



UNIVERSITY OF TORONTO

Office of the Vice-President, Research and Associate Provost

Ethics Review Office

UNDERGRADUATE ETHICS REVIEW PROTOCOL FORM
COURSE TEMPLATE

Faculty of Pharmacy Undergraduate Research Ethics Review Committee (FERC)

COURSE INSTRUCTOR:

Name _____ Personnel Number _____

Department _____

Mailing Address _____

Phone _____ Fax _____ Email _____

COURSE:

Course Title _____

Course Code _____ Number of Students in Course _____

Course Start Date _____ (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
- 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 or more expeditable cells as appropriate (if any proposals are non-expeditable, please consult your DERC):

Group vulnerability	Research Risk		
	Low	Medium	High
Low	Expedited	Expedited	Full
Medium	Expedited	Full	Full
High	Full	Full	Full

Briefly explain (max. 100 words) the group vulnerability and research 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: http://www.research.utoronto.ca/ethics/eh_u_inf.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 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.

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: _____