

Participating Site Initial Application Form

Orange text indicates an upload or action feature

Red/italics/bold indicates question/feature dependencies

Red/italics/bold text highlighted yellow indicates the logic behind why a shared question appears in this sub-form (does not appear on the online forms)

Green text/bold indicates the help text associated with the question

Black/italics/bold indicates instructional text for researchers

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 Clinical Trial Initial Application)

SECTION 1.0 – GENERAL INFORMATION

1.0 *Is this a resubmission in response to a request from System Administrators 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 select "No". If this is a re-submission for modifications requested by System Administrators or the REB select "Yes".

If 'Yes' to question 1.0, the following text appears:

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 9.1, 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 System Administrators.

Study-wide information: Questions 1.0.1 – 1.4 below reflect study-wide information previously provided to the REB and are here for reference purposes only:

← **1.0.1 *Is this a Canadian Collaboration for Child Health (CHEER) study?**
→ Yes No

← **1.1 *Enter the Complete Study Title: (Enter exactly as written in protocol)**
→

← **1.2 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.)**
→

← **1.4 *Explain this study in lay or non-scientific language (e.g., language suitable for a media release): (max 300 words)**
→

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

1.5 *Complete the 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.
- *Province: Click here to enter text.
- Telephone: Click here to enter text.
- *Email: Click here to enter text.

CONTACT TYPE: 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 (Participating Site Amendments), Participating Site Reportable Events, and Site Continuing Review applications.

1.6 *Complete the Participating Site Administrative Contact details:

- *First Name: Click here to enter text.
- *Surname: Click here to enter text.
- *Organization: Click here to enter text.
- Telephone: Click here to enter text.
- *Email: Click here to enter text.

CONTACT TYPE: PARTICIPATING SITE MAIN CONTACT

HELP TEXT:

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

1.7 *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:

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.

Q#1.7: The response to Q#1.7 should include the following statement:

"Appropriately qualified and trained Co-Investigators will be listed on the Site Delegation

1.7.1 List any Co-Investigators at this site (including name, address, organization and contact details): Click here to enter text.

Q#1.7.1: In order to avoid unnecessary participating site amendments (PSAMs); do not include or list the different CO-I's that will be listed on the Site 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.

1.8 *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.

Click here to enter text. Telephone: 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.

1.9 *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.

*Province: Click here to enter text.

Telephone: Click here to enter text.

*Email: Click here to enter text.

CONTACT TYPE: PARTICIPATING SITE INSTITUTIONAL REPRESENTATIVE

HELP TEXT:

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

For CanReview studies, visit canreview.ca/howitworks/participating-sites.

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

Yes No

If 'Yes':

1.10.1 *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.

*Province: Click here to enter text.

Telephone: Click here to enter text.

*Email: Click here to enter text.

CONTACT TYPE: PARTICIPATING SITE 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, go to the [Participating Sites](#) page and download the SRERS administration form for this institution, which contains this information.

For CanReview studies, visit canreview.ca/howitworks/participating-sites.

SECTION 2.0 – SITE-SPECIFIC STUDY DESCRIPTION

2.1 *Expected start date of this study at this site: [Click here to enter text.](#)

Q#2.1: Ensure the date provided in this response is a current or future date (month and year)

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 Clinical Trial Initial Application and protocol/research plan?

Yes No

Q#2.3: The response should be “Yes” unless there are components of the study in which this site is not participating (i.e. a sub-study or optional sample collection).

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 Clinical Trial Initial Application?

Yes No

Q#2.4: The response to this section is typically “No” however, if there is a difference in standard of care than that which is outlined in the Study-wide application, select “Yes” and clearly explain the differences below.

If ‘Yes’:

2.4.1 *Describe: [Click here to enter text.](#)

2.5 * Will any participant visits or study procedures occur at a location that is not part of this legal entity (e.g., a different hospital, clinic, or research site)? *Do not include interim blood testing at an outside lab*

Yes No

Q#2.5: If there are assessments that will take place at an external location as per the site’s service agreement, please select “Yes”. The most common procedures performed at external locations include, but are not limited to; eye exams at an optometrist or ophthalmologists’ office ; RECIST tumour measurements; PET Scans. These assessments should align with the schedule of activities outlined in the study protocol.

Pediatric Studies Only: If satellite sites may be used, please select “Yes”.

For Satellite Sites: Q#2.5.1: Provide the name of each satellite site that may be used.

Q#2.5.2: Please include “POGO Satellite Site contacts on file at OCREB and POGO” as applicable.

Q#2.5.3: Reference to Master Agreements may be made here, as well as addenda and POGO manuals rather than listing the visit and procedure details.

HELP TEXT:

This question refers to study participant visits or procedures that will take place outside the site this application is being submitted for (this includes satellite sites that are not part of the same legal entity).

If you are not sure which sites are under the legal entity, visit the Participating Sites page. For CanReview studies, visit canreview.ca/howitworks/participating-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 legal entity: Click here to enter text.

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

Q#2.6: Ensure this response includes reference to the 24-hour emergency contact number on the consent form(s) and study wallet card.

SECTION 3.0 – RECRUITMENT

Study-wide information:

Questions 3.1 - 3.2 below reflect study-wide information previously provided to the REB and are shown here for reference purposes only.

3.1 *How will potential participants learn/find out about the study? (Select all that apply): {CTIA 4.1}

- Referral from health care providers
- Introduction from community partner (including health charity, advocacy organization, community group, etc.) or other groups
- Advertisements, including brochures, newspaper, radio, flyers, posters, and/or web-based recruitment tools (participants will self-refer)
- Recruitment database
- Third-party organization or recruitment company
- Website
- Social media
- Survey panel (e.g., Mechanical Turk)
- Snowball sampling
- Video (recordings will not be reviewed without scripts)
- From the investigator or other study team member(s) (e.g., for research involving colleagues, where potential participants are identified through the use of public information, or for institutions that have a permission to contact framework)
- Other

If 'Other':

3.1.1 *Specify other: Click here to enter text.

3.2 *How will participants initially be contacted by the research team? (select all that apply)? {CTIA 4.2}

- Telephone
- Email
- In-person
- Letter
- Participants will contact the study team
- Materials not ready at this time (to be submitted later)
- Other

If 'Other':

3.2.1 *Describe the other methods of contact:

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

3.3 *Will the research team be accessing any personal health information about the participant prior to their consent (e.g., screening records prior to making initial contact)?

- Yes
- No

If 'Yes':

3.3.1 *Describe (if seeking a waiver of consent including justification according to requirements): [Click](#)

Description should include institutional processes allowing this i.e. Research Staff are considered to be part of the circle of care or considered to be agents of the Health Information custodian (HIC) or site has a pre-approved screening policy through EPIC or implied consent/opt-out recruitment model .

OCREB does NOT approve consent waivers for screening purposes

3.4 *How will potential participants learn/find out about the study at this site? (see study-wide information above in question 3.1) (select all that apply)

- We will use all of the methods identified in the Study-Wide Application
- We will use some of the methods identified in the Study-Wide Application
- We will use other methods

If 'We will use some of the methods identified in the Study-Wide Application' is selected in 3.4:

3.4.1 *Indicate which methods you will use at this site: [Click here to enter text.](#)

If 'We will use other methods' is selected in 3.4:

3.4.2 *Describe the other methods for finding potential participants at this site:

3.5 *How will the research team first make contact with potential participants? (see study-wide information above in question 3.2) (select all that apply):

- We will use all of the methods identified in the Study-Wide Application
- We will use some of the methods identified in the Study-Wide Application
- We will use other methods

If 'We will use some of the methods identified in the Study-Wide Application' is selected in 3.5:

3.5.1 *Indicate which methods you will use at this site: [Click here to enter text.](#)

If 'We will use other methods' is selected in 3.5:

3.5.2 *Describe the other methods for contacting potential participants at this site:

If 'Telephone', 'Email', 'Letter', 'Materials not ready to be submitted at this time', or 'Other' is selected in 3.2, then 3.6 appears:

3.6 *Is the person making first contact with potential participants part of the circle of care?

- Yes No

Q#3.6: This response should be "Yes". Only individuals within the patient's circle of care should have access to their PHI (Personal Health Information) for the purposes of study recruitment.

HELP TEXT:

Select “No” if ANY member of the research team making initial contact is outside of the circle of care. Select “Yes” only if ALL members of the research team making initial contact are part of the circle of care.

If ‘No’:

3.6.1 *How is consent obtained from the potential participant to permit the research team to contact them? [Click here to enter text.](#)

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: SITE-SPECIFIC RECRUITMENT MATERIALS

HELP TEXT:

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

Q#3.7: There should not be any site-specific recruitment materials. Participating sites will be able to use the recruitment materials that have been approved at the study-wide level, as applicable.

SECTION 4.0 – INFORMED CONSENT INFORMATION

Study-wide information: Questions 4.1.1 – 4.1.11 below reflect information previously provided to the REB and are shown here for reference purposes only.

- 4.1.1 *Will informed consent be obtained from potential participants (select all that apply)? {CTIA 5.1}
- Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)
 - Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)
- Note: The use of remote consent, use of a substitute decision maker (SDM) or different methods of documenting informed consent (e.g., written, verbal, implied) are NOT considered alterations**
- Informed consent will not be obtained from some or all participants/substitute decision makers (SDMs) (a waiver of the requirement to obtain informed consent is being requested for some/all participants)
 - This study involves incapacitated patients experiencing a medical emergency and we are seeking authorization to proceed with the research intervention without the prior consent of participants/SDM (if this is your entire study population, select only this option – you do not need to separately select the ‘alteration’ and ‘waiver’ options above)

(Question 4.1.2 will appear in the PSIA if ‘Informed consent will not be obtained from some or all participants/substitute decision makers (SDMs) (a waiver of the requirement to obtain informed consent is being requested for some/all participants)’ was selected in CTIA in question 5.1)

- 4.1.2 *A waiver of the requirement to obtain informed consent is being requested for: {CTIA 5.2}
- All participants/substitute decision makers (SDMs)
 - Some participants/SDMs

If ‘Some participants’:

- 4.1.2.1 *Describe the circumstances/participant population for whom you are seeking a waiver: {CTIA 5.2.1} [Click here to enter text.](#)

(Question 4.1.3 and 4.1.4 will appear in the PSIA if ‘Informed consent will be obtained from some or all participants/substitute decision maker (SDM)’ or ‘Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)’ was selected in question 5.1 of the CTIA or ‘Some participants’ was selected in question 5.2 of the CTIA)

- 4.1.3 *How will the informed consent discussion be held? (Select all that apply): {CTIA 5.9}
- In person
 - Remote
 - No discussion proposed

If ‘No discussion proposed’:

- 4.1.3.1 *Justify why no discussion proposed: [Click here to enter text.](#)

- 4.1.4 *Indicate how informed consent from participants/substitute decision makers (SDMs) will be documented (select all that apply): {CTIA 5.10}

- Written
- Verbally
- Implied consent
- Other

If 'Other':

4.1.4.1 *Describe the proposed documentation process: {CTIA 5.10.1} Click here to enter text.

If 'Written':

4.1.4.2 *Is there a proposal to use a central e-consent platform/consent repository for this study (i.e., will electronic consent forms be stored outside of the site where informed consent is obtained?): {CTIA 5.10.2}

- Yes
- No

(Questions 4.1.5-4.1.8) appear if 'This study involves incapacitated patients experiencing a medical emergency and we are seeking authorization to proceed with the research intervention without the prior consent of participants/SDM (if this is your entire study population, select only this option – you do not need to separately select the 'alteration' and 'waiver' options above) was selected in question 5.1 of the CTIA)

4.1.5 *With respect to obtaining consent from the SDM prior to proceeding with the research:

How will this informed consent discussion be held? (select all that apply): {CTIA 5.14}

- In person
- Remote
- No discussion proposed

If 'No discussion proposed':

4.1.5.1 *Justify why no discussion proposed: Click here to enter text.

4.1.6 *Whenever possible, the research team must attempt With respect to obtaining consent from the SDM prior to proceeding with the research.

How will informed consent from substitute decision makers (SDMs) be documented prior to proceeding with the research? (Select all that apply): {CTIA 5.15}

- Written
- Verbally
- Other

If 'Other':

4.1.6.1 *Describe the proposed documentation process: {5.15.1} Click here to enter text.

4.1.7 *When the previously incapacitated participant regains decision-making capacity, or when the SDM is found, consent needs to be obtained for the continuation of the project (including continued use of the data) and subsequent research procedures (if applicable).

How will this informed consent discussion be held? (Select all that apply): {CTIA 5.16}

- In person
- Remote
- No discussion proposed

If 'No discussion proposed':

4.1.7.1 *Justify why no discussion proposed: Click here to enter text.

4.1.8 *When the previously incapacitated participant regains decision-making capacity, or when the SDM is found, consent needs to be obtained for the continuation of the project (including continued use of the data) and subsequent research procedures (if applicable).

How will this informed consent be documented? (Select all that apply): {CTIA 5.17}

- Written
- Verbally
- Other

If 'Other':

4.1.8.1 *Describe the proposed documentation process: {CTIA 5.17.1} Click here to enter text.

(Question 4.1.9 and 4.1.10 appear if 'Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)' or 'Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' is selected in CTIA question 5.1, OR 'Some participants' is selected in CTIA question 5.2)

4.1.9 *Is it foreseeable that participant(s) may lose decision-making capacity during the study? {CTIA 5.20}

- Yes
- No

4.1.10 *Which of the following will be used? (Select all that apply): {CTIA 5.21}

- Assent form(s)
- Consent form(s)
- Debriefing material(s) (e.g., script and/or form)
- Other consent/assent material(s)

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

If 'Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)', 'Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' or 'This study involves incapacitated patients experiencing a medical emergency....' is selected in 4.1.1, OR 'Some participants/SDMs' is selected in 4.1.2 then 4.3-4.4 appear:

4.2 *When consenting participants at this site, how will the informed consent discussion be held? (see study-wide information above in question 4.1.3) (Select all that apply):

- We will use all of the methods identified in the Study-Wide Application
- We will use some of the methods identified in the Study-Wide Application
- We will use other methods

If 'We will use some of the methods identified in the Study-Wide Application' or 'We will use other methods' is selected in 4.2:

4.2.1 *Describe the other methods for holding the consent discussion at this site:

- In person

- Remote
- No discussion proposed

HELP TEXT:

For the purposes of this application, remote consent refers to situations where informed consent is obtained when the participant and the person conducting the consent discussion/obtaining informed consent are not physically in the same room (e.g., consent discussion held by phone, tele/videoconference, etc.).

If 'No discussion proposed':

4.2.1.1 *Justify why no discussion proposed:

4.3 *How will the informed consent of participants be documented at this site? (see study-wide information above in question 4.1.4) (select all that apply):

- We will use all of the methods identified in the Study-Wide Application
- We will use some of the methods identified in the Study-Wide Application
- We will use other methods

If 'We will use some of the methods identified in the Study-Wide Application' or 'We will use other methods' is selected in 4.3:

4.3.1 *Indicate which methods for documenting informed consent will be used at this site:

- Written
- Verbally
- Implied consent
- Other

HELP TEXT:

Written consent: a process where the participant personally signs and dates the informed consent form (ICF). This includes scenarios where the participants signs via electronic signature applications and/or e-consent tools/platforms, as well as original/wet-ink signature participant signatures and/or scanned/faxed copies of handwritten participant signature. For clarity, the key is that the participant is personally providing their signature/dating their signature, regardless of the method (e.g., wet-ink, electronic) or tool (e.g., paper, platform, etc.) used to obtain the signature.

Verbal consent: a consent process where the participant does not personally sign or date the ICF; instead, their consent is documented by the person conducting the consent discussion.

Implied consent: The research team concludes that the participant has given informed consent based on their action or inaction in particular factual circumstances. For example, when an individual completes a survey after being provided with written information about the study, the research team may reasonably infer that the participant consents to provide this information for research purposes. Implied consent does not require the participant to clearly state/affirm their consent (e.g., by signing a consent, a verbal consent process, or selecting 'I agree' on an online survey).

Reminder: Not all methods of documentation are appropriate/permissible for all studies. There may be restrictions based on funders, privacy legislation, and government regulations.

Researchers must not propose methods of documentation that are not permitted for their study.

If 'Other' is selected in 4.3.1, the following questions appear:

4.3.1.1 *Describe the proposed documentation process:

If 'Yes' is selected in question 4.1.4.2, question 4.3.2 appears:

4.3.2 *Will this site be using the central e-consent platform/consent repository?

Yes No

If 'Remote' is selected in 4.1.3, 4.1.5 or 4.1.7, AND 'We will use all of the methods identified in the Study-Wide Application' is selected in 4.3;

OR

If 'Remote' is selected in 4.2.1, question 4.4 appears:

4.4 *Describe how and when the informed consent form(s) will be provided to the participant/SDM: Click or tap here to enter text.

If 'In Person' or 'Remote' is selected in 4.1.3, 4.1.5 or 4.1.7 AND 'We will use all of the methods identified in the Study-Wide Application' is selected in 4.3;

OR

If 'In Person' or 'Remote' is selected in 4.2.1, question 4.5 appears:

4.5 *How much time will potential participants and/or substitute decision makers (SDMs) have to review the information and consider participation? Will there be an opportunity to discuss with others? Click here to enter text.

If 'Remote' is selected in 4.1.3, 4.1.5 or 4.1.7 AND 'We will use all of the methods identified in the Application' is selected in 4.2;

OR

If 'Remote' is selected in 4.2.1, question 4.6 appears:

4.6 *Describe how and when the fully signed informed consent form(s) documents will be provided to the participant/SDM (indicate "not applicable" if you are relying solely on implied consent):

If 'Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)' or 'Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' is selected in 4.1.1 OR 'Some participants/SDMs' is selected in 4.1.2, question 4.7 appears:

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

Yes

No

Not Applicable (no participant signature)

If 'Yes':

4.7.1 *Explain the nature of the relationship (e.g., treating physician or other healthcare provider with a clinical relationship to the participant, 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 'Assent form' is selected in 4.1.10, question 4.8 appears:

4.8 *Will this site enroll participants who are not capable of providing informed consent?

Yes No

Q#4.8: This response is generally "No" for Adult studies; however, this may be "Yes" for pediatric studies .

HELP TEXT:

Capability/capacity refers to the person's ability to understand and appreciate relevant information and appreciate the potential consequences of the decision on whether or not to participate in a research study.

If 'Yes' to question 4.8, questions 4.9-4.14 appear:

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

Q#4.9: For pediatric studies, the target population may include minors who are not yet capable of providing consent on their own. Assessment of capacity to provide their own consent should be described clearly (how /who makes this assessment during the study) ; including when reconsenting will be done once they are deemed capable to consent on their own.

***Note:** There is no legal age of consent in ON ; ability to consent depends on their capacity to provide consent on their own , at any age (e.g. they can be young adults or adolescents)

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

4.11 *Describe how assent will be obtained from the study participants (e.g., the assent discussion and documentation process): Click or tap here to enter text.

4.12 *Does this site require any changes (other than inclusion of site-specific letterhead, local contact information, and requirements outlined in the site's DIER) to the approved study-wide assent form(s)?

Yes No

Q#4.12: This response should always be "Yes" followed by providing the following: "See OCREB Guidance for approved administrative changes."

HELP TEXT:

DIER refers to Documented Institutional Ethics Requirements a site is required to follow when completing their site-specific application.

The DIER for all Ontario CTO Participating Sites is available for download on the [Participating Sites page](#).

For CanReview studies, visit canreview.ca/howitworks/participating-sites.

If 'Yes':

4.13.1 *Explain: Click here to enter text.

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

OCREB does NOT review Site-specific Assent forms

Q#4.13: DO NOT upload Assent forms; instead, upload the OCREB Memo for your site to this Section.

*Note: If you do not have your site-specific memo, please reach out to [OCREB staff](#).

- For Pediatric studies only: For PSIA's that include the use of Satellite Sites; upload the signed Site PI Attestation form.

- *Note: Ensure to provide the designated Satellite Site CTO Stream Account-holder with a Site Staff-Read Only role in CTO Stream.

4.14 *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: SITE-SPECIFIC ASSENT FORMS

Q#4.14: DO NOT upload Assent forms; instead, upload the OCREB Memo for your site to this Section.

*Note: If you do not have your site-specific memo, please reach out to [OCREB staff](#).

If 'Yes' selected in question 4.1.9, questions 4.15–4.16 appear:

4.15 *The study-wide Application indicates that it is foreseeable that participant(s) may lose decision-making capacity during the study. Describe how capacity will be assessed (initially and ongoing, including assessment of loss of capacity): Click or tap here to enter text.

4.16 *Describe the procedures that will be followed if/when a participant loses capacity during the study:
Click or tap here to enter text.

If 'Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)', 'Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)' or 'This study involves incapacitated patients experiencing a medical emergency...' is selected in 4.1.1 or 'Some participants/SDMs' is selected in 4.1.2, questions 4.17-4.20 appear:

4.17 *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':

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

Q#4.17.1: Ensure that procedures for BOTH those who have language barriers /need translation and those unable to read or write are clearly described

If 'No':

4.17.2 ***Justify:** Click here to enter text.

4.18 ***Does this site require any changes (other than inclusion of site-specific letterhead, local contact information, and requirements outlined in the site's DIER) to the approved study-wide consent form(s)?**

Yes No

Q#4.18: The response to this section should always be "YES".

HELP TEXT:

DIER refers to Documented Institutional Ethics Requirements a site is required to follow when completing their site-specific application.

The DIER for all Ontario CTO Participating Sites is available for download on the [Participating Sites](#) page.

For CanReview studies, visit canreview.ca/howitworks/participating-sites.

If 'Yes':

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

Q#4.18.1: Please respond with: "See OCREB Guidance for approved administrative changes"

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

OCREB does NOT review Site-specific Consent forms

Q#4.19: DO NOT upload your Site Consent form(s) ; instead, upload the OCREB Pre-Approved changes Memo for your site to this Section.

***Note: If you do not have your site-specific memo, please reach out to [OCREB](#) staff.**

4.20 ***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: SITE-SPECIFIC CONSENT FORM

Q#4.20: DO NOT upload your Site-Specific Consent form(s) ; instead, upload the OCREB Pre-Approved changes Memo for your site to this Section.

***Note: If you do not have your site-specific memo, please reach out to [OCREB](#) staff.**

4.21 Upload any additional other SITE-SPECIFIC materials that will be given to study participants that were not already submitted and approved through a study-wide 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: SITE-SPECIFIC MATERIALS

Q4.21: DO NOT upload your site-specific version of Study-wide study materials (e.g., wallet card; diaries)

4.22 Upload the site-specific debriefing script, if applicable:

UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT

Q#4.22: Debriefing materials would only apply IF the study involves and alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception); Otherwise, no materials should be uploaded here

SECTION 5.0 - PRIVACY AND CONFIDENTIALITY

Study-wide information: Question 5.0 – 5.01 below reflect information previously provided to the REB and is here for reference purposes only.

5.0 *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 (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 (e.g. year/month only)
- Age
- Sex
- Gender identity
- 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
- Identifiable photographs (e.g., full face photos, or other photos containing identifiable information)
- Voice/audio recording
- Video 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 information

If 'Other':

5.0.1 *Specify other information: Click here to enter text.

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

5.1 *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':

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

If 'Existing Database':

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

If 'Other':

5.1.3 *Specify any other types of records that must be accessed: Click here to enter text.

To help answer question 5.2, reference the list of PI/PHI identifiers approved to be collected for the overall study in question 5.0 above.

5.2 * Will this site be sending all the PI/PHI identifiers offsite that were approved to be collected for the overall study?

- Yes – this is the PI/PHI we will be sending off-site
- No – we will not be sending certain PI/PHI off-site
- No – we are requesting to send additional PI/PHI off-site

HELP TEXT:

Question 5.0 identifies the PI/PHI that is being disclosed/sent outside the institution for the study overall based on the information included in the Study-Wide Application.

Question 5.2 must reflect the information that THIS research site plans on disclosing/sending off-site and must be in accordance with institutional policies where applicable. If you are planning on sending ADDITIONAL information off-site for study purposes, it must be identified and justified.

If 'No – we will not be sending certain PI/PHI off-site':

5.2.1 *Please specify what PI/PHI will not be sent off-site: Click here to enter text.

If 'No – we are requesting to send additional PI/PHI off-site':

5.2.2 *Please specify the additional PI/PHI you wish to send off-site: Click here to enter text.

5.2.3 *Please justify sending this additional PI/PHI off-site: Click here to enter text.

5.3 *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':

5.3.1 *Specify other: Click here to enter text.

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

5.3.2 *Provide the encryption details for the laptops/mobile devices being used: Click here to enter text.

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

5.4 *What additional 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 (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 (e.g., year/month only)
- Age
- Sex
- Gender identity
- 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
- Identifiable photographs (e.g., full face photographs, or other photos containing identifying information)
- Voice/audio recording
- Video 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:

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

Gender identity refers to the socially constructed roles, behaviours, expressions and identities of girls, women, boys, men, and gender-diverse people. It influences how people perceive themselves and each other, how they act and interact, and the distribution of power and resources in society. There is considerable diversity in how individuals and groups understand, experience, and express it.

Sex refers to a set of biological attributes in humans. It is primarily associated with physical and physiological features including chromosomes, gene expression, hormone levels and function, and reproductive/sexual anatomy. It may also refer to a person's legal sex, i.e., the sex that is recognized under the law.

↩️ **If 'Other': 5.4.1 *Specify other information:** Click here to enter text.

↩️ **If 'Other': 5.4.2 *Justify other information:** Click here to enter text.

↩️ **If 'Full Name': 5.4.3 *Justify full name:** Click here to enter text.

↩️ **If 'Initials': 5.4.4 *Justify full initials:** Click here to enter text.

↩️ **If 'partial initials': 5.4.5 *Justify partial initials:** Click here to enter text.

↩️ **If 'full date of birth': 5.4.6 *Justify full date of birth:** Click here to enter text.

↩️ **If 'Partial Date of Birth': 5.4.7 *Justify partial date of birth:** Click here to enter text.

↩️ **If 'Full Date of Death': 5.4.8 *Justify full date of death:** Click here to enter text.

↩️ **If 'Partial Date of Death': 5.4.9 *Justify partial date of death:** Click here to enter text.

- ◀ **If 'Age': 5.4.10 *Justify age:** Click here to enter text.
- ◀ **If 'Sex': 5.4.11 *Justify sex:** Click here to enter text.
- ◀ **If 'Gender identity': 5.4.12 *Justify gender identity:** Click here to enter text.
- ◀ **If 'Address': 5.4.13 *Justify address:** Click here to enter text.
- ◀ **If 'Full Postal Code': 5.4.14 *Justify full postal code:** Click here to enter text.
- ◀ **If 'First 3 digits of Postal code': 5.4.15 *Justify first 3 digits of postal code:** Click here to enter text.
- ◀ **If 'Telephone Number': 5.4.16 *Justify telephone number:** Click here to enter text.
- ◀ **If 'Email Address': 5.4.17 *Justify Email address:** Click here to enter text.
- ◀ **If 'Fax Number': 5.4.18 *Justify fax number:** Click here to enter text.
- ◀ **If 'Health Card Number': 5.4.19 *Justify health card number:** Click here to enter text.
- ◀ **If 'Medical Record Number': 5.4.20 *Justify medical record number:** Click here to enter text.
- ◀ **If 'Admission Date': 5.4.21 *Justify admission date:** Click here to enter text.
- ◀ **If 'Discharge Date': 5.4.22 *Justify discharge date:** Click here to enter text.
- ◀ **If 'Pathology Specimen Number': 5.4.23 *Justify pathology specimen number:** Click here to enter text.
- ◀ **If 'Medical Device Identifier': 5.4.24 *Justify medical device identifier:** Click here to enter text.
- ◀ **If 'Driver's License Number': 5.4.25 *Justify driver's license number:** Click here to enter text.
- ◀ **If 'Voice/audio recording': 5.4.26 *Justify voice/audio recording:** Click here to enter text.
- ◀ **If 'Full face photograph': 5.4.27 *Justify identifiable photographs:** Click here to enter text.
- ◀ **If 'SIN number': 5.4.28 *Justify SIN number:**
- ◀ **If 'Device Identifier': 5.4.29 *Justify device identifier:** Click here to enter text.
- ◀ **If 'Internet Protocol address (IP address)': 5.4.30 *Justify internet protocol address (IP address):** Click here to enter text.
- ◀ **If 'Race and/or ethnicity': 5.4.31 *Justify race and/or ethnicity:** Click here to enter text.
- ◀ **If 'Family/caregiver names and/or contact information': 5.4.32 *Justify Family/caregiver names and/or contact information:** Click here to enter text.
- ◀ **If 'Video recording': 5.4.33 *Justify video recording:** Click here to enter text.

If 'Yes' is selected in 1.0.1, questions 5.5 will appear:

5.5 *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':

5.5.1 *Specify other agreement:

5.5.2 *Date that the Other Agreement was submitted to the legal department: Calendar Selection Field

5.5.3 *Has the Other Agreement been executed?

- Yes No

If 'Yes':

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

If 'Granting Agreement':

5.5.4 ***Date that the Grant Agreement was submitted to the legal department:** Calendar Selection Field

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

Yes No

If 'Yes':

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

If 'Clinical Trial Agreement':

5.5.6 ***Date that the Clinical Trial Agreement was submitted to the legal department:** Calendar Selection Field

5.5.7 ***Has the Clinical Trial Agreement been executed?**

Yes No

If 'Yes':

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

If 'Material Transfer Agreement':

5.5.8 ***Date that the Material Transfer Agreement was submitted to the legal department:** Calendar Selection Field

5.5.9 ***Has the Material Transfer Agreement been executed?**

Yes No

If 'Yes':

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

If 'Data Transfer Agreement':

5.5.10 ***Date that the Data Transfer Agreement was submitted to the legal department:** Calendar Selection Field

5.5.11 ***Has the Data Transfer Agreement been executed?**

Yes No

If 'Yes':

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

SECTION 6.0 - CONFLICT OF INTEREST

*****Any Conflict of Interest (COI) declarations must include confirmation that the COI was submitted to the Institutional Compliance Department ; actual report may NOT be available for OCREB submission but management plan should be clearly described. Where a COI exists for the Principal Investigator or a Sub-Investigator, OCREB may require that this be disclosed in the Site-specific ICF; the Approval letter will list the required language addition, if applicable.**

6.1 *Will the investigator or sub-investigators or anyone connected to them through 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':

6.1.1 *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.](#)

6.1.2 *Explain what this amount covers with respect to the direct costs associated with doing this research: [Click here to enter text.](#)

6.1.3 *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.](#)

6.1.4 *For what purpose did they receive these funds? [Click here to enter text.](#)

6.1.5 *Describe the proposed management plan: [Click here to enter text.](#)

6.2 *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':

6.2.1 *Please describe the benefits: [Click here to enter text.](#)

If 'Yes':

6.2.2 *Describe the proposed management plan: [Click here to enter text.](#)

6.3 *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':

6.3.1 *Describe the relationships, interests or incentives: [Click here to enter text.](#)

If 'Yes':

6.3.2 *Describe the proposed management plan: [Click here to enter text.](#)

6.4 *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':

6.4.1 *Describe the institutional conflicts of interest: [Click here to enter text.](#)

If 'Yes':

6.4.2 *Describe the proposed management plan: [Click here to enter text.](#)

6.5 *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':

6.5.1 *Describe the interest: [Click here to enter text.](#)

If 'Yes':

6.5.2 *Describe the proposed management plan: [Click here to enter text.](#)

6.6 *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.)

Q#6.6: This is the most common COI declared for studies where the PI or Sub-I has a current or past consulting role with the Study Sponsor. The response to this section should be "Yes" if this role exists.

Yes No

If 'Yes':

6.6.1 *Describe the association or connection: [Click here to enter text.](#)

Q#6.6.1: This section should clearly indicate the nature of this role ; including a confirmation of whether or not this is a previous or an ongoing role ; confirmation of whether this is a paid or unpaid role ; and whether this is directly related to the study being reviewed

If

'Yes':

6.6.2 *Describe the proposed management plan: [Click here to enter text.](#)

Q#6.6.2: This section should include the following as part of the management plan:

- that the COI is being disclosed to the REB for this study and to the institutional compliance dept.; plan to disclose to participants by way of the consent form, if required by the REB

6.6.3 *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:

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

Yes No

If 'Yes':

6.7.1 *Describe any real, potential, or perceived conflict of interest: [Click here to enter text.](#)

*****If Q#6.6.3 and 6.7 are both "Yes", then this is considered a COI and Q#6.7.1 and 6.7.2 should be completed.*****

Q#6.7.1: The following are examples of how the COI can be described:

The investigator has dual obligations:

- 1. To act in the patient's best clinical interest (as their doctor), and**
- 2. To successfully conduct and complete the research (as the sponsor and investigator)**

These dual roles can:

- **Undermine voluntariness of consent (patients may not feel free to say 'No'; or may feel pressure to participate out of trust or loyalty to their treating physician)**
- **Affect objectivity in enrollment and treatment decisions.**

6.7.2 *Provide the proposed management plan: [Click here to enter text.](#)

Q#6.7.2: The following are examples of strategies to manage the COI for dual roles:

a. For the Consent Process: A qualified research team member who is not involved in the patient's direct clinical care will approach potential participants, review study details, and obtain informed consent.

b. Eligibility Review Oversight: The PI will not independently issue eligibility waivers for their own patients. Any eligibility waiver (or exception to inclusion/exclusion criteria) will be reviewed and approved by an independent qualified physician or a study oversight committee.

c. Disclosure of COI to participants: will be done through language added to the ICF that will be provided by OCREB in the approval letter.

6.8 *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':

6.8.1 *Specify: [Click here to enter text.](#)

6.8.2 *Provide the proposed management plan: [Click here to enter text.](#)

SECTION 7.0 – PARTICIPANT REMUNERATION & COMMUNICATION OF STUDY RESULTS

7.1 *Will study participants and/or substitute decision makers (SDMs) be provided with remuneration in a different amount or method than that described in the Clinical Trial Initial Application?

Yes No

Q#7.1 – The response to this section should always be “Yes”.

HELPTXT:

For additional information about participant expense remuneration please see the Participant Experience Toolkit.

If ‘Yes’:

7.1.1 *Describe: Click here to enter text.

Q#7.1.1 – This section should outline the details on how participants at this site will be reimbursed, including what they will be reimbursed for; approximate \$ amount that may be provided, if known and any other information that will be added to the Compensation/reimbursement section of the site-specific consent form.

***Note: If the Study-wide application includes a third-party reimbursement vendor (e.g. Greenphire or Scout Clinical) this response should clearly indicate whether the site will be using this method of reimbursement, or not.**

OCREB is aware that some sites do not provide reimbursement. If no reimbursement is being provided at this site, please indicate that the template statement ‘You will be reimbursed for...’ will be removed from the Site-specific consent.

7.2 *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

Q#7.2 : TCPS2 requires that study results be shared with participants and/or the research community. Since most studies are registered, select ‘Publication’ and refer to Clinicaltrials.gov , in addition to any other plans such as providing a Study results summary at the end of the study

HELPTXT:

For additional information about communicating results to participants please see the Participant Experience Toolkit.

If ‘Other’:

7.2.1 *Specify other: Click here to enter text.

If ‘No plan’:

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

SECTION 8.0 – TRANSLATIONS

8.1 *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

Q#8.1 – The response to this section should be “No”. Translated materials should be submitted and approved at the Study-wide level for all participating sites to use.

If ‘Yes’ to question 8.1, question 8.2 will appear:

8.2 *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 Participating Site Amendment.

8.3 If applicable, 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: SITE-SPECIFIC TRANSLATED MATERIALS

8.4 If applicable, upload all translation certifications/supporting documentation for authenticity of the translation:

UPLOAD DOCUMENT - DOCUMENT TYPE: TRANSLATION CERTIFICATE

SECTION 9.0 – RE-SUBMISSION INFORMATION

If 'Is this a resubmission in response to a request from System Administrators 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 only appears when the response to Q#1.0 is "Yes". If there is no place to upload a response letter, or additional requested materials, review the application responses to check to make sure that Q#1.0 is answered "Yes". Any additional information that would assist in the OCREB review of this application should be entered in**

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

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

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

UPLOAD DOCUMENT - DOCUMENT TYPE: RESPONSE TO REB LETTER

NOTE: Tracked-changes versions of consent/assent forms and/or debriefing material(s) MUST be uploaded into SECTION 4.0 (do not upload here).

9.2 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

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

UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS

9.4 Provide any additional comments for the REB to consider (if applicable): [Click here to enter text.](#)

SECTION 10.0 – ATTESTATIONS AND SIGNATURES

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

10.1 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 Site 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 Streamlined Research Ethics Review System, any proposed site-specific:
 - modifications or amendments, such as changes in Site PI, site-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 study-wide REB materials (e.g., REB approved study-wide application forms including attachments, REB review letters, other correspondence between the REB and the Lead Applicant, REB approval letters, REB approved study-wide consent forms, etc.);

- I will ensure that all REB approved changes will be implemented at my site, 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 Site 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

PI Signature is REQUIRED for the initial submission of a PSIA

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

10.2 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 Participating Site Institutional Representative signature appears:

10.3 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: PARTICIPATING SITE INSTITUTIONAL REPRESENTATIVE

If 'Yes' to question 1.0; the Principal Investigator or Delegate signature appears:

10.4 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

Delegate /Study Staff may sign the application for RESUBMISSIONS only.