North Bay Regional Health Centre | Centre régional de santé de North Bay

Research Ethics Board (REB) Participant Adverse/Unanticipated Event Notification Form
For use only by Researchers

An **adverse or unanticipated event** is considered to be any undesirable experience or consequence that was not expected and not disclosed as a potential consequence in the original research application and written informed consent (i.e. emotional, psychological or physiological).

This form in no way supersedes reporting requirements of the North Bay Regional Health Centre's Event Reporting System (Ireport).If an adverse/unanticipated event occurs to a research participant directly as a result of their participation in the research study, you must initially follow standard hospital procedures and documentation requirements as outlined in the NBRHC "Disclosure of Adverse Events Policy" and *"Incident/Accident Reporting Policy", and subsequently complete this form to inform the REB that the incident has occurred. The Chair of the North Bay Regional Health Centre's REB must be notified no later than three business days following such an event.*

Please complete and submit one (1) signed original, and/or one (1) electronic version, including signatures of this form to:

North Bay Regional Health Centre
50 College Drive, North Bay, ON, P1B 5A4
Fax: 705-495-7956
REBOffice@nbrhc.on.ca

SECTION A: GENERAL INFORMATION

Principal Investigator	Protocol File Number
Protocol Title	
Address	
Telephone Number	Email Address

SECTION B: DESCRIPTION OF ADVERSE/UNANTICIPATED EVENT AND ACTION TAKEN:

1. Date of event:

2. Location:
Did the event occur at the North Bay Regional Health Centre?

❑ YES ❑ NO

If the event occurred off site, specify the location where the event occurred:_____

3. Describe the adverse/unanticipated event that occurred and include any relevant details of physical, emotional, psychological or physiological effects resulting from it.
4. What actions have been taken (if any), or will be taken in response to this event?
5. Will the adverse/unanticipated event require you to modify your originally submitted protocol? ❑ YES ❑ NO If yes, please explain and complete the Amendment Request Form to an Approved Protocol.

SECTION C: STATEMENT OF PRINCIPAL INVESTIGATOR

I certify that the details provided in this (REB) Participant Adverse/Unanticipated Event Notification Form are complete and accurate. I have complied with the Tri-Council Policy Statement and North Bay Regional Health Centre's policies and procedures governing the protection of human participants in research.

Signature of Principal Investigator: _____

Print Name: _____

Date: _____

For Administrative Use Only:

❑ Report Reviewed. ❑ North Bay Regional Health Centre REDS Form Completed.

Action Required: _____

Signature of REB Chair or designate: _____ Date: _____

Approval Period from: _____ to: _____