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**Office of the Vice-Principal, Research**

UNDERGRADUATE ETHICS REVIEW PROTOCOL FORM

STUDENT-INITIATED PROJECT

Please submit a completed form, including the appropriate signatures and copies of informed consent/relevant documents to **U of T Mississauga’s Research Office, Health Sciences Complex, Room 330, or a pdf can be emailed to veron.fernandes@utoronto.ca**

FACULTY SUPERVISOR:

 Name

 Email

**UNDERGRADUATE STUDENT (PRINCIPAL INVESTIGATOR):**

 Name

 Email

**PROJECT:**

 Project Title

 Course Code Project Start Date

(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:

* <http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/>
* <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>
* <http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/>

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:**

 **Research Risk**

**Group vulnerability 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, 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 Mississauga 🞏

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.**

**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.**

**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 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 🞏

 FinancialYes 🞏 No 🞏

 Course Credit Yes 🞏 No 🞏

 Other Yes 🞏 No 🞏

(b) If **Other**, 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: [**http://www.research.utoronto.ca/wp-content/uploads/2012/10/GUIDE-FOR-INFORMED-CONSENT-April-2010.pdf**](http://www.research.utoronto.ca/wp-content/uploads/2012/10/GUIDE-FOR-INFORMED-CONSENT-April-2010.pdf)

**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 participant’s identity be kept anonymous? Yes 🞏 No 🞏

If **Yes**, please describe the procedures to be used to protect the identity of the individual(s) during the conduct of research and in preparation of the final report.

If **No**—i.e., anonymity is not appropriate in the context of this assignment—please explain why identifying information is necessary.

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: