



Study Change-in-Status Notification Form

This form is to be used when there is a change in the status of the study that is not the final closure. Please consult the Study Change-in-Status Guidelines prior to completing this form. Submit the signed document to the Health Sciences North Research Ethics Board (HSN REB) along with the more detailed reports of the event(s) provided by the external study sponsor (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▼

2- Status

a Provide a detailed explanation in the space below for any "premature, early, or unplanned" change in status (i.e., reason for change in status, actions that have or will be implemented, rationale for the study to be re-opened, etc.). Attach any relevant correspondence from the sponsor▼

b Select the current status▼

- ☐ Target accrual met, as of:
- ☐ Accrual/recruitment prematurely closed, as of:
- ☐ Study suspended, as of:
- ☐ Study re-initiated, as of:
- ☐ Recruitment suspended, as of:
- ☐ Recruitment re-initiated, as of:

It is the responsibility of the Principal Investigator/Research Coordinator to ensure that departments/programs and/or other areas impacted by this change in status are aware of the change.

3- Recruitment Update

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Number of participants who have withdrawn their consent from participation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Number of participants that have completed the study (including completed follow-up and/or withdrawn by the PI) and no further contact for study purposes is planned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- Principal Investigator Attestation

The undersigned assures that the information provided in this form is complete and accurate, and that modifications to the approved project will not take place without prior review and approval by the HSN REB.

Principal Investigator Signature

Date of PI Signature