Rural Research Network (RRN) Research Ethics Board (REB) Amendments, Notifications, and Ongoing Communications Form

Drafted by RRN REB based on Sunnybrook HSC REB Amendments, Notifications, and Ongoing Communications form, and CTO Centre Amendment 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 - AMENDMENT DETAILS

2.0 Type of Amendment (select all that apply, documents must be attached):

- ☐ Amended protocol (including updated version number or date)
- ☐ Administrative change (Principal Investigator, Co-Investigator, administrative contact etc.)
- ☐ Summary of proposed changes with rationale (required for amendments)
- ☐ Tracked change and clean copy of revised Consent form – main study
- ☐ Tracked change and clean copy of revised Consent form – other (i.e. tissue)
  - **2.0.1** Specify:
- ☐ Health Canada No Objection Letter (NOL) / Investigational Testing Authorization (ITA) / Notice of Authorization (NOA)
- ☐ Investigator Brochure (IB) / Product Monograph
- ☐ Data Safety Monitoring Board/Committee Report
- ☐ Study Participant Materials (i.e. diary, questionnaire, wallet card, etc.)
  - **2.0.2** Specify:
- ☐ Other (i.e. telephone script, blog script, letters of information, advertisement, new/revised budget etc.)
  - **2.0.3** Specify:

2.1 Describe the reason for this submission (e.g. administrative change, change in study plan, revised safety information, sponsor update, change in privacy, new relationship/conflict declaration etc.):

2.2 Provide an update on the status of enrollment/participation (e.g. open, closed or on hold, number of participants enrolled, number of participants on study drug/treatment etc.):

2.3 Describe the changes to the risk profile for participants:

2.4 Will new/updated information be communicated to current and/or past participants. Please explain why and how (if applicable).

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 have assessed the safety implications of this submission and its impact on the study procedures. I understand that the attached document(s) must undergo REB review and approval prior to implementation, except where necessary to eliminate immediate hazards to study participants. I assume full responsibility for the scientific and ethical conduct of this study and agree to conduct this study in compliance with the current edition of 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: