**LAKEHEAD UNIVERSITY**

**UNDERGRADUATE RESEARCH ETHICS APPLICATION FORM**

Principal Investigator/Faculty member Supervisor: Telephone Number:

 Email address:

Co-Investigator(s): Telephone Number:

 Email address:

Student Investigator(s): Telephone Number:

 Email address:

Department:

Address where correspondence should be directed:

Project Title:

Is this project funded?: Yes **🞎** No **🞎**

If yes, provide Title of Funded Project:

 Name of Granting Agency:

 Granting Agency Project Number:

Proposed Start and End Dates of Research Involving Human Participants:

Project Key Words (up to five):

Type of Participants: Adults **🞎** Minors **🞎**

Estimated Enrollment:

Lakehead University campus (Thunder Bay or Orillia) **🞎** Local (outside of campus) **🞎** Non-Local **🞎**

Received approval, or seeking approval, from any other ethics committee? Yes **🞎** No **🞎**

Ethics Committee(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

(please attached approval letter if obtained)

**Preliminary Checklist:**

The [*Tri-Council Policy Statement* 2](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) (TCPS 2) recommends a proportionate review process in which “*the level of review is determined by the level of risk presented by the research: the lower the level of risk, the lower the level of scrutiny (delegated review); the higher the level of risk, the higher the level of scrutiny (full board review)*”. (see [*TCPS 2*, Article 2.9](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter2-chapitre2/)). The following questions are designed to aid the undergraduate review committee in determining which proposals qualify for full REB review rather than undergraduate committee review.

For each of the following questions, place a mark in the box to indicate “yes”:

1. Will your study involve more than minimal physical risk to your participants? (For a definition of minimal risk, see TCPS2, Chapter 2, Section B) **🞎**

2. Will your study involve the use of high-risk test instruments? i.e. surveys that may reveal that the participant intends to participate in dangerous activities such as self harm or harm to others. **🞎**

3. Will your study involve more than minimal psychological risk to your participants? **🞎**

4. Will your study likely lead to the discovery of your participants’ involvement in illegal activities? **🞎**

5. Will your study involve participants who are members of vulnerable populations? **🞎**

If yes, please elaborate briefly:

6. Will your study involve clinical research, the collection of bodily tissues or fluids, or the administration of drugs or dietary supplements? (A clinical trial, a form of clinical research (also known as patient-oriented research), is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. Interventions include, but are not restricted to, drugs, radiopharmaceuticals, cells and other biological products, surgical procedures, radiologic procedures, devices, genetic therapies, natural health products, process-of-care changes, preventive care, manual therapies and psychotherapies. Clinical trials may also include questions that are not directly related to therapeutic goals – for example, drug metabolism – in addition to those that directly evaluate the treatment of participants (see TCPS 2, Chapter 11). **🞎**

7. Will your study involve First Nations communities? **🞎**

If yes, please outline the community engagement/collaboration plan (including how the community has been engaged and plans for future engagement). See [*TCPS 2, Chapter 9, Article 9.10*](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/#toc09-1). For research focusing on First Nations peoples residing outside of First Nations communities, a similar plan of engagement with a representative group should be indicated ([*TCPS 2, Chapter 9, Article 9.4*](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/)). Please provide justification if there is not a community engagement/collaboration plan.

When aboriginal participation is incidental rather than scheduled, a community engagement plan is not required ([*TCPS 2, Chapter 9, Article 9*.2, Section 7](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/)).

For more information, please refer to the [*TCPS 2, Chapter 9*](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter9-chapitre9/).

**Research Ethics Review Criteria**

Please address each item and include a summary (either on this form or attached as a separate document) of how you will address each of these items (or indicate if they do not apply):

[ ] **Lay description**

 Provide a brief lay-word summary of the proposed project (40 words or less).

[ ] **Summary of purpose of research**

Be sure to include sufficient detail, described in terms that do not require extensive field-specific knowledge.

[ ] **Research participants**

 Describe required characteristics and number of participants.

[ ] **Data collection**

 Explain the method of data collection and analysis. Explain exactly what will be expected of participants (length of time commitment, etc.) All questionnaires and research instruments must be included as appendices.

[ ] **Secondary data**

 For research involving the use of secondary data (data which has been previously collected for a purpose other than the research project itself), ethics review is not required if the data is anonymized so long as the process of data linkage or recording or dissemination of results does not generate identifiable information (see TCPS 2, Chapter 2, Article 2.4). For secondary data that is identifiable ethical review is required. Please see TCPS 2, Chapter 5, Section D.

[ ] **Recruitment procedures**

Describe how potential participants will be selected and contacted. Include a copy of any advertisements used to recruit participants.

[ ] **Harm and/or** **potential risks to participants**

a) State clearly any potential harm or risks – physical, psychological, injury to reputation or privacy, and breach of any relevant law – for participants or for third parties (those affected by the research but who are not active research subjects).

b) If there is any apparent harm or risk, clearly explain all steps that are being taken to reduce this.

[ ] **Deception**

If deception is part of the research program, the researcher must:

a) State clearly why no alternative methodology, which does not involve deception, can fruitfully be used to answer the research question.

b) Provide evidence that the participant is not put at risk by the deception (or, in some cases, the failure to fully disclose the research procedure to participants because of fear of contamination of results).

[ ] **Benefits to subjects and/or society**

Describe in detail the potential benefits of the research for both participants and to general knowledge.

[ ] **Informed consent**

 Clearly outline the measures that will be used to ensure the informed consent of all research participants. Cover letters and consent forms must be attached as appendices on Lakehead University (or NOSM if appropriate) letterhead.

[ ] **Capacity to consent**

Capacity refers to the ability of prospective or actual participants to understand relevant information presented about a research project, and to appreciate the potential consequences of their decision to participate or not participate (TCPS 2, Chapter 3, Section C). Will the research participants sufficiently understand the nature of the research project, and the risks, consequences, and potential benefits associated with it?

[ ] **Right to withdraw**

 The researcher must illustrate that participants will be informed of their right to withdraw from the study at any time without penalty of any kind, and that they may choose not to answer any question asked as part of the research. For participants submitting information anonymously, the participants must be informed that withdrawal post-submission is not possible due to the anonymous nature of their data.

 \* In preparing cover letters and consent forms, please use the Informed Consent Checklist attached to this Form.

[ ] **Anonymity and confidentiality**

 The researcher must outline the procedures that will be used to guarantee confidentiality and/or anonymity for participants. Participants who wish to be named and to waive their right to privacy and confidentiality must provide written evidence.

(*Anonymized information*: The information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low. Anonymous information or the information never had identifiers associated with it (e.g. anonymous surveys) and risk of identification of individuals is low or very low. *Confidentiality*: An ethical and/or legal responsibility of individuals or organizations to safeguard information entrusted to them, from unauthorized access, use, disclosure, modification, loss or theft.)

[ ] **Storage of data**

Provide evidence that the data will be securely stored for 5 years following completion of the project, as per Lakehead University guidelines.

[ ] **Peer review**

Clearly state the intention, or non-intention to have the proposal peer reviewed by an external granting agency or thesis committee.

[ ] **Research partners and students**

Clearly state whether or not the research will involve researchers at another university/institution. TCPS 2 Tutorial Certificates must be attached for all research team members.

[ ] **Multi-jurisdiction research**

 If you are involved in multi-jurisdictional research, provide evidence that ethical approval is also being sought at any other institution where direct research with human participants will be undertaken. Ethical approval from another institution, while essential in a multi-jurisdiction project, is not itself sufficient for the commencement of research with human participants at Lakehead University.

[ ] **Conflict of Interest**

The researcher(s) shall disclose actual, perceived or potential conflicts of interest to the ethical review committee.

[ ] **Dissemination of research results**

Clearly state the means by which research will both be disseminated in the academic community and by which research participants may be made aware of the findings of the study.

[ ] **I have completed the** [***TCPS 2 Tutorial: Course on Research Ethics***](http://www.pre.ethics.gc.ca/eng/education/tutorial-didacticiel/)**and have attached a copy of my completion certificate to this form.** \*Please note that all investigators listed on this application must submit their Certificates.

I am familiar with the [Agreement on the Administration of Agency Grants and Awards by Research Institutions](http://science.gc.ca/default.asp?lang=En&n=56B87BE5-1), and the[***Tri-Council Policy Statement 2: Ethical Conduct for Research Involving Humans***](http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/) and I agree to comply with these guidelines, and the procedures approved by the Research Ethics Board and undergraduate research ethics committee, in carrying out this proposed research.

I attest that all information submitted is complete and truthful. I understand the consequences, for myself and for the institution, of failure to comply with the above regulations.

Researchers are required to report any changes in research design, procedures, sample characteristics, and so forth that are contemplated after ethical approval has been granted. Changes may not be implemented until approved by the ethical review committee. If any unforeseen incident occurs during the course of research that may indicate risk to participants, I will immediately cease research and inform the approving ethics committee.

I understand that my protocol will be subject to random review for compliance by the Office of Research Services.

I will inform the ethics committee when the research is complete by completing the Final Report Form found here: [https://www.lakeheadu.ca/research-and-innovation/forms](https://www.lakeheadu.ca/research-and-innovation/forms%20)

**SIGNATURES:**

**Principal Investigator or Supervisor if graduate student project** (please print):

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Co-Investigator(s)** (please print):

Signature(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Student Investigator(s)** (please print):

Signature(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Chair/Director** (please print):

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Please note that no one signature may be placed in two separate signature areas above.

**To submit your application for ethical approval you must submit one (1) copy of this Form, along with one (1) copy of the information required to address the Research Ethics Review Criteria above (including cover letters, consent forms, and research instruments), and one (1) copy of the completion certificate for the *TCPS 2 Tutorial: Course on Research Ethics* to your appropriate research ethics committee.**

Revised: January 2014

**Informed Consent Checklist**

**General**

[ ] Cover letters and consent forms are presented on Lakehead University letterhead (or NOSM if appropriate)

[ ] The language level is appropriate to the age and reading level of the subject population

[ ] Contact information for the researcher(s) (including the supervisor if a graduate student project) and the ethical review committee is always included in the cover letter that the participants will keep after they sign the consent form. Suggested wording: "This study has been approved by the [insert appropriate research ethics committee]. If you have any questions related to the ethics of the research and would like to speak to someone outside of the research team please contact [insert Chair name and email of the appropriate research ethics committee]".

**The Cover Letter/Introductory Information (including electronic letters and consent forms) should include:**

[ ] The title of the study

[ ] An explanation of the purpose of the research

[ ] The identity of the researcher and their affiliation with Lakehead University

[ ] The sponsor of the research, if applicable

[ ] A warm, non-coercive invitation to participate, addressed to the “Potential Participant”

[ ] The reason why the potential participant is being invited to participate in the research

[ ] That the individual’s participation is voluntary, that they may refuse to participate in any part of the study, and that they may withdraw from the study at any time (other than anonymously submitted information)

[ ] That participants may decline to answer any question

[ ] A description of the procedures the participants will be involved in and how much of their time will be required

[ ] Information regarding any audio or videotaping and explicit consent to such recording

[ ] Information about any foreseeable risks, harms, or inconveniences

[ ] Potential benefits (including information that there is no direct benefit, if appropriate)

[ ] A mechanism for providing referrals, if appropriate (i.e. if there is the possibility of emotional distress, or physical harm)

[ ] Information regarding who will have access to the data

[ ] Information about the storage of data (during and after completion of the research)

[ ] The degree of confidentiality and/or anonymity that will be provided and how this will be maintained (e.g. individual participants will not be identified in published results without their explicit consent, data will be published in aggregate form). For research involving anonymous surveys, it should be stated that the survey instrument will not be labeled to identify who completed it

[ ] Limits on confidentiality, if applicable (e.g. confidentiality disclaimer for focus groups)

[ ] A statement indicating the researcher’s intent to publish or make public presentations based on the research and whether or not the participant’s identity will remain confidential (e.g., will pseudonymous be used?)

[ ] Offer of a summary of the research results (and a mechanism to provide the summary)

**The Consent Form must state each individual’s agreement that:**

[ ] They have read and understood the cover/information letter for the study

[ ] They agree to participate

[ ] They understand the potential risks and/or benefits of the study, and what those are

[ ] That they are a volunteer and can withdraw from the study at any time, and may choose not to answer any question

[ ] The data they provide will be securely stored at Lakehead University for a period of five years

[ ] If applicable, that they understand that the research findings will be made available to them, and how this will be communicated

[ ] That they will remain anonymous in any publication/public presentation of research findings. Participants must explicitly agree to have their identities revealed.

**Other Consent Information**

[ ] All participants must sign and date the consent form then return it to the researcher.

[ ] Consent must also be obtained from all agencies, partners, schools, school boards etc. that provide access to the subject pools. Separate consent forms must be included for all of the above should this apply.

[ ] If the study involves the use of high-risk test instruments which could potentially reveal that the subject intends to participate in a dangerous activity(s), the consent should contain a clause such that there is a limit to the level of confidentiality when the subject may be at risk for harm to self or others.

[ ] While inclusive research is important, the researcher must ensure that consent is obtained from vulnerable populations in a sensitive manner. Vulnerable populations include children, and others not competent to give free and informed consent on their own behalf. In cases like this, parent/guardian (or the individual’s representative) consent must be obtained. Please note every effort should be made to ensure that participants understand and consent to their own participation as well.