Revision History

Version Date	Key Changes
February 28, 2018	CTO application form version 16 - original
May 1, 2019	CTO application form version 20 • Help text (in green) was added to several questions • Questions 1.1 to 1.5: shared Provincial Applicant (PA), sponsor and CRO contact details were removed and questions were renumbered • Question 1.6: “Centre Main Study Contact” was changed to “Centre Administrative Study Contact” • 2.3-2.6: new questions added • Section 3.0: debriefing materials and consent update forms were added as new options with corresponding new questions (3.7-3.13, as applicable).
February 13, 2020	Q2.1 and Section 13 : guidance for amending a CIA to add information about Satellite sites.

CTO Clinical Trial Centre 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 Provincial Initial Application)

SECTION 1.0 - GENERAL INFORMATION

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

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

1.1 ***Please enter the complete Study Title:**

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

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.)**

Site-specific information: The questions below reflect the site-specific information that has previously been provided to the REB. If changes are required, you must select "Change in name/contact information (Principal Investigator/Co-Investigator/centre administrative study contact)" in question 2.1.

1.4 ***Please complete the Centre Principal Investigator (PI) details:**
*Title: Click here to enter text.
*First Name: Click here to enter text.
*Surname: Click here to enter text.
*Organization: Click here to enter text.
*Address: Click here to enter text.
*City: Click here to enter text.
*Province/State: Click here to enter text.
*Postcode/Zip: Click here to enter text.
*Telephone: Click here to enter text.
Fax: Click here to enter text.
*Email: Click here to enter text.

1.5 ***Is there a Co-Investigator (Co-I) at this site?**
☐Yes ☐No
If 'Yes': **1.5.1** ***Enter the contact details of the Co-Investigator:**

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

If 'No': **1.5.1 AT ALL TIMES, there must be oversight of research participants by an appropriately trained, qualified and designated individual.**

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

1.6 ***Please complete the Centre Administrative Study Contact details:**

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

1.7 ***Please complete the Primary Institutional Representative details:**

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

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

☐Yes ☐No

1.8.1 *Please complete the Secondary Institutional Representative details:

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

SECTION 2.0 - AMENDMENT DETAILS

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

☐Site-specific changes to the consent/assent form(s) used at this site
☐Changes in the informed consent/assent process at this site
☐ Site -specific translation of approved material(s)
☐Changes in recruitment methods and/or recruitment material(s) (e.g., telephone, web or email scripts, flyers, brochures, etc.) used at this site
☐Changes to other site -specific material(s) that will be given to study participants (including surveys/questionnaires/scripts, diaries and wallet cards)
☐Changes to how personal information or personal health information is being accessed, collected, used, stored or transferred at this site
☐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
☐Changes in participant reimbursement and/or communication of study results
☐Changes in site -specific study conduct (including location of visits/procedures, standard of care, and protocol implementation)
☐Change in Principal Investigator or Co-Investigator
☐ Change(s) to contact details for the PI/Co-Investigator or the name/contact details for the centre administrative study contact/institution representative(s)
☐Other changes

Select "Other changes" if the CAM is to add Satellite sites. This will bring up Section 13.

Help Text: Site-specific recruitment materials refers to telephone, web or email scripts, flyers, brochures, etc., that will be used for the purpose of recruiting study participants at this centre that have not been otherwise reviewed and approved at a Provincial level.

Site-specific recruitment materials includes local changes to provincially approved materials.

Please note that OCREB studies are pre-approved for centre-specific administrative changes to provincially approved documents- this statement does not apply

Other site-specific materials refers 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 Provincial level.

Other site-specific materials include local changes to provincially approved materials.

Please note that OCREB studies are pre-approved for centre-specific administrative changes to provincially approved documents- this statement does not apply

If any option is selected in addition to "Change(s) to contact details for the PI/Co-Investigator or the name/contact details for the centre administrative contact/institution representative(s)", then the Principal Investigator signature will be required on the initial submission of this application.

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 or Co-Investigator at this site.

2.2 *Provide a brief lay summary of the proposed changes (maximum 5 lines): Click here to enter text.

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

☐Not yet activated
☐Activated, but no participants enrolled to date
☐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
☐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
☐Other

If 'Other': **2.3.1** ***Specify:** Click here to enter text.

If 'prematurely terminated': **2.3.2** ***Please provide details:** Click here to enter text.

2.4 ***Please provide a label for this amendment (e.g., an amendment identifier/description) that will appear in the project tree:** 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, please 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 for this amendment. This can be the same as the label entered in question 2.4.

2.6 ***Is this application associated with a previously submitted Provincial Amendment?**

☐Yes ☐No

If 'Yes': **2.6.1** ***Please enter the Review Reference # or amendment identifier/description from the project tree of the corresponding /Provincial Amendment Form:** Click here to enter text.

HELP TEXT: Research teams must CLEARLY IDENTIFY the Provincial Amendment that this Centre Amendment is related to in question 2.6.1.

Prior to version 20 of the application forms, research teams were required to submit an Implementation of Provincial Amendment (IPA) form in order to obtain approval for site-specific materials that were changed as a result of a Provincial Amendment. With Version 20, the IPA form was removed, and sites now provide this information to the REB via the Centre Amendment form.

SECTION 3.0 – SITE-SPECIFIC CHANGES TO THE CONSENT/ASSENT FORM(S) USED AT THIS SITE

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

3.1 ***Please provide a rationale for the consent/assent form change(s) at this site:** Click here to enter text.

3.2 ***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)

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 3.2, AND one of the following options in 2.3 is selected 'Not yet activated', 'Activated but no participants enrolled to date', 'Activated/open to enrolment, participants have enrolled but none are currently receiving study treatment/intervention', 'Activated/open to enrolment with one or more study participants receiving study treatment/intervention', 'Other' then Q3.3-3.4 appear:

3.3 **Please 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

3.4 ***Please upload the clean version(s) of the revised consent form(s:**
Upload Document - Document Type: Centre-Specific Consent Form

If 'Assent Form(s) is selected in question 3.2, AND one of the following options in 2.3 is selected 'Not yet activated', 'Activated but no participants enrolled to date', 'Activated/open to enrolment, participants have enrolled but none are currently receiving study treatment/intervention', 'Activated/open to enrolment with one or more study participants receiving study treatment/intervention', 'Other' then Q3.5 and 3.6 appear:

3.5 **Please 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

3.6 ***Please upload the clean version(s) of the revised assent form(s):**
Upload Document - Document Type: Centre-Specific Assent Form

If 'Debriefing material(s)' is selected in 3.2, question 3.7-3.8 will appear:

3.7 **Please 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

3.8 ***Upload clean versions of all new or revised debriefing material(s):**
Upload Document – DOCUMENT TYPE: Debriefing script

If 'Site-specific changes to the consent/assent form used at this centre' is selected in question 2.1, then the following appears:

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

☐Yes ☐No

If 'No': **3.9.1 *Justify:** Click here to enter text.

If 'Yes' in 3.9, questions 3.10 – 3.12 will appear:

3.10 ***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), please include this in the response.

3.11 ***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.

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

☐Yes ☐No

If 'Yes': **3.12.1 *How do you plan to communicate the updated information to participants?**

Click here to enter text.

If 'Consent/Assent Update Form' is selected in 3.2 OR 'Yes' to question 3.9, then 3.13 appears:

3.13 **Please 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 – CHANGES IN THE INFORMED CONSENT/ASSENT PROCESS AT THIS SITE

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

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

4.2 ***Please provide a rationale for the change(s):** Click here to enter text.

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 ***Please upload all site-specific translated material(s):**
Upload Document - Document Type: Centre-Specific Translated Materials

5.2 **Please upload all corresponding translation certification(s)/supporting documentation for authenticity of the translation:**
Upload Document - Document Type: Translation Certificate

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

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

If 'Changes in recruitment methods and/or recruitment material at this SITE is selected in question 2.1, the following questions 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)

Help Text: Site-specific recruitment materials refers 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 Provincial level.

Site-specific recruitment materials includes local changes to provincially approved materials.

Please note that OCREB studies are pre-approved for centre-specific administrative changes to provincially approved documents- this statement does not apply

If 'changes in recruitment methods' is selected in 6.1, the following questions will appear:

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

6.3 ***Please provide a rationale for the change(s):** Click here to enter text.

If 'changes in site-specific recruitment materials' is selected in 6.1, question 6.4 appears:

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

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

☐Changes to previously approved site-specific recruitment materials

If 'Addition of new site-specific recruitment material(s) that will be used to recruit potential participants' is selected in 6.4, question 6.5 will appear:

6.5 ***Upload any new site-specific recruitment material(s):**
Upload Document - Document Type: Centre-Specific materials for recruitment

If 'changes to previously approved site-specific recruitment materials that will be used to recruit potential participants' is selected in 6.4, question 6.6-6.8 will appear:

6.6 ***Please provide a rationale for the change(s):** Click here to enter text.

6.7 ***Please 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

6.8 ***Please upload the clean version(s) of the revised site-specific recruitment material(s):**
Upload Document - Document Type: Centre-Specific materials for recruitment

SECTION 7.0 - CHANGES TO SITE-SPECIFIC PARTICIPANT MATERIALS

If 'changes to site-specific participant materials' is selected in question 2.1, these questions 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

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

Help Text: Other site-specific materials refers 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 Provincial level.

Other site-specific materials includes local changes to provincially approved materials.

Please note that OCREB studies are pre-approved for centre-specific administrative changes to provincially approved documents- this statement does not apply

If 'Addition of new other site-specific materials that will be given to study participants' is selected in 7.1, question7.2-7.3 will appear:

7.2 ***Please upload the new other site-specific material(s) that will be given to study participants:**
Upload Document - Document Type: Centre-Specific materials

7.3 **Please provide the URL for any new electronic material(s) (as applicable):** Click here to enter text.
Add Another

If 'Changes to previously approved other site-specific materials that will be given to study participants' is selected in 7.1, question 7.4-7.7 will appear:

7.4 ***Please provide a rationale for the change(s):** Click here to enter text.

7.5 ***Please 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

7.6 ***Please 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: Centre-Specific materials

7.7 **Please provide the URL for any revised electronic material(s) (as applicable):** Click here to enter text.
Add Another

SECTION 8.0 - CHANGES TO 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, these questions 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 centre is authorized to disclose on the data collection tools leaving the institution' is selected in question 8.1, question 8.2-8.3 will appear:

8.2 ***Please 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 ***Have you updated the list of PI or PHI that this site is authorized to disclose on the data collection tools leaving the institution in question 14.1?**

☐Yes

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 ***Please 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 ***Have you updated the list of PI or PHI that is collected and retained locally for the purposes of the study (e.g., recruitment tools, recruitment or screening logs) in question 14.2?**

☐Yes

If 'change in how data is accessed, collected, used, stored or transferred' is selected in question 8.1, question 8.6-8.7 will appear:

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

8.7 ***Please provide a rationale for the change(s):** Click here to enter text.

If 'Linking of data with any other data sets, databases or registries' is selected in question 8.1, question 8.8-8.13 will appear:

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

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

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

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

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

8.13 ***Will any of the study data be entered into a database for future use?**

☐Yes ☐No

If 'Yes': **8.13.1** ***Please specify:** Click here to enter text.

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

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

Help Text: Custodian refers to a person or organization/institution who has responsibility for taking care of or protecting something.

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

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

SECTION 9.0 - CHANGES IN THE 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, these questions 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.)

☐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 *Please 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.

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

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.

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

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

SECTION 10.0 - CHANGES IN PARTICIPANT REIMBURSEMENT AND/OR COMMUNICATION OF STUDY RESULTS

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

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

☐Participant reimbursement
☐Communication of study results to participants

If 'participant reimbursement' is selected in 10.1, 10.2-10.3 appear:

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

10.3 ***Please provide a rationale for the change(s):** Click here to enter text.

If 'communication of study results to participants' is selected in 10.1, 10.4 – 10.6 appear:

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

10.5 ***Please provide a rationale for the change(s):** Click here to enter text.

10.6 ***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 10.6, 10.7 appear:

10.7 **If the amendment includes change(s) to previously submitted document(s), please 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

If 'Individual debriefing at end of test session' is selected in 10.6, 10.8 appear:

10.8 **Please upload the clean version(s) of the debriefing script:**
Upload Document - Document Type: Debriefing Script

If 'Group debriefing is selected in 10.6, 10.9 appear:

10.9 **Please upload the clean version(s) of the group debriefing:**
Upload Document - Document Type: Group Debriefing

If 'End of study letter is selected in 10.6, 10.10 appear:

10.10 **Please upload the clean version(s) of the end of study:**
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 are now conducted outside this site

☐Change in location of any of the study participant visits or procedures such that they are now conducted inside this site

☐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 provincial applications)

Q11.1: include the addition or the in location of any study visits or procedures/tests that will be done outside of the institution. Please ensure that a service agreement exists for the inclusion of tests or procedures conducted in other locations.

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

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

11.3 ***Main contact details:** Click here to enter text.

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

11.5 ***Please provide a rationale for the change(s):** Click here to enter text.

If 'change in location of any of the study participant visits or procedures such that they are now conducted inside this site' is selected in 11.1, question 11.6-11.7 appears:

11.6 ***Describe the visit(s) or procedure(s) that will now take place inside this site:** Click here to enter text.

11.7 ***Please provide a rationale for the change(s):** Click here to enter text.

If 'Change in standard of care for this participant population at this site' is selected in 11.1, 11.8-11.10 appears:

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

11.9 **How does the standard of care differ from that described in the currently approved provincial application (if applicable)?** Click here to enter text.

11.10 ***Please provide a rationale for the change(s):** Click here to enter text.

If 'Variation in protocol implementation at this site (e.g., compared to that described in provincial applications)' is selected in 11.1, 11.11-11.12 appears:

11.11 ***Please explain the site-specific difference(s):** Click here to enter text.

11.12 ***Please provide a rationale for the change(s):** Click here to enter text.

SECTION 12.0 - CHANGE IN NAME/CONTACT INFORMATION FOR STUDY

If "Change(s) to contact details for the PI/Co-Investigator or the name/contact details for the centre administrative contact/institution representative(s)?" selected in 2.1, question 12.1 appears:

12.1 *The change pertains to (select all that apply):

☐Contact details for the Principal Investigator
☐Contact details for the Co-Investigator
☐Name/Contact details for the centre administrative study contact/institution representative(s)

If "Name/Contact details for the centre administrative study contact/institution representative(s)":

12.1.1 *Specify Details: Click here to enter text.

If "Change in Principal Investigator or Co-Investigator" is selected in 2.1, question 12.2 appears:

12.2 *The amendment includes (select all that apply):

☐Change in Principal Investigator
☐Addition or change to Co-Investigator
☐Removal of Co-Investigator (no replacement)

If "Change in Principal Investigator or Co-Investigator" OR If "Changes to contact details for the PI/Co-Investigator or the name/contact details for the centre administrative contact/institution representative(s)?" selected in 2.1, then questions 12.3-12.4 appear:

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

☐Yes ☐No

If 'Yes' is selected in question 12.3, then questions 12.3.1-12.3.2 appear:

12.3.1 *Has Question 2.1 been updated to reflect the change in site-specific study document(s)?

☐Yes

12.3.2 *Have the revised site-specific study document(s) been uploaded in the appropriate section(s)?

☐Yes

12.4 *Have you updated the corresponding information in Section 1.0 of the application?

☐Yes

SECTION 13.0 – OTHER CHANGES

If 'Other changes' is selected in question 2.1, the following section appears:

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

Q13.1: when applicable, indicate that the CAM is to notify OCREB about the use of Satellite site(s).

13.2 ***Please provide a rationale for the change(s):** Click here to enter text.

Q13.2: provide the name(s) of the Satellite site(s). Note that Satellite site contacts are on file at OCREB and POGO.

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

Q13.3: Reference the master agreements and addenda with Satellites site(s), or list the visits and procedures that will be done at the Satellite site(s).

13.4 **Please upload any associated documents that have not been uploaded elsewhere (if applicable):**
Upload Document - Document Type: Other materials

13.4: Upload the completed, signed Centre PI Attestation form for the use of Satellite Sites ONLY if the CIA was submitted after January 31, 2020 - i.e., the attestation is required only if there is no REB of Record Agreement on file.

If the CAM is for the use of Satellite sites, remember to provide the designated Satellite CTO Stream Account-Holder with a "Centre Study Staff-Read Only" role in CTO Stream!

SECTION 14.0 – SHARED QUESTIONS

This section contains shared questions from the Centre 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.

The following question relates to a Change in the Personal Information (PI) or Personal Health Information (PHI) that this centre 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 questions 8.1-8.3 are not addressed, any changes made to this section of the form will NOT have REB approval.

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

- ☐None, Study Participant ID only
- ☐Full Name
- ☐Full Initials
- ☐Partial Initials
- ☐Full Date of Birth
- ☐Partial Date of Birth
- ☐Full Date of Death
- ☐Partial Date of Death
- ☐Age
- ☐Sex and/or Gender
- ☐Full Postal Code
- ☐First 3 Digits of Postal Code
- ☐Pathology Specimen Number
- ☐Medical Device Identifier
- ☐Admission Date
- ☐Discharge Date
- ☐Medical Record Number
- ☐Ontario Health Card Number e
- ☐Driver's Licence Number
- ☐Address
- ☐Telephone Number
- ☐Fax Number
- ☐E-mail Address
- ☐Full Face Photograph
- ☐Voice/Audio Recording
- ☐Other

***If 'Other':* 14.1.1 *Specify:** Click here to enter text.

The following question relates to a Change in the Personal Information (PI) or Personal Health Information (PHI) that this centre 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 questions 8.1 and 8.4-8.5 are not addressed, any changes made to this section of the form will NOT have REB approval.

14.2 ***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)?**

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

***If 'Other':* 14.2.1 *Specify other information:** Click here to enter text.
***If 'Other':* 14.2.2 *Justify other information:** Click here to enter text.
***If 'Full Name':* 14.2.3 *Justify full name:** Click here to enter text.
***If 'Initials':* 14.2.4 *Justify full initials:** Click here to enter text.
***If 'partial initials':* 14.2.5 *Justify partial initials:** Click here to enter text.
***If 'full date of birth':* 14.2.6 *Justify full date of birth:** Click here to enter text.
***If 'Partial Date of Birth':* 14.2.7 *Justify partial date of birth:** Click here to enter text.
***If 'Full Date of Death':* 14.2.8 *Justify full date of death:** Click here to enter text.
***If 'Partial Date of Death':* 14.2.9 *Justify partial date of death:** Click here to enter text.
***If 'Age':* 14.210 *Justify age:** Click here to enter text.
***If 'Sex and/or gender':* 14.2.11 *Justify sex and/or gender:** Click here to enter text.
***If 'Address':* 14.2.12 *Justify address:** Click here to enter text.
***If 'Full Postal Code':* 14.2.13 *Justify full postal code:** Click here to enter text.
***If 'First 3 digits of Postal code':* 14.2.14 *Justify first 3 digits of postal code:** Click here to enter text.
***If 'Telephone Number':* 14.2.15 *Justify telephone number:** Click here to enter text.
***If 'Email Address':* 14.2.16 *Justify Email address:** Click here to enter text.

- ***If 'Fax Number':*** **14.2.17 *Justify fax number:** Click here to enter text.
- ***If 'Ontario Health Card Number':*** **14.2.18 *Justify Ontario health card number:** Click here to enter text.
- ***If 'Medical Record Number':*** **14.2.19 *Justify medical record number:** Click here to enter text.
- ***If 'Admission Date':*** **14.2.20 *Justify admission date:** Click here to enter text.
- ***If 'Discharge Date':*** **14.2.21 *Justify discharge date:** Click here to enter text.
- ***If 'Date of Death':*** **14.2.22 *Justify date of death:** Click here to enter text.
- ***If 'Pathology Specimen Number':*** **14.2.23 *Justify pathology specimen number:** Click here to enter text.
- ***If 'Medical Device Identifier':*** **14.2.24 *Justify medical device identifier:** Click here to enter text.
- ***If 'Driver's License Number':*** **14.2.25 *Justify driver's license number:** Click here to enter text.
- ***If 'Voice/audio recording':*** **14.2.26 *Justify voice/audio recording:** Click here to enter text.
- ***If 'Full face photograph':*** **14.2.27 *Justify full face photograph:** Click here to enter text.

SECTION 15.0 – RE-SUBMISSION INFORMATION

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

This page appears only when "Yes" is answered in Q1.0. If you do not have a place to upload a response letter, or comments in response to REB queries, or additional requested materials, ensure that Q1.0 is answered "Yes". Any additional information that would assist in the OCREB review of this application should be entered into 15.3.

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

15.1 **Upload Principal Investigator Response to REB request for modification letter (if applicable)**:
Upload Document - Document Type: Response to REB letter

15.2 **Upload any additional materials requested by the REB (if applicable):**
Upload Document - Document Type: Track Changes Version Documents

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

SECTION 16. 0 – ATTESTATION AND SIGNATURES

If 1.0 = No AND 2.1 = Any option besides "Change(s) to contact details for the PI/Co-Investigator; and/or the name/contact details for the centre administrative contact/institution representative(s)"

16.1 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, and that I am a member in good standing with my respective regulatory authority;
- Following the initial submission of this application form, a member of the research team may submit edits to this application on my behalf. I acknowledge that I remain ultimately responsible for REB submissions and the overall conduct of the study in accordance with the currently approved documents. I attest that, should a designate sign on my behalf, the responsibility for corresponding with the REB has been appropriately delegated, and the delegation has been documented.

• As the Centre PI:
- I assume full responsibility for the scientific and ethical conduct of the trial at this institution
- I agree to conduct this trial in compliance with TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND with all other applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);
- I attest that I have sufficient space, time and resources to conduct this trial;

- I attest that the Centre Co-Investigator listed in this application (if applicable) is appropriately qualified to assume my responsibilities in the event that I am unable to do so;
- I certify that all Co-investigators, researchers and other personnel (research team) involved in this project at this institution are appropriately qualified and experienced, or will undergo appropriate training to fulfill their role in this project;
- I acknowledge that I am responsible for promptly reporting to the REB, through the Clinical Trials Ontario Streamlined Research Ethics Review System, any proposed centre-specific:
- modifications or amendments, such as changes in Centre PI, changes in Centre Co-investigator (if applicable), centre-specific required changes to the consent form, etc.;
- all local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the trial;
- trial progress report (renewal/ continuing review form), annually or as often as requested by the REB;
- trial completion or termination - I certify that REB approval and all external and local institutional approvals will be obtained before the trial will commence;
- I have reviewed the provincial REB materials (e.g., REB approved provincial application forms including attachments, REB review letters, other correspondence between the REB and the

Provincial Applicant, REB approval letters, REB approved provincial consent forms, etc.);
- I will ensure that all REB approved provincial changes will be implemented at my centre, when relevant;
- I certify that the research team will adhere to the protocol and consent form as approved by the REB unless to eliminate an immediate safety hazard to participants and in accordance with any conditions placed on the REB approval;
- I certify that all information provided in this application represents an accurate description of the conduct of the trial at this site.

Privacy and Security Acknowledgement:

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

Signature Type: Principal Investigator

If 1.0 = No AND 12.2 = Change in Principal Investigator

16.2 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 1.0 = No AND 12.2 = Change in Principal Investigator

16.3 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 1.0= Yes OR 2.1 is exactly = "Change(s) to contact details for the Principal Investigator/Principal Co-Investigator or the name/contact details for the centre administrative study contact/institution representative(s)", then Question 2.4 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: PI or Delegate

If 1.0 = No AND 12.2 = "Addition or Change to Co-Investigator"; then 16.8 appears:

16.5 Co-Investigator

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

Signature Type: Principal Investigator