Rural Research Network (RRN) Research Ethics Board (REB)
Initial Application for Review Form

SECTION 1.0 – GENERAL INFORMATION

1.0 Complete Study Title:

1.1 Lead Site Principal Investigator (PI) details:

Name:
Organization:
Telephone:
Email:

1.2 Local Site Principal Investigator (PI) details:

Name:
Organization
Telephone:
Email:

1.3 Lead Site Administrative Study Contact details:

Name:
Organization:
Telephone:
Email:

1.4 Is there a Co-Investigator (Co-I) at the lead site?

Yes ☐ No ☐

***If 'Yes':* 1.3.1 Co-Investigator Contact Details:**

Name:
Organization:
Telephone:
Email:

If 'No':1.3.2 Please outline the management plan to ensure an appropriately trained, qualified and designated individual will always be available:

1.5 Lead Site Department Approver/Department Head:

Name:
Organization:
Telephone:
Email:

*Drafted by RRN REB based on CTO Centre Initial Application form.

1.6 Have all necessary "Local Administration Approval Forms" been submitted for the involved departments?

☐ Yes
☐ No

1.7 Requested Review type:

☐ Full REB review
☐ Delegated REB review

SECTION 2.0 – STUDY DESCRIPTION

2.1 Expected start date of this study at this site:

2.2 How many participants will be enrolled at this site?

2.3 Will any study participant visits or procedures take place outside this site?

Yes ☐ No ☐

***If 'Yes':* 2.3.1 Where will the visits or procedures will take place (name, address, contact)?**

2.3.2 Describe the visits or procedures that will take place outside this centre:

2.4 Does this submission require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Application)?

Yes ☐
No ☐

***If 'Yes':* 2.4.1 Please describe the available care in case of an emergency:**

2.5 Please submit a summary of the planned study. Include details on purpose and rationale, methods, participant selection, potential benefits and risks, risk management, funding, and plans for dissemination.

SECTION 3.0 – RECRUITMENT

3.1 How will potential participants be identified for recruitment at this site?

3.2 How will the potential participant's permission be obtained to be contacted for research purposes?

3.3 How will initial contact be made and who will make initial contact?

3.4 Please submit any SITE-SPECIFIC materials that will be used to recruit potential study participants (e.g., telephone, web or email scripts, flyers, brochures, etc.) at this site (if applicable).

Sites are not required to submit non-consent participant facing materials when the only change to the provincially approved version is the insertion of local contact information and/or letterhead.

SECTION 4.0 – INFORMED CONSENT INFORMATION

4.1 **Is a waiver of the requirement to obtain informed consent being requested for this study?**

Yes ☐ No ☐

If 'Yes' **4.1.1 Please describe the participant population for whom you are seeking a waiver and whether there are any proposed alteration in the consent procedures.**

4.2 **Describe the initial consent process. Include details on the timeline and signature collection:**

4.3 **If there is a relationship between the potential participants and the person obtaining the signature, explain the nature of the relationship and how undue influence will be minimized.**

4.4 **Please explain the procedures in place for participants who may have communication difficulties (e.g., who may need translation, who are illiterate, who have trouble understanding or producing speech and require special support including the use of assistive devices)?**

4.5 **Please submit the proposed site-specific consent form(s), any additional site-specific materials that will be given to participants (e.g. diary cards, telephone or email scripts), and any site-specific debriefing script (if applicable).**

SECTION 5.0 - SPECIAL CONSENT CONSIDERATION

5.1 **Does this study permit/require the enrollment of participants who are not capable of providing consent?**

Yes ☐ No ☐

If 'Yes': **5.1.1 Describe by how capacity will be assessed (initially and ongoing), how substitute decision-makers will be identified, and/or how you will obtain assent from study participants.**

5.2 Please list the populations that this study will target.

5.3 If any of the the populations could potentially be subject to coercion and/or undue influence please describe how this will be minimized:

SECTION 6.0 - PRIVACY AND CONFIDENTIALITY

6.1 What types of records (information sources) need to be accessed for the purposes of this study? Specify the type and source of record that will be accessed.

6.2 What (if any) Personal Information or Personal Health Information will be SENT TO or collected by the lead researcher/research group for the purposes of this study? Please specify.

6.3 Indicate the measures in place to protect the confidentiality and security of any Personal Information (PI) or Personal Health Information (PHI) that is accessed, collected, used and disclosed.

- ☐ Access to medical records and study data will be limited to authorized personnel
- ☐ Access to electronic data will be password protected and auditable
- ☐ Electronic data collected for this study will be stored on a hospital or other institutional network with firewalls and other security and back-up measures in place.
- ☐ Study Data stored on laptops or mobile devices will be encrypted
- ☐ Paper copies of study data will be stored in locked filing cabinets in a secure location
- ☐ A master log linking study IDs with identifiers will be stored separately from the study data

If 'Other': **6.3.1 Specify:**

6.4 Indicate the measures in place to protect the confidentiality and security of the transfer of study data outside the institution (i.e., outside the custody of the Health Information Custodian). Please specify.

6.5 If any of the locally collected data will be entered into a database for future use, please provide details on where will it be stored, who will be the custodian, who will have access, and the security measures in place to protect the confidentiality of the data.

SECTION 7.0 - CONFLICT OF INTEREST

7.1 Will the investigator or sub-investigators or anyone connected to them though their interpersonal relationship (including their partners, family members, or their former or current professional associates) receive any personal or financial benefit in connection with this study? This may include patent or intellectual property rights, royalty income, employment, share ownership, stock options, or any other relationship, interest, partnership or incentive that may compromise their integrity, independence or ethical duties in the conduct of the research?

Yes ☐ No ☐

If 'Yes': **7.1.1 Please describe the benefits, relationships, interests, or incentives:**

If 'Yes': **7.1.2 Describe the proposed management plan:**

7.2 **Is the investigator or sub-investigator(s) aware of any institutional conflicts of interest (financial or non-financial) that may have an impact on the research?**

Yes ☐ No ☐

If 'Yes': **7.2.1 Describe the institutional conflicts of interest:**

If 'Yes': **7.2.2 Describe the proposed management plan:**

7.3 **Does the Investigator or sub-investigator or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any proprietary interest, association, or connection to any entity that is sponsoring or otherwise supporting the conduct of the study?**

Yes ☐ No ☐

If 'Yes': **7.3.1 Describe the interest, association, or connection:**

If 'Yes': **7.3.2 Describe the proposed management plan:**

7.4 **If this is an investigator-initiated study, are you or your institution the sponsor of this investigator-initiated/sponsored study?**

Yes ☐ No ☐

If 'Yes': **7.4.1 Describe any real, potential, or perceived conflict of interest:**

7.4.2 Provide the proposed management plan:

7.5 **Are there any other real, potential or perceived conflict of interest to declare to the REB?**

Yes ☐ No ☐

If 'yes': **7.5.1 Specify:**

7.5.2 Provide the proposed management plan:

SECTION 8.0 – PARTICIPANT REIMBURSEMENT & STUDY RESULTS

8.1 **Please describe if and/or how study participants at this site be reimbursed for any additional costs that may occur due to their participation in the study such as travel, parking and meals.**

8.2 **Explain the plans to share the study results with this site's study participants (individually or collectively) and/or with the local research community.**

SECTION 10 – ATTESTATIONS AND SIGNATURES

10.1 Lead Site Principal Investigator

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I attest that I am appropriately qualified to conduct this trial, entitled to provide medical oversight under the applicable laws, and that I am a member in good standing with my respective regulatory authority. Following the initial submission of this application form, a member of the research team may submit edits to this application on my behalf.
- I acknowledge that I remain ultimately responsible for REB submissions and the overall conduct of the study in accordance with the currently approved documents.
- I attest that, should a designate sign on my behalf, the responsibility for corresponding with the REB has been appropriately delegated, and the delegation has been documented.
- As the PI:
    - I assume full responsibility for the scientific and ethical conduct of the trial at this institution
    - I agree to conduct this trial in compliance with TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND with all other applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);
    - I attest that I have sufficient space, time and resources to conduct this trial;
    - I attest that the Centre Co-Investigator listed in this application (if applicable) is appropriately qualified to assume my responsibilities in the event that I am unable to do so;
    - I certify that all Co-investigators, researchers and other personnel (research team) involved in this project at this institution are appropriately qualified and experienced, or will undergo appropriate training to fulfill their role in this project;
- I acknowledge that I am responsible for promptly reporting to the REB, any proposed site-specific:
    - modifications or amendments, such as changes in PI, changes in Co-investigator (if applicable), centre-specific required changes to the consent form, etc.;
    - all local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the trial;
    - trial progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - trial completion or termination

- I certify that REB approval and all external and local institutional approvals will be obtained before the trial will commence;
- I have reviewed the provincial REB materials (e.g., REB approved provincial application forms including attachments, REB review letters, other correspondence with the REB, REB approval letters, etc.);
- I will ensure that all REB approved changes will be implemented at my centre, when relevant;
- I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the trial at this site.

Privacy and Security Acknowledgement:

- On behalf of all members of my research team, as the Centre PI, I am aware of my obligations in maintaining the importance of maintaining the confidentiality of personal health information and the privacy of individuals with respect to that information;
- I will ensure that the personal (health) information is used only as necessary, to fulfill the specific trial objectives and related trial questions described in the application approved by the REB. This includes all conditions and restrictions imposed by the REB and the institution in which the trial is being conducted, governing the use, security, disclosure, return or disposal of the trial participants' personal health information;
- I agree to take any further steps required by the REB or the institution to ensure that the confidentiality and security of the personal health information is maintained in accordance with the Personal Health Information Protection Act (PHIPA), its accompanying regulations, and the Tri-Council Policy Statement.

Lead Site Principal Investigator Signature:
Date:

10.2 Local Site Principal Investigator

- I attest that I am appropriately qualified to conduct this trial, entitled to provide medical oversight under the applicable laws, and that I am a member in good standing with my respective regulatory authority
- I agree to assume the role of On-Site Principal Investigator;
- As On-Site Principal Investigator, I agree to the relevant Principal Investigator and Privacy responsibilities (as noted above).

Local Site Principal Investigator Signature:
Date:

10.3 Lead Site Department Approver/Department Head

- I am aware of this proposal and support its submission for ethics review; I consider it to be feasible and appropriate;
- I attest that any internal department requirements will be met;
- I attest that the PI is qualified and has the experience and expertise to conduct this trial;
- I attest that the PI has sufficient space and resources to conduct this trial;
- There will be available care in the case of an emergency (for biomedical clinical trials)

Lead Site Department Head Signature:
Date: