CTO REB Initial Centre Application Form

Orange text *indicates an upload or action feature*
Red/italics/bold *indicates question/feature dependencies*
Questions with an asterisk (*) are mandatory and must be completed prior to signatures/submission
Indicates a shared question. If there is no associated data field in this form, the information is pulled into this form from another application (e.g., the Provincial Initial Application)

SECTION 1.0 – GENERAL INFORMATION

1.0 *Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application?
Choose an item.

Always answer 'YES" to Q1.0 if the application is being re-submitted in response to a request by OCREB or by the OCREB office.

1.1 *Please complete the Provincial Applicant (PA) details:
*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.2 *Is there a Provincial Co-Applicant?
Yes No
***If 'Yes':* *Please complete the Provincial Co-Applicant details:**
*Title:
*First Name:
*Surname:
*Organisation:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.3 Are the contact details for the Main Study Contact different than the Provincial Applicant named above?
Yes No
***If 'Yes':* *Please complete the Main Study Contact details:**
*Title:
*First Name:
*Surname:
*Organisation:
*Address:
*City:
*Province/State:

*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.4 *Please enter the Main Sponsor Contact details:

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.5 *Complete Study Title: (Enter exactly as written in protocol)

1.6 *Are the Main CRO Contact details available?

Yes No No CRO

***If 'Yes':* *Please enter the Main CRO Contact details:**

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
*Email:

1.7 Please enter the Sponsor's Study ID/Number:

1.8 *What is the acronym or nickname/short title for this study? (NOTE: The acronym or nickname/short title will be used to identify the study and will be included in all notifications and REB submissions.)

1.9 *Please complete the Centre Principal Investigator (PI) details:

*Title: Click here to enter text.
*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

1.10 *Please complete the Centre Main Study Contact details:

*Title: Click here to enter text.
*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

1.11 *Is there a Centre Co-Investigator (Co-I)?

☐Yes ☐No

***If 'Yes':* *Please enter the contact details of the Centre Co-Investigator:**

*Title: Click here to enter text.
*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

Q1.11: Recommend answering "No" Including a Co-Applicant does not grant the individual permissions to submit any REB materials on the PA's behalf. In addition, including a Co-Applicant will require the Co-Applicant to sign off on the initial submission of the PIA. Co-Is should be noted in the study delegation log.

If 'No': AT ALL TIMES, there must be oversight of research participants by an appropriately trained, qualified and designated individual.

***Please outline the management plan to ensure an appropriately trained, qualified and designed individual will always be available to ensure oversight of research participants:** Click here to enter text.

1.12 *Please provide details of Department Approver/Department Head:

*Title: Click here to enter text.
*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

1.13 *Please complete the Primary Institutional Representative details:

*Title: Click here to enter text.
*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
*Email: Click here to enter text.

Q1.13: CTO works with each institution to identify the appropriate IR(s) and will provide this information to each site. The institutional rep must be listed in the CIA and signs off on the CIA. Please check your centre's SRERS form provided by CTO or contact CTO to obtain this information.

1.14 Please complete the Secondary Institutional Representative details:

Title: Click here to enter text.
First Name: Click here to enter text.
Surname: Click here to enter text.
Organization: Click here to enter text.
Address: Click here to enter text.
City: Click here to enter text.
Province/State: Click here to enter text.
Postcode/Zip: Click here to enter text.
Telephone: Click here to enter text.
Email: Click here to enter text.

Q1.14: Most institutions do not have a secondary institutional rep. Please check your centre's SRERS form provided by CTO or contact CTO to obtain this information.

SECTION 2.0 – CENTRE-SPECIFIC STUDY DESCRIPTION

2.1 ***Expected start date of this study at this centre:** Click here to enter text.

2.2 ***How many participants will be enrolled at this centre?** Click here to enter text.

2.3 ***Will the protocol be implemented exactly as described in the currently approved provincial application?**

☐Yes ☐No

***If 'No': *Explain any centre-specific differences:** Click here to enter text.

Q2.3: If there are any aspects of the study in which your Centre is not participating, the response should be 'No' – e.g., if your site is not participating in a sub study.

2.4 ***Does the standard-of-care at this centre differ from that described in the currently approved provincial application?**

☐Yes ☐No

***If 'Yes': *Describe:** Click here to enter text.

2.5 ***Will any study participant visits or procedures take place outside this centre? *Do not include interim blood testing at an outside lab***

☐Yes ☐No

***If 'Yes': *Where will the visits or procedures will take place (name, address)?** Click here to enter text.

***Main Contact Details:** Click here to enter text.

***Describe the visits or procedures that will take place outside this centre:** Click here to enter text.

Q2.5: answer "yes" if satellite sites will be included for pediatric studies, **And/OR** if any study visits or procedures will be completed outside the centre.

For Satellite Sites: include the name of the satellite site and the name of the Designated Satellite Investigator (DSI). Remember to add the appropriate satellite site staff as collaborators on the CIA. You may reference the master agreement addendum and the POGO manual instead of providing the visit and procedures details.

2.18a ***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 – a Clinical Trial Application (CTA) under the Food and Drug Regulations
Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations
Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations
No

Q2.18a: except for sites required to provide a site-specific ITA form, it is unclear why the CTA question is included here, and linked to 2.6, which appears when "Yes" is selected.

If 2.18a in the PIA (question above) = 'yes – a clinical trial application under the food and drug regulations' and/or 'yes – a clinical trial application under the Natural Health Product Regulations' and/or 'yes – an investigational testing application under the Medical Device Regulations', question 2.6 will appear:

2.6 ***Please describe the available care in case of an emergency:** Click here to enter text.

Q2.6: recommended response is to reference the 24 hour emergency contact number on the consent form.

SECTION 3.0 – RECRUITMENT

3.1 ***How will potential participants be identified for recruitment into this study?** Click here to enter text.

Q3.1: keep in mind that initial contact should be either through the patient's permission to contact or by someone in the circle of care.

3.2 ***How will the potential participant's permission be obtained to be contacted for research purposes?** Click here to enter text.

3.3 ***Will initial contact be made with potential participants who have agreed to be contacted for research purposes?**

☐Yes ☐N/A (e.g., if potential participant self-refers in response to advertisement)

If 'Yes': ***Who will make the initial contact?** Click here to enter text.

3.4 ***How will initial contact be made (select all that apply)?**

☐In person
☐Telephone
☐Letter
☐Other

If 'Other': ***Specify:** Click here to enter text.

3.5 **Upload any centre-specific materials that will be used to recruit potential study participants (e.g., telephone, web or email scripts, flyers, brochures, etc., that you will use for the purpose of recruiting study participants at this centre):**

Upload Document

Q3.5: there should not be any centre-specific recruitment materials, which are provided provincially.

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

Q4.1: answer "No" unless a waiver is being requested for **ALL** participants.

If 'No' to question 4.1, questions 4.2-4.9 appear:

4.2 ***Describe the initial consent process, including how much time potential participants will be given to review the information before being asked to give consent:** Click here to enter text.

4.3 ***Who will obtain the participant's signature on the consent form?** Click here to enter text.

4.4 ***Is there a relationship between the potential participants and the person obtaining the signature?**
☐Yes ☐No
***If 'Yes':** ***Explain the nature of the relationship (e.g., treating physician, employer, supervisor, etc.):** Click here to enter text.
***If 'Yes':** ***Describe how you will minimize any undue influence:** Click here to enter text.

4.5 ***Are there 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)?**
☐Yes ☐No
***If 'Yes':** ***Explain the procedures:** Click here to enter text.
***If 'No':** ***Please justify:** Click here to enter text.

4.6 ***Does this centre require any changes (other than inclusion of centre letterhead and local contact information) to the approved provincial consent form(s)?**
☐Yes ☐No
***If 'Yes':** ***Explain:** Click here to enter text.

Q4.6: always answer "yes" and include one or both of the following statements (as applicable to your centre) to "Explain" the changes:

- **All centres:** "See OCREB Guidance for approved administrative changes";
- **Centres with OCREB pre-approved changes**: "See OCREB approved centre-specific changes document". (reference the document date.)

4.7 ***Upload the proposed CENTRE consent form(s) with the proposed centre-specific changes tracked:**
Upload Document

4.8 ***Upload a clean version of the proposed CENTRE consent form(s) (e.g., with the proposed centre-specific changes accepted):**
Upload Document

Q4.7: OCREB has a controlled honour system and does not review centre consent forms. Centres are approved to use the provincially approved consent form(s) with pre-approved changes ONLY, while retaining the provincial version date. OCREB will conduct audits of de-identified signed consent forms to ensure compliance with this process.

4.9 **Upload any additional other CENTRE-SPECIFIC materials that will be given to study participants that were not already submitted and approved provincially (e.g., diary cards, telephone or email scripts that you will use for communicating with study participants during the course of the study):**
Upload Document

4.9: there should not be any centre-specific materials.

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':* *Describe by whom and how capacity will be assessed (initially and ongoing, including assessment of attaining/regaining capacity):** Click here to enter text.

***If 'Yes':* *Describe how substitute decision-makers will be identified:** Click here to enter text.

***If 'Yes':* *Describe how you will obtain assent from the study participants:** Click here to enter text.

***Does this study include assent form(s)?**

Yes No

If yes, questions 5.2-5.4 appear:

5.2 ***Does this centre require any changes (other than inclusion of centre letterhead and local contact information) to the approved provincial assent form(s)?**

☐Yes ☐No

***If 'Yes':* *Explain:** Click here to enter text.

5.3 ***Upload the proposed CENTRE assent form(s) with the proposed centre-specific changes tracked:**

Upload Document

5.4 ***Upload a clean version of the proposed CENTRE assent form(s) (e.g., with the proposed centre-specific changes accepted):**

Upload Document

5.5 **This study will target the following population(s) (select all that apply):**

If any of the * below are selected, questions related to "special populations" will appear in the recruitment section (section 4), consent section (section 5) and/or in the Centre Initial Application form

Patients
Healthy Volunteers
Students*
Staff*
People with mental health issues*
People institutionalized*
Prisoners/persons in detention*
People in poverty/economically disadvantaged*
Educationally disadvantaged people*
People who are unable to read or write*
Children*
People in medical emergencies *
People who lack capacity to consent*
Cognitively impaired individuals*
Individuals with physical disabilities*
People who have trouble understanding and/or producing speech* (e.g., require special support including the use of assistive devices)
Adult individuals who are temporarily unable to provide consent* (e.g. unconscious)
Pregnant Women*
Elderly people
People in palliative care
People in long-term care
Aboriginal people and/or ethno-cultural minorities*
Other

Q5.5: for most oncology studies, the response will be patients for adult studies and patients and children for paediatric studies.

NOTE. For studies transferred from O2 ("legacy studies"). If this question is blank, please contact CTO Stream Support

If any of the * options are selected in 5.6, the following question appears:

***Describe how coercion and undue influence will be minimized:** Click here to enter text.

SECTION 6.0 - PRIVACY AND CONFIDENTIALITY

6.1 *What types of records (information sources) need to be accessed for the purposes of this study?

☐Health record
☐Existing database
☐Other

***If 'Health Record':* *Specify source of health records:** Click here to enter text.
***If 'Existing Database':* *Specify:** Click here to enter text.
***If 'Other':* *Specify any other types of records that must be accessed:** Click here to enter text.

6.2 *As per institutional privacy policies, which of the identifiers that were approved provincially are you authorized to disclose on the study data collection tools leaving the institution?

☐None, study participant ID only
☐Full name
☐Full initials
☐Partial initials
☐Full date of birth
☐Partial date of birth
☐Full date of death
☐Partial date of death
☐Age
☐Sex/gender
☐Full postal code
☐First 3 digits of postal code
☐Pathology specimen number
☐Medical device identifier
☐Admission date
☐Discharge date
☐Medical record number
☐Ontario health card number
☐Driver's licence number
☐Address
☐Telephone number
☐Fax number
☐E-mail address
☐Full face photograph
☐Voice/audio recording
☐Other

***If 'Other':* *Please specify:** Click here to enter text.

Q6.2: refer to the approved PIA for the identifiers that have been approved by OCREB for this study. **Do not fill out this question unless you have existing OCREB pre-approved changes supporting your institution's restriction on the disclosure of the identifiers**. For example, if full initials and full date of birth are approved in the PIA and your institution authorizes only the disclosure of partial initials and partial date of birth, check off the two relevant identifiers in the list. Providing you have centre-specific pre-approval do to so, you may include only partial initials and partial date of birth in your centre consent forms. The date of the consent forms remains the same as the approved provincial consent forms.

If changes in the privacy policies at your institution require new restrictions on the disclosure of identifiers, please contact the OCREB Research Ethics Officer (REO) with the supporting privacy policies. The REO will facilitate the review by OCREB. No changes can be implemented until OCREB issues a centre-specific pre-approval form.

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 and used (select all that apply):

☐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 will be stored on a hospital or other institutional network with firewalls and other security and back-up measures in place.
☐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 linking log with identifiers will be stored separately from the study data
☐Other

***If 'Other':* *Specify:** Click here to enter text.

6.4 *What PI or PHI do you need to collect and retain locally for the purposes of this study (e.g., recruitment tools, recruitment or screening logs)?

- ☐Full name
- ☐Full initials
- ☐Partial initials
- ☐Full date of birth
- ☐Partial date of birth
- ☐Full date of death
- ☐Partial date of death
- ☐Age
- ☐Sex/gender
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Ontario health card number
- ☐Driver's licence number
- ☐Address
- ☐Telephone number
- ☐Fax number
- ☐E-mail address
- ☐Full face photograph
- ☐Voice/audio recording
- ☐Other

Q6.4: refers to the identifiable participant information that is retained onsite to manage the study and study participants. This does not refer to any identifiers disclosed outside the institution. OCREB does not review this section. Study personnel are expected to comply with institutional privacy policies with respect to collecting and retaining identifiers in the study files.

Q6.4: for justification, indicate why you require the collection of identifiers. e.g., *"required for contact purposes only to manage study visits, source data, etc."*

***If 'Other':* *Specify other information:** Click here to enter text.
***If 'Other':* *Justify other information:** Click here to enter text.
***If 'Full Name':* *Justify full name:** Click here to enter text.
***If 'Initials':* *Justify full initials:** Click here to enter text.
***If 'partial initials':* *Justify partial initials:** Click here to enter text.
***If 'full date of birth':* *Justify full date of birth:** Click here to enter text.
***If 'Partial Date of Birth':* *Justify partial date of birth:** Click here to enter text.
***If 'Full Date of Death':* *Justify full date of death:** Click here to enter text.
***If 'Partial Date of Death':* *Justify partial date of death:** Click here to enter text.
***If 'Age':* *Justify age:** Click here to enter text.
***If 'Sex/gender':* *Justify sex/gender:** Click here to enter text.
***If 'Address':* *Justify address:** Click here to enter text.
***If 'Full Postal Code':* *Justify full postal code:** Click here to enter text.
***If 'First 3 digits of Postal code':* *Justify first 3 digits of postal code:** Click here to enter text.
***If 'Telephone Number':* *Justify telephone number:** Click here to enter text.
***If 'Email Address':* *Justify Email address:** Click here to enter text.)
***If 'Fax Number':* *Justify fax number:** Click here to enter text.
***If 'Ontario Health Card Number':* *Justify Ontario health card number:** Click here to enter text.
***If 'Medical Record Number':* *Justify medical record number:** Click here to enter text.
***If 'Admission Date':* *Justify admission date:** Click here to enter text.
***If 'Discharge Date':* *Justify discharge date:** Click here to enter text.
***If 'Date of Death':* *Justify date of death:** Click here to enter text.

If 'Pathology Specimen Number': ***Justify pathology specimen number:** Click here to enter text.
If 'Medical Device Identifier': ***Justify medical device identifier:** Click here to enter text.
If 'Driver's License Number': ***Justify driver's license number:** Click here to enter text.
If 'Voice/audio recording': ***Justify voice/audio recording:** Click here to enter text.
If 'Full face photograph': ***Justify full face photograph:** Click here to enter text.

6.5 ***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) (select all that apply):**

☐Data transfer agreement
☐Secure network
☐Other

If 'Other': ***Specify:** Click here to enter text.

6.6 ***Will any of the locally collected data be entered into a database for future use?**

☐Yes ☐No

If 'Yes': ***Where will it be stored?** Click here to enter text.
***Who will be the custodian?** Click here to enter text.
***Who will have access to the database?** Click here to enter text.
***Describe the security measures that will be in place to protect the confidentiality of the data:** Click here to enter text.

Q6.6: this refers to centre-specific study data. For most multi-centre studies, individual centres will not retain their participant-level study data. However, confirm with the sponsor, especially for investigator-initiated studies. De-identified data may be store for secondary/future use.

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 financial benefit in connection with this study?**

☐Yes ☐No

If 'Yes': ***State how much money (in Canadian dollars) is paid by the funder and to whom it is being paid, over and above the direct cost of conducting this study (e.g., recruitment incentives consulting fees, advisor fees):** Click here to enter text.

***Explain what this amount covers with respect to the direct costs associated with doing this research:** Click here to enter text.

***In the last three years, how much money (in Canadian dollars) or other benefits has the investigator or sub-investigator or anyone connected to them through their interpersonal relationship including their family members, friends, or their former or current professional associates (or any company owned or managed by the investigator or sub investigator or anyone connected to them through their interpersonal relationships) received from the sponsor and/or funder?** Click here to enter text.

***For what purpose did they receive these funds?** Click here to enter text.

***Describe the proposed management plan:** Click here to enter text.

7.2 ***Will the investigator or sub-investigators or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) receive any personal (financial or otherwise) benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc?**

☐Yes ☐No

If 'Yes': ***Please describe the benefits:** Click here to enter text.

If 'Yes': ***Describe the proposed management plan:** Click here to enter text.

7.3 ***Is the investigator or sub-investigator aware of any other community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research?**

☐Yes ☐No

If 'Yes': ***Describe the relationships, interests or incentives:** Click here to enter text.

If 'Yes': ***Describe the proposed management plan:** Click here to enter text.

7.4 ***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': ***Describe the institutional conflicts of interest:** Click here to enter text.

If 'Yes': ***Describe the proposed management plan:** Click here to enter text.

7.5 ***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 in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study?**

☐Yes ☐No

If 'Yes': ***Describe the interest:** Click here to enter text.

If 'Yes': ***Describe the proposed management plan:** Click here to enter text.

7.6 ***Will or 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 association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, board member, employee, director, etc.)

☐Yes ☐No

If 'Yes': ***Describe the association or connection:** Click here to enter text.

If 'Yes': ***Describe the proposed management plan:** Click here to enter text.

7.7 ***Is this an Investigator-initiated study?**

Yes No

If 'Yes', the following will appear:

7.7 ***Are you or your institution the sponsor of this investigator-initiated/sponsored study?**

☐Yes ☐No

If 'Yes': ***Describe any real, potential, or perceived conflict of interest:** Click here to enter text.

***Provide the proposed management plan:** Click here to enter text.

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

☐Yes ☐No

If 'yes': ***Specify:** Click here to enter text.

***Provide the proposed management plan:** Click here to enter text.

COI Declarations. The PI must include a proposed management plan for any declarations, or justification as to why a management plan is not required. OCREB expects that the institution will be informed of all declarations.

An example of a management plan to address a potential/perceived conflict related to an investigator-initiated study, may be to engage an independent party to conduct certain activities, - e.g., review of requests for eligibility waivers.

SECTION 8.0 – PARTICIPANT REIMBURSEMENT & STUDY RESULTS

8.1 ***Will study participants at this centre be reimbursed for any additional costs that may occur due to their participation in the study such as travel, parking and meals?**

☐Yes ☐No

***If 'Yes':* *Please describe:** Click here to enter text.

***If 'No':* *Justify:** Click here to enter text.

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

☐Individual debriefing at end of test session
☐Group debriefing
☐End of study letter
☐Publication
☐Other
☐No Plan

***If 'Individual debriefing at end of test session'*: Attach copy of debriefing script, if available:**
Upload Document
***If 'group debriefing':* Attach copy of group debriefing, if available:**
Upload Document
***If 'end of study letter':* Attach letter, if available:**
Upload Document
***If 'publication':* Describe publication plan:** Click here to enter text.
***If 'Other':* *Specify other:** Click here to enter text.
***If 'No plan':* *Justify no plan:** Click here to enter text.

SECTION 9.0 – TRANSLATIONS

9.1 ***Will translated materials (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.) be used at this centre?**

☐Yes ☐No

Q9.1: answer "Yes" only if the translated materials are available for uploading to the current application. If they are not available, submit them with a Centre Amendment (CAM).

If 'Yes' in 9.1, question 9.2 and 9.3 appear:

9.2 ***Please upload all CENTRE-SPECIFIC translated materials (e.g., consent or assent forms, etc.):**

Upload Document

9.3 **Please upload all translation certifications (if applicable):**

Upload Document

NOTE. Translation certificates are not required for Questionnaires that are validated in the translated language(s)

SECTION 10.0 – RE-SUBMISSION INFORMATION

If 'Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application?' (question 1.0) is 'Yes', this section will appear in the application.

10.1 Upload Principal Investigator response to REB request for modification letter (if applicable):
Upload Document

10.2 If changes have been made to a previously submitted consent/assent form at the request of the REB, please upload track-changes versions of all proposed consent and/or assent form (e.g. screening, main, optional), if applicable:
Upload Document

10.3 Upload any additional materials requested by the REB (if applicable):
Upload Document

10.4 Please provide any additional comments for the REB to consider (if applicable): Click here to enter text.

This page appears only when "Yes" is answered in Q1.0. If you do not have a place to upload a response letter, or additional requested materials, ensure that Q1.0 is answered "Yes". Any additional information that would assist in the OCREB review of this application should be entered in Q10.4.

11.1 *Centre Principal Investigator Signature – attestation

- 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.
- As the Centre 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, through the Clinical Trials Ontario Streamlined Research Ethics Review System, any proposed centre-specific:
    - modifications or amendments, such as changes in Centre PI, changes in Centre 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 between the REB and the Provincial Applicant, REB approval letters, REB approved provincial consent forms, etc.);
- I will ensure that all REB approved provincial 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 centre.

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.

11.3 *Centre Department Approver Signature – attestation

- 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)

11.4 *Institutional Representative Signature – attestation

- I attest that the Principal Investigator (and Co-Investigator, if applicable) is a researcher in good standing with this institution, and is appropriately qualified to act as the Principal Investigator (or Co-Investigator, if applicable) for the conduct of this study at this institution;
- I confirm that the Principal Investigator has access to the resources necessary to conduct the study;
- I attest that the Principal Investigator (and Co-Investigator, if applicable) has completed any mandatory clinical research training required at this institution, if applicable and, if a physician, has been appropriately credentialed;
- I attest that this institution has entered (or will enter) into appropriate contractual agreements with funders, sponsors and/or other institutions and that the study budget has been (or will be) reviewed and financial conflict of interest has been (or will be) addressed;
- I attest that this institution will notify the REB of Record if institutional approval is suspended or terminated for this study.