Clinical Trial Participating Site Amendment 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 Clinical Trial Initial Application (Provincial/CHEER Initial Application)

SECTION 1.0 - GENERAL INFORMATION

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

Choose an item.

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 the REB select "Yes".

If 'Yes' to question 1.0:

If required, ensure that you upload a PI response letter in question 16.1, outlining how each comment/question from the REB has been addressed in this re-submission.

Study-wide information:

Questions 1.0.1 – 1.4 below reflect study-wide information that has previously been 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 **[Not editable]**

1.1 *Enter the complete Study Title: [Not editable]

1.2 Enter the Study ID/Number (if applicable): [Not editable]

1.3 *What is the acronym or nickname/short title for the 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.) [Not editable]

1.4 *Explain this study in lay or non-scientific language (e.g., language suitable for a media release): (max 300 words) [Not editable]

Site-specific information:

Questions 1.5 – 1.7 below reflect site-specific information previously provided to the REB. If making changes to this section, research teams must select one of the following checkbox options in question 2.1: 'Change(s)

to CONTACT DETAILS ONLY for the Principal Investigator', 'Change in Principal Investigator', or 'Change(s) to the name and/or contact details for the Participating Site Administrative Contact'.

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.

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.

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.

SECTION 2.0 - AMENDMENT DETAILS

2.0 *Is this amendment submission solely related to an approved study-wide amendment (For example, the amendment only includes revised site-specific ICFs based on a new approved study-wide version)?

☐Yes

☐ We are implementing study-wide changes PLUS new additional changes

☐ N/A – this amendment is not related to a study-wide change

HELP TEXT:

"Yes" should only be selected if there are no additional site-specific changes (beyond the inclusion of site-specific letterhead, contact information, and DIER as applicable) included in the amendment.

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', or 'We are implementing study-wide changes PLUS new additional changes' is selected in 2.0:

2.0.1 *Enter the Review Reference # or amendment identifier/description from the project tree of the corresponding Study-Wide Amendment: Click here to enter text.

HELP TEXT:

The Review Reference # is the number that was assigned to the submission of the corresponding Study-Wide Amendment. The Review Reference Number can be found by selecting the study-wide amendment form in the project tree.

Research teams must CLEARLY IDENTIFY the Study-Wide Amendment that this Participating Site Amendment is related to.

If 'We are implementing study-wide changes PLUS new additional changes', or 'N/A-this amendment is not related to a study-wide change' is selected in question 2.0, question 2.1 appears:

2.1 *Type of Amendment (select all that apply):

☐Site-specific change(s) to the consent/assent form(s) or debriefing material(s) used at this site* ☐ Change(s) in the informed consent/assent/debriefing process at this site

☐Site-specific translation of approved material(s)

☐ Site-specific change(s) in recruitment methods and/or recruitment material(s) (e.g., telephone, web or email scripts, flyers, brochures, etc.) used at this site

☐Change(s) to other site-specific material(s) that will be given to study participants (including surveys/questionnaires/scripts, diaries and wallet cards)

☐Change(s) to how personal information or personal health information is being accessed, collected, used, stored or transferred at this site

☐Change(s) in the conflict of interest information previously provided to the REB for any of the investigators, study staff or members of their immediate families

☐Change(s) in participant remuneration and/or communication of study results**

**** Select if you are submitting changes to details about reimbursement at your site that you initially provided in your PSIA e.g. change to the amount; change to what expenses will be reimbursed**

☐Change(s) in site-specific study conduct (including location of visits/procedures, standard of care, and protocol implementation)*

***Select if you are submitting changes such as sending imaging to another site for RECIST measurements; sending participants to another site for PET CT; MRI, etc.**

☐Change in Principal Investigator **

**** If selected, ensure that the INCOMING /NEW PI signs the application**

☐Change(s) to CONTACT DETAILS ONLY for the Principal Investigator

☐Change to name and/or the contact details for the Participating Site Administrative Contact

☐Other changes ***

HELP TEXT:

Site-specific recruitment materials refer to telephone, web or email scripts, flyers, brochures, etc., that will be used for the purpose of recruiting study participants at this site that have not been otherwise reviewed and approved at a study-wide level. Site-specific recruitment materials includes local changes to study-wide approved materials.

Other site-specific materials refer to diaries, wallet cards, telephone or email scripts that you will use for communicating with study participants during the course of the study that have not been otherwise reviewed and approved at a study-wide level. Other site-specific materials include local changes to study-wide approved materials.

Institutional Representative and Department Approver/Department Head signatures are required on the initial submission of this amendment if it includes change(s) to the Principal Investigator at this site.

If 'Change to CONTACT DETAILS ONLY for the Principal Investigator' or 'Change to the Participating Site Administrative Contact' are the only options selected in 2.1, the following text appears:

Amendments exclusively for changes to study personnel (besides site PI) should not be submitted at this time. Please wait until there are additional changes to submit.

If 'We are implementing study-wide changes PLUS new additional changes', or 'N/A-this amendment is not related to a study-wide change' is selected in question 2.0, question 2.2 appears:

2.2 *Provide a brief lay summary and rationale for each of the proposed changes: Click here to enter text.

2.3 *What is the current study status at this site?

Q#2.3: When selecting study status, please do NOT count Screen Failures as 'enrolled' participants

☐Not yet activated **[Exclusive]**

☐Activated, but no participants enrolled to date **[Exclusive]**

☐Activated/open to enrollment, participants have been enrolled but none are currently receiving study treatment/intervention **[Exclusive]**

☐Activated/open to enrollment with one or more study participant(s) receiving study treatment/intervention **[Exclusive]**

☐Activated/open to enrollment with current participants in follow up only **[Exclusive]**

☐Permanently closed to enrolment, one or more study participant(s) receiving treatment/intervention **[Exclusive]**

☐Permanently closed to enrolment, no participants are receiving treatment/intervention, and all study participants are in long term follow up or data collection continues **[Exclusive]**

☐Study completed (i.e., no further involvement of study participants and no further data collection) **[Exclusive]**

☐Prematurely terminated **[Exclusive]**

☐Other **[Exclusive]**

If 'Other':

2.3.1 *Specify: Click here to enter text.

If 'Prematurely terminated':

2.3.2 *Provide details: Click here to enter text.

Q2.3.2: Provide details /reason for premature termination of the study at your site

2.4 *Provide a label for this amendment (e.g., an amendment identifier/description) that will appear in the project tree (40 CHARACTERS MAX): Click here to enter text.

HELP TEXT:

The information entered into this field will appear in the project tree and is used to easily distinguish between amendments. This information will not appear in the REB approval letter.

2.5 If applicable, provide an amendment reference number/ID/label that will appear in the REB letters: Click here to enter text.

HELP TEXT:

The information, if applicable, will appear on the REB approval letter to identify this amendment.

SECTION 3.0 – SITE-**SPECIFIC CONSENT/ASSENT FORM(S)** OR DEBRIEFING MATERIAL(S)

If 'Site-specific changes to the consent/assent form used at this site' is selected in question 2.1, the following questions appear:

3.1 ***Which of the following forms are being changed (select all that apply)?**

☐Consent form(s)

☐Assent form(s)

☐Debriefing material(s)

☐Consent/Assent update form(s)

☐Other consent/assent material(s)

HELP TEXT:

Consent/assent update form refers to a consent document containing only the new or updated information relevant to participants previously enrolled in the study.

If 'Consent Form(s) is selected in question 3.1, question 3.2-3.3 appears:

3.2 Upload the revised consent form(s) showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS

HELP TEXT:

When submitting a new site-specific consent form that is unrelated to a recent study-wide amendment, the tracked changes document should show all revisions being made to the most recent approved version of the site-specific ICF for your site.

3.3 *Upload clean version(s) of the new or revised consent form(s):

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC CONSENT FORM

If 'Assent Form(s)' is selected in question 3.1, question 3.4-3.5 appears:

3.4 Upload the revised assent form(s) showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES DOCUMENT

HELP TEXT:

When submitting a new site-specific assent form that is unrelated to a recent study-wide amendment, the tracked changes document should show all revisions being made to the most recent approved version of the site-specific assent form for your site.

3.5 *Upload clean version(s) of the new or revised assent form(s):

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC ASSENT FORM

If 'Debriefing material(s)' is selected in 3.1, questions 3.6-3.7 will appear:

3.6 Upload the revised debriefing material(s) showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT– DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS

HELP TEXT:

When submitting new site-specific debriefing material(s) that are unrelated to a recent study-wide amendment, the tracked changes document should show all revisions being made to the most recent

approved version of the site-specific debriefing material(s) for your site.

3.7 *Upload clean versions of all new or revised debriefing material(s):
UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT

If 'Other consent/assent materials' is selected in 3.1, questions 3.8-3.9 will appear:

3.8 Upload the revised other consent/assent material(s) showing the changes from the currently approved version (i.e., with the changes tracked):
UPLOAD DOCUMENT– DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS

3.9 *Upload clean versions of the new or revised other consent/assent material(s) that will be used at this site:
UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER CONSENT/ASSENT MATERIAL(S)

If 'Site-specific changes to the consent/assent form used at this site' is selected in question 2.1 AND 'Activated/open to enrollment, participants have been enrolled but none are currently receiving study treatment/intervention', 'Activated/open to enrollment with one or more study participant(s) receiving study treatment/intervention', Activated/open to enrollment with current participants in follow up only', Permanently closed to enrolment, one or more study participant(s) receiving treatment/intervention', 'Permanently closed to enrolment, no participants are receiving treatment/intervention, and all study participants are in long term follow up or data collection continues', 'Study completed (i.e., no further involvement of study participants and no further data collection)', 'Prematurely terminated', or 'Other' is selected in 2.3, then the following appears:

3.10 *Will the new/updated information be communicated to current or past participants (e.g., participants already enrolled on the study)?

☐Yes ☐No

If 'No':

3.10.1 *Justify: Click here to enter text.

If 'Yes' in 3.10, questions 3.11-3.13 will appear:

3.11 *Describe how this information will be communicated to participants who are currently enrolled in the study and receiving study treatment or intervention: Click here to enter text.

HELP TEXT:
For the purposes of this question, 'how' refers to the manner in which it will be communicated (e.g., orally or in writing, including whether participant signature is required), and the timelines associated with communication. In addition, if the information is being communicated to a specific component of this population (e.g., participants on Arm X only), please include this in the response.

3.12 *Describe how this information will be communicated to participants who are currently being followed for the purposes of the study but are no longer receiving study treatment or intervention: Click here to enter text.

3.13 ***Will this information be communicated to participants who are no longer being followed for the purposes of the study?**

☐Yes ☐No

If 'Yes':

3.13.1 ***How do you plan to communicate the updated information to participants?** Click here to enter text.

If 'consent/assent update form(s)' is selected in question 3.1 OR 'Yes' to question 3.10, then 3.14 appears:

3.14 Upload the consent/assent update form (if applicable):

UPLOAD DOCUMENT - DOCUMENT TYPE: CONSENT/ASSENT Update

HELP TEXT:

Consent/assent update form refers to a consent document containing only the new or updated information relevant to participants previously enrolled in the study.

SECTION 4.0 –INFORMED CONSENT/ASSENT/DEBRIEFING PROCESS AT THIS SITE

If 'Changes in the informed consent/assent/debriefing process at this site is selected in question 2.1, the following questions appear:

4.1 *Describe the proposed change(s) in the informed consent/assent/debriefing process at this site: Click here to enter text.

Q#4.1 – Examples of changes to the informed consent process:

a. **Addition of a remote consenting process for your site: Please provide all the details, including the rationale for using this process; mention any available institutional policies relating to the use of a remote consenting process; the steps to be followed when using the remote consent process; the patient population where this will be used ; include use of an electronic platform (e.g. RedCAp), if applicable ; also indicate how consent will be documented and include a reference to any OCREB pre-approval of the process, if applicable**
b. **Requesting for a consent waiver for some or all participants- if applicable, clearly describe the population to whom this request would apply and provide a justification for the request**

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SECTION 5.0 – SITE-SPECIFIC TRANSLATION OF APPROVED MATERIALS

If 'Site-specific translation of approved materials' is selected in question 2.1, the following questions appear:

5.1 ***Upload all site-specific translated material(s):**

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC TRANSLATED MATERIALS

5.2 Upload all corresponding translation certification(s)/supporting documentation for authenticity of the translation:

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC TRANSLATED MATERIALS

Q#5.2: Note: Translation Certificates are not required for validated paper questionnaires.; all other translated documents need to have a COT

SECTION 6.0 – RECRUITMENT METHODS AND/OR RECRUITMENT MATERIAL USED AT THIS SITE

If 'Change(s) in recruitment methods and/or recruitment material at this SITE is selected in question 2.1, question 6.1 will appear:

6.1 *The change(s) in recruitment affect (select all that apply):

☐Change(s) in recruitment methods at this site

☐Change(s) in site-specific recruitment material(s) *

***Unlikely to apply at site level – please contact OCREB first to discuss before submitting your site- specific materials (e.g. oral drug diaries, recruitment email templates)**

HELP TEXT:

Site-specific recruitment materials refer to telephone, web or email scripts, flyers, brochures, etc., that will be used for the purpose of recruiting study participants at this site that have not already been reviewed and approved at the study-wide level. Site-specific recruitment materials include local changes to study-wide approved materials.

If 'Changes in recruitment methods' is selected in 6.1, question 6.2 will appear:

6.2 *Describe the proposed change(s) in recruitment methods at this site: Click here to enter text.

If 'Change(s) in site-specific recruitment materials' is selected in 6.1, question 6.3 appears:

6.3 *The change(s) in recruitment material(s) involve (select all that apply):

☐Addition of new site-specific recruitment material(s)

☐Change(s) to previously approved site-specific recruitment materials

If 'Addition of new site-specific recruitment material(s)' is selected in 6.3, question 6.4 will appear:

6.4 *Upload any new site-specific recruitment material(s):

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC MATERIALS FOR RECRUITMENT

If 'Changes to previously approved site-specific recruitment materials' is selected in 6.3, question 6.5-6.6 will appear:

6.5 *Upload the revised site-specific recruitment material(s) showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

HELP TEXT:

When submitting new recruitment material(s) unrelated to a recently approved study-wide amendment, the tracked changes version should show all revisions being made to the most recent approved version(s) of the site-specific recruitment material(s) for your site.

6.6 *Upload the clean version(s) of the revised site-specific recruitment material(s):

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC MATERIALS FOR RECRUITMENT

SECTION 7.0 - SITE-SPECIFIC PARTICIPANT MATERIALS

If 'Change(s) to site-specific participant materials' is selected in question 2.1; question 7.1 will appear:

7.1 *The changes in other site-specific material(s) that will be given to study participants involve (select all that apply):

☐Addition of new other site-specific material(s) that will be given to study participants

☐Change(s) to previously approved other site-specific material(s) that will be given to study participants

HELP TEXT:

Other site-specific materials refer to diaries, wallet cards, telephone or email scripts that you will use for communicating with study participants during the course of the study and have not been reviewed and approved at the study-wide level. Other site-specific materials includes local changes to study-wide approved materials.

If 'Addition of new other site-specific materials that will be given to study participants' is selected in 7.1, questions 7.2-7.3 will appear:

New Site-Site Specific Materials:

7.2 *Upload the new other site-specific material(s) that will be given to study participants:

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC MATERIALS

7.3 Provide the URL for any new electronic material(s) (as applicable): Click here to enter text.

Add Another

Help Text:

Please ensure that a copy of each of these materials is uploaded in question 7.2.

If 'Changes to previously approved other site-specific materials that will be given to study participants' is selected in 7.1, question 7.4-7.6 will appear:

Revised Site-Site Specific Materials:

7.4 *Upload the revised other site-specific material(s) that will be given to study participants showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

7.5 *Upload the clean version(s) of the revised other site-specific material(s) that will be given to study participants (i.e., with the changes accepted):

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC MATERIALS

7.6 Provide the URL for any revised electronic material(s) (as applicable): Click here to enter text.

Add Another

SECTION 8.0 - HOW PI/PHI IS ACCESSED, COLLECTED, USED, STORED OR TRANSFERRED AT THIS SITE

If 'Changes to how personal information or personal health information is being accessed, collected, used, stored or transferred at this Site is selected in question 2.1, question 8.1 will appear:

8.1 ***This change involves the following (select all that apply):**

- ☐Change in the Personal Information (PI) or Personal Health Information (PHI) that this site is authorized to disclose on the data collection tools leaving the institution
- ☐Change in the Personal Information (PI) or Personal Health Information (PHI) that is collected and retained locally for the purposes of the study (e.g., recruitment tools, recruitment or screening logs)
- ☐Change in how data is accessed, collected, used, stored and/or transferred at this site
- ☐Linking of data with any other data sets, databases or registries at this site

If 'Change in the Personal Information or Personal Health Information that this site is authorized to disclose on the data collection tools leaving the institution' is selected in question 8.1, questions 8.2-8.3 will appear:

8.2 ***Describe the change in the Personal Information or Personal Health Information that this site is authorized to disclose on the data collection tools leaving the institution:** Click or tap here to enter text.

8.3 ***Researchers must ensure to update question 14.1 to indicate what PI or PHI that this site is authorized to disclose on the data collection tools leaving the institution.***

If 'Change in the Personal Information (PI) or Personal Health Information (PHI) that is collected and retained locally for the purposes of the study (e.g., recruitment tools, recruitment or screening logs)' is selected in question 8.1, question 8.4-8.5 will appear:

8.4 ***Describe the change in the Personal Information or Personal Health Information that is collected and retained locally for the purposes of the study (e.g., recruitment tools, recruitment or screening logs):** Click or tap here to enter text.

8.5 ***Researchers must ensure they have updated the list of PI or PHI collected and retained locally 15.2*.**

If 'Change in how data is accessed, collected, used, stored or transferred' is selected in question 8.1, question 8.6 will appear:

8.6 ***Describe all changes to data access/collection/use/storage/transfer:** Click here to enter text.

If 'Linking of data with any other data sets, databases or registries' is selected in question 8.1, questions 8.7-8.11 will appear:

8.7 ***Identify the data sets, databases or registries to which it will be linked:** Click here to enter text.

8.8 ***Explain the purpose for the linking:** Click here to enter text.

8.9 ***Describe how the linking will be done:** Click here to enter text.

8.10 ***Describe the likelihood that identifiable data will be created through the linkage:** Click here to enter text.

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

SECTION 9.0 - CONFLICT OF INTEREST INFORMATION

If 'Changes in the conflict of interest information previously provided to the REB for any of the investigators, study staff or members of their immediate families' is selected in question 2.1, question 9.1 will appear:

9.1 *This change affects the following types of conflict of interest (select all that apply):

☐Personal financial benefit in connection with this study

☐Benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc.

☐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

☐Institutional conflicts of interest (financial or non-financial) that may have an impact on the research

☐Proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study

☐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.)**

**** This is the most Common COI reported to the REB; this is to be selected if the PI or Sub-I has worked with or is still working with the Sponsor or drug company as a consultant, or as part of a Safety committee for a drug being developed by the drug company, or in any other role with the company who is also the sponsor of the study**

☐Other real, potential or perceived conflict of interest

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 'Personal financial benefit in connection with this study' is selected in 9.1, question 9.2 appears:

9.2 *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':

9.2.1 *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.

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

9.2.3 ***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.

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

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

If 'Benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc.' is selected in 9.1, question 9.3 appears:

9.3 ***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':

9.3.1 ***Describe the benefits:** Click here to enter text.

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

If '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' is selected in 9.1, question 9.4 appears:

9.4 ***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':

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

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

If 'Institutional conflicts of interest (financial or non-financial) that may have an impact on the research' is selected in 9.1, question 9.5 appears:

9.5 ***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':

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

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

If 'Proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study' is selected in 9.1, question 9.6 appears:

9.6 *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':

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

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

If '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.)' is selected in 9.1, question 9.7 appears:

9.7 *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':

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

Q#9.7.1: This section should clearly indicate the nature of this role or association with the company sponsoring the study or providing support to the study; 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

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

Q#9.7.2 – This section should include the following as part of the management plan:

- **that the COI is being disclosed to the REB for this study**
- **that the COI has been submitted to the institutional compliance dept. and**
- **the COI will be disclosed to participants by way of the consent form, if required by the REB**

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

☐Yes ☐No

If 'Yes':

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

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

SECTION 10.0 - PARTICIPANT REMUNERATION AND/OR COMMUNICATION OF STUDY RESULTS

If 'Changes in participant reimbursement and/or communication of study results' is selected in question 2.1, question 10.1 will appear:

10.1 ***This change involves which of the following (select all that apply):**

☐Participant remuneration

☐Communication of study results to participants

Q#10.1 : select "Participant remuneration" if there is a change in participant reimbursement

If 'Participant reimbursement' is selected in 10.1, question 10.2 will appear:

10.2 ***Describe the change(s) to participant remuneration:** Click here to enter text.

HELPTEXT:

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

If 'Communication of study results to participants' is selected in 10.1, question 10.3 and 10.4 will appear:

10.3 ***Describe the change in the communication of results to participants:** Click here to enter text.

HELPTEXT:

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

10.4 ***Which of the following communication plans are being changed (select all that apply):**

☐Individual debriefing at end of test session

☐Group debriefing

☐End of study letter

☐Publication

☐Other

If 'Individual debriefing at end of test session, Group Debriefing and/or End of study letter' is selected in 10.4, 10.5 will appear:

10.5 If the amendment includes change(s) to previously submitted document(s), upload the revised site-specific material(s) associated with communication of results (i.e., debriefing script, group debriefing and/or end of study letter) to participants showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS

HELPTEXT:

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

If 'Individual debriefing at end of test session' is selected in 10.4, question 10.6 appear:

10.6 Upload the clean version(s) of the debriefing script:

UPLOAD DOCUMENT - DOCUMENT TYPE: DEBRIEFING SCRIPT

If 'Group debriefing is selected in 10.4, question 10.7 will appear:

10.7 Upload the clean version(s) of the group debriefing:

UPLOAD DOCUMENT - DOCUMENT TYPE: GROUP DEBRIEFING

If 'End of study letter is selected in 10.4, question 10.8 will appear:

10.8 Upload the clean version(s) of the end of study letter:

UPLOAD DOCUMENT - DOCUMENT TYPE: END OF STUDY LETTER

SECTION 11.0 - CHANGES IN SITE-SPECIFIC STUDY CONDUCT

If 'Changes in site-specific study conduct (including location of visits/procedures, standard of care, and protocol implementation)' is selected in question 2.1, the following section appears:

11.1 *The change(s) in site-specific study conduct involve which of the following (select all that apply):

☐Change in location of any of the study participant visits or procedures such that they will now be conducted at a location outside of this legal entity

☐Change in standard of care for this participant population at this site

☐Variation in protocol implementation at this site (e.g., compared to that described in study-wide applications)**

****Q#11.1 – Select this If there are changes to how protocol will be implemented at the site compared to what was approved at the Study-wide level; e.g site is NOT participating in optional PK sample collection ; or optional biopsies**

HELP TEXT:

To see which sites fall under the legal entity, visit the Participating Sites page.

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

If 'Change in location of any of the study participant visits or procedures such that they are now conducted outside of this legal entity' is selected in 11.1, questions 11.2-11.5 appear:

11.2 *Describe the relationship (e.g., service provider, satellite site, or a research collaborator) between this legal entity and the external site(s) where participant visits or procedures will occur: Click here to enter text.

11.3 *Where will the visit(s) or procedure(s) will take place (name, address)? Click here to enter text.

11.4 Main contact details: Click here to enter text.

11.5 *Describe the visit(s) or procedure(s) that will take place outside this legal entity: Click here to enter text.

If 'Change in standard of care for this participant population at this site' is selected in question 11.1, 11.6-11.7 appears:

11.6 *Describe the change in standard of care for this participant population in this site: Click here to enter text.

11.7 How does the standard of care differ from that described in the currently approved study-wide application (if applicable)? Click here to enter text.

If 'Variation in protocol implementation at this site' is selected in question 11.1, question 11.8 appears:

11.8 *Explain the site-specific difference(s): Click here to enter text.

SECTION 12.0 – SITE STUDY TEAM INFORMATION

If 'Change(s) to the name and/or contact details for the Participating Site Administrative Contact' selected in 2.1, question 12.1 appears:

12.1 *Specify details for the change in name/contact details for the Participating Site Administrative Contact:
Click here to enter text.

If 'Change in Principal Investigator' OR If 'Change(s) to CONTACT DETAILS ONLY for the Principal Investigator' or 'Change(s) to the name/contact details for the Participating Site Administrative Contact' selected in 2.1, questions question 12.2-12.3 appear:

12.2 *Does this change in contact information affect any of the REB approved site-specific study documents (i.e., consent, recruitment material, etc.)?

☐Yes ☐No

Q#12.2 : Note that updating Study team contact information in the Consent form and other study documents (e.g. Wallet card) is a PRE-APPROVED change for all sites ; the change can be made without submitting an amendment for the revised document

If 'Yes' is selected in question 12.2, questions 12.2.1-12.2.2 appear:

12.2.1 ***Research teams must ensure the correct checkboxes have been selected in question 2.1 to reflect any change(s) to site-specific study documents.***

12.2.2 ***Research teams must ensure the revised site-specific study document(s) have been uploaded in the appropriate section(s).***

12.3 ***Research teams must ensure they have updated the corresponding information in Section 1.0 for the change in principal investigator, change(s) to CONTACT DETAILS ONLY for the Principal Investigator, or Change(s) to contact details for the Participating Site Administrative Contact.***

SECTION 13.0 – OTHER CHANGES

If 'Other changes' is selected in question 2.1, the following questions appear:

13.1 *Specify the 'other' changes made with this amendment: Click here to enter text.

Q#13.1 – For PAEDS studies: if applicable, please indicate that the PSAM is to notify OCREB about the inclusion of satellite site(s). Provide the name(s) of the satellite site(s) and indicate that the satellite site contact information is on file with OCREB and POGO.

13.2 Provide any additional information for the REB to consider (if applicable): Click here to enter text.

Q#13.2 – The master agreements, including addenda with satellite site(s), should be listed as well as the procedures and/or assessments that will be performed at these sites.

13.3 Upload any associated documents that have not been uploaded elsewhere (if applicable):

UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS

Q#13.3 – Please upload the signed and completed Site PI attestation form for the use of satellite site(s). The attestation is required only if there is no REB of Record Agreement on file.

SECTION 14.0 – SITE IMPLEMENTATION OF STUDY-WIDE CHANGE(S)

If 'Yes' is selected in question 2.0, question 14.1 appears:

****THIS DOES NOT APPLY TO OCREB STUDIES as Study-wide approval applies to all approved Participating sites**

14.1 *What changes are included in the amendment?

- ☐ Changes to consent/assent/debriefing materials
- ☐ Changes to PI or PHI that this site is authorized to disclose on the data collection tools leaving the institution
- ☐ Changes to participant recruitment materials

If 'Changes to consent/assent/debriefing materials' is selected in question 14.1, question 14.2 appears:

14.2 *Which of the following forms are being changed (select all that apply)?

- ☐ Consent form(s)
- ☐ Assent form(s)
- ☐ Debriefing material(s)
- ☐ Consent/Assent update form(s)

If 'Consent Form(s) is selected, questions 14.3-14.4 appear:

14.3 Upload the revised consent form(s) showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS

HELP TEXT:

The tracked changes document should show all revisions your site is making to the new approved study-wide ICF.

14.4 *Upload clean version(s) of the revised consent form(s):

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC CONSENT FORM

If 'Assent Form(s)' is selected, questions 14.5-14.6 appear:

14.5 Upload the revised assent form(s) showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES DOCUMENT

HELP TEXT:

The tracked changes document should show all revisions your site is making to the new approved study-wide assent form.

14.6 *Upload clean version(s) of the revised assent form(s):

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC ASSENT FORM

If 'Debriefing material(s)' is selected, questions 14.7-14.8 appear:

14.7 Upload the revised debriefing material(s) showing the changes from the currently approved version (i.e., with the changes tracked):

UPLOAD DOCUMENT– DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS

HELP TEXT:

The tracked changes document should show all revisions your site is making to the new approved study-wide debriefing material(s).

14.8 *Upload clean versions of all new or revised debriefing material(s):

UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT

If 'Changes to consent/assent/debriefing materials' is selected in question 14.1 AND 'Activated/open to enrollment, participants have been enrolled but none are currently receiving study treatment/intervention', 'Activated/open to enrollment with one or more study participant(s) receiving study treatment/intervention', Activated/open to enrollment with current participants in follow up only', Permanently closed to enrolment, one or more study participant(s) receiving treatment/intervention', 'Permanently closed to enrolment, no participants are receiving treatment/intervention, and all study participants are in long term follow up or data collection continues', 'Study completed (i.e., no further involvement of study participants and no further data collection)', 'Prematurely terminated', or 'Other' is selected in 2.3, then question 14.9 appears:

14.9 *Will the new/updated information be communicated to current or past participants (e.g., participants already enrolled on the study)?

☐Yes ☐No

If 'No':

14.9.1 *Justify: Click here to enter text.

If 'Yes' in 14.9, questions 14.11-14.13 will appear:

14.10 *Describe how this information will be communicated to participants who are currently enrolled in the study and receiving study treatment or intervention: Click here to enter text.

HELP TEXT:

For the purposes of this question, 'how' refers to the manner in which it will be communicated (e.g., orally or in writing, including whether participant signature is required), and the timelines associated with communication. In addition, if the information is being communicated to a specific component of this population (e.g., participants on Arm X only), include this in the response.

14.11 *Describe how this information will be communicated to participants who are currently being followed for the purposes of the study but are no longer receiving study treatment or intervention: Click here to enter text.

14.12 *Will this information be communicated to participants who are no longer being followed for the purposes of the study?

☐Yes ☐No

If 'Yes':

14.12.1 *How do you plan to communicate the updated information to participants? Click here to enter text.

If 'Consent/assent update form(s)' is selected in question 14.2 or 'Yes' is selected in question 14.9, question 14.13 appears:

14.13 **Upload the consent/assent update form (if applicable):**

UPLOAD DOCUMENT - DOCUMENT TYPE: CONSENT/ASSENT Update

HELP TEXT:

Consent/assent update form refers to a consent document containing only the new or updated information relevant to participants previously enrolled in the study.

If 'Changes to participant recruitment materials' is selected in 14.1, then questions 14.14-14.15 appear:

14.14 ***Upload the revised site-specific recruitment material(s) showing the changes from the currently approved version (i.e., with the changes tracked):**

UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENT

HELP TEXT:

The tracked changes document should show all revisions your site is making to the new approved study-wide recruitment material(s).

14.15 ***Upload the clean version(s) of the revised site-specific recruitment material(s):**

UPLOAD DOCUMENT - DOCUMENT TYPE: SITE-SPECIFIC MATERIALS FOR RECRUITMENT

If 'Changes to PI or PHI that this site is authorized to disclose on the data collection tools leaving the institution' is selected in 14.1, questions 14.16-14.17 appear

14.16 ***Describe the change in the Personal Information or Personal Health Information that this site is authorized to disclose on the data collection tools leaving the institution:** Click or tap here to enter text.

14.17 ***Researchers must ensure to update question 15.1 to indicate what PI or PHI that this site is authorized to disclose on the data collection tools leaving the institution.***

SECTION 15.0 – SHARED QUESTIONS

This section contains shared questions from the Participating Site Initial Application and appears for all amendments. DO NOT make changes to this section without updating the associated section of this application form as indicated below. If this amendment does not involve changes to the information in this section, do not modify the information in this section.

Question 15.1 below relates to the Personal Information (PI) or Personal Health Information (PHI) identifiers approved study-wide that this site is authorized to disclose on the data collection tools leaving the institution. Any changes to this question MUST be fully described in SECTION 8. If the questions in SECTION 8 are not addressed, any changes made to question 15.1 in this amendment will NOT have REB approval.

To help answer question 15.1 - reference the list of PI/PHI identifiers approved to be collected for the overall study in the Clinical Trial Initial Application (Q7.1), or the most recently approved Study-Wide Amendment (Q18.2).

15.1 *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

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

15.1.1 *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':

15.1.2 *Specify the additional PI/PHI you wish to send off-site: Click here to enter text.

15.1.3 *Justify sending this additional PI/PHI off-site: Click here to enter text.

The following question relates to a Change in the Personal Information (PI) or Personal Health Information (PHI) that this site is authorized to disclose on the data collection tools RETAINED LOCALLY. Any changes to this question MUST be fully described in SECTION 8.0. If questions in SECTION 8 are not addressed, any changes made to question 15.2 in this amendment will NOT have REB approval.

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

- ☐None, study participant ID only
- ☐Full name
- ☐Full initials
- ☐Partial initials
- ☐Full date of birth
- ☐Partial date of birth
- ☐Full date of death
- ☐Partial date of death

☐Age
☐Sex
☐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
☐Full face 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

If 'Other': **15.2.1 *Specify other information:**
If 'Other': **15.2.2 *Justify other information:**
If 'Full Name': **15.2.3*Justify full name:**
If 'Initials': **15.2.4 *Justify full initials:**
If 'partial initials': **15.2.5 *Justify partial initials:**
If 'full date of birth': **15.2.6 *Justify full date of birth:**
If 'Partial Date of Birth': **15.2.7 *Justify partial date of birth:**
If 'Full Date of Death': **15.2.8 *Justify full date of death:**
If 'Partial Date of Death': **15.2.9 *Justify partial date of death:**
If 'Age': **15.2.10 *Justify age:**
If 'Sex and/or gender': **15.2.11 *Justify sex and/or gender:**
If 'Gender identity': **15.2.12 *Justify gender identity:**
If 'Address': **15.2.13 *Justify address:**
If 'Full Postal Code': **15.2.14*Justify full postal code:**
If 'First 3 digits of Postal code': **15.2.15 *Justify first 3 digits of postal code:**

- *If 'Telephone Number':* **15.2.16** *Justify telephone number:
- *If 'Email Address':* **15.2.17** *Justify Email address:
- *If 'Fax Number':* **15.2.18** *Justify fax number:
- *If 'Health Card Number':* **15.2.19** *Justify health card number:
- *If 'Medical Record Number':* **15.2.20** *Justify medical record number:
- *If 'Admission Date':* **15.2.21** *Justify admission date:
- *If 'Discharge Date':* **15.2.22** *Justify discharge date:
- *If 'Pathology Specimen Number':* **15.2.23***Justify pathology specimen number:
- *If 'Medical Device Identifier':* **15.2.24** *Justify medical device identifier:
- *If 'Driver's License Number':* **15.2.25** *Justify driver's license number:
- *If 'Voice/audio recording':* **15.2.26** *Justify voice/audio recording:
- *If 'Full face photograph':* **15.2.27** *Justify full face photograph:
- *If 'SIN number':* **15.2.28** *Justify SIN number:
- *If 'Device Identifier':* **15.2.29** *Justify device identifier:
- *If 'Internet Protocol address (IP address)':* **15.2.30** *Justify internet protocol address (IP address):
- *If 'Race and/or ethnicity':* **15.2.31** *Justify race and/or ethnicity:
- *If 'Family/caregiver names and/or contact information':* **15.2.32** *Family/caregiver names and/or contact information:
- *If 'Video recording':* **15.2.33** *Justify video recording:

SECTION 16.0 – RE-SUBMISSION INFORMATION

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

Section 16 will only appear is the response to Q#1.0 is "Yes". Please ensure you respond YES to Q#1.0 if you are re-submitting the application .

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

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

16.2 Upload any additional materials requested by the REB (if applicable):
UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS

16.3 Provide any additional comments for the REB to consider (if applicable): Click here to enter text.

Q#16.3 – If a Response Letter is not provided above in Q#16.1, please indicate in this section that the changes requested were addressed, as per review letter or provide a reason if you were unable to address the questions

SECTION 17.0– AGREEMENT & APPROVAL

If 'No' to question 1.0 AND Any option other than or in addition to 'Change(s) to CONTACT DETAILS ONLY for the Principal Investigator'; 'Change(s) to the name and/or contact details for the Participating Site Administrative Contact' is selected in question 2.1; the Principal Investigator signature appears:

17.1 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 the 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

Q#17.1 – If the PSAM is for a change in PI, please ensure that the new/incoming PI signs off on the application at the initial submission.

If 'No' to question 1.0 AND 'Change in Principal Investigator' is selected in question 2,1; the Department Approver/Department Head signature appears:

17.2 Department Approver/Department Head

- I attest that the Principal Investigator is qualified and has the experience and expertise 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 AND 'Change in Principal Investigator' is selected in question 2.1; the Institutional Representative signature appears:

17.3 Institutional Representative

- 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.

  SIGNATURE TYPE: INSTITUTIONAL REPRESENTATIVE

If 'Yes' to question 1.0 AND/OR 'Change(s) in to CONTACT DETAILS ONLY for the Principal Investigator', or 'Change(s) to the name and/or contact details for the Participating Site Administrative Contact' is exclusively selected in question 2.1; the Principal Investigator or Delegate signature appears:

16.4 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: PRINCIPAL INVESTIGATOR OR DELEGATE

Q#16.4: PI Delegate or Study staff can sign applications when resubmitting them