Ethics Review Board

Ethics Review Board Unanticipated Issue
or Event Form

This form is to be used when reporting unanticipated issues or events involving participants or that may affect participants’ welfare. This includes unexpected negative consequences of participation (e.g. mental or physical health events), occurrences that might have implications for participants (e.g. confidentiality breach), or unexpected deviations from the approved protocol. Lead applicants are required to complete and sign the form in a timely manner.

To submit an Unanticipated Issue or Event Form, complete and email the following documents to PHO Ethics Services at ethics@oahpp.ca:

* ERB Unanticipated Issue or Event Form
* ERB Project Application Form and related material (e.g., consent form) with tracked changes and revised version dates

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](#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.

*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 Person 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. Description Of Issue Or Event

Date of occurrence: Enter date of occurance.

Location: Enter location.

Issue or event: Enter issue or event.

1. Response To Issue Or Event
2. What actions (if any) have already been taken by the project team or other stakeholders to address the issue or event?

Enter the actions taken by the project team or stakeholders to address the issue or event.

1. In light of the occurrence, are changes required to the **protocol**?

[ ]  Yes**.** Please enclose the revised protocol with a summary of changes.

[ ]  No. Please briefly explain why not:

Enter brief explanation of why changes to the protocol are not required.

1. In light of the occurrence, are changes required to the **Information and Consent Form**?

[ ]  Yes**.** Please enclose the revised consent form(s).

[ ]  No. Please briefly explain why not:

Enter brief explanation of why changes to the information and consent form are not required.

1. What additional actions (if any) will be taken in response to the current issue or event:

Enter additional actions that will be taken in response to the current issue or event.

1. What actions (if any) will be undertaken to prevent recurrence?

Enter any actions that will be undertaken to prevent recurrence.

1. Additional Documentation

Please list here any documents regarding the issue or event that you are appending to this form:

Enter a list of any documents regarding the issue or event.

1. Signatures

**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

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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