Health Sciences North
Horizon Santé-Nord

Research Ethics Office
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Amendment Request Form

Please consult the Amendment Request Guidelines prior to completing this form. Submit the signed document to the Research Ethics Office along with any supporting documentation (if any).

1- General

HSN REB Project Number▾ Local Principal Investigator▾

Protocol Title▾

Sponsor/Funding Agency▾

Primary Contact Name▾ Primary Contact Telephone▾ Primary Contact Email▾

For Clinical Trials, please add date you were notified of the amendment ▾

Current status of the study at the time of this submission▾
- ☐ Open to enrollment
- ☐ Closed to enrollment, participants being treated – total # active:
- ☐ Closed to enrollment, participants in follow up – total # enrolled:
- ☐ Performing a data analysis: total # enrolled:
- ☐ Temporarily closed to enrollment, explain why▾

2- Documentation

a Amendment involves revision to (check all that apply).▾
- ☐ Protocol ▸ Version/Date:
- ☐ Consent Form(s) ▸ Version/Date:
- ☐ Advertisement(s) ▸ Version/Date:
- ☐ Questionnaire(s) ▸ Version/Date:
- ☐ Patient Materials (i.e., diaries) ▸ Version/Date:
- ☐ Other, please list: ▸ Version/Date:
- ☐ Other, please list: ▸ Version/Date:
- ☐ Other, please list: ▸ Version/Date:

b Please list any other documents you are including with this submission (that do not require approval, i.e., Summary of Changes, Sponsor Information Letter, etc.). Include Version/Date if applicable.▾

1.

c Clinical Trials only, please include the Health Canada No Objection Letter
☐ Attached ☐ Not required

It is the responsibility of the Principal Investigator/Research Coordinator to ensure that departments/programs and/or other areas impacted by this amendment receive a copy of pertinent documents and the relevant training as per the Health Canada Regulations.

3- Details

a Please provide a brief outline of the amendment in your own words (in addition to any supplemental documentation that you may attach). Keep the description simple and to the point, suitable for non-medical personnel to review. Do not use acronyms.▾

b Is the proposed amendment a result of an Unanticipated Problem (see the Unanticipated Problem Guidelines for more information) ▾

- ☐ No
- ☐ Yes, date reported to the REB:

c Will there be any change in the risk, discomfort, inconvenience, or change in the vulnerability of participants?

- ☐ No
- ☐ Yes, please explain▾

d What follow up action is proposed once the amendment is implemented, for participants who are already enrolled in the study? ▾

- ☐ Inform study participants, please describe process▾
- ☐ Re-consent all participants with the revised consent/assent forms
- ☐ Re-consent active participants with the revised consent/assent forms
- ☐ Other action:
- ☐ No action required

4- Financial

a Will these amendments/modifications directly impact your current departmental service agreements or the study budget? ▾

- ☐ No
- ☐ Yes, please describe▾

5- Principal Investigator Attestation

My signature certifies that the above information is correct and that no additional procedures will be conducted without ethics clearance.

Principal Investigator Signature	Date of PI Signature