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

Annual Progress Report for Research Involving Humans
Health Canada-PHAC Research Ethics Board

If research is ongoing, it is the responsibility of the researcher to seek REB review prior to the expiry of the ethics certificate. The REB ethics approvals are valid for a maximum of one (1) year. The research must be reviewed at least annually by the REB and until it is completed (see the instructions for the Completion/Termination Report Form for more information regarding when a research project can be considered completed). Researchers should submit an Annual Progress Report Form approximately two months prior to the certificate expiry date.

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 PI 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 PI is from HC/PHAC, to designate another contact person in addition to the PI. If there is no contact person to name, enter "N/A" in the 'name' field.

Section 2.1: Plain language summary

If the project direction has not changed since the initial submission, the plain language summary that was originally provided in the Application for Initial Review of Research Involving Humans can be copied and pasted here. Otherwise please include a revised summary that more accurately reflects the current direction of the project.

Section 2.4: Study progress

If any articles, reports, presentations, etc. have been submitted, presented or published during the period covered by this report, provide the references in the text box or attach a copy to the report.

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 PI's supervisor (generally director-level or above). If the PI is external to Health Canada or PHAC, the manager of the HC/PHAC contact person should sign. The signature should normally be obtained prior to submitting the form to the REB. If obtaining this level of approval is not feasible, or 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, please contact the REB Secretariat at hc.reb-cer.sc@canada.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:	
Title:	
Place of work:	
Address:	
Telephone:	
E-mail:	

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

Name:	
Title:	
Branch:	
Department/Agency:	
Address:	
Telephone:	
E-mail:	

Section 2: Study Details

2.1 Plain language summary:

Provide a plain language summary of your research proposal (in 300 words or less):

2.2 Study dates:

(a) Date of original REB approval:

(b) When did the study begin?

(c) Anticipated completion date:

2.3 Study phase (select all that apply):

- ☐ Inactive / on hold / not started
- ☐ Active enrolment of participants
- ☐ Ongoing research and analysis
- ☐ Pilot study / initial scoping
- ☐ Final data analysis and manuscript/report preparation

2.4 Study progress:

(a) Provide a brief summary of the study progress and results achieved since the last REB review:

(b) Have there been any challenges or delays in carrying out this project?

◯ Yes – please explain:

◯ No

2.5 Participant recruitment and sample or data analysis:

(a) **If the study involves recruitment of human participants:**

- Number of participants enrolled to date:
- Number of additional participants required:
- Number of participants who have withdrawn:
- Number of participants who have completed the study and with whom no further contact for study purposes is planned:

(b) **If the study involves sample analysis (e.g., human biological materials, air or water samples):**

- Number of samples received to date:
- Number of samples analyzed to date:
- Number of additional samples to come:

(c) **If the study involves secondary use of data:** have all required datasets been received?

◯ Yes ◯ No

(d) Please explain any change to the recruitment target or total number of samples to be analyzed since the last annual progress report. In addition, if you wish to elaborate on any of the answers provided above, please use the space below:

Section 3: Administrative Information

3.1 Funding status:

◯ Funded – funding end date (if applicable):

◯ Unfunded

If the project funding has changed since the last REB review, please explain:

3.2 Amendments:

Have all modifications to the research (including changes to the research methods, recruitment material, consent documents, study instruments, research team, etc.) been submitted to the REB for approval?

- ◯ Yes
- ◯ No – complete and submit an Amendment Request Form to the REB Secretariat
- ◯ N/A (no modifications have been made to the study)

3.3 Adverse events:

Have all adverse events experienced by participants been reported to the REB?

- ◯ Yes
- ◯ No – complete and submit an Adverse Event Report Form to the REB Secretariat
- ◯ N/A (no adverse events have occurred)

3.4 Privacy and confidentiality:

Has there been a change in persons with access to study data, the location of stored data, security arrangements, or the duration of the data conservation period?

- ◯ Yes – please explain:

- ◯ No
- ◯ N/A

3.5 Conflicts:

Does the PI or any member of the study team have a new (i.e., previously undeclared) real, apparent or potential conflict of interest?

◯ Yes – disclose any conflicts and include a description of the proposed approach for managing those conflicts:

◯ No

Section 4: Signatures

4.1 Health Canada / PHAC departmental approval:

All annual progress reports must be approved by the Principal Investigator's supervisor (Director-level or above). If the Principal Investigator is external to Health Canada or PHAC, this section should be completed by the manager of 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 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 annual progress 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 annual progress report and is 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 the Public Health Agency of Canada's Privacy Management Division at 613-954-9165 or hc.privacy-vie.privee.sc@canada.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

hc.reb-cer.sc@canada.ca

If any signatures are not obtained electronically, include a scanned copy of Section 4 (Signatures) with the necessary signatures when submitting your form.

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