UNIVERSITY OF TORONTO
Office of the Vice-President, Research

Office of Research Ethics

Office Use Only Protocol Number:

GRADUATE COURSE TEMPLATE PROTOCOL SUBMISSION FORM

SECTION A – GENERAL INFORMATION

1. COURSE INSTRUCTOR:

Title:	Name:	
Department:		
Mailing address:		
Phone:	Fax:	Email:

2. COURSE:

Course Title:	
Course Code:	Number of Students in Course:
Course Start Date:	

Alternate Contact (e.g., Research Coordinator):

Title: Name:	
Phone:	Institutional e-mail:

3. UNIVERSITY OF TORONTO RESEARCH ETHICS BOARD to review this template:

Health Sciences ☐ HIV ☐ Social Science, Humanities and Education ☐

Student projects are marked <u>Complete</u> 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).

4. COURSE DESCRIPTION

Please describe the goals of the course and how the research project fits within these goals. Please explain how students will be educated on research ethics principles and issues, and whether there is a dedicated research ethics component to the course.

5. MINIMAL RISK AND DELEGATED 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.

RISK MATRIX: Review Type by Group Vulnerability and Research Risk – Check one or more cells as appropriate (if any proposals are more than minimal risk - i.e., greater than 1 on the Risk Matrix below- please consult with the ORE)

	Research Risk		
Group vulnerability	**Low**	**Medium**	**High**
Low	**1** ☐	**1** ☐	**2** ☐
Medium	**1** ☐	**2** ☐	**3** ☐
High	**2** ☐	**3** ☐	**3** ☐

Briefly explain the group vulnerability and research risk:

Review Type

Based on the level of risk, these are the types of review that a protocol may receive:

Risk level= 1: Delegated Review (formerly expedited); Risk level = 2 or 3: Full Board Review

For both delegated and full reviews (SSH&E, HS, or HIV REB), please submit one electronic copy of your protocol and appendices (e.g., recruitment, information/consent and debriefing materials, and study instruments) as a **single** Word document or a pdf. Please ensure that the electronic signatures are in place and e-mail to new.ethics.protocols@utoronto.ca

All other submissions, which are not new (e.g., revisions and continuing review submissions), as well as general inquiries, should be sent to ethics.review@utoronto.ca

The deadline for delegated review (SSH&E or HS) is EVERY Monday, or first business day of the week, by 4 pm. HIV REB reviews all protocols at full board level but applies proportionate review based on the level of risk.
REB meeting and submission due dates are posted on our website (SSH&E, HS or HIV).

Please note that the final determination of Review Type and level of monitoring will be made by the University of Toronto REB and the Office of Research Ethics.

6. 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.

7. 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 and specific the REB

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

SECTION B – PARAMETERS OF THE RESEARCH ASSIGNMENT

8. BACKGROUND, PURPOSE, AND OBJECTIVES:

Briefly describe the pedagogical goal of the assignment.

9. 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, as well as a description of how data will be analyzed.
- 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.

10. 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.

11. 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.

SECTION C – POTENTIAL RISKS AND BENEFITS

12. 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.

13. BENEFITS:

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

14. 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)

SECTION D – THE INFORMED CONSENT PROCESS

15. THE 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/wp-content/uploads/2010/01/GUIDE-FOR-INFORMED-CONSENT-April-2010.pdf

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 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.

SECTION E - PRIVACY AND CONFIDENTIALITY

16. 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. Please also 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. Data security measures should be consistent with UT's *Data Security Standards for Personally Identifiable and Other Confidential Data in Research*:

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).

17. PRIVACY REGULATIONS

For research involving extraction or collection of personally identifiable information, provincial, national and/or international laws may apply. I will report any apparent mishandling of personally identifiable information to the Office of Research Ethics. **My signature as Course Instructor, at the end of this protocol, 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.**

18. 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.

19. 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.

20. 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.

Signature: _____ Date:

As the **Graduate Chair/Dean**, my signature confirms that I am aware of the proposed activity and that it has received appropriate review prior to submission. 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.

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Print Name of Graduate Chair/Dean (or designate)

Signature: _____ Date: