Revision History

Version Date	Key Changes
February 28, 2018	CTO application form version 16 - original
July 24, 2018	CTO application form version 16 - updates • Change to 4.6: Always answer "YES" and include the following statement to "Explain" the changes: "See OCREB Guidance for approved administrative changes" • changes to 4.7 and 4.8: Only those sites that are not exempt from CTO consent form screening (St.Mike's; Ottawa; Michael Garron; Kingston and London) must upload their centre-specific consents. All other sites should upload only the Memo from OCREB. Refer to annotation. • changes to 6.2 annotation: Do not select any identifiers. Refer to annotation.
May 1, 2019	CTO application form version 20 • Help text (in green) was added to several questions • Questions 1.1 to 1.6: shared Provincial Applicant (PA), sponsor and CRO contact details were removed and questions were re-numbered • Follow up or sub-questions were numbered (e.g., 5.1.1; 5.1.2) • Section 4.0 (Informed consent information) was expanded to include waiver of consent and alteration in consent procedures; Question numbers updated • Q11.5 added to allow a delegate to sign off on resubmissions
February 13, 2020	Q2.5 and Q4.10: guidance for pediatric sites only when including the use of Satellite sites.
August 20, 2020	CTO application form version 21 • References to "CHEER" study added to instructions throughout the document • Question 1.0: Instructions about the PI response letter added. • Question 1.0.1: New question about the Canadian Collaboration for Child Health (CHEER) study added. • Question 1.6: Revised to list any Co-investigators the centre might have. • Question 1.10: New question about a lay-friendly explanation of the study added • Question 3.1.1: New question added "Will method of identification be the same for all participants? " • Question 3.5: New question added "Will initial contact/identification of participants be made by someone within the patient's circle of care? " • Question 3.6: New question added "What is the relationship between the person recruiting and the potential participants? " • Question 4.2.1: New question added "Who will be explaining the study and/or treatments to the potential participants? "

	• Question 4.2.2.: New question added “Will there be opportunity for participants and/or substitute decision makers (SDMs) to discuss the study with family members or others before signing the consent form? Describe the environment and location where consent will be obtained? “ • Question 4.2.3: New question added “Will consent be obtained from substitute decision makers (SDM) “ • Question 4.2.4: New question added “Will consent be obtained from non-patients (i.e., healthy volunteers, caregivers)? “ • Question 4.5: Section about substitute decision makers (SDMs) added. • Question 5.2: Section added about the qualifications of those who will be obtaining assent. • Question 5.5: Question revised to “**This study will target the following population(s)** “, “neonates” added as an option and the term “Aboriginal” revised to “Indigenous” • Question 6.0: New identifiers added (social insurance number, device identifier, Internet protocol address, race/ethnicity, family/caregiver information). • Question 6.2: New identifiers added (social insurance number, device identifier, Internet protocol address, race/ethnicity, family/caregiver information). • Question 6.4: New identifiers/options added (none/study participant ID only, social insurance number, device identifier, Internet protocol address, race/ethnicity, family/caregiver information). • Question 6.7: New question about agreements added (grant agreement, clinical trial agreement, material transfer agreement, data transfer agreement). • Question 8.1: Revised to “Will study participants and/or substitute decision makers (SDMs) be provided with compensation or reimbursement in a different amount or method than that described in the Provincial Initial Application/CHEER Initial Application ? ” • Question 8.1 : Section about SDMs added • Question 8.3: New question added “Who will cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided if a participant suffers an injury as a result of participation in this study? ” • Section 11: Instructions revised to clarify whan a signature/attestation page would appear for the study PI, PI delegate, and Institutional Representative
Nov 22 2023 **rev 14 Dec 2023**	**Q#6.2 annotation change**: sites will now select identifiers they are releasing for study purposes, as per their institutional policies , which may or may not coincide with Provincial applicant response. Any discrepancy will be explained by selecting ‘Other’ and providing details in the text box **Q#8.1 : new annotation** to provide new instruction to respond YES **Q#8.1.1: new annotation** to provide details about reimbursement of site participants **Q#8.3: clarification on expected response**

CTO Clinical Trial Centre Initial Application Form

Orange text *indicates an upload or action feature*
Red/italics/bold *indicates question/feature dependencies*
Green text *indicates the help text associated with the question*
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/CHEER Initial Application)

SECTION 1.0 – GENERAL INFORMATION

1.0 ***Is this a resubmission in response to a request from CTO or the Research Ethics Board to make changes to your application?**

Choose an item.

HELP TEXT: If this is the FIRST TIME this application is being submitted please select "No". If this is a re-submission for modifications requested by CTO or the REB please select "Yes".

If 'Yes' to question 1.0:

If you are re-submitting this application in response to a request for changes from the REB, you may be asked to upload a PI response letter in question 10.1, outlining how each comment/question from the REB has been addressed in this re-submission. A response letter is not required if re-submitting in response to a request for changes from CTO.

1.0.1 ***Is this a Canadian Collaboration for Child Health (CHEER) study?**

☐ Yes ☐No

1.1 ***Please enter the Complete Study Title: (Enter exactly as written in protocol)**

1.2 **Please enter the Study ID/Number if applicable:**

1.3 ***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 emails. The short title is not included in REB letters.)**

Please answer the following questions related to this site's participation in the study: **[TEXT ELEMENT]**

1.4 ***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.

CONTACT TYPE: CENTRE PRINCIPAL INVESTIGATOR

HELP TEXT:

Principal Investigator refers to a researcher who is appropriately credentialed and qualified to conduct this study and who is responsible for the conduct of the study at this site. This individual is also responsible for submitting all site-specific materials to the REB of Record. Site-specific materials include ongoing submissions such as proposed changes to the conduct of the research at this site (centre amendments), centre reportable events, and centre continuing review applications.

1.5 ***Please complete the Centre Administrative 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.

CONTACT TYPE: CENTRE MAIN CONTACT

HELP TEXT:

The Centre Administrative Study Contact is the person tasked with completing and coordinating the site-specific REB submissions for this study.

1.6 ***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.

HELP TEXT:

Add this statement: 'Appropriately qualified and trained Co-Investigators are listed in the Site Delegation Log'

This may include a description of whether a Study Delegation Log will be established, how it will be maintained and whether any Co-Investigators will be involved.

1.6.1 List any Co-Investigators at this site (including name, address, organization and contact details):

Click here to enter text.

HELP TEXT:

Co-Investigator refers to a qualified individual at this site who agrees to assume responsibilities of the Principal Investigator in his/her absence. All site-specific REB submissions remain the responsibility of the Principal Investigator.

1.7 *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.

CONTACT TYPE: DEPARTMENT HEAD

HELP TEXT:

Department Approver refers to an individual with the authority (on behalf of a department, division or the institution as a whole) to attest to the appropriateness of the study, to attest to the experience, qualifications and resources of the PI and to allow or disallow some or all aspects of the research to proceed. If you are not sure who this individual is, click here to go to the CTO website and download the SRERS administration form for this institution, which MAY contain this information.

1.8 *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.

CONTACT TYPE: CENTRE INSTITUTIONAL REPRESENTATIVE

HELP TEXT:

The primary institutional representative is an administrator identified by the organization. If you are not sure who this individual is, click here to go to the CTO website and download the SRERS administration form for this institution, which contains this information.

1.9 *Is there a Secondary Institutional Representative at this site?

☐Yes ☐No

If 'Yes':

1.9.1 *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.

Fax: Click here to enter text.

*Email: Click here to enter text.

CONTACT TYPE: CENTRE INSTITUTIONAL REPRESENTATIVE

HELP TEXT:

Some institutions also identify a secondary institutional representative. If you are not sure if your site has a secondary institutional representative or who this individual is, click here to go to the CTO website and download the SRERS administration form for this institution, which contains this information.

1.10 *Explain this study in lay or non-scientific language (e.g., language suitable for a media release): (max 300 words)

SECTION 2.0 – SITE-SPECIFIC STUDY DESCRIPTION

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

2.2 ***How many participants are planned to be enrolled at this site?** Click here to enter text.

2.3 ***Will the protocol be implemented exactly as described in the currently approved provincial initial application/CHEER initial application and protocol/research plan?**

☐Yes ☐No

If 'No':

2.3.1 ***Explain any site-specific differences:** Click here to enter text.

Q2.3: the response is "Yes" unless there are any aspects of the study in which your Centre is not participating - e.g., if your site is not participating in a sub study.

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

☐Yes ☐No

If 'Yes':

2.4.1 ***Describe:** Click here to enter text.

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

☐Yes ☐No

HELP TEXT:

This question refers to study participant visits or procedures that will take place outside the site this Centre Initial Application is being submitted for (this includes satellite sites).

If 'Yes':

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

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

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

Q2.5: answer "Yes" if satellite sites may be used (pediatric studies only), **or** if any study visits or procedures will take place outside your centre – e.g., under a service agreement.

For Satellite Sites (Paediatric studies only):
Q2.5.1: provide the name of each Satellite site that may be used.
Q2.5.2: "POGO Satellite site contacts on file at OCREB and POGO."
Q2.5.3: you may reference the master agreements, addenda and POGO manual instead of listing the visit and procedures details.

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

Q2.6.1: 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 at this site?** Click here to enter text.

HELP TEXT:

Describe the method(s) and the criteria used to identify potential participants (i.e., through the circle of care, by the treating physician, review of medical records, self referral, use of posters/social media, referral from another physician, use of a database, etc.)

Q3.1: Potential participants should be identified by someone in the circle of care.

3.1.1 ***Will method of identification be the same for all participants?**

☐Yes ☐No

If 'No':

3.1.1.1 ***Explain:** Click here to enter text.

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':

3.3.1 ***Who will make the initial contact?** Click here to enter text.

If 'N/A':

3.3.2 ***Please explain why no initial contact will be made:** Click here to enter text.

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

☐In person

☐Telephone

☐Letter

☐Other

If 'Other':

3.4.1 ***Specify:** Click here to enter text.

3.5 ***Will initial contact/identification of participants be made by someone within the patient's circle of care?**

☐Yes

☐No

HELP TEXT:

Circle of care - It is a term commonly used to describe the ability of certain health information custodians to assume an individual's implied consent to collect, use or disclose personal health information for the purpose of providing health care, in circumstances defined in PHIPA.

If 'No':

3.5.1 *Explain why initial contact/identification of participants is being done by an individual who is not in the circle of care: Click here to enter text.

3.6 *What is the relationship between the person recruiting and the potential participants?

☐ Circle of care

☐ Not in circle of care

HELP TEXT:

Circle of care - It is a term commonly used to describe the ability of certain health information custodians to assume an individual's implied consent to collect, use or disclose personal health information for the purpose of providing health care, in circumstances defined in PHIPA.

If 'Not in circle of care':

3.6.1 *Explain why recruiting is being done by an individual who is not in the circle of care:

3.7 Upload 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):

UPLOAD DOCUMENT - DOCUMENT TYPE: CENTRE-SPECIFIC RECRUITMENT MATERIALS

HELP TEXT:

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

Q3.7: For OCREB submissions, there generally should not be any centre-specific recruitment materials. Sites should use provincially-approved materials. Changes to add site-specific contact information do not need to be submitted as these are 'pre-approved' changes.

SECTION 4.0 – INFORMED CONSENT INFORMATION

Provincial/CHEER (study-wide) information: Questions 4.1.1 – 4.1.2 below reflect information that has previously been provided to the REB and is here for reference purposes only.

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

☐ Yes ☐ No

4.1.2 ***A waiver of the requirement to obtain informed consent is being requested for:**

☐All participants

☐Some participants

If 'Some participants':

4.1.2.1 ***Describe the participant population for whom you are seeking a waiver and justify why the REB should consider a waiver of consent:** Click here to enter text.

If 'No' to question 4.1.1, questions 4.2-4.4 appear:

4.2 ***Describe the initial consent process, including how much time potential participants and/or substitute decision makers (SDMs) will be given to review the information before being asked to give consent:** Click here to enter text.

4.2.1 ***Who will be explaining the study and/or treatments to the potential participants?** Click here to enter text.

4.2.2 ***Will there be opportunity for participants and/or substitute decision makers (SDMs) to discuss the study with family members or others before signing the consent form? Describe the environment and location where consent will be obtained?** Click here to enter text.

HELP TEXT:

A substitute decision maker (SDM) is the term used for the person who would make health and personal care decisions on your behalf when you are unable to do so. Please see the Health Care Consent Act for more information.

4.2.3 ***Will consent be obtained from substitute decision makers (SDM)**

☐ Yes ☐ No ☐N/A

If 'Yes':

4.2.3.1 ***Explain and justify why consent is being obtained from a substitute decision maker:** Click here to enter text.

4.2.3.2 ***If a participant gains the capacity to consent please explain how and when consent from them will be obtained:** Click here to enter text.

4.2.4 ***Will consent be obtained from non-patients (i.e., healthy volunteers, caregivers)?**

☐ Yes ☐ No ☐N/A

4.3 ***Who will obtain the participant's signature (or substitute decision maker's) on the informed consent form?** Click here to enter text.

4.4 ***Is there a relationship between the potential participants and the person obtaining informed consent?**

☐Yes ☐No

If 'Yes':

4.4.1 ***Explain the nature of the relationship (e.g., treating physician, employer, supervisor, etc.):**
Click here to enter text.

If 'Yes':

4.4.2 ***Describe how you will minimize any undue influence:** Click here to enter text.

HELP TEXT:

Undue Influence refers to the impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority over them (e.g. doctor/patient, teacher/student, employer/employee).

If 'Some participants' is selected in 4.1.2, questions 4.5-4.7 appear:

4.5 ***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.

HELP TEXT:

Will there be opportunity for participants and/or substitute decision makers (SDMs) to discuss the study with family members or others before signing the consent form? Describe the environment and location where consent will be obtained. How will it be determined that the participant (or SDM) understands the information provided?

4.6 ***Who will obtain the participant's (or substitute decision maker's) informed consent?** Click here to enter text.

4.7 ***Is there a relationship between the potential participants and the person obtaining informed consent?**

☐Yes ☐No

If 'Yes':

4.7.1 ***Explain the nature of the relationship (e.g., treating physician, employer, supervisor, etc.):**
Click here to enter text.

If 'Yes':

4.7.2 ***Describe how you will minimize any undue influence:** Click here to enter text.

HELP TEXT:

Undue Influence refers to the impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority over them (e.g. doctor/patient, teacher/student, employer/employee).*If 'No' to question 4.1.1, questions 4.8-4.9 appear:*

4.8 ***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':

4.8.1 ***Explain the procedures:** Click here to enter text.

If 'No':

4.8.2 ***Please justify:** Click here to enter text.

4.9 ***Does this site require any changes (other than inclusion of centre letterhead and local contact information) to the approved provincial/CHEER consent form(s)?**

☐Yes ☐No

If 'Yes':

4.9.1 ***Explain:** Click here to enter text.

Q4.9: Always answer "YES" and include the following statement to "Explain" the changes:
"See OCREB Guidance for approved administrative changes"

If 'No' is selected in 4.1.1, questions 4.10-4.12 will appear:

4.10 ***Upload the proposed SITE-SPECIFIC consent form(s) with the proposed site-specific changes tracked:**
UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

Q4.10: for Pediatric CIAs only that include the use of Satellite sites: upload the signed Centre PI Attestation form.
Remember to provide the designated Satellite CTO Stream Account-Holder with a "Centre Study Staff-Read Only" role in CTO Stream!

4.11 ***Upload a clean version of the proposed SITE-SPECIFIC consent form(s) (e.g., with the proposed site-specific changes accepted):**
UPLOAD DOCUMENT - DOCUMENT TYPE: CENTRE-SPECIFIC CONSENT FORM

Q4.10 & 4.11: Upload ONLY your centre-specific OCREB Memo "Consent Guidelines for OCREB Centres-*centre name*", not your Centre consent(s). Contact OCREB if you do not have access to your site Memo.

4.12 **Upload any additional other SITE-SPECIFIC materials that will be given to study participants that were not already submitted and approved through a provincial application/CHEER application (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 - DOCUMENT TYPE: CENTRE-SPECIFIC MATERIALS

Q4.12: **Do NOT** upload your centre versions of provincial study materials (e.g., wallet card; diaries)

If 'Some Participants' is selected in 4.1.2, questions 4.13-4.15 will appear:

4.13 ***Upload the proposed SITE-SPECIFIC consent form(s) with the proposed site-specific changes tracked:**
UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

4.14 ***Upload a clean version of the proposed SITE-SPECIFIC consent form(s) (e.g., with the proposed site-specific changes accepted):**
UPLOAD DOCUMENT - DOCUMENT TYPE: CENTRE-SPECIFIC CONSENT FORM

4.15 **Upload any additional other SITE-SPECIFIC materials that will be given to study participants that were not already submitted and approved through a provincial application/CHEER application (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 - DOCUMENT TYPE: CENTRE-SPECIFIC MATERIALS

4.16 **Please upload the site-specific debriefing script, if applicable:**
UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT

SECTION 5.0 - SPECIAL CONSENT CONSIDERATION

5.1 ***Does this study permit/require the enrollment of participants who are not capable of providing consent (e.g., children, those who temporarily or permanently lack capacity)?**

☐Yes ☐No

If 'Yes':

5.1.1 *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':

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

If 'Yes':

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

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

☐ Yes ☐ No

If 'Yes', questions 5.2-5.4 appear:

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

☐Yes ☐No

If 'Yes':

5.2.1 *Explain: Click here to enter text.

5.2.2 *Provide the qualifications of those who will be obtaining assent: Click here to enter text.

5.3 ***Upload the proposed SITE-SPECIFIC assent form(s) with the proposed site-specific changes tracked:**
UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES DOCUMENT VERSION

5.4 ***Upload a clean version of the proposed SITE-SPECIFIC assent form(s) (e.g., with the proposed site-specific changes accepted):**
UPLOAD DOCUMENT - DOCUMENT TYPE: CENTRE-SPECIFIC ASSENT FORMS

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

☐ Patients
☐ Healthy Volunteers
☐ Students*
☐ Staff*
☐ People with mental health issues*
☐ Institutionalized People *
☐ Prisoners/persons in detention*
☐ People in poverty/economically disadvantaged*
☐ Educationally disadvantaged people*
☐ People who are unable to read or write*

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.

☐ Children*
☐ Neonates*
☐ 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
☐ Indigenous peoples and/or other distinct communities *
☐ Other

If any of the categories marked with an asterisk are selected, questions related to "special populations" will appear in the Provincial Initial Application/CHEER Initial Application and the Centre Initial Application

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

Click here to enter text

HELP TEXT:

Undue Influence refers to the impact of an unequal power relationship on the voluntariness of consent. This may occur when prospective participants are recruited by individuals in a position of authority over them (e.g., doctor/patient, teacher/student, employer/employee).

SECTION 6.0 - PRIVACY AND CONFIDENTIALITY

Provincial/CHEER (study-wide) information: The question below reflects information that has previously been provided to the REB and is here for reference purposes only.

6.0 *What (if any) Personal Information or Personal Health Information will be SENT TO or COLLECTED BY the lead researcher/research group/sponsor for the purposes of this study (select all that apply)?

- ☐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 and/or gender
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Health card number
- ☐Driver's license number
- ☐Address
- ☐Telephone number
- ☐Fax number
- ☐E-Mail address
- ☐Full face photograph
- ☐Voice/audio recording
- ☐Social Insurance Number (SIN) number
- ☐Device identifier
- ☐Internet Protocol address (IP address)
- ☐Race and/or ethnicity
- ☐Family/caregiver names and/or contact information
- ☐Other

Please answer the following questions related to this site's participation in the study:

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

☐Health record

☐Existing database

☐Other

HELP TEXT:

Types of records refers to any information source that must be accessed for the purposes of conducting the study. The medical record includes a variety of types of "notes" entered over time by health care professionals, recording observations and administration of drugs and therapies, orders for the administration of drugs and therapies, test results, x-rays, reports, etc.

Health Record refers to the terms medical record, health record, and medical chart are used somewhat interchangeably to describe the systematic documentation of a single patient's medical history and care across time within one particular health care provider's jurisdiction.

If 'Health Record':

6.1.1 ***Specify source of health records:** Click here to enter text.

If 'Existing Database':

6.1.2 ***Specify source of the existing database:** Click here to enter text.

If 'Other':

6.2.3 ***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/CHEER (study-wide) (shown above in question 6.0) 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 and/or gender

☐Full postal code

☐First 3 digits of postal code

☐Pathology specimen number

☐Medical device identifier

☐Admission date

☐Discharge date

☐Medical record number

☐Health card number

Q6.2: (NEW)
Please select what identifiers your site will be collecting and disclosing outside the institution for study purposes, and as per your institutional policies. If the response or the identifiers chosen here DO NOT match the identifiers approved at the Provincial level (as noted in Q#6.0), then please also select: **OTHER,** and specify in Q#6.2.1 what identifier/s is/are collected and provide an explanation for the discrepancy

☐Driver's license number
☐Address
☐Telephone number
☐Fax number
☐E-Mail address
☐Full face photograph
☐Voice/audio recording
☐Social Insurance Number (SIN) number
☐Device identifier
☐Internet Protocol address (IP address)
☐Race and/or ethnicity
☐Family/caregiver names and/or contact information
☐Other

HELP TEXT:

Question 6.0 is pre-populated with the PI/PHI that is being disclosed/sent outside the institution for the study overall, based on the information included in the previously approved application. If you have any questions regarding this information please contact the Provincial/CHEER Study Team.

If 'Other':

6.2.1 *Please specify: Click here to enter text.

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 (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 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
☐Other

HELP TEXT:

Encrypted refers to information or data that has been secured by adding a cipher or code, especially to prevent unauthorized access.

If 'Other':

6.3.1 *Specify other: Click here to enter text.

If 'Study Data stored on laptops or mobile devices will be encrypted':

6.3.2 *Please provide the encryption details for the laptops/mobile devices being used: Click here to enter text.

6.3.3 *Who will have access to the laptop/mobile devices and where will they be stored? Click here to enter text.

6.4 *What PI or PHI do you need to collect and RETAIN LOCALLY/on-site for the purposes of this study (e.g., recruitment tools, contact with participants, shadow files, recruitment or screening logs)?

- ☐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 and/or gender
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Health card number
- ☐Driver's license number
- ☐Address
- ☐Telephone number
- ☐Fax number
- ☐E-Mail address
- ☐Full face photograph
- ☐Voice/audio recording
- ☐Social Insurance Number (SIN) number
- ☐Device identifier
- ☐Internet Protocol address (IP address)
- ☐Race and/or ethnicity
- ☐Family/caregiver names and/or contact information
- ☐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 identifiers disclosed outside the institution. 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."*

HELP TEXT:
Please identify and justify any PI/PHI that will be retained locally (i.e., kept on-site) for the purposes of the study.

***If 'Other':* 6.4.1 *Specify other information:** Click here to enter text.

***If 'Other':* 6.4.2 *Justify other information:** Click here to enter text.

- *If 'Full Name':* **6.4.3 *Justify full name:** Click here to enter text.
- *If 'Initials':* **6.4.4 *Justify full initials:** Click here to enter text.
- *If 'partial initials':* **6.4.5 *Justify partial initials:** Click here to enter text.
- *If 'full date of birth':* **6.4.6 *Justify full date of birth:** Click here to enter text.
- *If 'Partial Date of Birth':* **6.4.7 *Justify partial date of birth:** Click here to enter text.
- *If 'Full Date of Death':* **6.4.8 *Justify full date of death:** Click here to enter text.
- *If 'Partial Date of Death':* **6.4.9 *Justify partial date of death:** Click here to enter text.
- *If 'Age':* **6.4.10 *Justify age:** Click here to enter text.
- *If 'Sex and/or gender':* **6.4.11 *Justify sex and/or gender:** Click here to enter text.
- *If 'Address':* **6.4.12 *Justify address:** Click here to enter text.
- *If 'Full Postal Code':* **6.4.13 *Justify full postal code:** Click here to enter text.
- *If 'First 3 digits of Postal code':* **6.4.14 *Justify first 3 digits of postal code:** Click here to enter text.
- *If 'Telephone Number':* **6.4.15 *Justify telephone number:** Click here to enter text.
- *If 'Email Address':* **6.4.16 *Justify Email address:** Click here to enter text.
- *If 'Fax Number':* **6.4.17 *Justify fax number:** Click here to enter text.
- *If 'Health Card Number':* **6.4.18 *Justify health card number:** Click here to enter text.
- *If 'Medical Record Number':* **6.4.19 *Justify medical record number:** Click here to enter text.
- *If 'Admission Date':* **6.4.20 *Justify admission date:** Click here to enter text.
- *If 'Discharge Date':* **6.4.21*Justify discharge date:** Click here to enter text.
- *If 'Pathology Specimen Number':* **6.4.22 *Justify pathology specimen number:** Click here to enter text.
- *If 'Medical Device Identifier':* **6.4.23 *Justify medical device identifier:** Click here to enter text.
- *If 'Driver's License Number':* **6.4.24 *Justify driver's license number:** Click here to enter text.
- *If 'Voice/audio recording':* **6.4.25 *Justify voice/audio recording:** Click here to enter text.
- *If 'Full face photograph':* **6.4.26 *Justify full face photograph:** Click here to enter text.
- *If 'SIN number':* **6.4.27 *Justify SIN number:** Click here to enter text.
- *If 'Device Identifier':* **6.4.28 *Justify device identifier:** Click here to enter text.
- *If 'Internet Protocol address (IP address)':* **6.4.29 *Justify internet protocol address (IP address):** Click here to enter text.
- *If 'Race and/or ethnicity':* **6.4.30 *Justify race and/or ethnicity:** Click here to enter text.
- *If 'Family/caregiver names and/or contact information':* **6.4.31 *Justify Family/caregiver names and/or contact information:** 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

HELP TEXT:

Study Data refers to data collected in the course of a clinical trial or any existing information from both study sources and external sources that may need to be accessed in order to conduct this study.

If 'Other':

6.5.1 *Specify other: Click here to enter text.

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

☐Yes ☐No

Q6.6: this refers to centre-specific study data. Confirm (especially for investigator-initiated studies) if there is a database where de-identified data will be stored for secondary/future use.

If 'Yes':

6.6.1 *Where will it be stored? Click here to enter text.

6.6.2 *Who will be the custodian? Click here to enter text.

6.6.3 *Who will have access to the database? Click here to enter text.

6.6.4 *Describe the security measures that will be in place to protect the confidentiality of the data:
Click here to enter text.

6.6.5 *How long will the data be stored? Click here to enter text.

If 'Yes' is selected in 1.0.1, questions 6.7 will appear:

6.7 *Which type of legal agreement were submitted to the contracts office (Select all that apply)

☐Grant agreement
☐Clinical Trial Agreement
☐Material Transfer Agreement
☐Data Transfer Agreement
☐Other

If 'Other':

6.7.1 *Specify other agreement: Click here to enter text.

6.7.2 *Date that the Other Agreement was submitted to the legal department: Click here to enter text.

6.7.3 *Has the Other Agreement been executed?

☐Yes ☐No

If 'Yes':

6.7.3.1 *Date that the Other Agreement was executed: Calendar Selection Field

If 'Granting Agreement':

6.7.4 *Date that the Grant Agreement was submitted to the legal department: Click here to enter text.

6.7.5 *Has the Grant Agreement been executed (grant awarded)?

☐Yes ☐No

If 'Yes':

6.7.5.1*Date that the Grant Agreement was executed (date grant was awarded): Calendar Selection Field

If 'Clinical Trial Agreement':

6.7.6 *Date that the Clinical Trial Agreement was submitted to the legal department: Click here to enter text.

6.7.7 *Has the Clinical Trial Agreement been executed?

☐Yes ☐No

If 'Yes':

6.7.7.1 *Date that the Clinical Trial Agreement was executed: Calendar Selection Field

If 'Material Transfer Agreement':

6.7.8 *Date that the Material Transfer Agreement was submitted to the legal department: Click here to enter text.

6.7.9 *Has the Material Transfer Agreement been executed?

☐Yes ☐No

If 'Yes':

6.7.9.1 *Date that the Material Transfer Agreement was executed: Calendar Selection Field

If 'Data Transfer Agreement':

6.7.10 *Date that the Data Transfer Agreement was submitted to the legal department: Click here to enter text.

6.7.11 *Has the Data Transfer Agreement been executed?

☐Yes ☐No

If 'Yes':

6.7.11.1 *Date that the Data Transfer Agreement was executed: Calendar Selection Field

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':

7.1.1 ***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.

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

7.1.3 ***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.

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

7.1.5 ***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':

7.2.1 ***Please describe the benefits:** Click here to enter text.

If 'Yes':

7.2.2 ***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':

7.3.1 ***Describe the relationships, interests or incentives:** Click here to enter text.

If 'Yes':

7.3.2 ***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':

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

If 'Yes':

7.4.2 ***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':

7.5.1 ***Describe the interest:** Click here to enter text.

If 'Yes':

7.5.2 ***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':

7.6.1 ***Describe the association or connection:** Click here to enter text.

If 'Yes':

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

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

☐Yes ☐No

HELP TEXT:

Investigator-initiated study refers to a research effort in which the investigator designs and implements the study protocol and the investigator, or the institution acts as the study sponsor.

If 'Yes': to 'Is this an investigator-initiated study'; the following will appear:

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

☐Yes ☐No

If 'Yes':

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

7.7.2 ***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

HELP TEXT:

Conflict of interest refers to the incompatibility of two or more duties, responsibilities, or interests (personal or professional) of an individual or institution as they relate to the ethical conduct of research, such that one cannot be fulfilled without compromising another. A conflict of interest often is a routine occurrence and not necessarily indicative of any inappropriate conduct.

If 'Yes':

7.8.1 *Specify: Click here to enter text.

7.8.2 *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. Institutional documents describing the management plan should be submitted (if available)

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 or inclusion in the Consent COI section of statements about a PI or Sub-I's potential conflict such as the receipt of honorariums from the Study Sponsor, which is subject to OCREB's review and approval

SECTION 8.0 – PARTICIPANT REIMBURSEMENT & STUDY RESULTS

8.1 ***Will study participants and/or substitute decision makers (SDMs) be provided with compensation or reimbursement in a different amount or method than that described in the Provincial Initial Application/CHEER ~~Initial Application~~?**

☐Yes ☐No

(NEW) 8.1 Please always respond **YES** here

If 'Yes':

8.1.1 ***Please Describe:** Click here to enter text.

(NEW) 8.1.1: Provide details on how your participants will be reimbursed, including what they will be reimbursed for ; approximate $ amount that may be provided and any other information that will be added to the **Compensation/reimbursement section** of your Centre consent form. If no reimbursement is provided, then please indicate that the template statement ***('You will be reimbursed for..)*** will be removed from the Centre consent.

8.2 ***Explain the plans to share the study results with this site's: study participants (individually or collectively), substitute decision makers (SDMs) and/or the local research community**

☐Individual debriefing at end of test session

☐Group debriefing

☐End of study letter

☐Publication

☐Other

☐No Plan

If 'Publication':

8.2.1 ***Describe publication plan:** Click here to enter text.

If 'Other':

8.2.2 ***Specify other:** Click here to enter text.

If 'No plan':

8.2.3 ***Justify no plan:** Click here to enter text.

8.3 ***Who will cover reasonable out-of-pocket expenses to ensure that immediate medical care is provided if a participant suffers an injury as a result of participation in this study?**

☐Sponsor

☐Funder

☐Institution

☐Other

If 'Other':

8.3.1 ***Please describe other:**

(NEW) Q. 8.3: If selecting 'Other', then please describe in 8.3.1 who will cover these expenses e.g. Provincial health plan ; private insurance etc. Participants should NOT be asked to pay for these types of study-related expenses.

SECTION 9.0 – TRANSLATIONS

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

☐Yes ☐No

Q9.1: answer "No". Translated Consent and participant materials should be submitted as provincial amendments

If 'Yes' to question 9.1, question 9.2 will appear:

9.2 ***Are the translated materials available for REB submission at this time?**

☐Yes ☐No

HELP TEXT:

If any site-specific translated materials are not available for REB submission at this time, they may be submitted later as a Centre Amendment.

9.3 **If applicable, please upload all SITE-SPECIFIC translated materials (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.:**

UPLOAD DOCUMENT - DOCUMENT TYPE: CENTRE-SPECIFIC TRANSLATED MATERIALS

9.4 **If applicable, please upload all translation certifications/supporting documentation for authenticity of the translation:**

UPLOAD DOCUMENT - DOCUMENT TYPE: TRANSLATION CERTIFICATE

SECTION 10.0 – RE-SUBMISSION INFORMATION

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

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, check to make sure 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.

This re-submission information section is not required to be completed when the resubmission is in response to changes requested by CTO.

Any revised documents should be deleted and re-uploaded into the appropriate section(s) of the application.

10.1 **Upload Principal Investigator response to REB request for modification letter (if applicable)**:
UPLOAD DOCUMENT - DOCUMENT TYPE: RESPONSE TO REB LETTER

NOTE: track-changes versions of consent/assent forms and/or debriefing material(s) MUST be uploaded into section 4 (do not upload here).

10.2 **If changes have been made to a previously submitted NON-CONSENT document at the request of the REB, please upload track-changes versions of the document (if applicable)**:
UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES DOCUMENT VERSION

10.3 **Upload any additional materials requested by the REB (if applicable):**
UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS

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

SECTION 11.0 – ATTESTATIONS AND SIGNATURES

If 'No' to question '1.0'; the Centre Principal Investigator signature appears:

11.1 Centre 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 (if applicable), 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 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 in accordance with all applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice; and provincial privacy laws
    - I attest that I have sufficient space, time and resources to conduct this trial;
    - I certify that all 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 site-specific:
    - modifications or amendments, such as changes in Centre PI, , 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/CHEER REB materials (e.g., REB approved provincial application forms/CHEER application forms including attachments, REB review letters, other correspondence

between the REB and the Provincial Applicant/CHEER Applicant, REB approval letters, REB approved provincial/CHEER consent forms, 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 all applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice; and provincial privacy laws

  SIGNATURE TYPE: PRINCIPAL INVESTIGATOR

If 'No' to question '1.0'; the Department Head signature appears:

11.2 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)

SIGNATURE TYPE: DEPARTMENT HEAD

If 'No' to question '1.0', the Centre Institutional Representative signature appears:

11.3 Institutional Representative

- I attest that this institution authorizes delegation of ethical oversight to the Research Ethics Board of Record appointed in respect of the Study, in keeping with the obligations as set out in the Inter-Institutional Agreement or REB of Record Agreement.

- I attest that the Principal Investigator is a researcher in good standing with this institution, and is appropriately qualified to act as the Principal Investigator 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 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.

SIGNATURE TYPE: CENTRE INSTITUTIONAL REPRESENTATIVE

If 'Yes' to question 1.0; the Principal Investigator or Delegate signature appears: (FOR RE-SUBMISSIONS)

11.5 Principal Investigator or Delegate

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I confirm that I have obtained any authorizations as applicable to make changes to this application. If signing on behalf of the Principal Investigator, I attest that the delegation of this responsibility has been documented.

SIGNATURE TYPE: PI OR DELEGATE