CTO Provincial Amendment Form

Orange text *indicates an upload or action feature*
Red/italics/bold *indicates question/feature dependencies*
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.

Always answer 'YES" to Q1.0 if this is not the FIRST time the application is being submitted – i.e., if the application is being re-submitted with changes requested by the REB or by the REB office.

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.

NOTE. Any changes made in a PAM to Q1.1 to 1.8 take effect immediately in all open or new provincial and centre applications as soon as the change is made in a PAM in Pre Submission. This includes a change to the PA/PI without the PA/PI accepting the role, or the REB approving the change.

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

***If 'Yes':** ***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.

Please complete and submit a PAM involving a change in PA/PI as quickly as possible.

NOTE. Until an issue with the new Centre PI not populating in PAM approval letters is fixed, both old and new Centre PIs will appear. If more than one Centre PI at your centre appears in a PAM approval letter, please place a note-to-file in your study files to explain this.

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

☐Yes ☐No

***If 'Yes':* *Please complete the Main 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 Main CRO Contact details available?**

☐Yes ☐No ☐No CRO

***If 'Yes':* *Please enter the Main CRO 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 ***Complete Study Title: (Enter exactly as written in protocol)** Click here to enter text.

1.7 **Please enter the Sponsor's Study ID/Number:** 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 REB submissions.)**
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 **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
☐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':* *Specify:** Click here to enter text.

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

Select "Other" if the study is OPEN to enrollment and participants were enrolled (see definition in Q3.1) but none remain on treatment.

"Specify": the study is OPEN to enrollment

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':* *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 and/or Assent Form(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 in name/contact information (e.g., for the Provincial Applicant, Provincial Co-Applicant, main study contact, CRO or Sponsor) or change in study information (e.g., study title, study acronym/nickname/short name, sponsor's study ID)
☐New information about a rejection/disapproval of the study by another REB
☐Other

For migrated studies that do not display the questions regarding Health Canada CTA or ITL submission requirements:
1. Q2.3. Check "Other" and indicate that the NOL has been received or is pending;
2. Q16.1 and 16.2. Comment on the NOL status as above;
3. Q 16.4 upload the NOL if available.

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

2.5 **Protocol amendment reference number/ID (e.g., the identifier assigned by the Sponsor to the modification):** Click here to enter text.

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

☐Yes ☐No

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

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

☐Full Board
☐Delegated
☐Not specified

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.

Q2.5: this is a text field that maps to the submission tree. Please enter the sponsor's amendment ID or number. If the amendment does not include a revised protocol, please enter information to distinguish this amendment from others – e.g., Consent Feb 2018; IB v2017-Nov-11; Change in PA; etc.

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:

***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

2.8 ***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:

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

☐Yes
☐Pending

***If 'Yes':** ***Please upload Health Canada authorization letter:**
Upload Document

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

2.11 ***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

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

Upload Document

2.12 **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

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': *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

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

☐Yes ☐No

***If 'Yes': *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

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

If 'Investigator Brochure (IB)':

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

Upload Document

If 'Product Monograph (PM)':

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

Upload Document

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

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':

***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)':

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

Upload Document

If 'Product Monograph (PM)':

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

Upload Document

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

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':** ***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':** ***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

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'*: *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

***If Other:* *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': *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': *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

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':

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

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

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

If 'No':

d) ***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.

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)

If "Changes to the consent and/or assent form(s)" is selected in question 2.3, the following questions 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':** ***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

If 'Not yet activated', 'Activated, but no participants enrolled to date' and/or 'One or more study participant(s) receiving study treatment/intervention', question 5.3 will appear:

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

☐Consent Form(s)
☐Assent Form(s)

If 'Consent Form(s) is selected in 5.3', question 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

5.5 ***Please upload "clean" versions of the revised consent form(s) (i.e., with the changes accepted):**
Upload Document

If 'Assent Form(s) is selected in 5.3', question 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

5.7 ***Please upload "clean" versions of the revised assent form(s) (i.e., with the changes accepted):**
Upload Document

Q5.4: because an upload is mandatory, when the study is closed to enrolment and an updated main consent form is NOT needed, upload a note-to-file to explain why an updated consent is not uploaded.

Q5.5: because an upload is mandatory, when the study is closed to enrolment and an updated main consent form is NOT needed, upload a note-to-file to explain why an updated consent is not uploaded.

NOTE. Consent updates are stand-alone new documents. Do not track changes on a previously **approved** consent update. The consent update associated with a new PAM must be clean. If the REB requests changes to a consent update, the tracked copy can be uploaded in Q5.4 when re-submitted.

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

☐Yes ☐No

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

Q5.8 justification for 'No' – e.g., information is not relevant OR no study participants are on active treatment or intervention at any of the Ontario centres.

If 'Yes' in 5.8, questions 5.9 – 5.12 will appear:

5.9 ***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.

Q5.9 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.

5.10 ***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.

Q5.10 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.

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

☐Yes ☐No

If 'Yes': ***How do you plan to communicate the updated information to participants?** Click here to enter text.

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

5.12 ***Please upload the consent/assent update form:**

Upload Document

Q5.11: if "Yes", send consent update form by certified mail; include a contact for requesting additional information. Document in health record.
If "No" explain why not – e.g., the new information does not include long term effects.

Q5.12 NOTE. Consent updates are stand-alone new documents. Do not track changes to a previously **approved** consent update. The consent update associated with a new PAM must always be clean. If the REB requests changes to a consent update, the tracked copy can be uploaded in Q5.4 at the time of the resubmission.

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

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

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

6.7 *Please upload the "clean" version of all revised survey(s)/questionnaire(s), screen shot(s) and/or interview/focus group script(s) (i.e., with the changes accepted):
Upload Document

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) are being added (select all that apply)?

☐Brochures, flyers, poster
☐Recruitment database
☐Third-party recruitment company
☐Newspaper ad
☐Telephone call scripts
☐Website
☐Video
☐Other

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

6.10 *Upload all new recruitment material(s):
Upload Document

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

6.13 *Please upload the "clean" version of the revised recruitment material(s) (i.e., with the changes accepted):
Upload Document

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

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

6.17 *Please upload the "clean" version of the revised other material(s) that will be provided to study participants (i.e., with the changes accepted):
Upload Document

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

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)':

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

Upload Document

If 'Product Monograph (PM)':

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

Upload Document

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

☐Yes ☐No

***If 'No':* *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

8.2 **Please upload all translation certificate(s), if applicable:**
Upload Document

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 HOW DATA IS 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 ***The question below reflects the information that has previously been provided to the REB. Please update the information in the question below to reflect the changes being made with this amendment. Please ensure that this list includes all information being collected (e.g., not just the change(s) being made with this amendment).**

***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

Q9.2: this question appears in all provincial amendments even when "*Change to the data collected and/or how data is accessed, collected, used or stored*" is NOT selected in question 2.3 (**Type of Amendment**). Do not make any changes unless "*Change to the data collected and/or how data is accessed, collected, used or stored*" has been selected in Q2.3. OCREB will not review Q9.2 unless the change to this section has been noted in Q2.3.

☐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': *Specify other information: Click here to enter text.
If 'Other': *Justify other information: Click here to enter text.
If 'Full name': *Justify full name: Click here to enter text.
If 'Full initials': *Justify full initials: Click here to enter text.
If 'Partial initials': *Justify partial initials: Click here to enter text.
If 'Full date of birth': *Justify full date of birth: Click here to enter text.
If 'Partial date of birth': *Justify partial date of birth: Click here to enter text.
If 'Full date of death': *Justify full date of death: Click here to enter text.
If 'Partial date of death': *Justify partial date of death: Click here to enter text.
If 'Age': *Justify age: Click here to enter text.
If 'Sex/gender': *Justify sex/gender: Click here to enter text.
If 'Full postal code': *Justify full postal code: Click here to enter text.
If 'First 3 digits of postal code': *Justify first 3 digits of postal code: Click here to enter text.
If 'Pathology specimen number': *Justify pathology specimen number: Click here to enter text.
If 'Medical device identifier': *Justify medical device identifier: Click here to enter text.
If 'Admission date': *Justify admission date: Click here to enter text.
If 'Discharge date': *Justify discharge date: Click here to enter text.
If 'Medical record number': *Justify medical record number: Click here to enter text.
If 'Ontario health card number': *Justify Ontario health card number: Click here to enter text.
If 'Driver's license number': *Justify driver's license number: Click here to enter text.
If 'Address': *Justify address: Click here to enter text.
If 'Telephone number': *Justify telephone number: Click here to enter text.
If 'Fax number': *Justify fax number: Click here to enter text.
If 'E-Mail address': *Justify E-mail address: Click here to enter text.
If 'Full face photograph': *Justify full face photograph: Click here to enter text.
If 'Voice/audio recording': *Justify voice/audio recording: Click here to enter text.

If 'change in how data is accessed, collected, used or stored' is selected in question 9.2, question 9.3-9.4 will appear:

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

9.4 ***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 'Linking of data with any other data sets, databases or registries' is selected in question 9.1, questions 9.5-9.6 will appear:

9.5 ***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':

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

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

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

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

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

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

☐Yes ☐No

If 'Yes':

***Please specify:** Click here to enter text.

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

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

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

***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, PARTICIPANT COMPENSATION/REIMBURSEMENT, PROVISION OR ACCESS TO PRODUCT(S)/DEVICE(S), AND/OR FINANCIAL PRESSURE(S)/INCENTIVE(S)

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:* *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 Funding Agency
☐Government
☐Charitable Foundation
☐Granting Agency
☐Internal funding
☐US federal funds
☐Other

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

If 'Industry (e.g. Pharmaceutical or Biotech Company)':
Industry (e.g., Pharmaceutical or Biotech Company)
***Name(s):** Click here to enter text.

If 'Government Funding Agency':
Government Funding Agency
***Name(s):** Click here to enter text.

If 'Government':
Government
***Name(s):** Click here to enter text.

If 'Charitable Foundation':
Charitable Foundation
***Name(s):** Click here to enter text.

If 'Granting Agency':
Granting Agency
***Name(s):** Click here to enter text.

If 'Internal funding':
Internal funding
***Name(s):** Click here to enter text.

If 'US Federal Funds':
US Federal Funds
***Name(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':** ***Describe the management plan:** Click here to enter text.
***If 'No':** ***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 - 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

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

11.6 *Please upload "clean" version(s) of the debriefing script (i.e., with the changes accepted, if applicable):
Upload Document

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

11.7 *Please upload "clean" version(s) of the group debriefing (i.e., with the changes accepted, if applicable):
Upload Document

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 (i.e., with the changes accepted, if applicable):
Upload Document

SECTION 12 – 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 – CHANGE IN US REGULATORY INFORMATION

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

Section 13: This section currently appears in all provincial amendments and will not be reviewed by OCREB unless *Change in US regulatory information* is selected in 2.3.

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 *The question below reflects the information that has previously been provided to the REB. Please update the information to reflect the changes being made with this amendment.

***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

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

13.3 *The question below reflects the information that has previously been provided to the REB. Please update the information to reflect the changes being made with this amendment.

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

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 – CHANGE IN NAME/CONTACT INFORMATION OR STUDY INFORMATION

If 'Change in name/contact information (e.g., for the Provincial Applicant, Provincial Co-Applicant, main study contact, CRO or Sponsor) or change in study information (e.g., study title, study acronym/nickname/short name, sponsor's study ID)' is selected in question 2.3, the following section appears:

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

- ☐Provincial Applicant
- ☐Provincial Co-Applicant
- ☐Main Study Contact
- ☐Main Sponsor Contact
- ☐Main CRO Contact
- ☐Study Title
- ☐Study acronym/nickname/short title
- ☐Sponsor's Study ID/Number

Please ensure that the corresponding information is updated in Section 1 of the application.

SECTION 15 – NEW INFORMATION ABOUT A REJECTION/DISAPPROVAL OF THE STUDY BY ANOTHER REB

If 'New information about a rejection/disapproval of the study by another REB' is selected in 2.3, then the following question appears:

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

15.2 **Upload any relevant documents:**
Upload Document

SECTION 16 - OTHER

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

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

16.2 ***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.

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

16.4 **Please upload any associated documents that have not been uploaded elsewhere (if applicable):**
Upload Document

For migrated studies that do not display the questions regarding Health Canada CTA or ITL submission requirements:
1. Q2.3. Check "Other" and indicate NOL received or NOL pending, as applicable.
2. Q16.1 and 16.2. comment on the NOL status as above.
3. Q 16.4 upload the NOL if available.

SECTION 17 – 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.

17.1 Upload Provincial Applicant Response to REB request for modification letter (if applicable):
Upload Document

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

Q17.1: a response letter is required for a PAM that is reviewed by the full Board (at an OCREB meeting) unless the changes requested only are to the consent form. Always include the OCREB requirements and recommendations in the letter 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.

17.3 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.

18.1 Provincial Applicant Signature - attestation

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- After the initial submission of this Provincial Amendment, I authorize the main provincial trial contact, or other delegated members of the research team, to submit any further edits to this application on my behalf

18.2 Provincial Applicant Signature (for PAM involving a change in PI/Provincial Applicant)

Incoming Provincial Applicant Signature/Attestation

I agree to assume the role of Provincial Applicant for this trial;

- 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.