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 • Application questions were re-ordered • Q2.1: revised to add more options for study status • Q5.3: revised to include consent Update form and debriefing materials to the options; • Section 5.0 expanded to accommodate additional questions • Section16 added to record changes to the consenting process • Section 18 (formerly section 9), includes shared questions from the PIA related to data collection and use. This section appears in ALL amendments and should only be modified if the amendment involves changes to the information in this section (if selected in 2.3) • Questions 18.4 to 18.10 added to address changes to the informed consent/assent/debriefing process, including waivers of consent (if selected in 2.3) • Question 20.2 added to allow a delegate to sign off on resubmissions

CTO Clinical Trial Provincial 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".

The questions below reflect the information that has previously been provided to the REB. If changes are required, please update the information in the corresponding question to reflect the changes being made with this amendment.

1.1 ***Please complete the Provincial Applicant (PA) 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.

1.2 ***Is there a Provincial Co-Applicant?**
☐Yes ☐No

If 'Yes': **1.2.1** ***Please complete the Provincial Co-Applicant 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.

1.3 ***Are the contact details for the Provincial Administrative Study Contact different than the Provincial Applicant named above?**

☐Yes ☐No

If 'Yes': **1.3.1 *Please complete the Provincial 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.

1.4 ***Please complete the Main Sponsor 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.
*Email: Click here to enter text.

1.5 ***Are the external third party (i.e., Contract Research Organization) contact details available?**

☐Yes ☐No ☐No CRO

If 'Yes': **1.5.1 *Please enter the third party 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.

1.6 ***Please enter the complete study title:** Click here to enter text.

1.7 **Please enter the Study ID/Number (if applicable):** Click here to enter text.

1.8 ***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)**
Click here to enter text.

1.9 ***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.
Fax: Click here to enter text.
*Email: Click here to enter text.

1.10 ***Is there a Secondary Institutional Representative at the Provincial Applicant's Institution? (Organization listed in question 1.2)?**
☐Yes ☐No

If 'Yes' to Question 1.10, then the following appears:

1.10.1 ***Please complete the Secondary Institutional Representative details:**
Title: Click here to enter text.
First Name: Click here to enter text.
Surname: Click here to enter text.
Organization: Click here to enter text.
Address: Click here to enter text.
City: Click here to enter text.
Province/State: Click here to enter text.
Postcode/Zip: Click here to enter text.
Telephone: Click here to enter text.
Fax: Click here to enter text.
Email: Click here to enter text.

SECTION 2.0 – AMENDMENT DETAILS

2.1 *What is the current overall status of this study at participating centres in Ontario?

☐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

Help Text: Participating centres in Ontario refers to any/all of the Ontario centres using the CTO Streamlined Research Ethics System.

If 'Other': **2.1.1 *Specify:** Click here to enter text.

If 'prematurely terminated': **2.1.2 *Please provide details:** Click here to enter text.

If 'Not yet activated', 'Activated, but no participants enrolled to date' and/or 'One or more study participant(s) receiving study treatment/intervention', question 2.2 will appear:

2.2 *Is the enrolment of new participants currently on hold or temporarily suspended?

☐Yes ☐No

If 'Yes': **2.2.1 *Please explain why enrolment is on hold/suspended:** Click here to enter text.

2.3 *Which of the following changes are included in the Amendment(s) (select all that apply):

☐Changes to the protocol
☐Changes to biological specimen collection/use
☐ Changes to the consent form(s), assent form(s), debriefing material(s)
☐Changes to participant materials (such as study instruments/questionnaires, recruitment materials, participant diaries, wallet cards, etc.)
☐Updated/new Investigator Brochure (IB) or Product Monograph (PM)
☐Translation of approved materials
☐Change to the data collected and/or how data is accessed, collected, used or stored
☐Changes in study funding, participant compensation/reimbursement, provision or access to product(s)/device(s), and/or financial pressure(s)/incentive(s)
☐Change/updates relating to the communication of results
☐Change in clinical trial registry information
☐Change in US regulatory information
☐ Change(s) to Provincial Applicant or Provincial Co-Applicant; and/or change in study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID)
☐New information about a refusal to approve the study by another REB

☐Change to informed consent/assent/debriefing process
☐Change(s) to contact details for the Provincial Applicant/Provincial Co-Applicant; and/or the name/contact details for the provincial administrative study contact/institution representative(s)/Main Sponsor Contact/Main CRO Contact
☐Other

Help Text: For the purposes of this question and subsequent dependent questions, please ensure that all applicable options are selected. For example, if the changes made to the protocol includes changes to biological specimen collection, you must select both options.

If any option is selected in addition to "Change(s) to contact details for the Provincial Applicant/Provincial Co-Applicant or the name/contact details for the provincial administrative study contact/institution representative(s)/Main Sponsor Contact/Main CRO Contact", then the Provincial Applicant signature will be required on the initial submission of this amendment.

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

Q2.4: this should be a stand-alone, comprehensive summary of the changes in the amendment, clearly stating the rationale for the changes, the seriousness of any findings resulting in the changes, any other specific actions taken (e.g., suspension of enrolment). This information will facilitate the REB determination for level of review required.

2.5 If applicable, please provide a protocol amendment reference number/ID (e.g., the identifier assigned by the lead group/Sponsor to the modification) 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.

Q2.5: Will appear as blank in the approval letter if there is no information entered here.

2.6 *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.

Q2.6: The label entered here appears in the Project tree, which helps to identify the details of the submitted amendment and distinguishes one amendment from another. Examples of labels might be: revised protocol; updated IB; consent revisions; change in PA, etc.

2.7 *Is this application associated with or related to a previously submitted Provincial Reportable Event or Provincial Amendment?

☐Yes ☐No

***If 'Yes':* 2.7.1 *Please enter the Review Reference # of the corresponding Provincial Reportable Event Form/Provincial Amendment Form:** Click here to enter text.

Help Text: The Review Reference # is the number that was assigned to the submission of the corresponding Provincial Reportable Event Form/Provincial Amendment Form. The Review Reference

Number can be found by selecting the form within the project. For more information please consult Section 1 in the Application Feature Manual.

2.8 ***Please specify the type of review requested:**

☐Full Board
☐Delegated
☐Not specified

Help Text: Type of review refers to the type of ethics review that will be used by the REB. While the sponsor or investigator may propose the type of review, the REB makes the final decision regarding whether the submission will undergo delegated review (by one or more REB members) or full Board review (at a convened meeting of the REB).

***Does this submission require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Application)?**

☐ Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations
☐ Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations
☐ Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations
☐ No

If 2.18a in the PIA = yes – a clinical trial application under the food and drug regulations and/or yes – a clinical trial application under the Natural Health Product Regulations and/or yes – an investigational testing application under the Medical Device Regulations, question 2.8 will appear:

2.9 ***Do these changes require authorization from Health Canada?**

☐Yes, a No Objection Letter (NOL)/Notice of Authorization (NOA)/revised Investigational Testing Authorization (ITA) will be issued
☐Notification to Health Canada only
☐No

If 'Yes, a No Objection Letter/Notice of Authorization/revised Investigational Testing Authorization', question 2.9 will appear:

2.10 ***Has Health Canada authorization been received?**

☐Yes
☐Pending

If 'Yes': **2.10.1** ***Please upload Health Canada authorization letter:**
Upload Document - Document Type: NOL/NOA

2.11 ***Describe any change to the risk, discomfort or inconvenience to study participants as a result of this amendment:** Click here to enter text.

2.12 ***Is there a Summary of Changes document, tracked-changes protocol, or other document identifying the proposed changes made with the amendment(s) and/or the rationale for the changes?**

☐Yes ☐No

Help Text: A summary of changes describes all changes that have been to a document, typically identifying the previous wording, revised wording, and rationale for the change. For studies under Health Canada oversight, the summary of changes document that is provided to Health Canada may be used.

If 'yes' to question 2.11: **2.12.1 *Please upload**

Upload Document - Document Type: Summary of Changes

2.13 **Upload any additional information such as related sponsor correspondence: *(e.g., sponsor cover letters or memos, including Action Letters even if they were previously submitted with a reportable event),* if applicable:**

Upload Document - Document Type: Sponsor Correspondence/Newsletter

SECTION 3.0 – CHANGES TO THE PROTOCOL

If 'Changes to the Protocol' is selected in question 2.3, the following questions appear:

3.1 ***Which of the following are included in the proposed protocol changes (select all that apply)?**

☐Study objectives, procedures or design
☐Study instruments embedded within the protocol (e.g., questionnaires)
☐Duration of study
☐Number of participants/sample size
☐Participant recruitment methods
☐Eligibility criteria (inclusion/exclusion)
☐Known or anticipated harms/risks/benefits
☐Safety monitoring
☐Addition of sub-studies/correlative studies
☐Addition of new product [e.g., drug, biologic (including vaccines), genetic therapy or radiopharmaceutical]/health product (natural or non-prescription)/device to the study
☐Administrative updates
☐Other

If 'Other': **3.1.1 *Specify other changes:** Click here to enter text.

3.2 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:**

Click here to enter text.

Q3.2: clearly state the rationale for the protocol changes, including the seriousness of any findings related to the amendment.

3.3 ***Please upload the revised protocol (this must be a 'clean' version):**
Upload Document - Document Type: Protocol

3.4 ***Did the changes to the protocol require immediate implementation to reduce or eliminate immediate hazard to current participants?**

☐Yes ☐No

If 'Yes': **3.4.1 *Identify the changes that required immediate implementation, and provide the rationale for implementing these changes immediately:** Click here to enter text.

If 'Addition of new product [e.g., drug, biologic (including vaccines), genetic therapy or radiopharmaceutical]/health product (natural or non-prescription)/device to the study' is selected in 3.1:

3.5 ***Is the new product [e.g., drug, biologic (including vaccines), genetic therapy or radiopharmaceutical]/health product (natural or non-prescription)/device subject to an application to Health Canada under the Food and Drugs Act (select all that apply)?**

☐Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations;
☐Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations;

☐Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations;
☐No

If 'Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations' is selected in 3.5, question 3.6-3.7 appear:

3.6 *Please indicate the status of the new product(s) covered under the CTA with Health Canada (select all that apply):

☐Approved (e.g., has Drug Identification Number (DIN)), but being used in the study outside the conditions of use approved by Health Canada
☐Investigational

Help Text: Approved drug refers to marketed drugs, with conditions of use identified in the Notice of Compliance (NOC), Notice of Compliance with Conditions (NOC/c) or Drug Identification Number (DIN)

Conditions of use refers to the parameters under which the agent (e.g., drug, natural health product) has been approved for use in Canada. Includes the indication(s) and clinical use; target patient populations(s); route(s) of administration; and dosage regimen(s).

Drug Identification Number (DIN) refers to a computer-generated eight digit number assigned by Health Canada to a drug product prior to being marketed in Canada. It uniquely identifies all drug products sold in a dosage form in Canada and is located on the label of prescription and over-the-counter drug products that have been evaluated and authorized for sale in Canada. A DIN uniquely identifies the following product characteristics: manufacturer; product name; active ingredient(s); strength(s) of active ingredient(s); pharmaceutical form; route of administration.

Investigational product(s) refers to a drug that has not been marketed in Canada and does not have a Drug Identification Number (DIN)

If 'Approved (e.g. has Drug Identification Number (DIN)), but being used in the study outside the conditions of use approved by Health Canada':

3.6.1 *Describe how the new product(s) is/are being used in the study outside the conditions of use approved by Health Canada: Click here to enter text.

3.7 *Please indicate which of the following document(s) were submitted to Health Canada for the new product(s) covered under the Clinical Trial Application (CTA) (select all that apply):

☐Investigator Brochure (IB)
☐Product Monograph (PM)

Help Text: Clinical Trial Application (CTA) refers to an application made to Health Canada requesting authorization to conduct a clinical trial involving a drug, biologic, genetic therapy, radiopharmaceutical or natural or non-medicinal health product in Canada.

If 'Investigator Brochure (IB)':

3.7.1 *Please upload Investigator Brochure (IB):
Upload Document - Document Type: Investigator Brochure

If 'Product Monograph (PM)':

3.7.2 *Please upload Product Monograph (PM):
Upload Document - Document Type: Product Monograph

If 'Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations' was selected from list in question 3.4, questions 3.8-3.9 appear:

3.8 ***Please indicate the status of the new health product(s) covered under the CTA with Health Canada (select all that apply):**

☐Approved (e.g., has Natural Product Number (NPN or Homeopathic Medicine Number (DIN-HM)), but being used in the study outside the conditions of use approved by Health Canada

☐Investigational

Help Text: Approved health product refers to licensed natural or non-prescription health products, with a Natural Product Number (NPN) or homeopathic medicine number (DIN-HM).

Conditions of use refers to the parameters under which the agent (e.g., drug, natural health product) has been approved for use in Canada. Includes the indication(s) and clinical use; target patient populations(s); route(s) of administration; and dosage regimen(s).

Natural Product Number refers to an eight (8) digit numerical code assigned to each natural health product approved to be marketed under the Natural Health Products Regulations.

Homeopathic Medicine Number (DIN-HM) refers to an eight (8) digit numerical code assigned to each homeopathic medicine approved to be marketed under the Natural Health Products Regulations.

Investigational health product(s) refers to a natural or non-prescription health product that has not been licensed in Canada and does not have a natural product number (NPN) or homeopathic medicine number (DIN-HM).

If 'Approved (e.g has Natural Product Number (NPN or Homeopathic Medicine Number (DIN-HM)), but being used in the study outside the conditions of use approved by Health Canada':

3.8.1 ***Describe how the new Health Product is being used in the study outside of the parameters of the conditions of use approved by Health Canada**: Click here to enter text.

3.9 ***Please indicate which of the following document(s) were submitted to Health Canada for the new health product(s) covered under the Clinical Trial Application (CTA) (select all that apply)?**

☐Investigator Brochure (IB)

☐Product Monograph (PM)

If 'Investigator Brochure (IB)':

3.9.1 ***Please upload Investigator Brochure (IB):**

Upload Document - Document Type: Investigator Brochure

Q3.9.1 and 3.9.2: when naming these documents, please include the name of the drug or compound.

If 'Product Monograph (PM)':

3.9.2 ***Please upload Product Monograph (PM):**

Upload Document - Document Type: Product Monograph

If 'Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations' selected in question 3.4, questions 3.10-3.13 appear:

3.10 ***Name of all new device components, parts and/or accessories as per product label for devices covered under the ITA with Health Canada:** Click here to enter text.

Add Another

Help Text: Investigational Testing Authorization (ITA) refers to an application made to Health Canada requesting authorization to conduct a clinical trial involving a medical device in Canada.

3.11 ***Please indicate the status of the new device(s) with Health Canada (select all that apply):**

☐Licensed (e.g., has Medical Device License (MDL)), but being used outside of current Health Canada authorization

☐Investigational

If 'Licensed (e.g. has Medical Device License (MDL)), but being used outside of current Health Canada authorization':

3.11.1 ***Describe how the new device component, parts and/or accessories is/are being used in the study outside of the parameters of the conditions of use approved by Health Canada:** Click here to enter text.

3.12 ***Does this new device contain drug(s)?**

☐Yes ☐No

If 'Yes': **3.12.1** ***Drug(s) used:** Click here to enter text.

3.13 ***For each new device covered under the ITA, upload the Product Monograph (PM) or equivalent:**

Upload Document - Document Type: Product Monograph

SECTION 4.0 – CHANGES TO BIOLOGICAL SPECIMEN COLLECTION/USE

If 'Changes to biological specimen collection/use' is selected in question 2.3, the following questions appear:

4.1 ***The changes to the biological specimen collection/use include (select all that apply):**

☐Changes to previously approved biological specimen collection/use information

☐Addition of new biological specimen collection/use

If 'Changes to previously approved biological specimen collection/use information' is selected question 4.2 appears:

4.2 ***Identify the changes being made to the previously approved biological specimen collection/use, and provide a rationale. If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

If 'Addition of new biological specimen collection/use' questions 4.3 – 4.9 appear:

4.3 ***What type of new specimen(s) will be collected from the study participants?** Click here to enter text.

4.4 ***Will stem cells be collected or used in this study?**

☐Yes ☐No

If 'Yes': **4.4.1** ***Describe the stem cell component of the study:** Click here to enter text.

4.5 ***How will the new specimens be collected (select all that apply)?**

☐Previously acquired clinical specimens (i.e., leftover or archived specimens)

☐Prospectively collected for this study (i.e., not yet collected)

☐Other

Help Text: Prospectively refers to collection which will be done in the future.

If Other: **4.5.1** ***Specify Details:** Click here to enter text.

4.6 ***Will the new specimens be linked to any study participant identifying information, directly or indirectly via a code or link?**

☐Yes ☐No

If 'Yes': **4.6.1** ***Who will have access to the code or link?** Click here to enter text.

4.7 ***Describe the security measures to protect the confidentiality of the new specimens:** Click here to enter text.

4.8 ***Does the sponsor plan to put a material transfer agreement (MTA) or similar contract in place with each participating centre to ensure secure transfer and storage of the new specimens?**

☐Yes ☐No ☐N/A (specimens will not be transferred out of the centres)

If 'No': **4.8.1** ***Explain and justify:** Click here to enter text.

4.9 ***Select the purpose(s) for which the new specimens will be collected (select all that apply):**

☐For the purposes of this study (excluding specimens taken as part of normal care or for safety)

☐For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)

☐Stored or retained or banked for any future testing

Help Text: Purposes of this study means collection of specimens is necessary to achieve the objectives of the study.

Genetic testing involves examining a person's DNA (the chemical database that carries instructions for the body's functions). Genetic testing can reveal changes or alterations in a person's genes that may cause illness or disease including inherited diseases. Genetic testing also can be used to determine a person's biological relationship (e.g., parent), or a person's ancestry.

Stored or retained or banked for any future testing refers to the retention of samples and/or data as part of a study that potentially will be used at a later date for a defined purpose or for an as yet undefined purpose.

If 'For the purposes of this study (excluding specimens taken as part of normal care or for safety)' is selected in 4.9, questions 4.10- 4.15 appear:

4.10 ***Please indicate whether the specimen collection for the purposes of this study is (select all that apply):**

☐Optional
☐Mandatory

4.11 ***Describe how the specimens will be used in this study:** Click here to enter text.

4.12 ***Where will the specimens be sent (e.g., name & address including country)?** Click here to enter text.

4.13 ***Indicate how long the new specimens will be retained:** Click here to enter text.

4.14 ***Describe what will happen to the new specimens at the end of that period (e.g., destroyed, returned):** Click here to enter text.

4.15 ***Please indicate to what extent the study participant is able to withdraw the new specimens collected for the purposes of the study after the specimens have been shipped offsite, and any limitations to the withdrawal:** Click here to enter text.

If 'For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)' is selected in 4.9, questions 4.16-4.22 appear:

4.16 ***Please indicate whether the sample collection for genetic testing is (select all that apply):**

☐Optional
☐Mandatory

4.17 ***Describe the planned genetic testing:** Click here to enter text.

4.18 ***Where will specimens be sent (e.g. name & address including country)?** Click here to enter text.

4.19 ***Indicate how long the specimens will be retained:** Click here to enter text.

4.20 ***Describe what will happen to the specimens at the end of that period (e.g., destroyed, returned):** Click here to enter text.

4.21 ***Please indicate to what extent the study participant is able to withdraw specimens collected for genetic testing after the specimens have been shipped offsite, and any limitations to the withdrawal:** Click here to enter text.

4.22 ***Will study participants or their family members or their health care providers be informed of any genetic testing results?**

☐Yes ☐No

If 'Yes':

4.22.1 ***Describe what information will be shared and with whom?** Click here to enter text.

4.22.2 ***How will consent be obtained to release this information?** Click here to enter text.

4.22.3 ***Describe whether participants will be given the option of not receiving information about themselves:** Click here to enter text.

If 'No':

4.22.4 ***Please explain/justify:** Click here to enter text.

If 'stored or retained or banked for any future testing' is selected in 4.9, questions 4.23-4.29 appears:

4.23 ***Please indicate whether the sample collection to be stored or retained or banked for any future testing is (select all that apply):**

☐Optional

☐Mandatory

4.24 ***Where will the biobank(s)/repositories be located (e.g., name of bank & address including country)?** Click here to enter text.

4.25 ***Where will the associated data be located (e.g., name & address including country)?** Click here to enter text.

4.26 ***Who will be the custodian of the specimens that will be stored or retained or banked for any future testing?** 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.

4.27 ***Who will have access to the banked specimens?** Click here to enter text.

4.28 ***Describe what will happen to the specimens (e.g., destroyed, returned) at the end of the banking period (e.g., at the end of the retention period, or if a participant withdraws their consent):** Click here to enter text.

4.29 ***Please indicate to what extent the study participant is able to withdraw banked specimens, and any limitations to the withdrawal:** Click here to enter text.

SECTION 5.0 – CHANGES TO CONSENT/ASSENT FORM(S) OR DEBRIEFING MATERIAL(S)

If "Changes to the consent form(s), assent form(s), debriefing material(s)" is selected in question 2.3, questions 5.1 – 5.3 will appear:

5.1 ***Please select the reason(s) for the proposed consent/assent form change(s) (select all that apply):**

☐Changes to the protocol
☐Updated adverse effects profile
☐Administrative changes
☐Other

If 'Other': **5.1.1 *Please specify other reason:** Click here to enter text.

5.2 ***Did the new information require urgent oral communication with current/past participants, to eliminate an apparent/potential immediate hazard, for which approval from the REB was obtained prior to the submission of this amendment?**

☐Yes ☐No

5.3 ***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 5.3 AND question 2.1 = 'Not yet activated', 'Activated, but no participants enrolled to date', 'Activated/open to enrollment, participants have enrolled but none are currently receiving study treatment/intervention', 'Activated/open to enrollment with one or more study participants receiving study treatment/intervention', or 'Other' is selected, then questions 5.4 and 5.5 will appear:

5.4 **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 Document

5.5 ***Please upload clean versions of the new and/or revised consent form(s):**
Upload Document - Document Type: Provincial Consent Form

If 'Assent Form(s)' is selected in 5.3 AND question 2.1 = 'Not yet activated', 'Activated, but no participants enrolled to date', 'Activated/open to enrollment, participants have enrolled but none are currently receiving study treatment/intervention', 'Activated/open to enrollment with one or more study participants receiving study treatment/intervention', or 'Other' is selected, then questions 5.6 and 5.7 will appear:

5.6 **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

5.7 ***Please upload clean versions of the new and/or revised assent form(s):**
Upload Document - Document type: Provincial assent forms

If 'debriefing material(s)' is selected in 5.3: questions 5.8 and 5.9 will appear:

5.8 **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

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

5.10 ***Will the new/updated information be communicated to current or past participants (e.g., participants already enrolled in or completed the study)?**
☐Yes ☐No
If 'No': **5.10.1** ***Justify:** Click here to enter text.

Q5.10: select 'No' if the new information is not relevant to any past or current participants, OR there are no current or past study participants at any of the Ontario centres.

If 'Yes' in 5.10, questions 5.11 – 5.12 will appear:

5.11 ***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.

Q5.11 use one of the following options:
- Recall participant immediately to provide consent update form and obtain signature
- Contact participant (via phone) to provide new information orally (using the approved consent update form). Document in health record. At next visit, provide consent update form and obtain signature
- At next visit, provide consent update form and obtain signature
- At next visit, provide consent update form. Document in health record.

5.12 ***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.

Q5.12 use one of the following options:
- Contact participant (via phone) to provide new information orally (using the approved consent update form). Provide consent update form at next visit.
- Contact participant (via phone) to provide new information orally (using the approved consent update form). Document in health record. Mail the consent update form (if no further visits are scheduled) and confirm receipt.
- At the next visit, provide consent update form. Document in health record.
- Mail consent update form. Document in health record. Confirm receipt at next visit.

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

☐Yes ☐No

If 'Yes': **5.13.1 *How do you plan to communicate the updated information to participants?**

Click here to enter text.

Example: send consent update form by certified mail; include a contact for requesting additional information. Document in health record.

If 'Yes' in 5.10 OR 'Consent/Assent Update Form' is selected in 5., then question 5.14 appears:

5.14 **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.

NOTE. Consent updates are stand-alone new documents. Do not track changes on a previously **approved** consent update. If the REB requests changes to the current consent update, the tracked and clean copies should be uploaded here.

SECTION 6.0 – CHANGES TO PARTICIPANT MATERIALS

If 'Changes to participant materials (such as study instruments/questionnaires, recruitment materials, participant diaries, wallet cards, etc.)' is selected in question 2.3, the following questions appear:

6.1 ***Please identify the revisions to the participant material(s) as a result of this amendment (select all that apply):**

☐Addition of new survey/questionnaire/interview/focus group
☐Changes to previously approved survey/questionnaires/interview/focus group
☐Addition of new recruitment material
☐Changes to previously approved recruitment material
☐Addition of new other material to be provided to study participants (e.g., diaries, wallet cards)
☐Changes to previously approved other materials that will be provided to study participants (e.g., diaries, wallet cards)
☐Other

Help Text: "Other Materials" refers to certain materials provided to study participants, such as diaries and wallet cards. "Other materials" does not include:

- **Recruitment material;**
- **Interview or focus group scripts;**
- **Surveys, questionnaires, screen shots;**
- **Consent/assent forms or form updates.**

If 'addition of new survey/questionnaire/interview/focus group' is selected in 6.1, 6.2-6.4 appears:

6.2 ***How will the new survey(s)/questionnaire(s)/interview(s)/focus group(s) be administered (e.g., paper, electronic)?** Click here to enter text.

6.3 ***Please upload the new survey(s)/questionnaire(s), screen shot(s) and/or interview/focus group script(s):**
Upload Document - Document Type: Surveys or interview/focus group scripts

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

If 'Changes to previously approved survey/questionnaires/interview/focus group' is yes, above, 6.5-6.8 appear:

6.5 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

6.6 ***Please upload all revised survey(s)/questionnaire(s), screen shot(s) and/or interview/focus group script(s) showing the change(s) from the currently approved version (i.e., with the changes tracked):**
Upload Document - Document Type: Track Changes

6.7 ***Please upload the clean version of all revised survey(s)/questionnaire(s), screen shot(s) and/or interview/focus group script(s):**
Upload Document - Document Type: Surveys or interview/focus group scripts

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

If 'addition of new recruitment material' is selected in 6.1, 6.9-6.10 appears:

6.9 ***What recruitment material(s)/methods are being added (select all that apply)?**

- ☐Brochures, flyers, poster
- ☐Recruitment database
- ☐Third-party organization or recruitment company
- ☐Newspaper/radio ad
- ☐Telephone call scripts
- ☐Website
- ☐Social Media
- ☐Video
- ☐Email scripts
- ☐Other

If 'Other': **6.9.1 *Specify other type of recruitment material**: Click here to enter text.

6.10 ***Upload all new recruitment material(s):**
Upload Document - Document Type: Recruitment materials

If 'Changes to previously approved recruitment material' is selected in 6.1, questions 6.11-6.13 appears:

6.11 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

6.12 ***Please upload the revised recruitment material(s) showing the changes from the currently approved version (i.e., with the changes tracked):**
Upload Document - Document Type: Track Changes

6.13 ***Please upload the clean version of the revised recruitment material(s):**
Upload Document - Document Type: Track Changes

If 'Addition of new other material to be provided to study participants' is selected in 6.1, questions 6.14 appears:

6.14 ***Upload all new other material(s) to be provided to study participants:**
Upload Document - Document Type: Other materials

If 'changes to previously approved other materials that will be provided to study participants' is selected in 6.1, questions 6.15-6.17 appear:

6.15 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

6.16 ***Please upload the revised other material(s) that will be provided to study participants showing the changes from the currently approved version (i.e., with the changes tracked):**
Upload Document - Document Type: Track Changes

6.17 ***Please upload the clean version of the revised other material(s) that will be provided to study participants:**
Upload Document - Document Type: Other Changes

If 'Other' is selected in 6.1, questions 6.18-6.20 appears:

6.18 ***Please describe the other change(s):** Click here to enter text.

6.19 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

6.20 **Please upload any additional information that will be provided to participants, if applicable:**
Upload Document - Document Type: Other materials

SECTION 7.0 - UPDATED/NEW INVESTIGATOR BROCHURE (IB) OR PRODUCT MONOGRAPH (PM)

If 'Updated/new Investigator Brochure (IB) or Product Monograph (PM)' is selected in question 2.3, the following questions appear:

7.1 ***Please indicate which of the following document(s) is/are being updated (select all that apply):**

☐Investigator Brochure (IB)
☐Product Monograph (PM)

If 'Investigator Brochure (IB)':

7.1.1 *Please upload the updated version of the Investigator Brochure (IB):

Upload Document - Document Type: Investigator Brochure

Q7.1.1 and 7.1.2: when naming these documents, please include the name of the drug or compound.

If 'Product Monograph (PM)':

7.1.2 *Please upload the updated version of the Product Monograph (PM):

Upload Document - Document Type: Product Monograph

7.2 ***Is this update to the IB/PM associated with any changes to the consent form(s) and/or changes to the protocol?**

☐Yes ☐No

***If 'Yes':* 7.2.1 *Are these changes included within this amendment submission?**

☐Yes ☐No

***If 'No':* 7.2.2 *When are the corresponding changes expected to be submitted to the REB?**

Click here to enter text.

SECTION 8.0 – TRANSLATION OF APPROVED MATERIALS

If 'translation of approved materials' is selected in question 2.3, the following questions appear:

8.1 ***Please upload all translated approved material(s) (e.g., consent or assent forms, recruitment materials, and/or participant materials such as diaries or questionnaires, etc.):**
Upload Document - Document Type: Translated Materials

8.2 **Please upload all translation certificate(s) /supporting documentation for authenticity of the translation, if applicable:**
Upload Document - Document Type: Translation Certificate

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

SECTION 9.0 – CHANGE TO THE DATA COLLECTED AND/OR ACCESSED, COLLECTED, USED OR STORED

If 'Change to the data collected and/or how data is accessed, collected, used or stored' is selected in question 2.3, the following questions appear:

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

☐Change in the Personal Information or Personal Health Information collected on the study data collection tools (including specimens, questionnaires, diaries, registration forms, case report forms, etc.)

☐Change in how data is accessed, collected, used or stored

☐Linking of data with any other data sets, databases or registries

If 'change in the Personal Information or Personal Health Information collected on the study data collection tools (including specimens, questionnaires, diaries, registration forms, case report forms, etc.)' is selected in question 9.1:

9.2 ***Please describe the change in the Personal Information or Personal Health Information collected on the study data collection tools (including specimens, questionnaires, diaries, registration forms, case report forms, etc.:** Click or tap here to enter text.

9.3 ***Have you updated the list of personal information collected on the study data collection tools to reflect this change in question 18.1?**

☐Yes

If 'change in how data is accessed, collected, used or stored' is selected in question 9.2, question 9.4-9.5 will appear:

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

9.5 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

If 'Linking of data with any other data sets, databases or registries' is selected in question 9.1, questions 9.6-9.7 will appear:

9.6 ***Is there a plan to link any of the study data with any other data sets, databases or registries (e.g., health registries, Statistics Canada)?**

☐Yes ☐No

If 'Yes':

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

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

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

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

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

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

☐Yes ☐No

If 'Yes':

9.7.1 *Please specify: Click here to enter text.

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

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

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

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

SECTION 10.0 – CHANGES IN STUDY FUNDING/COMPENSATION

If 'Changes in study funding, participant compensation/reimbursement, provision or access to product(s)/device(s), and/or financial pressure(s)/incentive(s)' is selected in question 2.3, the following questions appear:

10.1 *Please select the type of change (select all that apply):

- ☐Addition of new funder(s)
- ☐Change to previous funder(s)
- ☐Change to participant compensation/reimbursement
- ☐Change in provision of or access to agent(s)/devices used in the study
- ☐Change in financial incentive(s)/pressure(s)
- ☐Other

If Other: **10.1.1 *Please specify:** Click here to enter text.

If 'Addition of new funder(s) is selected in 10.1, question 10.2 will appear:

10.2 *New Study funder(s) (select all that apply):

- ☐Industry (e.g. Pharmaceutical or Biotech company)
- ☐Government (e.g., Ministry of Health and Long Term Care, Department of National Defence)
- ☐Charitable Foundation
- ☐Tri- Council (e.g., CIHR, SSHRC, NSERC, NCE)
- ☐Internal funding
- ☐US federal funds
- ☐Other

If 'Other': **10.2.1 *Specify other funder(s):** Click here to enter text.

If 'Industry (e.g. Pharmaceutical or Biotech Company)':

10.2.2 *Name(s) of Industry funder: Click here to enter text.

If 'Government':

10.2.3 *Name(s) of government: Click here to enter text.

If 'Charitable Foundation':

10.2.4 *Name(s) of charitable foundation(s): Click here to enter text.

If 'Tri-Council':

10.2.5 *Name(s) of funding agency/ies: Click here to enter text.

If 'Internal funding':

10.2.6 *Name(s) of internal funding sources: Click here to enter text.

If 'US Federal Funds':

10.2.7 *Name(s) of US federal funder(s): Click here to enter text.

If 'Change in previous funder(s)' is selected in 10.1, question 10.3-10.4 will appear:

10.3 ***Describe all changes in study funder(s):** Click here to enter text.

10.4 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

If 'Change to participant compensation/reimbursement' is selected in 10.1, questions 10.5-10.6 will appear:

10.5 ***Describe all changes in participant compensation/reimbursement:** Click here to enter text.

10.6 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

If 'Change in provision of or access to agent(s)/devices used in the study' is selected in 10.1, questions 10.7-10.8 will appear:

10.7 ***Describe all changes in provision/access:** Click here to enter text.

10.8 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

If 'Change in financial incentive(s)/pressure(s)' is selected in 10.1, question 10.9 will appear:

10.9 ***Are there any financial incentives or financial pressures associated with the study (e.g., recruitment incentives, higher payments per completed visit, or payments for procedures that exceed the standard amount) that might compromise or influence the conduct of the study?**
☐Yes ☐No
If 'Yes': **10.9.1** ***Describe the management plan:** Click here to enter text.
If 'No': **10.9.2** ***Describe the changes in financial incentive(s)/pressure(s):** Click here to enter text.

If 'other' is selected in 10.1, question 10.10 will appear:

10.10 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

SECTION 11.0 - CHANGE/UPDATES RELATING TO THE COMMUNICATION OF RESULTS

If 'Change/updates relating to the communication of results' is selected in question 2.3, this section will appear:

11.1 ***This change/update relates to communication of results to (select all that apply):**

☐stakeholders
☐participants

11.2 ***Describe the change/update relating to the communication of results:** Click here to enter text.

11.3 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

If 'participants' is selected in 11.1, question 11.4-11.5 will appear:

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

☐Debriefing script
☐Group debriefing
☐End of study letter
☐Publication
☐Other

11.5 **If the amendment includes change(s) to previously submitted document(s), please upload the revised 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 Document

Help Text: If you are revising a document that was previously approved by the REB, please provide a track-changes version.
Material associated with the communication of results to participants includes, for example, debriefing scripts, group debriefing scripts or end of study letters.

If 'Debriefing Script' is selected in 11.4, question 11.6 will appear:

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

If 'Group debriefing' is selected in 11.4, question 11.7 will appear:

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

If 'End of study letter' is selected in 11.4, question 11.8 will appear:

11.8 ***Please upload clean version(s) of the end of study letter:**
Upload Document - Document Type: End of study letter

SECTION 12.0 - CHANGE IN CLINICAL TRIAL REGISTRY INFORMATION

If 'change in clinical trial registry information' is selected in question 2.3, this section will appear:

12.1 ***Describe the change in registry information (including new registration number if applicable):**

Click here to enter text.

SECTION 13.0 - CHANGE IN US REGULATORY INFORMATION

If 'change in US regulatory information' is selected in question 2.3, this section will appear:

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

☐Change in the US FDA application status
☐Change in support from United States Federal Government.
☐Other change relating to US regulatory information

If 'Change in the US FDA application status' is selected, question 13.2 appears:

13.2 ***Have you updated question 18.2 to reflect this change?**

☐Yes

If 'Change in support from United States Federal Government' is selected, question 13.3 appears:

13.3 ***Have you updated question 18.3 to reflect this change?**

☐Yes

If 'Other change relating to US regulatory information' is selected, question 13.4 appears:

13.4 ***Please describe the other type of change relating to US regulatory information:** Click here to enter text.

SECTION 14.0 – CHANGE IN NAME/CONTACT INFORMATION OR STUDY INFORMATION

If 'Change(s) to contact details for the Provincial Applicant/Provincial Co-Applicant; and/or the name/contact details for the provincial administrative study contact/institution representative(s)/Main Sponsor Contact/Main CRO Contact', is selected in Question 2.3, then question 14.1 appears:

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

☐Contact details for the Provincial Applicant

☐Contact details for the Provincial Co-Applicant

☐Name/contact details for the provincial administrative study contact/institution representative(s)/main sponsor contact/main third party (e.g., CRO) contact

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

14.1.1 *Specify Details: Click here to enter text.

If 'Change in Provincial Applicant or Provincial Co-Applicant; or change in study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID)' is selected in question 2.3, questions 14.2 appears:

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

☐Change in Provincial Applicant

☐Addition or change to Provincial Co-Applicant

☐Removal of Co-Applicant (no replacement)

☐Study title

☐Study acronym/nickname/short title

☐Study ID/Number

If 'Change(s) to Provincial Applicant or Provincial Co-Applicant; and/or change in study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID)' OR 'Change(s) to contact details for the Provincial Applicant/Provincial Co-Applicant; and/or the name/contact details for the provincial administrative study contact/institution representative(s)/Main Sponsor Contact/Main CRO Contact' OR is selected in question 2.3 then questions 14.3-14.4 appear:

14.3 *Does this change in contact information affect any of the REB approved study documents (ie consent, protocol etc)?

☐Yes ☐No

If 'Yes' to question 14.3, then questions 14.3.1-14.3.2 appear:

14.3.1 *Has Question 2.3 been updated to reflect the change in documents?

☐Yes

14.3.2 *Have the revised materials been uploaded in the appropriate section?

☐Yes

14.4 *Have you updated the corresponding information in Section 1 of the application?

☐Yes

SECTION 15.0 – NEW INFORMATION ABOUT A REFUSAL TO APPROVE THE STUDY BY ANOTHER REB

If 'New information about a refusal to approve the study by another REB' is selected in 2.3, then the following question appears:

15.1 ***If another REB has refused to approve this study, or required an amendment to this study (e.g., required protocol change(s)), please describe:** Click here to enter text.

HELP TEXT: "Refused to approve" means that an REB has reviewed the study and determined that it doesn't meet the standards for approval and revision is unlikely to enable the REB to reach a positive determination.

15.2 **Upload any relevant documents:**

Upload Document - Document Type: REB Rejection Documents

SECTION 16.0 – CHANGE TO INFORMED CONSENT/ASSENT/DEBRIEFING PROCESS

If 'Change to informed consent/assent/debriefing process is selected in 2.3, then the following question appears:

16.1 * This change involves:

☐Request for a waiver of informed consent for some or all participants

☐Request for an alteration in consent procedures

☐Other

***If "other":* 16.1.1 *Please describe the change in process:** Click here to enter text.

***If "other":* 16.1.2 *Have you made the corresponding changes to the questions in Section 18.0?**

☐ Yes

Help Text: A waiver of consent implies that no consent process is required; there is no information and consent form or verbal review of study information with participants.

An alteration in consent means that there is a departure from the general principles of consent as described in Chapter 3 of TCPS 2. Alterations to consent requirements may include providing prospective participants with only partial disclosure about the purpose of the study, deceiving prospective participants entirely about the purpose of the study, and obtaining informed consent at a later time in the study.

16.2 *What is the reason for this change? Click here to enter text.

If "Request for a waiver of informed consent from some or all participants" is selected in 16.1, question 16.3 appears"

16.3 *Have you updated questions 18.4-18.7 to reflect the updated information regarding the request for a waiver of consent?

☐ Yes

If "Request for an alteration in consent procedures" is selected in question 16.1, questions 16.4 appears:

16.4 *Have you updated questions 18.7-18.10 to reflect the updated information regarding the request for an alteration in consent procedures?

☐ Yes

SECTION 17.0 - OTHER

If 'Other' is selected in question 2.3, the following section appears:

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

17.2 ***Please provide a rationale for the change(s). If all changes/rationale are identified in a document uploaded into this application (e.g., summary of changes), please indicate so:** Click here to enter text.

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

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

SECTION 18.0 – SHARED QUESTIONS

This section contains shared questions from the Provincial 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 or Personal Health Information collected on the study data collection tools (including specimens, questionnaires, diaries, registration forms, case report forms, etc.). Any changes to this question MUST be fully described in SECTION 9; if questions 9.1-9.3 are not addressed, any changes made to this section of the form will NOT have REB approval.

18.1 ***What (if any) Personal Information or Personal Health Information is the sponsor requesting on the study data collection tools (this includes specimens, questionnaires, diaries, registration forms, case report forms, etc.) (select all that apply)?**

- ☐None, study participant ID only
- ☐Full name
- ☐Full initials
- ☐Partial initials
- ☐Full date of birth
- ☐Partial date of birth
- ☐Full date of death
- ☐Partial date of death
- ☐Age
- ☐Sex/gender
- ☐Full postal code
- ☐First 3 digits of postal code
- ☐Pathology specimen number
- ☐Medical device identifier
- ☐Admission date
- ☐Discharge date
- ☐Medical record number
- ☐Ontario health card number
- ☐Driver's license number
- ☐Address
- ☐Telephone number
- ☐Fax number
- ☐E-Mail address
- ☐Full face photograph
- ☐Voice/audio recording
- ☐Other

If 'Other': **18.1.1 *Specify other information:**

If 'Other': **18.1.2 *Justify other information:**

If 'Full name': **18.1.3** ***Justify full name:**
If 'Full initials': **18.1.4** ***Justify full initials:**
If 'Partial initials': **18.1.5** ***Justify partial initials:**
If 'Full date of birth': **18.1.6** ***Justify full date of birth:**
If 'Partial date of birth': **18.1.7** ***Justify partial date of birth:**
If 'Full date of death': **18.1.8** ***Justify full date of death:**
If 'Partial date of death': **18.1.9** ***Justify partial date of death:**
If 'Age': **18.1.10** ***Justify age:**
If 'Sex/gender': **18.1.11** ***Justify sex/gender:**
If 'Full postal code': **18.1.12** ***Justify full postal code:**
If 'First 3 digits of postal code': **18.1.13** ***Justify first 3 digits of postal code:**
If 'Pathology specimen number': **18.1.14** ***Justify pathology specimen number:**
If 'Medical device identifier': **18.1.15** ***Justify medical device identifier:**
If 'Admission date': **18.1.16** ***Justify admission date:**
If 'Discharge date': **18.1.17** ***Justify discharge date:**
If 'Medical record number': **18.1.18** ***Justify medical record number:**
If 'Ontario health card number': **18.1.19** ***Justify Ontario health card number:**
If 'Driver's license number': **18.1.20** ***Justify driver's license number:**
If 'Address': **18.1.21** ***Justify address:**
If 'Telephone number': **18.1.22** ***Justify telephone number:**
If 'Fax number': **18.1.23** ***Justify fax number:**
If 'E-Mail address': **18.1.24** ***Justify E-mail address:**
If 'Full face photograph': **18.1.25** ***Justify full face photograph:**
If 'Voice/audio recording': **18.1.26** ***Justify voice/audio recording:**

The following questions relate to the status of this study with the US federal government. Any changes to these questions MUST be fully described in SECTION 13; if question(s) in section 13 are not addressed, any changes made to this section of the form will NOT have REB approval.

18.2 ***Has this study been submitted to the US Food and Drug Administration (FDA) under an Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) Application?**
☐Yes ☐No

18.3 ***Is this research supported by the United States federal government?**
☐Yes ☐No

The following questions relate to the study-wide description of the informed consent/assent/debriefing process. Any changes to these questions MUST be fully described in SECTION 16; if the questions in section 16. are not addressed, any changes made to this section of the form will NOT have REB approval.

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

☐Yes ☐No

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

☐All participants

☐Some participants

If 'Some participants':

18.5.1 ***Describe the participant population for whom you are seeking a waiver:**

18.6 ***Do the following criteria apply to this study (select all that apply)?**

☐ The research involves no more than minimal risk to the participants

☐ The waiver of informed consent is unlikely to adversely affect the welfare of participants

Click here to enter text.

☐ It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required

☐ Research relies exclusively on secondary use of non-identifiable data/specimens

If "The waiver of informed consent is unlikely to adversely affect the welfare of participant" is selected, then the following appears:

18.6.1 ***Please explain why there is unlikely to be an adverse effect:**

If "It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required" is selected, then the following appears:

18.6.2 ***Please explain why it is impossible or impracticable to conduct the research without prior consent:**

HELP TEXT: Minimal risk research is defined by the Tri-Council Policy Statement (TCPS 2) as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Impracticable refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience.

Secondary use refers to the use in research of data or biospecimens originally collected for a purpose other than the current research purpose.

If "The research involves no more than minimal risk to the participants", "The alteration to consent requirements is unlikely to adversely affect the welfare of participants" or "It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, if the prior consent of participants is required" is selected in 16.4, question 16.5 appears:

18.7 ***Is there a plan to provide a debriefing to participants which may also offer participants the possibility of refusing consent and/or withdrawing data/specimens?**

☐Yes ☐No

If 'Yes': **18.7.1** ***Describe:** Click here to enter text.

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

☐ Yes ☐ No

18.9 ***Please describe the proposed consent procedures, including an explanation of the nature and extent of the proposed alteration:** Click here to enter text.

HELP TEXT: Please refer to the Tri-Council Policy Statement (TCPS 2) Chapter 3 for more information on the general principles of consent and alterations to these procedures.

18.10 ***Do the following criteria apply to this study (select all that apply)?**

☐ The research involves no more than minimal risk to the participants

☐ The alteration to consent requirements is unlikely to adversely affect the welfare of participants

☐ It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, without the alteration in consent procedures

Click here to enter text.

☐ Participants will be provided an opportunity to refuse consent and/or withdraw data/specimens

If "The alteration to consent requirements is unlikely to adversely affect the welfare of participants" selected:

18.10.1 *Please explain why there is unlikely to be an adverse effect: Click here to enter text.

If "It is impossible or impracticable to carry out the research and to address the research question properly, given the research design, without the alteration in consent procedures" is selected:

18.10.2 *Please explain why it is impossible or impracticable to conduct the research without the alteration:

HELP TEXT: Minimal risk research is defined by the Tri-Council Policy Statement (TCPS 2) as research in which the probability and magnitude of possible harms implied by participation in the research is no greater than those encountered by participants in those aspects of their everyday life that relate to the research.

Impracticable refers to undue hardship or onerousness that jeopardizes the conduct of the research. It does not refer to mere inconvenience.

SECTION 19.0 – 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.

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

19.1 **Upload Provincial Applicant Response to REB request for modification letter (if applicable)**:
Upload Document - **Document Type: Response to REB Letter**

Q19.1: an applicant response letter is required for a PAM that is reviewed by the Full Board (at an OCREB meeting) unless the changes requested only involve the consent form. Always include the OCREB requirements and recommendations in the letter along with the responses. The letter should have PI or sponsor input as necessary, but does not require a signature by the PA/PI. Do not remove any PA/PI response letters previously uploaded.

19.2 **Upload any additional materials requested by the REB (if applicable):**
Upload Document - **Document Type: Other materials**

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

Q17.3: this is a free text field. Provide any additional information which would assist OCREB with the review and approval of the amendment.

SECTION 20.0 – ATTESTATIONS AND SIGNATURES

If* Any checkbox in Question 2.3 is selected other than "*Change(s) to contact details for the Provincial Applicant/Provincial Co-Applicant; and/or the name/contact details for the provincial administrative study contact/institution representative(s)/Main Sponsor Contact/Main CRO Contact", AND Question 1.0 = 'No', then the following question appears:

20.1 Provincial Applicant

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I agree to assume the role of Provincial Applicant for this trial;
- 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 Provincial Applicant:
  - I attest that this application is and all subsequent trial-related provincial applications will be completed and submitted in compliance with TCPS2 (2nd edition of the 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 the Provincial Co-Applicant listed in this application (if applicable) is appropriately qualified to assume my responsibilities as Provincial Applicant in the event that I am unable to do so;
  - I acknowledge that I am responsible for promptly reporting to the REB, through the Clinical Trials Ontario Streamlined Research Ethics Review System, all trial wide (provincial):
  - proposed modifications or amendments, including but not limited to, changes to the protocol, to the consent form, to the participant materials, to the recruitment materials, to the provincial application, or to the Investigator Brochures or Product Monographs;
  - reportable events that meet the REB reporting criteria, including but not limited to DSMB/C reports, interim analysis reports and any new information that might 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
  - Once the provincial initial submission is approved, I am aware that if I also am a centre PI on this trial, I must submit, through the Clinical Trials Ontario Streamlined Research Ethics Review System, a Centre Initial Application Form for approval to conduct the trial at my centre;
  - I am aware that the REB review materials (e.g., provincial application forms including

attachments, review letters, other correspondence between the REB and the Provincial Applicant, approval letters, etc.) will be shared with all Ontario sites participating in this trial;

• I am aware that CTO will make the following trial information available to all Ontario sites participating in this trial: CTO Project I.D. #, Sponsor Name, Sponsor Protocol I.D. #, Trial Title, REB review status, name of Provincial Applicant, and the names of the participating centres and PIs.

Signature Type: Principal Investigator

If Question 1.0 = yes OR 2.3 is exactly = "Change(s) to contact details for the Provincial Applicant/Provincial Co-Applicant; and/or the name/contact details for the provincial administrative study contact/institution representative(s)/Main Sponsor Contact/Main CRO Contact", then following appears:

20.2 Provincial Applicant 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 Provincial Applicant, I attest that the delegation of this responsibility has been documented.

Signature Type: PA or Delegate

If 1.0 = "No" AND "Addition or change to Provincial Co-Applicant" is selected in 14.2, the following appears:

20.3 Provincial Co-Applicant

• I agree to assume the role of Provincial Co-Applicant;

• As Provincial Co-Applicant, I agree to assume the Provincial Applicant responsibilities (as noted above) in the event that Provincial Applicant is unable to do so.

Signature Type: Provincial Co-Applicant