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Scientific Peer Review of Research Involving Humans

To be ethically acceptable, research involving humans must be methodologically sound and meet the scholarly standards of the relevant research discipline. The REB relies on independent scientific peer review to support its assessment of the methodological rigour and validity of the proposed research. Applicants are encouraged to use this template when soliciting reviews of their research protocol. If the research has already undergone independent scientific review not using this template, these reviews may be sufficient for the REB's purposes if they address all the evaluation criteria in the template.

Instructions for completing this form

General information

Reviewers should assess the proposed research against each of the criteria in Sections 2 through 6 and provide their comments in the text boxes. If the allotted space in any section is insufficient, extra pages can be submitted with the review 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 review is being continued, and include the name of the principal investigator and the project title in the header.

Criteria for being a peer reviewer

Peer reviews must be independent and free of potential bias. Thus, reviewers should not be directly associated with the research project team and should have no real, potential or perceived conflicts of interest concerning the research. Guidance on what constitutes a conflict of interest in peer review can be found in the Conflict of Interest and Confidentiality Policy of the Federal Research Funding Organizations and the CIHR Peer Review Manual. Reviewers should also be highly knowledgeable and experienced in the relevant field, and sufficiently qualified to provide an expert assessment of the scientific merit and quality of the proposed research.

Research involving Indigenous populations

For research involving Indigenous populations, reviewers should consider the following points in addition to those listed in the form:

- Is the proposed research relevant to First Nations, Inuit and/or Métis priorities and does it have the potential to produce valued outcomes from the perspective of First Nations, Inuit and/or Métis participants and Indigenous Peoples more broadly?
- In addition to demonstrating scientific excellence (Western, Indigenous, or both), do the proposed research approaches and methods respect Indigenous values and ways of knowing

and sharing? Does the proposed research abide by the Tri-Council Policy Statement, Chapter 9: Research Involving the First Nations, Inuit and Métis Peoples of Canada, and/or Indigenous partnering community/organizational ethical guidelines, or clearly explain why other guidelines have been developed and agreed upon with the study governance body?

- Consider the appropriateness of the team based on their overall scientific experience (Western, Indigenous, or both) and skills as well as their Indigenous community-based research experience, track record, relevance of past experience, including expertise related to Indigenous health research. Is there evidence of collaboration with Indigenous researchers or community?

Clinical trials

A clinical trial is any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes. Some clinical trials may involve the risk of serious harm or death and may involve large numbers of participants whose circumstances may make them vulnerable in the context of research. Thus, reviewers should pay particular attention to the trial design (e.g., sample size, power calculations) and management (e.g., need for a data and safety monitoring board) when evaluating the proposal. Please consult the CIHR RCT Evaluation Criteria for additional guidance.

Sex and gender

The Government of Canada is committed to using Gender-Based Analysis Plus (GBA+) to develop effective policies and programs. GBA+ is an analytical tool used to assess the potential impacts of policies, programs, services and other initiatives on diverse groups of people, taking into account sex, gender and other intersecting identity factors (such as age, culture, language, education, sexual orientation, ability and faith). From an ethical perspective, GBA+ aligns with the core principle of justice – the obligation to treat people fairly and equitably. Where relevant, reviewers should evaluate whether and how the researchers have considered sex and gender in their research design, methodology and analysis.

Official languages

Health Canada and PHAC have obligations and responsibilities under the *Official Languages Act* and to Official Language Minority Communities (OLMCs). These include ensuring respect for English and French; ensuring equality of status and equal rights and privileges as to the use of both languages in federal institutions; supporting the development of English and French linguistic minority communities; and advancing the equal status and use of English and French. Where relevant, reviewers should evaluate whether appropriate consideration is given to the use of French and English, and to the engagement of individuals from both linguistic communities (including linguistic minority communities).

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

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Scientific Peer Review of Research Involving Humans

Section 1: General

Principal investigator:	
Project title:	
Reviewer's name:	
Job title:	
Place of work:	
Address:	
Telephone:	
E-mail:	

Brief description of the project (to be completed by the reviewer):

Section 2: Significance and impact

When evaluating this criterion, consider the following points:

- Is the rationale for the project idea sound?
- Are the overall goals and objectives of the project well-defined?
- Are the anticipated project contributions likely to advance health-related knowledge or health outcomes?

Section 3: Feasibility

When evaluating this criterion, consider the following points:

- Are the approaches and methods appropriate to deliver the proposed output(s) and achieve the proposed contribution(s) to advancing health-related knowledge or health outcomes?
- Are the timelines and related deliverables of the project realistic?
- Does the proposal identify potential challenges and appropriate mitigation strategies? Are there any limitations that might prevent the researchers from achieving their objectives?

Section 4: Expertise, experience and resources

When evaluating this criterion, consider the following points:

- Does the applicant(s) bring the appropriate expertise and experience to lead and deliver the proposed output(s), and to achieve the proposed contribution(s)?
- Is the environment (federal laboratory, academic institution and/or other organization) appropriate to enable the conduct and success of the project?

Section 5: Human participants

When evaluating this criterion, consider the following points:

- Are participant inclusion and exclusion criteria carefully delineated?
- Is the sample size discussed and justified? If yes, is the sample size sufficient to provide likelihood of an interpretable result?
- Do the potential benefits to the population outweigh the potential harms?

Section 6: Budget

When evaluating this criterion, consider the following points:

- Is the budget justified in the application, and is the justification appropriate?
- Is the budget adequate to support the proposed research?

Section 7: Ranking

Please provide two separate rankings for the research proposal: one for the proposal as is, and a second for the proposal if the comments in this review have been addressed.

	Outstanding	**Excellent**	**Good**	**Fair**	**Poor**
Proposal as is	◯	◯	◯	◯	◯
Proposal if comments are addressed	◯	◯	◯	◯	◯

Definitions of descriptors:

Outstanding: The application excels in most or all relevant aspects. Any shortcomings are minimal.

Excellent: The application excels in many relevant aspects, and reasonably addresses all others. Certain improvements are possible.

Good: The application excels in some relevant aspects, and reasonably addresses all others. Some improvements are necessary.

Fair: The application broadly addresses relevant aspects. Major revisions are required.

Poor: The application fails to provide convincing information and/or has serious inherent flaws or gaps.

Section 8: Signature

In signing this form, I confirm that I have no conflict of interest and that I am free of any biases that would prevent me from giving my best independent scientific opinion on this research proposal.

_____

Signature of reviewer

Date

Privacy notice: The personal information provided in this review is handled in accordance with the *Privacy Act*. We only collect the information we need to process your review 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.

Please return the completed review to the principal investigator who will include it with their application to the Research Ethics Board.

If the form is not signed electronically, include a scanned copy of Section 8 (Signature) with the necessary signature when submitting your form.

If you have any questions about this form, contact the Health Canada-PHAC Research Ethics Board Secretariat at reb-cer@hc-sc.gc.ca or 613-941-5199.