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Amendment Request for Research Involving Humans
Health Canada-PHAC Research Ethics Board

If a researcher wishes to make any changes to their REB-approved research, they must notify the REB by submitting an Amendment Request Form. Researchers may only implement changes to their study protocols once the amendment has been reviewed by the REB and a Certificate of Ethics Review has been provided. If the change is necessary to eliminate an immediate hazard to a participant, the change can be implemented prior to REB review; however, the REB must be immediately notified and the modification submitted for consideration immediately thereafter (see the instructions for the Adverse Event Report Form for more information regarding changes to research protocols in response to unanticipated issues).

Depending on the extent of the modifications, the request may require review by the full REB at a monthly REB meeting rather than at a weekly delegated review meeting. If the changes are time-sensitive, please inform the REB Secretariat to determine whether the review can be expedited.

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 2.1: Proposed changes

If the request is to change the principal investigator (PI) of the project, a signed statement from the original PI stating that they approve of the change of PI must be included with the form. If for some

reason it is not possible to obtain a statement from the original PI, provide an explanation in place of the PI's declaration. Requests to change the PI will not be accepted without the original PI's approval or an adequate explanation for the absence of approval.

If new individuals are being added to the core study team, a copy of their current CV must be included. A relatively short CV (approx. 10 pages or fewer) describing only the most relevant contributions and experience is sufficient (e.g., following the format of the CIHR Biosketch or the NIH Biosketch). It is not necessary to provide an exhaustive record of each researcher's professional and academic background.

If the amendment request involves changes to the previously-approved research protocol or consent/ assent forms, include revised versions of these documents with the changes clearly indicated by using track changes, highlighting, comments, etc. Similarly, any new documents associated with the amendment request (e.g., recruitment materials, surveys, communications) must be submitted with the form.

Section 2.3: Scientific peer review

Scientific peer review is only required for major modifications to the research protocol. If there is uncertainly about the need for peer reviews, contact the REB Secretariat before submitting the amendment request. More information about the requirements for independent scientific peer review can be found in the instructions for the application form for initial ethics review (section 2.8).

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.

Canada

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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: Amendment Details

2.1 Proposed change(s) (select all that apply):

- ☐ Study team
- ☐ Consent process
- ☐ Research site(s)
- ☐ Study population
- ☐ Research protocol
- ☐ Other
- ☐ Recruitment process
- ☐ Data collection materials (e.g., surveys, interview guides)

2.2 Description:

Describe the proposed study amendment or modification and rationale for the change(s):

2.3 Scientific peer review:

Have the changes undergone scientific peer review?

- ◯ Yes – attach a copy of the peer review(s) and a document that outlines your response to the peer reviewers' comments
- ◯ No

2.4 Participant risk and communication:

(a) Could the proposed changes increase the level of risk to participants and/or potentially influence participants' willingness to continue in the study?

◯ Yes – please explain:

◯ No

(b) How will the proposed changes be communicated to study participants (select all that apply)?

☐ Inform study participants through a letter, email, verbal communication, etc.

☐ Revise consent/assent forms and:

- ☐ Seek consent from remaining participants using the revised forms
- ☐ Seek a new consent from already-enrolled participants using the revised forms

☐ No action is required

☐ Other – please describe:

Section 3: Signatures

3.1 Health Canada / PHAC departmental approval:

All amendment requests 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 approve of the proposed changes. I 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 additional changes are made to the research protocol or if any errors are discovered in this amendment request.

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 amendment request 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.

Section 4: Attachments

Specify the attachments that have been included with your amendment request. If any additions or revisions have been made to previously submitted documents, clearly indicate the changes using track changes, highlighting, comments, etc.:

- ☐ Research protocol
- ☐ Data collection materials (e.g., questionnaires, surveys)
- ☐ Recruitment materials
- ☐ Consent/assent form(s)
- ☐ Communications with participants (e.g., notifications, letters)
- ☐ CVs of other investigators/team members
- ☐ Peer reviews
- ☐ Response to peer reviews
- ☐ Other:

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.