review of Approved Research Protocol (ERO File):

Notes:

Consultation with P.I.:

Members of Research Team Present (check all that apply):
☐ Principal Investigator
☐ Co-Investigator(s)
☐ Research Manager/Coordinator
☐ Research Assistant(s)
☐ Student(s)
☐ Other: __________________________

Location of Data Collection:
☐ University of Toronto
☐ Another institution: __________________________
☐ Private Research Organisation: __________________________
☐ Collaborating Community-Based Agency: __________________________
☐ Other: __________________________

Location of Visit:
☐ Office (University of Toronto)
☐ Office (another institution)
☐ Home Office
☐ Field
☐ Other: __________________________

Current Status of Project

Date of REB approval:
Date of first study-related procedures:

Date of most recent interaction with participants:

Target sample size (if applicable):

Number of research subjects:

Approached: _______________________
Screened: _______________________
Enrolled: _______________________
Completed: _______________________
Withdrawn: _______________________
Ongoing: _______________________

Stage (Check all that apply):
- Preliminary Information Gathering (Literature review, consultation, etc.)
- Pilot-testing
- Data collection
- Data analysis
- Report writing

Funding:
Source: _________________________________
Name of Funding Body: _________________________________
- Ongoing
- Completed
- Unfunded
- Other (explain): _________________________________

Additional funding sources/status: _________________________________

Proposed time frame:
Data collection: _________________________________
Data analysis: _________________________________
Publication/Report production: _________________________________
Data retention: _________________________________

Personnel

Host/Partner Institutions and Roles: _________________________________
_____________________________________________________________
_____________________________________________________________
Co-investigators at UT and other sites:

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<th>Name</th>
<th>Role (if applicable)</th>
<th>Institution</th>
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Post Doctoral Fellows and Roles:

Graduate/Undergraduate Students and Roles:

Employees/Volunteers and Roles:

Did the members of the research team receive any Research Ethics training?

- [ ] No
- [ ] Yes

If yes, what kind of training (check all that apply)?

- [ ] TCPS On-line Tutorial
- [ ] Course on Research Ethics
- [ ] Research Ethics 101 Workshop
- [ ] Visiting lecture from REO or other
- [ ] Other: ___________________________

Did the other members of the research team read the protocol which was approved by the REB?

- [ ] No
- [ ] Yes

Notes:
Administrative Consent/Community Consultation:

Additional ethics review required from other institution(s)?
☐ No
☐ Yes
Institution(s): __________________________________________________________

Administrative consent required from other institution(s)/community groups, etc.?
☐ No
☐ Yes
Institution(s): __________________________________________________________

Was/will community consultation (be) undertaken at any stage in the research process?
☐ No
☐ Yes
Details:
Consent Process:

Was consent sought for participation?

☐ No ➔ If no, why (check all that apply)?
☐ Waiver of consent
☐ Implied consent
☐ Other: __________________________

☐ Yes ➔ If yes, how was the consent process given/documentated (check all that apply)?
☐ Written Consent
☐ Informed Consent Form
☐ Verbal Consent
☐ Audio- or Video-recording
☐ Documentation of process in field notes/lab book
☐ Other: __________________________

What, if any, were factors relevant to waiving default consent procedures?

Was proxy (e.g., parental) consent given for participation?

☐ No
☐ Yes ➔ If yes, what was the reason that proxy consent was required/allowed:
☐ Age of participant
☐ Capacity of participant
☐ Requested by participant
☐ Other: __________________________

➔ If yes, how was the Substitute Decision Maker (SDM) chosen (check all that apply)?
☐ Parent/Guardian
☐ Legal SDM
☐ Caregiver
☐ Identified by Participant
☐ Other: __________________________

➔ Was there an opportunity for the participant to state their assent or dissent?
☐ No
☐ Yes ➔ If yes, how (check all that apply)?
☐ Implied (by participation)
☐ Verbal Assent/Dissent
☐ Written Assent/Dissent
☐ Other: __________________________
If proxy consent was given as a result of diminished capacity of the participant, what procedures were followed in determining whether or not that participant could or could not consent to participation, themselves?

If a participant below the age of 16 was allowed to consent for him/herself, what was the reason for the determination that proxy consent was not required?

Debriefing, Research Summary or Final Report Distribution:

Was any deception or intentional non-disclosure part of the research procedure?

☐ No
☐ Yes  
If yes, what was the process for debriefing the participant?

☐ Yes, were participants given the option of removing their data from the study?

☐ Yes (Please explain)

Did any of the participants voice concerns about the deception/intentional nondisclosure related to the study?

☐ No
☐ Yes (Please explain)

As far as you are aware, did any of the participants withdraw themselves or their data from the study because they were discontented with the deception/intentional non-disclosure?

☐ No
☐ Yes (Please explain)

Was/will member-checking (be) conducted for the results of any qualitative interviews?

☐ N/A
☐ No
☐ Yes (Please describe the process)

Can study personnel still be reached via the contact information on the ICF?

☐ N/A
☐ No
Was/will a final report or research summary be distributed or presented to individual participants or communities?
- Yes
- N/A
- No
- Yes (Please describe the process)

Research procedures:
Description:

Data Storage/Transfer:
Were raw data ever stored in a location other than where it is currently located?
- No
- Yes

If yes, where (check all that apply)?
- Office (University of Toronto)
- Office (another institution)
- Home Office
- Other: _________________________________

Are there copies of the raw data currently being stored elsewhere?
- No
☐ Yes ➡️ If yes, where (check all that apply)?
☐ Office (University of Toronto)
☐ Office (another institution)
☐ Home Office
☐ Study Sponsor
☐ Collaborating Community-Based Agency
☐ Other: _________________________________

In the research procedure, were (are) data ever transferred physically or electronically?
☐ No
☐ Yes ➡️ If yes, please describe the method of transfer:
☐ E-mail
☐ Physical transfer of paper
☐ Physical transfer or audio or video data
☐ USB key or other portable storage device
  ➡️ Describe: _________________________________
☐ Other: _________________________________

➡️ If yes, how was the data protected (check all that apply)?
☐ Encryption
☐ Anonymisation
☐ Password-protection
☐ Physical locks
☐ Other: _________________________________

Comments:

Are any of the collections taken as part of this study being banked for purposes of future research?
☐ No
☐ Yes ➡️ If yes, for how long will it be banked?

➡️ If yes, is there a plan for the data to be transferred to and/or stored at another site?
☐ No
☐ Yes _________________________________
  Details:

➡️ If yes, what type of data (check all that apply)?
☐ Tissue
☐ Video footage
☐ Audio footage
☐ Electronic data
☐ Hard copy data
□ Other: ________________

➔ If yes, are the data anonymised?
   □ No
   □ Yes

➔ If yes, how (check all that apply)?
   □ Stripping of unique identifiers (e.g. name, SIN, etc.)
   □ Stripping of potential identifiers (Postal Code, dob, etc.)
   □ Masking of features on video data
   □ Voice masking
   □ Encryption of data
   □ Other: _______________________________

Progress/Difficulty:

Were any real or perceived conflicts of interest raised over the course of the research project (i.e. after the study had received REB approval)?
   □ No
   □ Yes  ➔ If yes, please provide details:

➔ If yes, what steps were taken to avoid this real or perceived conflict of interest?

➔ If yes, were these reported to the REB?
   □ No
   □ Yes

➔ If no, why not?

Any changes to consent or research procedures?
   □ No
   □ Yes  ➔ If yes, were Amendment applications submitted to the ERO?
      □ Yes, for some
      □ Yes, for all
      □ No

Details: _____________________________________________

Did any of the participants withdraw from the study?
   □ No
   □ Yes  ➔ If yes, how many? __________

➔ If yes, what was the rate of attrition? __________
If yes, please detail the reason(s) for withdrawal:

Have any ethical issues arisen over the course of the project?
□ No
□ Yes  If yes, please provide details:

If yes, were these reported to the REB?
□ No
□ Yes

If no, why not?

Have there been any adverse/unanticipated events over the course of the project?
□ No
□ Yes  If yes, please provide details:

If yes, were these reported to the REB?
□ No
□ Yes

If no, why not?

Have any verbal or written complaints been made to the researchers or institutions involved in the research?
□ No
□ Yes  If yes, please provide details:

If yes, were these reported to the REB?
□ No
□ Yes

If no, why not?

Have there been any breaches of the security of the data over the duration of the project?
No
Yes
If yes, please provide details:

If yes, were these reported to the REB?
No
Yes
If no, why not?

Review of Consent Documentation

Copy of up-to-date ethics approval from other applicable institutions?
No
Yes
Comments:

Copy of consent letters/letters of support from other institutions or groups?
No
Yes
Comments:

Any problems/issues arising (check all that apply):

Missing consent documentation for participant
Missing proxy consent documentation for participant
Missing assent documentation for participant
Most recent version of consent not used.
Consent documentation not signed and dated appropriately.
Other: ____________________________________________________

Documentation of participant questions/requests for withdrawal:
No
Yes
N/A
Comments:
Level 3:

Review of Data Storage/Protection of Privacy and Confidentiality:

Identifying information removed from raw data:
- □ No
- □ Yes
- □ N/A

Names of participants kept in separate cabinet from raw data:
- □ No
- □ Yes
- □ N/A

Filing cabinets in low traffic area:
- □ No
- □ Yes
- □ N/A

Keys kept in defined location, away from filing cabinet:
- □ No
- □ Yes
- □ N/A

List/Log of people with access to data:
- □ No
- □ Yes
- □ N/A

Data Storage (Computers)

Computer password required for access to computer with raw data:
- □ No
- □ Yes
- □ N/A

Password required to access to portable data storage device:
- □ No
- □ Yes
- □ N/A

Computer terminal screen visible:
- □ No
- □ Yes
- □ N/A

Computer connected to LAN:
☐ No
☐ Yes
☐ N/A

Comments:
Review of Raw Data:

Existing Raw Data (check all that apply):

☐ Paper records (files, field notes)
☐ Electronic records (e.g., data bases)
☐ Audio tapes
☐ Video tapes
☐ Other: _________________________________

Raw Data Reviewed (check all that apply):

☐ Paper records (files, field notes)
☐ Electronic records (e.g., data bases)
☐ Audio tapes
☐ Video tapes
☐ Other: _________________________________

Overall perception of adherence to/deviation from protocol:

☐ Excellent
☐ Good
☐ Fair
☐ Poor

Comments:

Adverse/Unanticipated Events:

Were adverse/unanticipated events reported to the REB in a timely manner?

☐ Yes
☐ No ➨ If no, please provide details:

Was the participant’s confidentiality maintained in the reporting of said event?

☐ N/A
☐ Yes
☐ No ➨ If no, why not?

 Gould, if no, was this appropriate?

Data Quality:

Any problems/issues arising (check all that apply):

☐ Missing data for individual participant
☐ Missing pages in log books
☐ Evidence of changes made to raw data
☐ Collection of information beyond that approved by REB
☐ Other: ____________________________________________

<table>
<thead>
<tr>
<th>Issue Arising</th>
<th>Example</th>
<th>Number of Occurrences</th>
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Comments:
Level 3+

Under unusual circumstances, continuing review may also include:

**Observation of consent or study procedures:**

Did the researcher receive permission from the participant for the monitor’s presence?

- [ ] No
- [ ] Yes
- [ ] N/A

Observed process of consent?

- [ ] No
- [ ] Yes
- [ ] N/A

Comments:

**Contacting current or former participants:**

Method of contact (check all that apply):

- [ ] Phone
- [ ] Mail
- [ ] E-mail
- [ ] Listserv
- [ ] Appending Questions to research instruments
- [ ] Recruiting participants through study procedures (with the permission of researcher)
- [ ] Other: ___________________________________________________________________

Comments:

(Issues may include:

- how they were recruited
- who they interacted with and in what capacity
- whether they were given an opportunity to ask questions
- what they know about the research
- whether they felt pressure to participate or continue
- what they know about their rights as a research participant
- whether they are satisfied with their experience as a participant
- whether they have any other questions or comments)
Post-Consultation:

Review of REB Process:

Type of Review (check all that apply):
☐ Full Board
☐ Expedited
☐ Escalated from Expedited to Full

Review of Documentation (matching PI and REB files):

*University of Toronto Ethics Review Documentation*

<table>
<thead>
<tr>
<th>Type of documentation</th>
<th>Original</th>
<th>Copy</th>
<th>Up-to-date (Version No.)</th>
<th>Matches REB file</th>
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<tr>
<td>Approved Protocol</td>
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<td>REB Approval Letter</td>
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<td>Protocol-Related Contracts</td>
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<td>Approval Letters from other Institutions</td>
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<td>Regulatory Body Documentation/Letter</td>
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<td>A/UE Report Response Letters</td>
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Are all documents present and accessible?
☐ Yes
☐ No

Comments:
Final Recommendations

**Issues arising during site visit:**

Issues discussed with PI at Site Visit:

Issues resulting from review of documentation and REB review:

**Recommendations:**

**Researcher/Research Team**

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<th>Concern/Issue</th>
<th>Recommended Action</th>
<th>Best Practice</th>
<th>Timeline</th>
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**Research Ethics Board and Ethics Review Office**

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Reporting requirements:

Researcher’s response to draft report:
29 May, 2007

Dr. John Challis
Vice-President, Research and Associate Provost
University of Toronto
27 King's College Circle
Suite 109
Toronto, ON M5S 1A1

Dear Dr. Challis,

On behalf of the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council (NSERC) and the Social Sciences and Humanities Research Council (SSHRC), we thank you for having provided a revised copy of your institutional policy governing the ethics review of research involving humans.

We are pleased to inform you that your revised institutional policy has now been deemed satisfactory.

Should you have any questions or concerns, please do not hesitate to contact the Senior Policy Analyst of the Secretariat on Research Ethics, Hanan Abdel-Akher, who has been assigned to provide information on your file (see coordinates below).

We would like to thank all those who continue to be involved in the adoption and implementation of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) at your institution, and recognize the substantial amount of time and effort which is being devoted to this important task.

Sincerely,

Christine Fitzgerald
Executive Vice-President
Canadian Institutes of Health Research

Barbara Conway
Corporate Secretary
Natural Sciences and Engineering Research Council

Christine Trauttmandorff
Corporate Secretary
Social Sciences and Humanities Research Council

Canada
c.c.: Dr. Rachel Zand, Director, Ethics Review Office, University of Toronto

Interagency Management Committee
Christine Fitzgerald, CIHR, 613.954.1974 or CFitzgerald@cihr.gc.ca
Barbara Conway, NSERC, 613.995.5896 or Barbara.Conway@nserc.ca
Christine Trauttmansdorff, SSHRC, 613-943-7739 or Christine.Trauttmansdorff@sshrc.ca

Secretariat on Research Ethics
Hanan Abdel-Akher, Senior Policy Analyst, 613.996.2564 or hanan.abdel-akher@pre.ethics.gc.ca

Address:
Secretariat on Research Ethics
(CIHR, NSERC, SSHRC)
350 Albert Street
Ottawa, ON  CANADA  K1A 1H5

Tel: 613.996.0072
Fax: 613.996.7117
Secretariat@pre.ethics.gc.ca

Encl.