Health Sciences North
Horizon Santé-Nord

Research Services Office
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Annual Renewal / Final Report Form

Please consult the Annual Renewal/Final Report Guidelines prior to completing this form. Submit the signed document to the Research Services Office along with any supporting documentation (if any).

1- General

HSN REB Project Number▾

This form is being completed (pick one)▾
☐ As an Annual Renewal
☐ As a Final Report

Protocol Title▾

Sponsor/Funding Agency▾

Local Principal Investigator▾

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

Initial REB Approval Date▾

Please provide a brief description of the study (i.e., this is a treatment study involving 2 different arms of chemotherapy; this is a retrospective chart review looking at.., etc.). Keep the description simple and to the point, suitable for non-medical personnel to review. Do not use acronyms. 1-2 sentences only.▾

2- Current Status

a Expiry Date of Current REB Approval▾

If this form is being submitted after the expiry date, please explain why, describe what research activities have occurred since the expiry date, and what procedures will be implemented to avoid future lapses in approval▾

Note: If progress reports are not submitted as scheduled, the study will be suspended. No research related activities may occur after the approval expiration date.

b Current Status (pick one)▾
☐ Health Chart/Database/Tissue study only (skip to Section 4)
☐ No enrollment, not started (Skip to Section 4)
Reason▾

☐ Partially complete but study on hold
Reason▾

☐Currently enrolling patients
☐ Enrollment complete but study is ongoing (i.e. participants receiving intervention, data collection)
☐ Intervention & follow-up complete for all local participants; however, data clarification and/or data transfer ongoing
☐ Study completed (i.e., no further participant involvement/data collection)

3- Summary of Participants

a Number of research participants proposed for the study

b Number of participants consented

Note: Each participant should be entered below only once so that the sum of the numbers below should be equal to the number of participants consented.

Number of participants consented but did not meet inclusion criteria
Number of participants consented but have not yet started study procedures
Number of participants who have withdrawn their consent from participation
Number of participants receiving study intervention (i.e., study drug, questionnaires, tests, or procedures done for study purposes)
Number of participants in post-intervention follow-up
Number of participants that have completed the study (including completed follow-up and/or withdrawn by the PI) and no further contact for study purposes is planned

4- Study Summary

a Please provide a brief summary of the progress or outcome of the study to date (i.e., recruitment issues, preliminary findings, changes to funding, development of a conflict of interest, change in PI, etc.). If chart or tissue reviews, include number reviewed. Keep the description simple and to the point, suitable for non-medical personnel to review and do not use acronyms. ▾

b Is there any new information in the literature or from other recent studies that would change the rationale or risk/benefit ratio for this study (i.e., changes in standard of care, new information about the side effects, approval of another drug for this indication, etc.)? ▾

☐ No

☐ Yes, please describe▾

c If any participants have been withdrawn from the study prematurely or have withdrawn consent, provide the reasons for participant withdrawal. ▾

☐ N/A - No consent for this study

☐ No participant withdrawal

☐ Yes, please describe▾

d Have there been any participant complaints or feedback about the research?

☐ No

☐ Yes, please describe▾

5- Potential Risks

a If you have attached the Protocol Deviation Log, in the opinion of the Principal Investigator, is there a trend in the deviations (e.g. higher number of participants than usual did not meet the eligibility as stated in the protocol, numerous missed study procedures, etc.) ▾

☐ N/A – No Protocol Deviations

☐ No

☐ Yes, please describe▾

b Have there been any deaths related to the study intervention? ▾

☐ N/A – no study interventions

☐ No
☐ Yes, please describe▾

c Have there been any reports from the data safety monitoring committee/board (DSMC/B)? ▾
☐ No DSMC/B
☐ Yes, attach most recent report(s)

d In the opinion of the Principal Investigator, are there any other safety issues the board should be aware of (e.g. unexpectedly a higher number of local participants developed a particular adverse event, trend in adverse events experienced by the participants, etc.) ▾
☐ No
☐ Yes, please describe▾

e Have there been any audits or inspections by the sponsor, institution, or a regulatory body?
☐ No
☐ Yes, attach most recent report(s)

f Have there been any changes to the consenting procedures outlined in the initial submission not yet reported to the REB? ▾
☐ No
☐ Yes, submit amendment request form with the revised documents

g Have there have been any changes to the procedures and security measures regarding Privacy & Confidentiality that have not been approved by the REB (i.e. within an amendment). ▾
☐ No
☐ Yes, submit amendment request form with any revised documents

6- Study Results (complete only if Final Report)

a Have any articles been published or presentations given using the results of the study?▾
☐ No
☐ Yes, please attach abstract(s)
☐ Will be forwarded to the REB once received

b If not a multi-site study, please attach a brief summary describing your research findings▾
☐Attached

7- Principal Investigator Attestation

My signature certifies that the above information is correct and that no additional procedures will be conducted without ethics clearance. I am not aware of any new information that may affect the results or continuation of the study or require change in the study protocol. Proper safeguards to confidentiality and security of data will be maintained until all data are destroyed.

Principal Investigator Signature	Date of PI Signature

Reminder: All changes to the study protocol, consent form(s) and all other study related documents must be submitted for REB review and approval prior to implementation using the Amendment Request Form.