Interior Health
RESEARCH ETHICS OFFICE

Community Health and Services Centre
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Date received (OFFICE USE ONLY)
Click here to enter a date.

Amendment Request
for an approved research study submitted to the IH RESEARCH ETHICS BOARD

1. IH REB file #

2. Principal Investigator (PI)

3. PI Email

4. Primary Contact (if different from PI)

5. Primary Contact Email

6. Title of Research Study

7. Proposed Changes to study. Describe all changes including changes to known risks, eligibility criteria, recruitment strategy or other procedures, administrative changes, etc, including the reason for each change.

8. Brief progress report

9. Level of risk to participants

10. Changes to Consent Form or consent process

List of revised documents. Include Tracked Changes version of each revised document.

11. Signature of Principal Investigator	12. Date Signed
	Click here to enter a date.

How to complete the IH REB Amendment Application

Amendments are changes to an ongoing study. IH REB approval is required prior to any changes to an approved study being implemented. Use this form to apply for approval to amendments.

The term of approval for the amendment expires at the same time as the current ethical approval certificate (either the initial ethical approval or annual renewal certificate).

The following notes may assist you in completing each section of the application.

Section 1: Fill in the unique file identifier as it appears on your IH REB Certificate of Ethical Approval.

Section 4/5: If the primary contact changes, insert the new person's contact information here.

Section 6: Provide the full title of project as it appears on the IH REB Certificate of Ethical Approval.

Section 7: Describe **all** changes to the study, including any changes in: known risks, eligibility criteria, recruitment strategy or other procedures, or administrative changes such as change in end date or study personnel. **Explain why each change was made**.

Section 8: Describe the progress of the study, including if the study is still recruiting; how many participants are enrolled; interim analysis if available; any participant withdrawals; and any problems encountered.

Section 9:

- Changes that pose minimal or no risk to participants and that do not substantially change the aims and/or design of the study may be reviewed by delegated review. The REB may delegate minimal risk reviews to the Chair or other designate.
- If the risk posed to participants by the proposed amendment is more than minimal, the amendment will undergo full board review. Application deadlines and meeting dates are available here.
- The REB reserves the right to forward any amendment for full board review if the proposed changes may pose greater than minimal risk to participants.

Health Canada Requirements

The following types of amendments for previously approved clinical trials of drugs, devices or natural health products must be referred to the full Board for review.

i. Addition of genetic testing, new genetic tests or tissue banking where genetic testing may or will be performed;
ii. Addition of an open label extension phase following a randomized trial;
iii. Emergency amendments that arise because of participant safety concerns and that are submitted after implementation as a result, and;
iv. Significant changes to a protocol that may affect participant safety and may include a (but are not limited to):
    1. change in drug dosing/duration of exposure,
    2. decrease in monitoring,
    3. change in recruitment technique that may affect confidentiality or the perception of coercion,
    4. change in experimental procedure or study population.
    5. Any amendment that requires approval from Health Canada

US Federal Government Requirements

Amendments to studies funded by the US Federal Government, e.g. DHHS, NIH require full board review.

If the proposed changes require changes to the Consent Form, include information on how currently enrolled participants will be contacted and how the new information about their participation in the study will be given to them. Document new risks in a revised consent form. Depending on the nature of the risk, the REB may require that current participants be re-consented.

For studies involving banking of biospecimens, if the sponsor or the tissue storage facility has changed, participants may either be notified by letter or re-consented. Participants must be given the opportunity to withdraw their tissue from storage if they wish.

Section 11: List all documents that have been revised as a result of this amendment. Submit one copy of each as follows:

(a) Use Tracked Changes mode in revised documents.
(b) Update the version number and version date in the footer of each revised document.
(c) For revised documents that have been forwarded from a study sponsor (not created or changed by the local study team), ensure that the name of the document allows it to be easily identified by the REB, e.g. “Consent Form, version 3” rather than DCR2-12-284ICF.

Section 12: For signatures, the IH REB can accept:

- a scanned version of the application form that has been printed and signed by the PI, or
- the electronic signature of the PI, or,
- applications forwarded from the institutional email address that the REB has on file for the PI.

*If a date-stamped electronic signature is not used, the PI must fill in the date s/he signed the application.

Submission Checklist

☐ All sections of the Amendment application form are complete; PI has signed and dated the copy submitted to the IH REB.

☐ All documents that were revised as a result of this amendment are submitted in Tracked Changes mode along with this application form

☐ All new documents have the updated version number and date in a footer

☐ Amendments to the Investigator’s Brochure are accompanied by the Summary of IB Changes.

☐ If the amendments cause a change to the IH resources used, an updated IH Application for Operational Approval has been submitted to research@interiorhealth.ca.

☐ Submit the signed, completed form and all new or revised documents to researchethics@interiorhealth.ca.

☐ **Possible Additional Requirements for Clinical Trials**
Updated Health Canada No Objection Letter