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

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Application for Initial Review of Research Involving Humans
Health Canada-PHAC Research Ethics Board

Completing the Form

Detailed instructions for completing this form are available on the REB website. Incomplete applications will not be accepted for REB review; thus, applicants are strongly advised to follow these instructions carefully to ensure that their application packages are complete and accurate. For questions that are not addressed in these instructions, please contact the REB Secretariat at reb-cer@hc-sc.gc.ca or 613-941-5199.

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: General Information

1.1 Project title:

1.2 Principal investigator:

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

Canada

1.3 Other investigators and team members:

Name (1):		**Name (2):**	
Role:	Choose from list	**Role:**	Choose from list
Job title:		**Job title:**	
Place of work:		**Place of work:**	
E-mail:		**E-mail:**	

Name (3):		**Name (4):**	
Role:	Choose from list	**Role:**	Choose from list
Job title:		**Job title:**	
Place of work:		**Place of work:**	
E-mail:		**E-mail:**	

Name (5):		**Name (6):**	
Role:	Choose from list	**Role:**	Choose from list
Job title:		**Job title:**	
Place of work:		**Place of work:**	
E-mail:		**E-mail:**	

Name (7):		**Name (8):**	
Role:	Choose from list	**Role:**	Choose from list
Job title:		**Job title:**	
Place of work:		**Place of work:**	
E-mail:		**E-mail:**	

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

If the principal investigator is external to Health Canada or PHAC, or if you wish to designate another contact person in addition to the Health Canada/PHAC principal investigator, provide the name and contact details of the Health Canada / PHAC contact person:

Name:

Title:

Branch:

Department/Agency:

Address:

Telephone:

E-mail:

1.5 Role of Health Canada / PHAC in the project (select all that apply):

☐ Principal investigator

☐ Co-investigator / collaborator

☐ Funder (i.e., through a contract or grant/contribution to an external researcher)

Briefly explain the role of Health Canada / PHAC in the project:

1.6 Proposed study period:

Start date:

End date:

1.7 Other REB approval:

(a) Has this study been (or will this study be) submitted to another REB?

- ○ Yes
- ○ No

(b) If yes, provide the following information about all other completed and/or pending REB reviews:

Name of external REB	Date of review / decision	Outcome of REB review	Decision letter attached
		Choose an item.	☐
		Choose an item.	☐
		Choose an item.	☐
		Choose an item.	☐

1.8 Additional approvals:

(a) Are any other approvals or authorizations required to conduct the study (e.g., data/biobank access committees, Indigenous research offices, employers, school boards, Health Canada's Therapeutic Products Directorate, biosafety and animal care committees, etc.)?

- ○ Yes
- ○ No

(b) If yes, indicate the additional approval(s) required:

(c) Copy of additional approval letter(s) attached:

- ○ Yes
- ○ No
- ○ N/A

1.9 Funding information:

(a) Has funding been secured for this project?

- ○ Yes
- ○ No

(b) If yes, indicate the funding source (check all that apply) and provide details in the text box below (including name of funding organization, grant number, amount and duration of funding):

- ☐ Health Canada/PHAC internal funding
- ☐ Contract from Health Canada/PHAC
- ☐ Grant or contribution agreement from Health Canada/PHAC
- ☐ Granting agency (federal/provincial/charitable etc.)
- ☐ Industry/private sector
- ☐ Other

Funding details:

(c) If no, indicate reason:

- ○ No funding required
- ○ In process of obtaining funding – please elaborate:

(d) Study budget sheet enclosed:

- ○ Yes
- ○ No

Section 2: Proposed Research

2.1 Plain language summary:

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

2.2 Key words:

Provide up to five key words that describe your research:

1)
2)
3)
4)
5)

2.3 Detailed research protocol:

Attach a detailed research protocol to your application. Refer to the research protocol instructions on the REB website for details on elements to address in the protocol.

2.4 How does the research involve human participants (select all that apply):

☐ Use of human tissue and/or biological specimens (e.g., blood, urine, etc.) – source:

- ☐ Fetal tissues
- ☐ Human cell lines
- ☐ Biobank or previously-collected materials
- ☐ Living individuals
- ☐ Deceased individuals

☐ Use of information or data from individuals – source:

- ☐ Focus groups / interviews
- ☐ Questionnaires / surveys
- ☐ Previously-collected personal information or administrative data (e.g., health, census, etc.)
- ☐ Other – please specify:
- ☐ Ethnographic or observational study
- ☐ Physical measures

2.5 Study population (select only those groups specifically recruited or targeted for the study):

- ☐ Females
- ☐ Newborns / infants
- ☐ Pregnant women
- ☐ Indigenous Peoples
- ☐ Sexual and gender minorities
- ☐ Market research panel
- ☐ Other – please specify:
- ☐ Males
- ☐ Children / minors
- ☐ Students
- ☐ Specific population (ethnic) groups
- ☐ Health Canada/PHAC employees
- ☐ Adults with diminished decision-making capacity

2.6 Collection of samples, data or personal information (select all that apply):

- ☐ Collection will begin after Health Canada-PHAC REB approval has been granted
- ☐ Primary collection for this study has been completed or is in progress under the authority of an external REB
- ☐ Study involves secondary use of samples/data/personal information collected previously for another purpose

2.7 Study attributes (select all that apply):

- ☐ Creation of a biobank
- ☐ Clinical trial
- ☐ Human genetic research
- ☐ Biomonitoring
- ☐ Student research project
- ☐ Surveillance
- ☐ Pilot study
- ☐ None of the above

2.8 Independent scientific peer review:

(a) Have you included two independent scientific peer reviews?

- ○ Yes
- ○ No

(b) If yes:

- ○ Attach a document that outlines your response to the peer reviewers' comments and includes a description of the revisions made to the project as a result of the reviews.

  OR:

- ○ No response to the reviews are attached as no changes were made to the project as a result of the reviews.

(c) If no independent peer reviews are included, please explain:

Section 3: Recruitment and Consent Process

3.1 Compensation and incentives:

Will participants receive any compensation (e.g., reimbursement of parking or travel expenses, etc.) or incentives (e.g., meals, gift card, cash, etc.) for participating in the research?

- ○ Yes – please specify:

- ○ No
- ○ N/A

3.2 Obtaining consent and assent:

Will you be seeking informed consent or assent from participants?

- ○ Yes – attach a copy of the consent/assent form(s)
- ○ No – please explain:

Section 4: Privacy and Confidentiality

4.1 Privacy Management Division (PMD) review:

(a) Has the Health Canada-PHAC Privacy Management Division (PMD) completed a preliminary privacy risk assessment for this study?

- ○ Yes – attach PMD's assessment and your response to any recommendations
- ○ No, assessment by PMD is in progress
- ○ No, do not intend to complete a preliminary privacy risk assessment – please explain:

(b) If PMD completed a privacy risk assessment, were you also required to complete a PMD privacy protocol checklist?

- ○ Yes, completed – attach PMD's recommendations, as well as a response indicating how you will implement the recommendations
- ○ Yes, in progress
- ○ No, not required
- ○ N/A (privacy risk assessment not completed)

Section 5: Third Party Involvement

5.1 Third party implications:

Does your research involve any parties external to Health Canada or PHAC not named in Section 1?

- ○ Yes – please specify:

- ○ No

5.2 Contracts and agreements:

Are there any contracts or research agreements (including data sharing agreements and funding agreements) related to this study?

- ○ Yes – if completed, list the agreements and attach a signed copy; if in development, provide details on status and expected completion date, and attach a draft copy if available:

- ○ No / not applicable

Section 6: Conflicts of Interest

6.1 Declaration of conflicts:

It is the responsibility of the principal investigator to determine if any members of the research team have a real, apparent or potential conflict of interest relating to this project. All conflicts (whether real, apparent or potential) must be disclosed, with a description of the proposed approach for managing those conflicts.

- ○ There are no real, apparent or potential conflicts of interest to disclose.
- ○ One or more team members has a real, apparent or potential conflict of interest.

If there is a real, apparent or potential conflict of interest, describe the conflict(s) and how it/they will be managed:

Section 7: Signatures

7.1 Health Canada / PHAC departmental approval:

(a) For PHAC projects: A completed and signed Departmental Approval of Research Involving Humans form must be attached for your application to be accepted. No additional signature is required in this section.

(b) For Health Canada projects: All applications to the REB 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, this section should be completed by the Health Canada contact person.

Name:

Position:

Branch:

Department/Agency:

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

Signature: Date:

7.2 Attestation of principal investigator and other investigators / team members:

For 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 application.

For principal investigator and all other investigators/team members: By signing this application, I agree to conduct this project in accordance with the ethical principles set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*, as well as all relevant departmental, national and international policies, and applicable legislation (e.g., *Privacy Act*) and regulations that govern research involving human participants. I also understand that the principal investigator must obtain a certificate of ethics review and the approval of the Health Canada/PHAC Decisional Authority before any activities associated with this proposal can begin, including recruitment of participants, data collection, and/or accessing collections of data or human biological material.

Principal Investigator:

Signature: Date:

Other Investigator/Team Member #1:

Signature: Date:

Other Investigator/Team Member #2:

Signature: Date:

Other Investigator/Team Member #3:

Signature: Date:

Other Investigator/Team Member #4:

Signature: Date:

Other Investigator/Team Member #5:

Signature: Date:

Other Investigator/Team Member #6:

Signature: Date:

Other Investigator/Team Member #7:

Signature: Date:

Other Investigator/Team Member #8:

Signature: Date:

Privacy notice: The personal information provided in the application is handled in accordance with the *Privacy Act*. We only collect the information we need to process your Research Ethics Board application 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 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 8: Attachments

Please indicate the attachments that have been included with your application:

- ☐ [Section 1.2] CV of principal investigator
- ☐ [Section 1.3] CVs of other investigators/team members
- ☐ [Section 1.7] Other REB decision letter(s)
- ☐ [Section 1.8] Additional approval letter(s)
- ☐ [Section 1.9] Study budget sheet
- ☐ [Section 2.3] Research protocol
- ☐ [Section 2.8] Scientific peer reviews
- ☐ [Section 2.8] Response to peer reviews
- ☐ [Section 3.2] Consent/assent form(s)
- ☐ [Section 4.1] PMD privacy risk assessment
- ☐ [Section 4.1] PMD privacy protocol checklist
- ☐ [Section 4.1] Response to PMD privacy recommendations
- ☐ [Section 5.2] Contract(s), research agreement(s) and data-sharing agreement(s)
- ☐ [Section 7.1] PHAC Departmental Approval form
- ☐ Other:

Submit an electronic copy of the completed application 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 7 (Signatures) with the necessary signatures when submitting your application.