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

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)

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".

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:

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 *Is there a Co-Investigator (Co-I) at this site?
☐Yes ☐No

Q1.6: Recommend answering "No"
A response of 'YES' will require the Co-Applicant(s) to sign off on the CIA submission. Co-I's should be noted in the study delegation log.

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.

***If 'Yes':* 1.6.1 *Please enter the contact details of the 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.

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

1.6.2 *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.

Indicate the following: 'Appropriately qualified and trained Co-Investigators are listed in the Site Delegation Log'

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.

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 unaware of who this individual is please contact CTO at 1-877-715-2700 or streamline@ctontario.ca

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 unaware of whether your site has a secondary institutional representative or are unsure who this individual is please contact CTO at 1-877-715-2700 or streamline@ctontario.ca

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 will 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 application and protocol/research plan?**

☐Yes ☐No

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.

***If 'No':* 2.3.1 *Explain any site-specific differences:** Click here to enter text.

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

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): include the name of the satellite site (Q2.5.1) and the name of the Designated Satellite Investigator (DSI) and main Satellite contact (Q2.5.2). Remember to give the main satellite contact a Centre Study Staff role. Q2.5.3: you may reference the master agreement and addendum and the POGO manual instead of listing the visit and procedures details.

***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.

2.6 ***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

If 2.18a in the PIA (2.6 in this form) = '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', then the following will appear:

2.6.1 ***Please describe the available care in case of an emergency:**

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.

Q3.1: keep in mind that initial contact should be either through the patient's permission to be contacted by study staff, 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': **3.3.1** ***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': **3.4.1** ***Specify:** Click here to enter text.

3.5 **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 approved version is the insertion of local contact information and/or letterhead

Q3.5: there generally should not be any centre-specific recruitment materials.

SECTION 4.0 – INFORMED CONSENT INFORMATION

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:**

4.1.3 ***Is there any proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)**

☐ Yes ☐ No

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 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':* 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.

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

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

☐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 consent form(s)?**

☐Yes ☐No

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

If 'Yes': **4.9.1 *Explain:** Click here to enter text.

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

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: for those centres that are exempt from CTO Consent Form screening, upload ONLY your centre-specific OCREB Memo "Consent Guidelines for OCREB Centres-*centre name*". Contact OCREB if you are unsure if your centre is exempt from CTO consent form screening.

4.12 **Upload any additional other SITE-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 - 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 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 - Document Type: Centre-Specific Materials

If "yes" is selected in 4.1.1 or 4.1.3, question 4.13 will appear:

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?**
☐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.

***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 assent form(s)?**
☐Yes ☐No
***If 'Yes':* 5.2.1 *Explain:** 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):**
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*
☐ Institutionalized People *
☐ 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)

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.

☐ 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

If any of the * options are selected in 5.5, the following question appears:

5.5.1 *Describe how coercion and undue influence will be minimized: 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 (study-wide) information: The question below reflects information that has previously been provided to the REB and is here for reference purposes only.

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

- ☐ None, study participant ID only
- ☐ Full name
- ☐ Full initials
- ☐ Partial initials (e.g. first/last only)
- ☐ Full date of birth
- ☐ Partial date of birth (e.g., year/month only)
- ☐ 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
- ☐ Ontario health card number
- ☐ Driver's license number
- ☐ Address
- ☐ Telephone number
- ☐ Fax number
- ☐ E-Mail address
- ☐ Full face photograph
- ☐ Voice/audio recording
- ☐ 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:** 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 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
☐Ontario health card number
☐Driver's licence number
☐Address
☐Telephone number
☐Fax number
☐E-mail address
☐Full face photograph
☐Voice/audio recording
☐Other

Q6.2: **Do not select** any of the identifiers. Instead, select "OTHER" and add the following :
"As per institutional policy."

If 'Other': **6.2.1 *Please specify:** Click here to enter text.

HELP TEXT: Question 6.2 identifies the PI/PHI that is being disclosed/sent outside the institution for the study overall based on the information included in the Provincial application. Question 6.3 MUST reflect the information that THIS research site plans on disclosing/sending off-site and must be in accordance with institutional policies where applicable.

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:** 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)?

- ☐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
- ☐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': **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 'Ontario Health Card Number': **6.4.18 *Justify Ontario 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 'Date of Death': **6.4.22 *Justify date of death:** Click here to enter text.
If 'Pathology Specimen Number': **6.4.23 *Justify pathology specimen number:** Click here to enter text.
If 'Medical Device Identifier': **6.4.24 *Justify medical device identifier:** Click here to enter text.
If 'Driver's License Number': **6.4.25 *Justify driver's license number:** Click here to enter text.
If 'Voice/audio recording': **6.4.26 *Justify voice/audio recording:** Click here to enter text.
If 'Full face photograph': **6.4.27 *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

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:** 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.

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.

***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', 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.

7.7 ***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.

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 site 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': **8.1.1** ***Please describe:** Click here to enter text.

If 'No': **8.1.2** ***Justify:** Click here to enter text.

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

☐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.

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 "Yes" only if the translated materials are available for uploading to the current application. If they are not available, answer "No" and submit them when available as a Centre Amendment (CAM).

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

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.:**

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.

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

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 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, 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.

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):**

SECTION 11.0 – ATTESTATIONS AND SIGNATURES

If 1.0 = No:

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, 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 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 site-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 site.

Privacy and Security Acknowledgement:

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

Signature Type: Principal Investigator

If 11.0 = No

11.2 *Centre Co-Investigator

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

Signature Type: Principal Co-Investigator

If 1.0 = No

11.3 * 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 1.0 = No

11.4 *Institutional Representative

- 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.

Signature Type: Centre Institutional Representative

If 1.0 = Yes

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