Health Sciences North
Horizon Santé-Nord

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Unanticipated Problem Reporting Form

Please consult the Unanticipated Problem (UP) Guidelines prior to completing this form. Submit the signed document to the Health Sciences North Research Ethics Board (HSN REB) along with any other detailed reports of the event(s)(eg. from the research sponsor)..

1- General

HSN REB Project Number▾ Principal Investigator▾

Protocol Title▾

Sponsor/Funding Agency▾

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

Please indicate the type of study event▾

- ☐ Serious Adverse Event (SAE) - If you have checked SAE, please choose ☐ Internal or ☐ External
- ☐ Periodic Safety Update Report or Updated Investigational Product Documentation
- ☐ Protocol Deviation
- ☐ Privacy Breach
- ☐ Research Participant Complaint
- ☐ Other Unanticipated Problem:
  Specify:

2- Screening

a	Is the problem unexpected in terms of nature, severity, or frequency?	☐ Yes	☐ No
b	Is the event related or possibly related to participation in the research (i.e., at least a reasonable possibility exists that the incident, experience, or outcome may have been caused by the drugs, devices, or procedures involved in the research)?	☐ Yes	☐ No
c	Does the event suggest a potential greater risk of harm (including physical, psychological, economic or social harm) to participants or others than was previously known or recognized?	☐ Yes	☐ No

COMPLETE AND SUBMIT THIS UP FORM TO THE HSN REB ONLY IF YOU ANSWERED YES TO <u>ALL</u> THREE QUESTIONS.

Important Note: Study events that do not constitute unanticipated problems do not require reporting to the REB but may still require documentation (i.e., logging) and reporting. See the Guidance Document for more information.

3- Description

Type of Report▾

- ☐ Initial, or
- ☐ Follow Up #

Participant Code/SAE Identifier▾

Date Unanticipated Problem Occurred▾

Date of Discovery of Unanticipated Problem▾

a Provide a brief description of the study event. Keep the explanation simple and to the point, suitable for non-medical personnel to review and do not use acronyms.▾

4- Impact

a Did the event result in any harm to one or more study participants at your site? ☐ Yes ☐ No

b Result in any harm to others at your site (study team members, patients, visitors, etc.)? ☐ Yes ☐ No

c Have an impact on study integrity? ☐ Yes ☐ No

If Yes to any of the above, describe▾

5- Response Plan

a Is it possible to mitigate or minimize any harm caused by the UP ▾

☐ N/A

☐ Yes ▸ i. What will be done/was done? ▾

ii. What are/were the anticipated outcomes of these actions? ▾

☐ No ▸ Explain why this is not possible▾

Complete d and e ONLY if Study Participant(s) was / were affected

b Can they remain enrolled in the study? ▾

☐ No ▸ Explain the withdrawal plan: process, documentation, plans for inclusion or exclusion of data in the final study data analysis, timelines.

☐ Yes ▸ Is an explicit reconfirmation of consent planned? ▾

☐ Yes ▸

Please describe plan (process, documentation, timelines) ▾

☐ No ▸ Explain why reconfirmation of consent is not necessary▾

c Is it possible to minimize the risk of this same event happening to other research participants?

☐ Yes ▸ Describe plan (process, documentation, timelines) ▾

☐ No ▸ Explain why this is not possible▾

For Impacted Documents/Procedures at Your Site

d Does this Problem impact the content of ▾

- ☐ The informed consent form(s)?
- ☐ The research protocol?
- ☐ Other protocol-related documents that guide the conduct of the study (i.e., standard operating procedures)?
- ☐ The Investigational Product documentation (e.g. Investigator's Brochures)?

☐ Yes ▸ Please describe the plan to revise this documentation (changes proposed, process, timeline) ▾

Please forward a completed Amendment Form to the Research Ethics Office for the next available REB meeting.

☐ No ▸ Explain why this isn't necessary ▾

For Impact to Study Integrity

e Is it possible to correct any impact to study integrity? ▾

☐ No

☐ Yes ▸ Describe the actions that will be taken to correct the impact on study integrity ▾

6- Communication Plan

a Do you plan to inform local research participants about this Problem? ▾

☐ No ▸ Explain why it is not necessary to inform local research participants ▾

☐ Yes ▸ i. Describe the plan (process, documentation, timelines) ▾

ii. Is an explicit reconfirmation of consent planned? ▾

☐ Yes ▸

Describe the plan (process, documentation, timelines) ▾

☐ No ▸ Explain why reconfirmation of consent is not necessary ▾

7- Principal Investigator Attestation

I confirm that I have reviewed this Unanticipated Problem Report and that all information contained herein is complete and accurate.

Principal Investigator Signature _____ Date of PI Signature _____