Protected A When Completed

Completion/Termination Report for Research Involving Humans Health Canada-PHAC Research Ethics Board

Upon completion or termination of the research, the researcher must submit a Completion/Termination Report. Study completion is defined in TCPS 2 as the last contact with the last participant for the purposes of collecting data or human biological materials, or for the purposes of follow-up monitoring, and/or the point at which final data analysis is complete. If a study is in the final phases of data analysis and manuscript or report preparation, it may be closed as long as there will be no further contact or follow-up with participants, no additional data incorporated into the analyses, and no modifications to the REB-approved research protocol. If there is uncertainty as to whether a study can be closed, contact the REB Secretariat.

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 4: 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.

Health Canada and the Public Health Agency of Canada | Santé Canada et l'Agence de la santé publique du Canada

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Health Canada-PHAC Research Ethics Board

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: Project Information

2.1 Study closure details:

(a) Why is the study being closed?

- ◯ Study has been completed
- ◯ Study has been terminated – please explain and specify if participants were informed:

(b) Study completion/termination date:

2.2 Adverse event reporting:

Were all adverse events experienced by participants reported to the REB?

- ◯ Yes
- ◯ No – please complete and submit an Adverse Event Report Form to the REB Secretariat
- ◯ N/A

Section 3: Study Outcomes and Outputs

3.1 Research findings:

Describe the research outcomes and identify whether the original study objectives were met:

Continued on the next page…

Research findings continued…

3.2 Publication and dissemination of research findings:

If any articles, reports, presentations, etc. have resulted from this study, provide the references in the text box below or submit a copy with this report. If results have not been shared publicly or are in the process of being published, please explain:

3.3 Community engagement:

If the study involved collaborative or participatory research with communities, were the community representatives given the opportunity to participate in the interpretation of the data and the review of research findings?

◯ Yes ◯ No ◯ N/A

If yes, explain how; if no, explain why not:

3.4 Feedback to participants:

Were the research findings shared with the study participants?

◯ Yes ◯ No ◯ N/A

If yes, explain how; if no, explain why not:

3.5 Retention, storage and destruction of data/samples:

Describe how long any data or samples will be retained for following study closure, how the data or samples will be stored in a secure/confidential manner, and how they will be disposed of:

Section 4: Signatures

4.1 Health Canada / PHAC departmental approval:

All completion/termination 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 report and recommend its submission to the Health Canada-PHAC REB.

Signature: _____ Date:

4.2 Attestation of principal investigator:

I certify that all the information provided herein is accurate and complete, and that no study participants have been recruited, tested or followed since the date of study closure indicated above.

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 completion/termination 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 4 (Signatures) with the necessary signatures when submitting the form.