



Office Use Only
Application Number:

Office of the Vice-President, Research and Innovation

Human Research Ethics Program

ETHICS REVIEW APPLICATION FORM FOR SUPERVISED AND SPONSORED RESEARCHERS

(For use by graduate students, post-docs, residents, external investigators, and visiting professors/researchers)

Before you start, familiarize yourself with:
[TCPS2](#)
[Application instructions](#)
Office [FAQs](#)

SECTION A – GENERAL INFORMATION

1. TITLE OF RESEARCH PROJECT

2. INVESTIGATOR INFORMATION

Investigator:

Title (e.g., Dr., Ms., etc.):	Name:
Department (or organization if not affiliated with U of T):	
Mailing address:	
Phone:	Institutional e-mail:

Level of Project:

Student Research:	Doctoral <input type="checkbox"/>	Masters <input type="checkbox"/>
Post-Doctoral Research <input type="checkbox"/>	Visiting professor/External researcher <input type="checkbox"/>	Course Based <input type="checkbox"/>
CBR/CBPR <input type="checkbox"/>	Other <input type="checkbox"/> (specify:)	

Supervisor/Sponsor (must be a UofT faculty member with research privileges):

Title:	Name:
Department:	
Mailing address:	
Phone:	Institutional e-mail:

Co-Investigators:

Are co-investigators involved? Yes No

Title:	Name:
Department (or organization if not affiliated with U of T):	
Mailing address:	
Phone:	Institutional e-mail:

Title:	Name:
Department (or organization if not affiliated with U of T):	
Mailing address:	
Phone:	Institutional e-mail:

Please append additional pages with co-investigators' names if necessary.

3. UNIVERSITY OF TORONTO RESEARCH ETHICS BOARD:

Social Sciences, Humanities and Education Health Sciences HIV/AIDS

To determine which Research Ethics Board (REB) your application should be submitted, please consult: <http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/>

4. LOCATION(S) WHERE THE RESEARCH WILL BE CONDUCTED:

(a) If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a school), please include all 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.

University of Toronto
 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)

(b) For all off-campus research, whether in the local community or internationally, the researcher should consult with the [Framework on Off-Campus Safety](#), [Guidelines on Off-Campus Safety](#), and [Guidelines on Safety in Field for institutional requirements](#).

(c) **The University of Toronto has an agreement with the Toronto Academic Health Sciences Network (TAHSN) hospitals regarding ethics review of hospital-based research where the University plays a peripheral role. Based on this agreement, certain hospital-based research may not require ethics review at the University of Toronto. If your research is based at a TAHSN hospital, please consult the following document to determine whether or not your research requires review at the University of Toronto.** <http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/humans-in-research/> - "Administrative review" heading toward the bottom of the page.

5. 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

If **Yes**, please provide a copy of the approval letter upon submission of this application.

If **No**, will any other REB be asked for approval?

Yes (please specify which REB) No

6. FUNDING OF THIS PROJECT

(a)

Funding Status	Source and Type	Details
Funded <input type="checkbox"/>	Agency:	Fund #: 4 (6 digits)
	Agency:	Fund #:4 (6 digits)
Applied for funding <input type="checkbox"/>	Agency:	Submission date:
	Agency:	Submission date:
Unfunded <input type="checkbox"/>	If unfunded, please explain why no funding is needed:	

7. CONTRACTS AND AGREEMENTS

(a) Is this research to be carried out as a contract or under a research agreement? Yes No

If yes, is there a University of Toronto funding or non-funded agreement associated with the research?

Yes No

If **Yes**, please append a copy of the agreement with of this application.

Is there any aspect of the contract that could put any member of the research team in a potential conflict of interest? Yes No

If yes, please elaborate under #10.

(b) Is this a Division 5, Health Canada regulated clinical trial that involves drugs, devices or natural health products?

Yes No (if so, the application must be reviewed by the full board)

8. PROJECT START AND END DATES

Estimated start date for the component of this project that involves human participants or data:

Estimated completion date of involvement of human participants or data for this project:

9. SCHOLARLY REVIEW:

(a) Please check one:

- I. The research has undergone scholarly review by thesis committee, departmental review committee, peer review committee or some other equivalent (Specify review type – e.g., departmental research committee, supervisor, CIHR, SSHRC, OHTN, etc.):
- II. The research will undergo scholarly review prior to funding (Specify review committee – e.g., departmental research committee, SSHRC, CIHR peer-review committee, etc.):
- III. The research will not undergo scholarly review (Please note that all research greater than minimal risk requires scholarly review)

(b) If box I or II above was checked, please specify if:

The review was/will be specific to this application

The review was/will be part of a larger grant

10. CONFLICTS OF INTEREST

(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 with this study? Yes No

(ii) If **Yes**, please provide further details and discuss how any real, potential or perceived conflicts of interest will be managed during the project. (Do not include conference and travel expense coverage, or other benefits which are considered standard for the conduct of research.)

(b) Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that have been placed on the investigator(s). These restrictions include controls placed by the sponsor, funding body, 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; clinician-patient; minister-congregant). Please pay special attention to relationships in which there may be a power differential – actual or perceived.

SECTION B – SUMMARY OF THE PROPOSED RESEARCH

11. RATIONALE

Describe the purpose and scholarly rationale for the proposed project. State the hypotheses/research questions to be examined. The rationale for doing the study must be clear. Please include references in this section.

12. METHODS

(a) Please describe all formal and informal procedures to be used. Describe the data to be collected, where and how they will be obtained and how they will be analyzed.

(b) Attach a copy of all questionnaires, interview guides and/or any other instruments.

(c) Include a **list of appendices** here for all additional materials submitted (e.g., Appendix A – Informed Consent; Appendix B – Interview Guide, etc.):

13. PARTICIPANTS, DATA AND/OR BIOLOGICAL MATERIALS

(a) Describe the participants to be recruited list the eligibility criteria, and indicate the estimated sample size (i.e. min-max # of participants). Where applicable, please also provide a rationale for your choice in sample size and/or sample size calculation.

(b) Where the research involves extraction or collection of personally identifiable information, please describe the purpose, from whom the information will be obtained, what it will include, and how permission to access the data is being sought. (Strategies for recruitment are to be described in section #15.)

(c) Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulties understanding informed consent, history of exploitation by researchers, power differential between the researcher and the potential participant)? If so, please provide further details below.

(d) If your research involves the collection and/or use of biological materials (e.g. blood, saliva, urine, teeth, etc.), please provide details below. Be sure to indicate how the samples will be collected and by whom.

14. EXPERIENCE OF INVESTIGATORS WITH THIS TYPE OF RESEARCH

(a) Please provide a brief description of previous experience by (i) the principal investigator/supervisor or sponsor, (ii) the research team and (iii) the people who will have direct contact with the participants. If there has not been previous experience with this type of research, please describe how the principal investigator/research team will be prepared.

15. RECRUITMENT OF PARTICIPANTS

Where there is recruitment, please describe how, by whom, 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). If relevant, describe any translation of recruitment materials, how this will occur and whether or not those people responsible for recruitment will speak the language of the participants.

Attach a copy of all posters, advertisements, flyers, letters, e-mail text, or telephone scripts to be used for recruitment as appendices.

16. COMPENSATION

Please see U of T's [Compensation and Reimbursement Guidelines](#).

(a) Will participants receive compensation for participation?

Financial	Yes <input type="checkbox"/>	No <input type="checkbox"/>
In-kind	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Other	Yes <input type="checkbox"/>	No <input type="checkbox"/>

(b) If **Yes**, please provide details and justification for the amount or the value of the compensation offered.

(c) If **No**, please explain why compensation is not possible or appropriate.

(d) Where there is a withdrawal clause in the research procedure, if participants choose to withdraw, how will compensation be affected?

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

17. POSSIBLE RISKS

(a) Please indicate all potential risks to participants as individuals or as members of a community that may arise from this research:

- (i) Physical risks (e.g., any bodily contact or administration of any substance): Yes No
- (ii) Psychological/emotional risks (e.g., feeling uncomfortable, embarrassed, or upset): Yes No
- (iii) Social risks (e.g., loss of status, privacy and/or reputation): Yes No
- (iv) Legal risks (e.g., apprehension or arrest, subpoena): Yes No

(b) Please briefly describe each of the risks noted above and outline the steps that will be taken to manage and/or minimize them.

18. POSSIBLE BENEFITS

- Describe any potential direct benefits to participants from their involvement in the project
- Describe any potential direct benefits to the community (e.g., capacity building)
- Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

SECTION D – INFORMED CONSENT

19. CONSENT PROCESS

(a) Describe the process that will be used to obtain informed consent and explain how it will be recorded. Please note that it is the quality of the consent, not the form that is important. The goal is to ensure that potential participants understand to what they are consenting.

(b) If the research involves extraction or collection of personally identifiable information from or about a research participant, please describe how consent from the individuals or authorization from the data custodian (e.g., medical records department, district school board) will be obtained.

20. CONSENT DOCUMENTS

(a) **Attach an Information Letter/Consent Form**

For details about the required elements in the information letter and consent form, please refer to our informed consent guide (<http://www.research.utoronto.ca/wp-content/uploads/documents/2014/10/GUIDE-FOR-INFORMED-CONSENT-V-Oct-2014.pdf>)

Additional documentation regarding consent should be provided such as:

- **screening materials introductory letters, letters of administrative consent or authorization**

(b) If any of the information collected in the screening process - prior to full informed consent to participate in the study - is to be retained from those who are later excluded or refuse to participate in the study, please state how potential participants will be informed of this course of action and whether they will have the right to refuse to allow this information to be kept.

21. COMMUNITY AND/OR ORGANIZATIONAL CONSENT, OR CONSENT BY AN AUTHORIZED PARTY

(a) If the research is taking place within a community or an organization which requires that formal consent be sought prior to the involvement of individual participants, describe how consent will be obtained and attach any relevant documentation. If consent will not be sought, please provide a justification and describe any alternative forms of consultation that may take place.

(b) If any or all of the participants are children and/or individuals that may lack the capacity to consent , describe the process by which capacity/competency will be assessed and/or, the proposed alternate source of consent.

(c) If an authorized third party will be used to obtain consent:

- i) Submit a copy of the permission/information letter to be provided to the person(s) providing the alternative consent
- ii) Describe the assent process for participants and attach the assent letter.

22. DEBRIEFING and DISSEMINATION

(a) If deception or intentional non-disclosure will be used in the study, provide justification. Please consult the [Guidelines for the Use of Deception and Debriefing in Research](#)

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

(c) If participants and/or communities will be given the option of withdrawing their data following the debriefing, please describe this process.

(d) Please describe what information/feedback will be provided to participants and/or communities after their participation in the project is complete (e.g., report, poster presentation, pamphlet, etc.) and note how participants will be able to access this information.

23. PARTICIPANT WITHDRAWAL

(a) Where applicable, please describe how participants will be informed of their right to withdraw from the project and outline the procedures that 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. Ensure this information is included in the consent process and consent form.

SECTION E – CONFIDENTIALITY AND PRIVACY

24. CONFIDENTIALITY

Data security measures must be consistent with UT's [Data Security Standards for Personally Identifiable and Other Confidential Data in Research](#). All identifiable electronic data that is being kept outside of a secure server environment must be encrypted.

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

(b) Describe the procedures to be used to protect the confidentiality of participants or informants, where applicable

(c) Describe any limitations to protecting the confidentiality of participants whether due to the law, the methods used, or other reasons (e.g., a duty to report)

25. DATA SECURITY, RETENTION AND ACCESS

(a) Describe how data (including written records, video/audio recordings, artifacts and questionnaires) will be protected during the conduct of the research and dissemination of results.

(b) Explain how long data or samples will be retained. (If applicable, referring to the standard data retention practice for your discipline) Provide details of their final disposal or storage. Provide a justification if you intend to store your data for an indefinite length of time. If the data may have archival value, discuss how participants will be informed of this possibility during the consent process.

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

(d) If data will be shared with other researchers or users, please describe how and where the data will be stored and any restrictions that will be made regarding access.

SECTION F – LEVEL OF RISK AND REVIEW TYPE

See the [Instructions for Ethics Review Submission Form](#) for detailed information about the Risk Matrix.

26. RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY and RESEARCH RISK

(a) Indicate the Risk Level for this project by checking the intersecting box

Group Vulnerability	Research Risk		
	Low	Medium	High
Low	1 <input type="checkbox"/>	1 <input type="checkbox"/>	2 <input type="checkbox"/>
Medium	1 <input type="checkbox"/>	2 <input type="checkbox"/>	3 <input type="checkbox"/>
High	2 <input type="checkbox"/>	3 <input type="checkbox"/>	3 <input type="checkbox"/>

(b) Explain/justify the level of research risk and group vulnerability reported above:

(Please note that the final determination of Review Type and level of monitoring will be made by the reviewing University of Toronto REB)

Based on the level of risk, these are the types of ethics review that an application may receive:

Risk level = 1: Delegated Review; Risk level = 2 or 3: Full Board Review

For both delegated and full reviews (SSH&E, HS, or HIV), please submit one electronic copy of your application and all appendices (e.g., recruitment, information/consent and debriefing materials, and study instruments) as a **single** Word document or a pdf. *Do not submit your entire research proposal.* Please ensure that the electronic signatures are in place and e-mail to new.ethics.protocols@utoronto.ca

The deadline for delegated review (SSH&E or HS) is EVERY Monday, or first business day of the week, by 4 pm. Information about full REB meeting and submission due dates are posted on our website (SSH&E, HS or HIV).

HIV REB reviews all applications at full board level but applies proportionate review based on the level of risk.

All other submissions (e.g., amendments, adverse events, and continuing review submissions) should be sent to ethics.review@utoronto.ca

SECTION G – SIGNATURES

27. PRIVACY REGULATIONS

My signature as Investigator, in Section G of this application form, confirms that I am aware of, understand, and will comply with all relevant laws governing the collection and use of personally identifiable information in research. I understand that for research involving extraction or collection of personally identifiable information, provincial, national and/or international laws may apply and that any apparent mishandling of personally identifiable information must be reported to the Office of Research Ethics.

For U of T **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 or equivalent (where applicable). If my status as a student changes, I will inform the Office of Research Ethics.

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. In addition to the supervisor/sponsor, the chair or the dean of the UoT sponsor's/supervisor's department is required to approve and sign the form

As the UofT **Faculty Supervisor** of this project, my signature confirms that I have reviewed and approve the scientific merit of the research project and this ethics application 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 UofT **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.

Signature of Faculty Supervisor/Sponsor: _____ Date: _____

As the **Departmental Chair/Dean**, my signature confirms that I am aware of the [requirements for scholarly review](#) and that the ethics application for this research has received appropriate review prior to submission.

In addition, my administrative unit will follow guidelines and procedures to ensure compliance with all relevant University, provincial, national or international policies and regulations that govern research involving human participants. 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.

Print Name of Departmental Chair/Dean (or designate) : _____
Signature of Departmental Chair/Dean: _____ Date: _____

(or authorized designate)