Ethics Review Board

Project Application Form

This form is to be used when submitting a project for ethics review and approval by PHO’s Ethics Review Board (ERB). Only projects with a validated level 2 or 3 RST score will be considered for review. Lead applicants are required to complete and sign the form.

The ERB Project Application Form is the key source of information used by the ERB to assess the ethical acceptability of a project. Applicants may be asked to re-submit their application if information in the ERB application form is incomplete.

To submit an ERB Project Application Form, complete and email the form and supplementary documentation to ethics@oahpp.ca.

If you require assistance completing this form, contact your PHU’s ethics designate or PHO Ethics Services at ethics@oahpp.ca.

PHO internal use only:

Date of receipt: Click here to enter a date.

ERB project identification number (ID): Enter ERB project ID number.

Application Details

Version date: Click here to enter a date.

A. Project Information and Documents

Project Title: Enter project title here.

Estimated **Project** [Start Date for involvement of human participants](#startdatehumanpts)/data/biological materials:

Click here to enter a date.

Estimated [Project End Date](#projectenddate), i.e. completion of data collection, analysis, and dissemination activities involving project participants:

Click here to enter a date.

Indicate which of the following supplementary documents are attached, as applicable:

[ ]  Completed Risk Screening Tool

[ ]  List of additional project team members

[ ]  Recruitment materials (recruitment flyers, announcements, emails, telephone scripts, or any other communication with potential participants)

[ ]  Information letters and consent/assent documents, etc.

[ ]  Data collection materials (surveys, interview guides, data extraction forms, etc.)

[ ]  Privacy review documentation

[ ]  Documentation from other ethics review boards/committees

[ ]  List of references

[ ]  Other documents, listed here. List other attached documents here, if applicable.

B. [Lead Applicant](#LeadApplicant)

(The authorized individual at the institution responsible for the scientific and ethical conduct of the project and for the conduct of the project team)

First Name: Enter first name.

Last Name: Enter last name.

Job title: Enter job title.

Program area or department: Enter program area or department.

Credentials (MPH, PhD, MD etc.): Enter your credentials here

Public health unit or organization name: Enter organization name.

Mailing address: Enter mailing address.

Phone: Enter phone number.

Email: Enter email.

Completion of the [**TCPS 2 tutorial course**](https://tcps2core.ca/welcome) is mandatory for the lead applicant and strongly encouraged for the rest of the project team. The certificate of completion must be attached to this document if it has not already been submitted to PHO Ethics Services at ethics@oahpp.ca.

[ ] Certificate attached

[ ] Certificate previously submitted

C. Contact for Project Correspondence

Same as lead applicant: [ ]  If different than lead applicant, please fill in information below:

First name: Enter first name.

Last name: Enter last name.

Job title: Enter job title.

Program area or department: Enter program or department details.

Public health unit or organization name: Enter organization name.

Phone: Enter phone number.

Email Enter email.

Role in project: [ ]  Coordinator [ ]  Co-applicant

 [ ]  Other (Please specify): Specify other role in project.

D. Additional Project Team Members

Are there additional project team members apart from those listed above?

[ ]  No additional project team members.

[ ]  Yes. A list of additional project team members (names, titles, roles in the project, and contact
 information) is attached.

E. Other Required Review Processes

Ethics review and approval by an external board may be required for multi-site projects where part of the project is being conducted by another institution or site, either within their jurisdiction or under their auspices (i.e., by their faculty, staff or students). It is the responsibility of the lead applicant to determine what other approvals are required (e.g. *privacy review, school board review, quality review*), and to obtain approval prior to starting the project. Some jurisdictions may also have additional licensing requirements for scientific research, e.g. Nunavut, Yukon, and Northwest Territories*.*

**The project cannot begin until all approvals/letters are received by PHO Ethics Services.**

1. Did you or will you [seek](#ethicsreviewbyothers" \o "Consider whether ethics review is also required by another ethics review board when the project involves other organizations (and these organizations are not merely the focus of inquiry).) [ethics review by another board/committee](#otherethicsreview" \o "Consider whether ethics review is also required by another ethics review board when the project involves other organizations (and these organizations are not merely the focus of inquiry).)?

[ ]  No.

[ ]  Yes. Review completed by (name of board or committee)

Enter the name of board or committee.

[ ]  Yes. Review pending by (name of board or committee):

Enter the name of board or committee.

Attach other ethics review approvals**,** or forward to PHO Ethics Services once received**.**

Projects are required to undergo some form of scientific or methodological quality review prior to submission. The individual(s) conducting the review should have relevant methodological knowledge and experience and be separate from the project team. A project that has been funded by an external granting agency and has undergone a competitive review and approval process (*e.g. peer review committee*) will be considered to have had a sufficient form of scientific review, provided that the project being submitted to the ERB is within the scope of the originally funded proposal.

1. Has this project undergone a scientific or methodological quality review?

[ ]  No. Contact PHO Ethics Services at ethics@oahpp.ca for instructions.

[ ]  Yes. Reviewed by (choose):

[ ]  Funding agency

[ ]  Other. Describe: Enter description of other review.

1. Has this project undergone a privacy review?

[ ]  No. Explain why the project has not undergone a privacy review.

[ ]  Yes. A copy of the privacy review is attached.

1. Will there be any organizational or administrative approval or agreement from participating organizations or data collection sites (e.g., community groups, other agencies, school boards, local governments)?

[ ]  No.

[ ]  Yes. List the name of each organization or data collection site. Attach letters of
organizational or administrative support, approval or agreement (other than approval from another ethics review board) from each, or forward to PHO Ethics Services once received.

List the name of each organization or data collection site.

1. Will any aspect of the project be conducted outside of Ontario?

[ ]  No

[ ]  Yes. (Describe below)

Describe the aspect of the project that will be conducted outside of Ontario.

F. Funding

List [funding sources](#fundingsource" \o "That is, monetary funding not \"in kind\" support.) (i.e., monetary funding not “in-kind” support), amounts and indicate the funding status:

[ ]  Applied [ ]  Received Enter source of funding and amount.

[ ]  Applied [ ]  Received Enter source of funding and amount.

Funding not required, explain: Describe why funding is not required here.

G. Conflict of Interest

Project leads are responsible for disclosing to the ERB any actual, potential or perceived [**conflicts of interest**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=99)related to their project. This disclosure is critical as it allows for the consideration of such conflicts, thereby preventing them from potentially influencing a project team’s duties or responsibilities related to a project.

A conflict of interest is defined as an activity or situation that places a project team member or an institution affiliated with a project, in an actual, potential or perceived conflict between the duties or responsibilities related to the project and personal, institutional or other competing interests. Other competing interests include but are not limited to, business or financial interests pertaining to an institution and/or the individual, their family members, friends or professional associates.

[ ]  There are no conflicts of interests to disclose.

[ ]  There are actual, potential or perceived conflicts of interest related to this project.

Describe in detail, any actual, potential or perceived conflicts of interest related to this project, and explain how they will be managed:

Describe the conflict of interest and how it will be managed.

Project Details

H. Project Description (Please include references)

1. Background and Rationale - Describe briefly the reasons for undertaking the project, the current state of knowledge, and how the project will address gaps in knowledge and improvements in public health.

Enter the project description.

1. Purpose - State the project aim, or question to be addressed.

Enter the project aim or question.

1. Objectives - List the specific objectives related to the purpose above.

List the specific project objectives.

1. Project Design/Methods - Describe the project design and methods and how stated objectives will be met.

Describe the project design and methods and how the objectives will be met.

1. Data Analysis - Describe briefly the data analysis plan, and how analyses relate to the objectives.

Describe the data analysis plan.

I. Expertise

1. Describe briefly the expertise of the lead applicant and project team members in terms of their ability to carry out the proposed project effectively and safely.

Describe the expertise of the lead applicant and project team members.

1. Is additional training required for team members?

[ ]  No.

[ ]  Yes. Describe briefly any special training or qualifications the lead applicant or project team
members need and how it will be acquired (e.g., interview technique, privacy training).

Describe any special training or qualification needed and how they will be required.

J. Project Sample

1. Describe the project sample (e.g., [the population you are selecting to participate in the project](#popsample)). Specify inclusion and exclusion criteria. Indicate the sample size and how was it determined.

Describe the project sample.

1. How will you identify potential participants (individuals, groups or organizations) for inclusion in the project?

Describe how potential participants will be identified.

1. Is the source of information for participant selection publically available?

[ ]  Yes.

[ ]  No. Describe how this information will be accessed and by whom.

Describe how this information will be accessed and by whom.

K. Recruitment

1. Describe recruitment procedures, including how, when, where, and by whom participants will be recruited.

Describe recruitment procedures.

1. Will participants be reimbursed for expenses (e.g., paying for transportation to the project site), compensated for their time, or given an incentive for participation (e.g., gifts, money, gift cards)?

[ ]  No.

[ ]  Yes, reimbursed for expenses only. Describe what expenses will be covered.

Describe what expenses will be covered.

[ ]  Yes, compensated or given an incentive. Justify amount and nature of the compensation or incentive. Describe how the compensation or incentive will be disbursed and when.

Describe amount and nature of the incentive and the disbursement plan.

L. Consent

1. Will consent (and **[assent](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf%22%20%5Cl%20%22page%3D53)** if applicable) be obtained from individual participants, or their parent(s)/guardian(s)/[**authorized third party decision maker**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=35)**(s)** as appropriate?

[ ]  No. Explain how your request to waive consent meets TCPS 2 requirements (i.e., [**Articles 3.7 to 3.11**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=45) and [**5.5A of the TCPS2**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=73))? For assistance, contact PHO Ethics Services at ethics@oahpp.ca.

 Explain how your request to waive consent meets the TCPS 2 requirements

**If no, proceed to section 7 Community Engagement**

[ ]  Yes. Describe the process for obtaining consent or assent, including:

* 1. How, when, where, and by whom consent (and assent, if applicable) will be obtained.

Describe the process for obtaining consent from participants.

* 1. How the participant’s or parent’s/guardian’s/[authorized third party’s](#substitutedecisionmaker) **[capacity to consent](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf%22%20%5Cl%20%22page%3D52)** will be assessed.

Describe the process for assessing capacity.

1. Are you or any of your project team members in any way [in a position of authority or influence](#authorityinfluence) over the potential participants you wish to recruit (i.e., relationships in which there is a power imbalance, such as employer and employees, doctors and patients, teachers and students).

[ ]  No.

* 1. [ ]  Yes. Describe:
	2. The nature of the relationship.

Describe the nature of the relationship.

* 1. The safeguards or steps which will be taken to protect autonomy in decision making for those potential participants where there is a power difference.

Describe the steps taken to protect autonomy in decision making

1. Does the project involve participants who may require accommodations (translation, verbal explanation, ensuring appropriate literacy level, etc.) to support the consent/assent process?

[ ]  No.

[ ]  Yes. Describe the accommodations.

Describe accommodations.

1. Will there be any [**deception of participants or partial disclosure**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=46) during the consent/assent process?

[ ]  No.

[ ]  Yes. Answer the following.

* 1. Justify why deception or partial disclosure is necessary.

Describe why deception or partial disclosure is necessary.

* 1. If deception or partial disclosure will be used, describe the process for **[debriefing](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf%22%20%5Cl%20%22page%3D48)**.

 Describe the process for debriefing.

* 1. Participants should be able to consent to or refuse the continued use of their data or biological materials at the time of debriefing. If this will not be possible, please justify.

Describe justification for not allowing withdrawal of participant data or biological materials at the time of debriefing.

1. Do you plan to use participants’ information in another project
(e.g., use data for future projects, data sharing)?

[ ]  No.

[ ]  Yes. Notice of this possibility or consent for this future use is included in the consent form.

1. Do you anticipate re-contacting participants to take part in future studies?

[ ]  No.

[ ]  Yes. This information is included in the consent form.

1. Describe the procedures for withdrawal of consent.

Describe the procedures for withdrawal of consent.

1. Are there any limitations on participants’ right to withdraw?

[ ]  No.

[ ]  Yes. Provide justification and describe these limitations (include if applicable, the time beyond which participants cannot withdraw their data).

Provide justification for the limitations on a participants’ right to withdraw.

M. Community Engagement

Will there be any engagement with participating communities (including obtaining approvals and consent if appropriate)? [**See TCPS 2, chapter 9 for best practices regarding community engagement)**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=115)

[ ]  Not applicable. Provide justification:

Justify why engagement is not applicable.

[ ]  No. Provide justification:

Justify why engagement is not possible.

[ ]  Yes. Please describe:

Describe the engagement plan with participating communities.

N. Benefits, Burdens and Risks

1. Describe any potential benefits for the participants and others (consider individuals, communities and populations).

Enter description of potential benefits.

1. Describe the anticipated [**burdens**](#burdens) to participants resulting from taking part in the project
(e.g., time, inconvenience, frequency of participating in interviews)?

Enter description of anticipated burdens to participants.

1. Describe the foreseeable [**risks**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=29) **(i.e. potential harms)** to**[participants](#privacyriskstoparticipants" \o "Particularly consider risks to participant privacy during data collection)** (individuals or groups)? Examples of risks include anything that has a negative effect on welfare, including social, behavioral, psychological, legal, professional, and economic (e.g. loss of property value) [x]  consequences.
	1. Describe these foreseeable risks.

Describe the foreseeable risks to participants.

* 1. How will these risks be mitigated? Where possible, projects should be designed to avoid risks (e.g. gathering only the information necessary to address the objectives). Where potential risks are unavoidable, plans should be made to reduce the impact if possible.

Describe how risks will be mitigated.

1. Is it anticipated that some participants might be particularly vulnerable to project-related harms including physical, psychological or social harms? (Refer to the [Framework for the Ethical Conduct of Public Health Initiatives](http://www.publichealthontario.ca/en/eRepository/PHO%20%20Framework%20for%20Ethical%20Conduct%20of%20Public%20Health%20Initiatives%20April%202012.pdf) for details)

[ ]  No.

[ ]  Yes. Please specify.

Describe vulnerable participants.

Describe how risks will be mitigated.

1. Will the project include reporting or disclosure of anticipated results about an individual to the individual, health care providers, or other organizations (e.g., Public Health Units)? Examples include lab tests, cognitive tests, etc., that may have health or psychological implications for the participant.

[ ]  No.

[ ]  Yes. Ensure notice of this possibility is included in the consent form.

* 1. How will the disclosure(s) be handled?

Describe how the disclosure of results to the individual will be handled.

* 1. What measures are in place to mitigate any foreseeable risks from this disclosure?

Describe the measures in place to mitigate risks from the disclosure.

1. Do you foresee **[incidental findings](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf%22%20%5Cl%20%22page%3D41%22%20%5Co%20%22This%20question%20relates%20to%20material%20incidental%20findings%20which%20have%20been%20interpreted%20as%20having%20significant%20welfare%20implications%20for%20the%20participant%2C%20whether%20health-related%2C%20psychological%20or%20social.%20%20E.g.%2C%20abuse%2C%20paternity%20issues)** [about a](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf%22%20%5Cl%20%22page%3D41%22%20%5Co%20%22This%20question%20relates%20to%20material%20incidental%20findings%20which%20have%20been%20interpreted%20as%20having%20significant%20welfare%20implications%20for%20the%20participant%2C%20whether%20health-related%2C%20psychological%20or%20social.%20%20E.g.%2C%20abuse%2C%20paternity%20issues)n identifiable individual that might be of interest to the individual (e.g., when conducting genetic analysis) or reported to the project team, health care providers, or other organizations (e.g., project team suspects a situation of abuse)?

[ ]  No.

[ ]  Yes. Ensure notice of this possibility is included in the consent form.

* 1. How will this disclosure be handled and what information will be reported?

Describe how incidental findings will be handled.

* 1. What measures will be in place to mitigate any risks from this disclosure?

Describe the measures in place to mitigate risks from the disclosure.

1. Are there any foreseeable [**risks**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=29) **(i.e. potential harms)** tomembers of the project team?

[ ]  No.

[ ]  Yes

* 1. Describe these foreseeable risks.

Describe the foreseeable risks to project team members

* 1. How will these risks be mitigated?

Describe how risks will be mitigated.

O. Dissemination of Results

1. What results will be shared, how and with whom (e.g., participants, community groups, academic venues, government departments)?

Enter description of how results will be shared and with whom.

If results will not be shared with participants, please explain/justify:

Justify why results will not be shared.

1. Are there any foreseeable [risks](http://www.ethics.gc.ca/pdf/eng/tcps2/TCPS_2_FINAL_Web.pdf#page=22)to communities or groups as a result of reporting and disseminating results, including health equity or potential longer-term social consequences (e.g., stigmatization of community)?

[ ]  No.

[ ]  Yes.

* 1. Describe these foreseeable risks.

Describe the foreseeable risks to communities.

* 1. How will these risks be mitigated?

Describe how foreseeable risks will be mitigated.

P. Privacy, Confidentiality and Security

1. Which of the following types of information will be collected and/or used:

[ ]  [Directly identifying information: information which identifies a specific individual through direct identifiers (e.g., name, social insurance number, personal health number or provincial health card, videotaped interactions, photos).](#directlyidentifying) Specify the identifiers and explain why each is necessary.

Enter direct identifiers and explain why each is necessary.

[ ]  [Indirectly identifying information](#indirectlyidentifying): information that can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g., date of birth, place of residence, unique personal characteristics). Specify the indirect identifiers and explain why each is necessary.

Enter indirect identifiers and explain why each is necessary.

1. Are there any limits to maintaining confidentiality (e.g., reportable diseases, harm to self or others)?

[ ]  No.

[ ]  Yes. Please specify.

Specify limits to maintaining confidentiality.

1. Linkage of Data - Will there be any linkage of data from different sources?

[ ]  No.

[ ]  Yes. Indicate whether there has been consent for this purpose, and explain why
linkage is necessary.

Enter explanation of why linkage of data is necessary.

1. Access to Data - What [limits to access will be placed](#limitstoaccess" \o "That is, who will and will not have access to the data?) on sharing and use of data or samples to preserve participant confidentiality (i.e. who will and who will not have access to the data)?

Enter the limits to access the data.

1. Security of Data - Describe the data **[security measures](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf%22%20%5Cl%20%22page%3D66)** (e.g., physical, procedural or administrative and technical safeguards, including [**anonymization**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf#page=67)) for the transportation, sharing and storage of data, samples, etc.

Enter a description about security measures for the data.

1. Retention of Records - [Describe how long project records and/or samples will be retained, and the plan for when and how these records will be destroyed](#retention" \o "Most PHO projects will fall under the retention schedule for Knowledge Product Files, which requires file retention for the current fiscal year plus seven years after date of project approval or abandonment).

Please describe how long project records and or samples will be retained or destroyed.

Request to Appoint the Public Health Ontario Ethics Review Board as Board of Record for the Project

This application is being completed pursuant to the terms and conditions of the Board of Record Services Agreement entered between the Ontario Agency for Health Protection and Promotion (Public Health Ontario) and

Click here to enter text. (Institution).

By submitting this application to Public Health Ontario, the Institution is requesting the Public Health Ontario Ethics Review Board to act as Board of Record (PHO ERB) for the Project entitled

Click here to enter the project name.

Lead Applicant:

1. I assume full responsibility for the scientific and ethical conduct of this Project as described in the accompanying application and documents.
2. I agree to have PHO ERB act as the Ethics Review Board of Record for the Project.
3. I agree to comply with all PHO ERB Determinations with respect to the Project, and to conduct the Project in accordance with the Agreement, Project Materials, [TCPS 2 (2018),](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf) PHO ERB policies, procedures and requirements, and all applicable laws.

Name: Enter first and last name.

Date: Click here to enter a date.

Signature: Please sign on the line below, scan and send this page with this application form
**OR** add a scanned signature image to the image field below.

Please sign here: .\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OR** Double click on the field below to select an image file.



Approval by the Institution to appoint PHO ERB as the
Board of Record for this Project:

Without limiting any obligations in the Agreement, by retaining PHO ERB, the Institution acknowledges and agrees to the following:

1. Institution agrees to comply with all PHO ERB Determinations with respect to the Project and shall, with respect to its own role, conduct the Project in accordance with the Project Materials, [TCPS 2 (2018)](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf), PHO ERB policies, procedures and requirements, and all applicable laws.
2. Institution supports submission of the Project described above for ethics review and considers it to be feasible, methodologically sound, and meeting other local requirements as determined by Institution.
3. As the Board of Record for this Project, PHO ERB may approve, reject, propose modifications to, or suspend or terminate approval of the Project at its sole discretion.
4. Institution shall notify the PHO ethics office immediately in writing if the Project has been placed on hold or terminated at the Institution.

Name and Title: Enter first and last name, and title

Date: Click here to enter a date

Signature: Please sign on the line below, scan and send this page with this application form
**OR** add a scanned signature image to the image field below.

Please sign here: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**OR** Double click on the field below to select an image file.



Contact Information

Contact us at: [ethics@oahpp.ca](file://OTO101PFILE01V.oahpp.ca/Kate.Curzon%24/PHO%20Graphic%20Design%20Files/Forms/ERB_forms/ethics%40oahpp.ca)

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