Ethics Review Board

Project Amendment Form

This form is to be used prior to making a substantive change to an approved project. Changes are considered substantive if they affect the scientific purpose/objectives, study design, or risk to participants or others impacted by the project. Approval of changes may require delegated or full-board ethics review depending on the nature of the substantive change (e.g., change in purpose or objectives) and/or the change in the level of risk (i.e., increase in risk). To determine the impact of changes on the project’s risk level, please complete the [Risk Screening Tool](https://www.publichealthontario.ca/en/about/research/ethics/ethics-services/risk-screening-tool). ERB approval is required prior to implementation of amendments, unless when it is necessary to eliminate an immediate risk(s) to the participants.

To submit a Project Amendment Form, complete and email the following documents to PHO Ethics Services at ethics@oahpp.ca:

* ERB Amendment Form
* ERB Project Application Form and related material (e.g., consent form) with tracked changes and revised version dates
* Risk Screening Tool

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 Please select date.

1. Project Information

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

Project title: Enter project title.

1. Lead Applicant

(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.

*Complete the following section if the information has changed since the original PHO ERB Project Application Form submission.*

Job title: Enter job title here.

Program area or department: Enter program area or department.

Public health unit or organization name: Enter organization name.

Mailing address: Enter mailing address.

Phone: Enter phone number.

Email: Enter email.

1. 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.

1. Other Ethics Board Approvals

Have or will you seek ethics approval for this amendment from another board?

[ ]  No

[ ]  Yes

If yes, please provide the name of the boards, indicate whether approval is complete or pending,
and forward approval letters to PHO Ethics Services as soon as they become available:

Enter names of other ethics review boards and indicate whether approval is complete or pending.

1. Proposed Changes
2. Please describe the proposed project amendment and the reason for the amendment. A copy of the revised protocol and ERB Application Form with the changes tracked should be submitted with this form.

Click here to enter proposed amendment.

1. Will the proposed amendment change the overall purpose or objective(s) of the project?

 [ ]  No

 [ ]  Yes. Briefly describe the change in overall purpose or objective(s):

 Describe the change in the overall purpose or objective(s)

1. Will the proposed amendment affect the risk associated with the project?

 [ ]  No

 [ ]  Yes (Complete the [Risk Screening Tool](https://www.publichealthontario.ca/en/about/research/ethics/ethics-services/risk-screening-tool) again and submit with this form)

[ ]  Unsure *(Contact* *ethics@oahpp.ca* *for support)*

1. What follow-up action do you recommend for project participants who are already enrolled in the project? (check all that apply)

 [ ]  No action required

 [ ]  Inform project participants. Please attach a copy of any letters, email messages or other
communications, and explain how and when participants will be informed:

 Enter details of how and when participants will be informed.

 [ ]  Revise consent and/or assent forms. Please attach a copy with the changes and explain
how and when consent will be renewed:

 Enter details of how and when consent will be renewed.

 [ ]  Other (please describe): Enter other details.

1. Signature

As the lead applicant of this project, I assume full responsibility for the scientific and ethical conduct of this activity as described in this form and accompanying documents. I agree to conduct this activity in compliance with the [**Tri-Council Policy Statement 2 (TCPS2 2018)**](http://www.pre.ethics.gc.ca/eng/documents/tcps2-2018-en-interactive-final.pdf), and other legislation as appropriate.

Name: Enter name here.

Date: Please select 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

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

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