Adverse Event Report for Research Involving Humans
Health Canada-PHAC Research Ethics Board

Researchers must report any unanticipated issue or event that may increase the level of risk to participants, or that has other ethical implications that may affect participants' welfare, by completing the Adverse Event Report Form. The REB requires the reporting of any issue or event that meets **all** of the following criteria:

- **Unexpected:** Over the course of the implementation of the approved research project, issues may arise that the researcher did not anticipate when originally submitting the research for ethics review.
- **Related or possibly related to participation in the research:** Unanticipated issues include unexpected reactions by participants to a research intervention (e.g., unintended stimulation of traumatic memories, unforeseen side effects of a medication or natural health product), as well as unavoidable single incidents (e.g., a translator not available for a day, or a failure to follow correct research procedure for one participant on one occasion).
- **Places participants or others at a greater risk of harm:** Any unanticipated issue that increases the level of risk to participants (including social, behavioural, psychological, physical or economic harm) or has other ethical implications should be reported to the REB without delay.

Researchers are reminded to request the REB's approval for any changes to the research protocol or consent forms as a result of the unanticipated adverse event(s) using the Amendment Request Form. Changes that are necessary to eliminate an immediate risk(s) to the participants may be implemented as needed, but must be reported to the REB at the earliest opportunity.

Instructions for completing this form

General information

All sections of the application form should be completed. If a section does not apply, select "No" or "N/A", or enter "N/A" in the text box, as appropriate.

If the allotted space in any section is insufficient, extra pages can be submitted with the application as a separate document. Make a note in the relevant text box that the entry is continued on an additional

page. Indicate on the additional page which section of the application is being continued, and include the name of the principal investigator and the project title in the header.

Section 1.4: Health Canada/PHAC contact person

For projects where the principal investigator is external to HC/PHAC, the contact person is typically the HC/PHAC project authority, project officer, funding officer, research coordinator, or another relevant HC/PHAC employee associated with the project. This section may also be used when the principal investigator is from HC/PHAC, to designate another contact person in addition to the principal investigator. If there is no contact person to name, enter "N/A" in the 'name' field.

Section 3: Signatures

Digital signatures are accepted and encouraged. If any signatures are not obtained electronically, print the Signatures section of the form and obtain all necessary signatures in hard copy. Once the Signatures section is complete, scan the signed pages and include them with the submission, along with an electronic copy of the completed form in PDF format and all other supporting documents as required.

Health Canada / PHAC departmental approval: Sign-off is required from the principal investigator's supervisor (manager-level or above) with Section 34 authority. If the principal investigator is external to Health Canada or PHAC, the HC/PHAC contact person should sign. The signature should normally be obtained prior to submitting the form to the REB. If the authorized individual is not available to sign the form at the time of submission, contact the REB Secretariat to determine if an exception can be made.

Additional information

For questions that are not addressed in these instructions, contact the REB Secretariat at reb-cer@hc-sc.gc.ca or 613-941-5199.

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Section 1: General Information

1.1 Protocol number:

1.2 Project title:

1.3 Principal investigator:

Name:	
Job title:	
Place of work:	
Address:	
Telephone:	
E-mail:	

1.4 Health Canada / PHAC contact person (if applicable):

Name:	
Job title:	
Branch:	
Department/Agency:	
Address:	
Telephone:	
E-mail:	

Section 2: Event Details

2.1 Date of the event:

Specify when the event occurred and when the study team became aware of the event:

2.2 Nature of the event:

(a) Was the event caused or exacerbated by study procedures and/or interventions?

◯ Yes ◯ No ◯ Uncertain

(b) Did the event increase the level of risk to participants or others?

◯ Yes ◯ No

2.3 Description of the event and immediate response:

Summarize the event and describe the immediate actions that were taken in response to the event:

2.4 Proposed corrective measures:

Indicate what actions will be taken to reduce the likelihood of the event happening again (select all that apply from the list below and provide additional details in the text box that follows):

- ☐ Changes to the research protocol – complete and submit an Amendment Request Form
- ☐ Modification of consent/assent form(s) – complete and submit an Amendment Request Form
- ☐ Suspension of enrolment of new participants
- ☐ Temporary study suspension
- ☐ Study termination – complete and submit a Completion/Termination Report Form
- ☐ No corrective measures are proposed
- ☐ Other

2.5 Other actions:

(a) Has the event been reported to another REB?

◯ Yes – indicate which REB(s) and when they were notified of the event:

◯ No

(b) If the event involved a privacy breach, has the Privacy Management Division (PMD) been contacted?

◯ Yes – attach the outcome of PMD's investigation and/or the Privacy Occurrence Report, if available

◯ No

(c) Will participants be notified of the event?

◯ Yes – attach a copy of the communications directed to participants

◯ No

Section 3: Signatures

3.1 Health Canada / PHAC departmental approval:

All adverse event reports must be approved by the principal investigator's supervisor (manager-level or above) with Section 34 authority. If the principal investigator is external to Health Canada or PHAC, this section should be completed by the Health Canada/PHAC contact person.

Name:

Position:

Branch:

Department/Agency:

By signing this form, I attest that I have reviewed this form and recommend its submission to the Health Canada-PHAC REB.

Signature: _____ Date:

3.2 Attestation of principal investigator:

I certify that all the information provided herein is accurate and complete, and that I will inform the Research Ethics Board Secretariat immediately if any changes are made to the research protocol or if any errors are discovered in this adverse event report.

Principal investigator:

Signature: _____ Date:

Privacy notice: The personal information provided in this form is handled in accordance with the *Privacy Act*. We only collect the information we need to process your adverse event report as authorized under section 4 of the *Department of Health Act.* In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correction of your personal information. For more information about these rights, or about our privacy practices, please contact the Health Canada and Public Health Agency of Canada Privacy Management Division at 613-954-9165 or privacy-vie.privee@hc-sc.gc.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Submit an electronic copy of the completed form and all supporting documents to:
Health Canada-PHAC Research Ethics Board Secretariat

reb-cer@hc-sc.gc.ca

If any signatures are not obtained electronically, include a scanned copy of Section 3 (Signatures) with the necessary signatures when submitting the form.