North Bay Regional Health Centre

Research Ethics Board (REB)

Participant Adverse/Unanticipated Event

Notification Form

The principal investigator is required to report to the REB only those local adverse events that are deemed to be unanticipated problems (unexpected, related and involving greater risk – see definition below).

A Local (Internal) adverse event:

*Local adverse events* are those adverse events experienced by research participants enrolled by the investigator(s) at one or more centres under the jurisdiction of the REB of Record. In the context of a single-centre clinical trial, all adverse events would be considered *local adverse events.*

Reportable local adverse events (i.e., those that represent unanticipated problems) should be reported to the REB within 15 calendar days of the principal investigator becoming aware of them. Fatal or life-threatening reportable local adverse events should be reported to the REB within in 7 calendar days.

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Participant Adverse / Unanticipated Event

Notification Form

DATE:

 (dd/mm/yy)

|  |  |
| --- | --- |
| **Name of Principal Investigator** |       |
| **Title of Project** |       |
| **Protocol File Number** |  |
| **Discovery Date of Event***(dd/mm/yy)* |  |
| 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:* |
|  |
| ***DIAGNOSIS*** |  |
| ***PLEASE CHECK ALL THAT APPLY:*** |
| ***Severity of Diagnosis:*** |
| *[ ]*  | *Mild* | *[ ]*  | *Moderate* | *[ ]*  | *Severe* | *[ ]*  | *Life threatening*  | *[ ]*  | *Death* |
|  |
| ***Results of Serious Adverse / Unanticipated Event:*** |
| *[ ]*  | *Hospitalization* | *[ ]*  | *Prolonged Hospitalization* | *[ ]*  | *Life threatening* |
| *[ ]*  | *Death* | *[ ]*  | *Persistent/significant disability/incapacity* |
| *[ ]*  | *Congenital anomaly/birth defect* |
| *[ ]*  | *Requires intervention to prevent permanent impairment or damage* |
|  |
| ***Relationship to Trial Medication:*** |
| *[ ]*  | *Definite* | *[ ]*  | *Probable* | *[ ]*  | *Possible* | *[ ]*  | *Unlikely* | *[ ]*  | *Not related* |
|  |
| ***Please describe in full detail the Serious Adverse/Anticipated event that occurred:*** |
|  |
| ***Actions taken: (e.g. lab results, tests procedures, medication and any other treatment)*** |
|  |
| ***Follow up Required?*** | *[ ]*  | *Yes* | *[ ]*  | *No (If yes, please explain)* |
|  |

*I certify that the details provided in this REB* ***(Local)*** *Serious Adverse/Unanticipated Event*

*Notification Form are complete and accurate and have complied with the Tri-Council Policy Statement.*

*Signature of Principal Investigator:*

*Print Name:*

*Date:*

The Canadian Association of Research Ethics Boards (CAREB) Guidance on Reporting of Unanticipated Problems including Adverse Events to Research Ethics Boards in Canada, is located at
 <https://www.careb-accer.org/sites/default/files/downloads/careb_guidance_-_ae_reporting_-_july_2010.pdf>

Please indicate that you have read and understand this document by checking the box below.

[ ]  I have read and understand this document

FOR ADMINISTRATIVE USE ONLY:

Date report was reviewed:

Action required:

Dr. Robert Butcher

REB Chair (please print) REB Chair Signature