

Rural Research Network (RRN) Research Ethics Board (REB) Continuing Review Form

Drafted by RRN REB based on Sunnybrook HSC REB Renewal form, and CTO Continuing Review 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 - STUDY STATUS

- 2.0 Date of Initial REB Approval:**
- 2.1 Was there a lapse in approval?**
 Yes
 No
If 'yes': Was there a need to continue research activity or treatment of current research participants for their safety and well-being?
 Yes
 No

Provide the reason for the lapse and identify the steps taken to prevent future lapses:

- 2.2 Is this study open for enrollment?**
 Yes
Attach a copy of the current Informed Consent form(s).
 No
Provide reasoning:

- 2.3 How many participants:**
- Were planned for enrollment:**
 - Were enrolled:**
 - Are currently receiving study treatment/intervention:**
 - Completed study treatment/intervention and are currently on follow-up:**
 - Completed study treatment/intervention and follow-up:**
 - Withdrew consent:**
 - Were planned for inclusion in a chart review:**
 - Were included in a chart review:**

2.4 Have all SAEs experienced been reported to the REB?

Yes

No

2.5 Is there a concern or trend in the SAEs that have occurred?

2.6 Have all significant protocol deviations/violations been reported to the REB?

Yes

No

2.7 Since the last REB approval, is there any new ethical or scientific information outside of a protocol amendment that would be relevant to the continuing review of this study?

2.8 Since the last REB approval, is there any change in the conflict of interest information provided to the REB for any of the investigators, study staff or members of their immediate family?

SECTION 3.0 – SUBMISSION DETAILS

3.0 Submitting Personnel Details:

Name:

Organization:

Address:

City:

Province:

Postal code:

Telephone:

Fax:

Email:

3.1 Statement of Principal Investigator or Delegate

I assume full responsibility for the scientific and ethical conduct of this study and agree to conduct this study in compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Human Subjects (TCPS), Personal Health Information Protection Act (PHIPA) and any other relevant regulations or guidelines. I certify that all researchers and personnel involved in this study at this institution are appropriately qualified and trained to fulfill their role in this study.

Name:

Signature:

Date: