



Instructions for Ethics Review Application Form

Prior to filling out the ethics application submission form we recommend that researchers familiarize themselves with the relevant [U of T policies and guidelines](#). In addition to these documents, it is imperative that researchers familiarize themselves with the [TCPS2: Ethical Conduct for Research Involving Humans](#). We advise that graduate and undergraduate students complete the [TCPS2 tutorial](#). Finally, the University of Toronto Human Research Ethics Program (HREP) offers individual research consults for specific research ethics concerns.

Selecting the correct form to submit for Research Ethics Board (REB) review

There are three main forms that researchers need fill out depending on their status with University of Toronto:

1. U of T faculty researchers – This form is reserved exclusively for U of T faculty members with research privileges.
2. Supervised and sponsored research – This form is for U of T graduate students, post-docs, residents, and non-U of T faculty who are supervised or sponsored by a U of T faculty member with research privileges.
3. Community-based researchers doing HIV/AIDS research – This form is for community-based researchers doing HIV/AIDS research brokered by Ontario HIV Treatment Network (OHTN).

The same forms are used for full board and delegated reviews. To determine the type of review you need, please refer to section #26 – risk matrix.

The HREP also has some other specialized forms. If you are an undergraduate student doing minimal risk research, contact the relevant undergraduate Delegated Ethics Review Committee ([DERC](#)). Please see your [department](#) or faculty Undergraduate Coordinator to determine what this process entails.

If you are a graduate course instructor whose course includes student research projects, fill out the Graduate Course Template.

Section A – General Information:

1. Title of the research project

Generally speaking, titles should reflect the subject of the research. Where more than one ethics application is required to cover the research of a specific project, please use the title plus subtitle or other form of identification. When submitting multiple protocols for review, ensure that the titles are different.

2. Investigator information

For faculty research, the principal investigator (PI) is the person who assumes responsibility for the conduct of the research. For supervised and sponsored research, the faculty

supervisor is the researcher who assumes 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 investigator.

Note that the ORE does not list co-investigators in our correspondence. Alternate Contact can be added as someone who would be copied on all the communication but not listed on any approval letters, for example, a study coordinator. We only accept institutional e-mail accounts such as utoronto.ca due to privacy concerns.

Post-doctoral fellows and Visiting Professors may serve as an investigator 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 investigator conducts the research project ethically, in accordance with the REB-approved protocol.

Undergraduate course-based research that is minimal risk should be reviewed by the appropriate Delegated Ethics Review Committee (DERC). Please see your [department](#) or faculty Undergraduate Coordinator to determine what this process entails.

3. University of Toronto research ethics board

Social Sciences Humanities and Education (SSHE) and Health Sciences (HS) REBs are department specific. SSHE REB reviews protocols from all departments within social sciences, humanities, OISE/UT, physical sciences and engineering. HS REB reviews protocols from faculty of medicine, IBBME, nursing, pharmaceutical sciences, social work, kinesiology and physical education, and dentistry. REBs are normally responsible for specific departments within the University, with the exception of the HIV/AIDS REB. The HIV/AIDS REB reviews all research that has a significant component which deals with HIV/AIDS. In situations where it may be more appropriate for the proposed research to be reviewed by another REB, the ORE may choose to re-assign the protocol. In cases where the student and the primary supervisor are from different departments, the protocol gets reviewed by the supervisor’s respective REB.

4. Location(s) where the research will be conducted

Specify all the locations where the research (i.e., recruitment and/or data collection) will be conducted and the data will be stored. 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. See the [HHS](#) site to determine the processes in place in the country where the research is to be conducted. 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 that covers the participants but that the research is culturally and ethically acceptable is recommended. 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. Refer to the University’s policy on Safety in Field Research at <http://www.ehs.utoronto.ca/resources/manindex/policies/fieldres.htm>

5. Other research ethics board approval

If there are any other research ethics approval letters, they should be submitted as appendices with the application. If some other board has rejected this proposal that should be explained.

6. Funding of the project

For funded research, ORE requires that investigators stipulate the source of funding (e.g., SSHRC, CIHR, etc.), type of fund (e.g., operating grant, meeting grant, etc.) and the 6-digit fund which begins with the number 4. To find out this fund number, researchers should log into My Research Online (MROL) click on the "Research" option in the list of services on the left side of the page, and follow the links to the MROL log on screen.

Once you're logged into MROL, you should click on "My Applications" to see a report of all of your application for research funding. On the right side of this report you will see the live links to the FReDs which you can click to see the full FReD details.

Please see below:

University of Toronto Office of the Vice President, Research Funded Research Digest			
Principal Investigator: Matthew, Brenda	MTRS Application: 25272	Funded Research No.: 72006063	Page: 1
Department: DEPT OF SURGERY	Fund No.: 410223	Type of Agreement: Operating Contract	
Sponsor: 301167 Nelson Arthur Hyland Foundation	Sponsor's Reference: 12345	Fund Period: April 1, 1995 to March 31, 1998	
PI Fund Center:	Department Fund Center: 100850 - Med:Surgery	Grant Period: April 1, 1995 to March 31, 1998	
Location of Research: Ramsay Wright Zoological Laboratories,...	Fiscal Year: Apr-Mar	Internal Order: 123456	Cost Center:
Short Title of Research: Sample FReD			
BUDGET			
	Jun 1997	Dec 1997	Total Budget
Open	30,000.00		30,000.00
Total compensation	11,000.00	5,000.00	16,000.00
Total Expense	41,000.00	5,000.00	46,000.00
TERMS & CONDITIONS			
Central Financial Report Schedule: Annual:March			
Overhead Distribution			

When one protocol covers several grants, make sure to include all agency and known funding information.

When one grant funds several research projects (each of which will be covered by a separate ethics protocol,) provide the number of protocols you anticipate will be submitted in order to cover the entire funded research activity, and to specify that this is # X of total number.

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

If the research is not funded but it entails costs (e.g., participant reimbursement, purchasing equipment, etc.), provide an explanation for how costs will be covered.

7. Contracts and agreements

Please include a copy of all agreements associated with the research, whether or not funding is involved, as appendices.

8. Project start and end dates

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 at which data analysis has been completed in order to answer the original research question(s). Researchers are not to engage in data collection or recruitment until they have REB approval.

9. Scholarly review

Scholarly review is required for all supervised/sponsored research as well as all research that is greater than minimal risk. Student research should be reviewed by the thesis committee or supervisor and at least one other expert in the research area if no thesis committee exists. In some situations, departments or faculties may have their own internal scholarly review committees. The REB maintains the authority to review the science or scholarship for any of the protocols it is assigned.

Dentistry studies submitted to the Health Sciences REB should be accompanied by a letter from the Associate Dean of Graduate/Postgraduate Studies (for graduate studies related projects) or the Associate Dean of Research Faculty of Dentistry (for all other submissions), attesting to the scientific merit of the proposal. The Health Sciences REB cannot issue an ethics approval letter until we have received a copy of this scientific merit approval letter.

Also, note that submission to the HIV/AIDS REB from community investigators, scientific review is a pre-requisite for ethics review. If a study is unfunded and comes from community investigators, please contact Jenn Major at OHTN to arrange scientific review prior to completing the ethics submission.

Sometimes funders approve large grants which include multiple research protocols. Please outline whether the scholarly review was done for this specific protocol or whether the review was part of a larger grant.

10. Conflict of Interest

Outline any real, potential or perceived conflicts of interests and how they will be managed or eliminated.

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 already been done in this area. It should be assumed that the REB is not familiar with the discipline, but is knowledgeable in research. In general, lengthy literature and thesis proposals are not appropriate. Researchers should describe the purpose and scholarly rationale for the study and provide some references.

12. Methods

This section should include a description of all formal and informal procedures to be used in the study with respect to human participants, data, and/or biological materials. When presenting a complex proposal, tables, figures and timelines may be useful. It is not necessary to describe standard procedures (e.g., DNA analysis, MRI scans, etc.). It is the responsibility of the researcher to obtain the proper permission to use certain standard instruments (e.g., Beck's Depression Inventory) in their research. Article 2.7 of the TCPS2 states that "as part of research ethics review, the REB shall review the ethical implications of methods and design of the research."

Please append all tests, questionnaires, and tools, including standard instruments. Interview guides and focus group questions should also be appended. For semi-structured and unstructured interviews, please submit a document that gives a general sense of the type of questions you plan to ask. It is understandable that some interview questions may change once the research begins.

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

13. Participants and/or data

This section should include all the relevant details about the study participants. List the inclusion and exclusion criteria. When using existing data, explain how the data will be collected/extracted, what it will include, and how you will gain access to the data. . For data that could lead to identification, directly or indirectly, the degree of this possibility should also be discussed (e.g., names, postal codes or parts thereof, OHIP numbers, etc.). If appropriate, state sample size and justify it.

14. Experience of investigators with this type of research

This section should outline the training and experience of the individuals involved in the research relevant to this study. If the research is to involve methods that pose greater than minimal risk, collection of sensitive data, and/or a vulnerable population, provide a brief description of the research team's experiences and/or ability to conduct the research. If the research is supervised or sponsored, the degree of supervision, by the faculty supervisor and/or sponsor should be included. If the project involves community members or research associates, their training should be outlined with special attention to privacy and confidentiality in research.

15. Recruitment of participants

This section should describe how, by whom, and from where the participants will be recruited. In cases where formal recruitment methods will not be used provide a description and rationale of the method. When potential participants will be known to the researcher prior to the submission of the protocol, discuss any power differences and, if applicable, how undue influence will be mitigated. Copies of any recruitment materials (e.g., posters, advertisements, flyers, letters, e-mail text, etc.) should be appended, as well as all the possible venues where they might be presented.

16. Compensation

Before completing this section, you should be familiar with [U of T's Compensation and Reimbursement Guidelines](#). If applicable, justify the amount of compensation to be offered to participants. If you will not be providing compensation or reimbursement, and participants will incur cost (e.g., child care, travel), provide a rationale. Compensation is offered in foreign currency, a Canadian equivalent should be provided.

Whenever possible, participants who withdraw should receive prorated compensation.

Section C – Description of the risks and benefits of the proposed research

17. Possible risks

All research carries some risk. Evaluate risk based on the probability that it will occur and seriousness of the harm.

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

18. Possible benefits

It is important that possible benefits listed are realistic. If there is no benefit to the participant, this should be expressed. Discuss the potential benefits to the community/society if applicable. Also discuss any benefits to the scientific or scholarly community.

Section D – Informed Consent

19. The consent process

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.]

While the default, according to the TCPS2, 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.

This section should include a full description of how you will obtain free and informed consent from participants, in addition to appending all relevant consent materials. REBs are interested in reviewing the consent documents but also wish to know how the consent process will take place (e.g., who will approach whom, where will it take place, etc.).

If your data will be used for purposes other than what the participants originally consented to, describe how consent was or will be obtained for this new purpose.

20. Consent documents

The various consent documents should be appended and properly labelled as appendices. Please see our website for a [Guide](#) for Informed Consent. Given the variety of disciplines and departments at U of T, we do not have sample consent forms.

21. Community and/or organizational consent, or consent by an authorized party

If applicable, community consent should be sought prior to any data collection. Certain communities may have their own review boards and they should be consulted, as well. 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 at 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.

Community engagement is a key component of research taking place in traditional communities. Researchers should outline their process of engagement and provide all letters of support. Similarly, letters of administrative support should be provided if the research is taking place with organizations or companies. If consent will not be sought, please provide justification and describe alternative consultation that may take place.

22. Debriefing and dissemination

Researchers engaging in deception should be familiar with [U of T's guidelines for Deception and Debriefing in Research](#). 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). Deception is considered a risk, as it can have a negative 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 format. Please describe the format by which participants can access findings (e.g., newsletter, summary of thesis material, town hall meetings, etc.), and how they will be notified of this.

23. Participant withdrawal

Describe how participants can withdraw from the study. Specify whether or not participants can withdraw their data after their participation. If participants cannot withdraw their data after a certain point for any reason (e.g., de-linking of data), this should be explained.

Section E – Confidentiality

24. Confidentiality

The procedures and measures used to protect participants' confidentiality should be outlined in detail. There are some cases where participants would not wish to keep their data confidential. In these situations, the researcher needs to make an argument why this is the case. . Encryption should be used for all electronic data outside of a secure server. Describe any limits to confidentiality (e.g., focus groups, duty to report, etc.).

25. Data security, retention and access

Researchers should outline how data will be stored and disposed. In some cases data can be stored for an indefinite period of time. Any data sharing with other researchers or users should be described. The ORE does not have guidelines for how long data should be retained. Some of the factors that should be considered are sensitivity of data, disciplinary or departmental practices and how long the data will be needed. Health Canada requires that data for clinical trials are retained for at least 25 years. Data that is truly anonymous can be retained indefinitely.

Section F – Level of risk and review type

26. Risk matrix: Review type by group vulnerability and research risk

To use the Risk Matrix, please determine the Group Vulnerability (low, medium, high) and Research Risk (low, medium high). The point at which the two points intersect is the **Risk Level** (1, 2 or 3). Group vulnerability is usually defined as the ability to give free and informed consent while research risk is usually defined as the invasiveness of the procedures. If there are multiple groups with various vulnerabilities and research risks, the REB sets the risk by ranking the most vulnerable of the groups.

Section G - Signatures

All required signatures need to be in place before you submit your protocol for review. Scanned signatures are accepted but the whole application should be submitted as a single document. Under certain circumstances, an email from the researcher's institutional account may be accepted in lieu of an e-signature. We do not accept verbal assurances, phone calls or names typed out. If the research supervisor is also the Chair/Dean of the department/faculty, the person who is the next level up in authority from the Chair/Dean should sign.