Rural Research Network (RRN) Research Ethics Board (REB)
Reportable Events Form

Drafted by RRN REB based on Sunnybrook HSC REB Internal and External Reportable Events forms, and CTO Centre Reportable Event form.

SECTION 1.0 - GENERAL INFORMATION

1.0 Complete Study Title:

1.1 Study ID/Number (if applicable):

1.2 Principal Investigator:

SECTION 2.0 - LOCAL (INTERNAL) SERIOUS ADVERSE EVENT (SAE)

If the reportable event was unexpected AND related or possibly related to the participation of the research AND suggests that the research places the research participants or others at a greater risk of harm than was previously known or recognized:

2.0 Date first member of study team aware of the SAE:

2.1 Onset Date and Resolution Date of SAE:

2.2 Name or Medical Term of SAE:

2.3 Description of SAE:

2.4 Patient Outcome:

2.5 Response to Event:

2.6 Confirm that the event was unexpected AND related or possibly related to study intervention: ☐ Yes

2.7 Changes Recommended by PI (if applicable):

2.8 If amendments are required, please submit amendments via Amendments, Notifications, and Ongoing Communications form.

2.9 **Does this SAE meet the criteria for submission to Health Canada?**

☐ Yes
☐ No

SECTION 3.0 – EXTERNAL SERIOUS ADVERSE EVENT (SAE)

If the reportable event occurred at an external site AND was serious AND unexpected AND related or possibly to the study AND requires a change to protocol and/or informed consent form and/or requires immediate notification to participants for safety reasons:

3.0 **Date first member of study team aware of the SAE:**

3.1 **Onset Date and Resolution Date of SAE:**

3.2 **Description of SAE:**

3.3 **Response to Event:**

3.4 **Confirm that the event was unexpected AND related or possibly related to study intervention:** ☐ Yes

3.5 **Changes Recommended by PI (if applicable):**

3.6 **If amendments are required, please submit amendments via Amendments, Notifications, and Ongoing Communications form.**

SECTION 4.0 – EXTERNAL SERIOUS ADVERSE EVENT (SAE)

4.0 **Submitting Personnel Details:**

Name:
Organization:
Address:
City:
Province:
Postal code:
Telephone:
Fax:
Email:

4.1 Statement of Principal Investigator or Delegate

I have reviewed all of the serious adverse events and safety reports listed above, as well as their safety implications. I understand that it is my responsibility to retain copies of these reports in the Investigator study file as per Health Canada Regulations. I attest to the accuracy of this form.

Name:

Signature:

Date: