

# Clinical Trial Study-Wide Amendment Form

**Orange text** indicates an upload or action feature


**Red/italics/bold** indicates question/feature dependencies

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

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

**Black/italics/bold** indicates instructional text for researchers

Questions with an asterisk (\*) are mandatory and must be completed prior to signatures/submission

 Indicates a shared question. If there is no associated data field in this form, the information is pulled into this form from another application (e.g., the Clinical Trial Initial Application )

## SECTION 1.0 – GENERAL INFORMATION

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

Choose an item.

**HELP TEXT:**

**If this is the FIRST TIME this application is being submitted select "No".**

**If this is a re-submission for modifications requested by the REB select "Yes".**

**If 'Yes' to question 1.0:**

**If required, ensure that you upload a response letter in question 19.1, outlining how each comment/question from the REB has been addressed in this re-submission.**

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

 **1.0.1 \*Is this a Canadian Collaboration for Child Health (CHEER) study?**

Yes  No

 **1.1 \*Complete the Lead 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.

Telephone: Click here to enter text.

\*Email: Click here to enter text.

 **1.2 \*Are the contact details for the Lead Administrative Contact different than the Lead Applicant named above?**

Yes  No

**If 'Yes':**

1.2.1 \*Complete the Lead Administrative Contact details:

\*First Name: Click here to enter text.

\*Surname: Click here to enter text.

\*Organization: Click here to enter text.

Telephone: Click here to enter text.

\*Email: Click here to enter text.

1.3 \*Who is the study sponsor?

\*Sponsor name: Click here to enter text.

\*Contact Email: Click here to enter text.

1.4 \*Will a Contract Research Organization (CRO) be used for this study?

Yes

No

*If 'Yes':*

1.4.1 \*Provide the name of the CRO:

\*CRO name: Click here to enter text.

\*Email: Click here to enter text.

1.5 \*Enter the complete study title: Click here to enter text.

1.6 Enter the Study ID/Number (if applicable): Click here to enter text.

1.7 \*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.

## SECTION 2.0 – AMENDMENT DETAILS

### 2.1 \*What is the current overall status of this study at the research sites participating through the Stream platform?

- Not yet activated
- Activated, but no participants enrolled to date
- Activated/open to enrollment, participants have been enrolled but none are currently receiving study treatment/intervention
- Activated/open to enrollment with one or more study participant(s) receiving study treatment/intervention
- Permanently closed to enrolment, one or more study participant(s) receiving treatment/intervention
- Permanently closed to enrolment, no participants are receiving treatment/intervention, and all study participants are in long term follow up or data collection continues
- Study completed (i.e., no further involvement of study participants and no further data collection)
- Prematurely terminated
- Other

If there is a temporary enrollment suspension, DO NOT select "Other". Select the applicable study status and confirm any temporary suspension of enrollment in Q#2.2 and Q#2.2.1

#### HELP TEXT:

Research sites refer to any sites submitting for ethics approval via the Stream platform.

*If 'Other':*

2.1.1 \*Specify other: Click here to enter text.

*If 'Prematurely terminated':*

2.1.2 \*Provide details: Click here to enter text.

*If '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' is selected in question 2.1; question 2.2 will appear:*

### 2.2 \*Is the enrolment of new participants currently on hold or temporarily suspended at any research sites participating in Stream?

- Yes  No

*If 'Yes':*

2.2.1 \*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 (including changes to sample size)
- Changes to biological specimen collection/use
- Changes to the consent/assent form(s), debriefing material(s) or other consent/assent material(s)
- Change to informed consent/assent/debriefing process
- Changes to recruitment plan and/or materials

Change to informed consent/assent/debriefing process should only be selected if there is a request for a waiver of consent for some or all participants.

- Changes to participant materials (such as study instruments/questionnaires, participant diaries, wallet cards, etc.)
- Updated/new Investigator Brochure (IB) or Product Monograph (PM), or Instructions for Use (IFU)
- Translation of approved materials
- Change to the data collected and/or how data is accessed, collected, used or stored
- Changes in study funding, participant remuneration, 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 US regulatory information
- New information about a refusal to approve the study by another REB
- Change to study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID)
- Change to current Lead Applicant
- Change to **CONTACT DETAILS ONLY** for the Lead Applicant
- Change to the Lead Administrative Contact, study sponsor, or CRO
- Other

**HELP TEXT:**

For the purposes of this question and subsequent dependent questions, 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 checkbox options in question 2.3.

*If 'Change to the Lead Administrative contact, study sponsor, or CRO' is the only option selected in 2.3, the following text appears:*

**Amendments exclusively for changes to study personnel (except Lead Applicant) should not be submitted at this time. Please wait until there are additional changes to submit.**

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

**Q#2.4 – This section should include a concise summary of all the key changes being made as a result of the amendment. If study is actively enrolling/treating participants on multiple arms, please also provide a summary of the enrollment status at all Ontario sites (i.e. how many are on active treatment; how many are on FU ; what treatment arms/dose level they are enrolled to)**

**2.5 If applicable, 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 to identify this amendment.

**Q#2.5 – As noted in the application, this field will appear on the Approval/Acknowledgement Letter. If there is no label inserted, this field will remain blank.**

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

**HELP TEXT:**

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

**2.7 \*Is this application associated with or related to a previously submitted Study-Wide Reportable Event or Study-Wide Amendment?**

Yes  No

*If 'Yes' question 2.7.1 appears:*

**2.7.1 \*Enter the Review Reference # of the corresponding Study-Wide Reportable Event or Study-Wide Amendment Form:** Click here to enter text.

**HELP TEXT:**

The Review Reference # is the number that was assigned to the submission of the corresponding Study-Wide Reportable Event Form or Study-Wide Amendment. The Review Reference Number can be found by selecting the form within the project tree.

For guidance on how to find this information, please Section 1 of the Application Features user guide available for download from the [Manuals & Guides](#) page of the. For CanReview projects, [click here](#).

**Q#2.7.1 – The Review Reference Number can also be found on the top of the page of the application (Review Reference: CTO ID-SWRE/SWAM-Mmm/yyyy-123456).**

**2.8 \*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).

*If 'Drugs, Biologics (including vaccines), Genetic Therapies, Cannabis or Radiopharmaceuticals', 'Natural Health Products or non-prescription or disinfectant drugs (as per the Natural and Non-prescription Health Products Directorate (NNHPD))', or 'Medical Devices or Software as Medical Device (SaMD)' is selected in 2.18 of the CTIA, the text below and question 2.8.1 appear:*

Note Question 2.8.1 pertains to the Health Canada requirement for the study overall, not this amendment application.

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

- 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 Authorization (ITA) under the Medical Device Regulations

No

*If 'Yes - a Clinical Trial Application under the Food and Drug Regulations' AND/OR 'Yes – a Clinical Trial Application under the Natural Health Product Regulation's AND/OR 'Yes – an Investigational Testing Authorization under the Medical Device Regulations' is selected to question 2.18a in the CTIA, then question 2.9 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

**Q#2.9 - If the amendment is for an updated Investigator's Brochure (IB), a Notification to Health Canada only should be selected.**

*If 'Yes, a No Objection Letter/Notice of Authorization/revised Investigational Testing Authorization', question 2.10 will appear:*

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

- Yes
- Pending

*If 'Yes':*

**2.10.1 \*Upload Health Canada authorization letter:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: NOL/NOA**

**Q#2.10.1 – The NOL is not required for submission ; if submitted, it will NOT be listed in the approval letter**

**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 change in the quality of study data, data integrity, or study validity as a result of this amendment?**

- Yes  No

*If 'Yes':*

**2.12.1 \*Describe and justify the continuation of the study:** [Click here to enter text.](#)

**2.13 \*Upload a Summary of Changes document identifying all proposed changes made with the amendment(s) and the rationale:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: SUMMARY OF CHANGES**

**HELP TEXT:**

**A summary of changes document describes all changes that have been made 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.

**Q#2.13 – A summary of changes document is not the same as the Tracked Changes version of the document. Please upload the summary of protocol/investigator brochure changes here, listing the changes and rationale for each change. This is a MANDATORY document. Do not upload the tracked changes version of the protocol here as there is now a separate section for this upload (Q#3.5).**

**2.14 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**

**Q#2.14 – Upload Sponsor Memos or Cover Letters or email documentation related to the Amendment here.**

**For COG studies, please also upload CIRB documents here.**

## SECTION 3.0 – PROTOCOL

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

**3.1 \*Does this amendment include a change to the number of participants/sample size?**

Yes  No

*If 'Yes' in question 3.1, question 3.1.1 appears:*

**3.1.1 Research teams must ensure question 18.20 has been updated to indicate the new number of participants being enrolled in the overall study.**

**3.2 \*Does this amendment include the addition of new product [e.g., drug, biologic (including vaccines), genetic therapy or radiopharmaceutical]/health product (natural or non-prescription)/device to the study?**

Yes  No

*If 'Yes' to question 3.2, question 3.2.1 appears:*

**3.2.1 \*Is an application to Health Canada (CTA or ITA) required for the new product(s)?**

Yes  No

*If 'Yes' to question 3.2.1, 3.2.1.1 and 3.2.1.2 appear:*

**3.2.1.1 Research teams must update question 2.8.1 in the previous section (if necessary) to ensure it accurately reflects Health Canada requirement for the study overall.**

**3.2.1.2 Investigator Brochure(s) (IB), Product Monograph(s) (PM), and/or Instructions for Use (IFU) for the new product(s) or device(s) must be uploaded in SECTION 8.0. SECTION 8.0 appears in this form when "Updated/new Investigator Brochure (IB), Product Monograph (PM), or Instructions for Use (IFU)" is selected in question 2.3.**

**3.3 \*Does this amendment include a change to the study design?**

Yes  No

*If 'Yes' to question 3.3:*

**3.3.1 \*Does the change in the study design require an update to the study lay summary?**

Yes  No

**Q#3.3.1 – If there is a change in the study design (e.g. the amendment is adding new treatment arms; the phase of the study is changing from Phase I to Phase II/III) this response should be selected as "Yes" and the Lay Summary updated with the changes in Sec 18; Q#18.1**

*If 'Yes' to question 3.3.1:*

**3.3.2 Ensure the lay summary for the study in question 18.1 has been updated, if necessary, to ensure it encapsulates the protocol changes.**

**3.4 \*Upload the revised protocol (this must be a 'clean' version):**

**UPLOAD DOCUMENT - DOCUMENT TYPE: PROTOCOL**

**3.5 \*Upload the revised protocol/study plan with all changes tracked:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: TRACKED CHANGES DOCUMENT**

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

Yes  No

**If 'Yes':**

**3.6.1 \*Identify the changes that required immediate implementation and provide the rationale for implementing these changes immediately:** [Click here to enter text.](#)

**SECTION 4.0 – 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. If all changes 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 – 4.8 appear:***

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

**4.4 \*Does the addition of new biological specimen collection/use involve the addition of a stem cell component to the study?**

Yes  No

**If 'Yes':**

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

**4.4.2 Upload the Stem Cell Oversight Committee (SCOC) approval letter (if applicable):**

**UPLOAD DOCUMENT – DOCUMENT TYPE: SCOC APPROVAL LETTER**

**HELP TEXT:**

**As per TCPS 2 Article 12.10: Research involving human pluripotent or human totipotent stem cells that have been derived from an embryonic source, and/or that will be grafted or transferred in any other form into humans or non-human animals requires review and approval by SCOC and an REB. The researcher shall provide evidence of SCOC approval to the REB.**

**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 \*In question 4.1 it was indicated that this amendment involves biological specimen collection. How are these samples identified/labelled?**

Non-identifiable – samples do not identify an individual, for all practical purposes, when used alone or combined with other available information

De-identified/Coded – samples are labelled or stored with a code only

Directly identifiable – samples are labelled or stored with directly identifiable participant information (e.g., name, initials, DOB)

**If 'directly identifiable':**

**4.6.1 \*Why is it necessary to include directly identifiable participant information/Why can't the samples be de-identified or coded?** Click here to enter text.

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

**If 'de-identified/coded':**

**4.6.3 \*Who will have access to the code or link?** Click here to enter text.

**Q#4.6.3 – Please note that only the study site staff should have access to this link. The Sponsor can view this information during routine monitoring visits.**

**4.7 \*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 future unspecified research

**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 future unspecified research 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 4.7, questions 4.8-4.13 appear:*

You have indicated samples are collected 'for the purposes of this study'. Answer questions 4.8 - 4.13 for these samples only.

**4.8 \*Indicate whether the specimen collection for the purposes of this study is (select all that apply):**

- Optional
- Mandatory

**4.9 \*Describe how the specimens will be used in this study:** [Click here to enter text.](#)

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

**4.11 \*Indicate how long the new specimens will be retained:** [Click here to enter text.](#)

**Q#4.11 – Please include the duration in years OR “until they are used up.” if there is no definite timeline.**

**4.12 \*Describe what will happen to the new specimens at the end of that period (e.g., destroyed, returned):**

[Click here to enter text.](#)

**4.13 \*Will study participants be provided the opportunity to withdraw specimens collected for the purpose of the research study?**

- Yes  No

*If 'Yes':*

**4.13.1 \*Are there any limitations to the withdrawal?** [Click here to enter text.](#)

**Q#4.13.1 – Please include when participants may withdraw (i.e. anytime). If there are other conditions regarding withdrawal, they should also be noted in this section (e.g. samples have been sent to the lab where they have been anonymized; samples are no longer linked to the participants and therefore cannot be withdrawn.**

**Please also indicate what will happen to the samples if participants withdraw (e.g. samples will be destroyed or discarded or sent back to the study site where they were collected, if requested).**

*If 'No':*

**4.13.2 \*Explain why not:** [Click here to enter text.](#)

*If 'For genetic testing (e.g., gene identification, gene mapping, genomic analysis, DNA screening)' is selected in 4.7, questions 4.14-4.20 appear:*

You have indicated samples are collected 'for genetic testing'. Answer questions 4.14 - 4.20 for the genetic testing only.

**4.14 \*Indicate whether the sample collection for genetic testing is (select all that apply):**

- Optional

Mandatory

**4.15 \*Describe the planned genetic testing:** [Click here to enter text.](#)

**4.16 \*Where will specimens be sent (e.g. name & address including country)?** [Click here to enter text.](#)

**4.17 \*Indicate how long the specimens will be retained:** [Click here to enter text.](#)

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

**4.19 \*Will study participants be provided the opportunity to withdraw specimens collected for the purpose of genetic testing?**

Yes  No

**If 'Yes':**

**4.19.1 \*Describe any limitations to the withdrawal:** [Click here to enter text.](#)

**Q#4.19.1 – Please include when participants may withdraw (i.e. anytime). If there are other conditions regarding withdrawal, they should also be noted in this section (e.g. samples have been sent to the lab where they have been anonymized; samples are no longer linked to the participants and therefore cannot be withdrawn.**

**Please also indicate what will happen to the samples if participants withdraw (e.g. samples will be destroyed or discarded or sent back to the study site where they were collected, if requested).**

**If 'No':**

**4.19.2 \*Explain why not:** [Click here to enter text.](#)

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

Yes  No

**If 'Yes':**

**4.20.1 \*Describe what information will be shared and with whom?** [Click here to enter text.](#)

**4.20.2 \*How will consent be obtained to release this information?** [Click here to enter text.](#)

**4.20.3 \*Describe whether participants will be given the option of not receiving information about themselves:** [Click here to enter text.](#)

**If 'No':**

**4.20.4 \*Explain/justify:** [Click here to enter text.](#)

***If 'Stored or retained or banked for future unspecified research' is selected in 4.7, questions 4.21-4.32 appears:***

**You have indicated samples are 'stored or retained or banked for future unspecified research'. Answer questions 4.21 – 4.32 for this use only.**

**4.21 \*Confirm whether the sample storage/retention/banking for future unspecified research (and collection of any additional samples for this purpose, if applicable) is optional:**

Yes – this is optional

No – this application is strictly for establishing a repository

**HELP TEXT:**

Please note as per TCPS 2 2022 the sample storage/retention/banking for future unspecified research must be optional.

**4.22 \*Where will the samples be stored? For example, where is the biobank(s)/repositories located (e.g., name of bank & address including country) or where will the lead researcher/research group be storing the samples (e.g., name of the institution and address including country)?** Click here to enter text.

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

**4.24 \*Who will be the custodian of the specimens that will be stored or retained or banked for future unspecified research?** 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.

**4.25 \*Provide a general description of the nature and types of future research that may be conducted:**

**4.26 \*Could specimens be shared with researchers outside of Canada?**

Yes  No

**Q#4.26 – Please only select “Yes” if there is a plan for other researchers outside of Canada to ACCESS and USE the samples. If the samples are only being stored or processed in labs outside of Canada, this response should be “No”.**

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

**4.28 \*Could banked samples be used for whole genome sequencing or similar technologies that may pose a substantial risk of re-identification of the participant?**

Yes  No

**4.29 \*Could future research include sequencing or technologies that might result in identification of material incidental findings?**

Yes  No

**4.30** \*Is it anticipated that data derived from the samples could be linked with other data about participants, either in public (for example, social media, public registries) or personal records (for example, medical records, administrative databases)?

Yes  No

**4.31** \*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.

**4.32** \*Will study participants be provided the opportunity to withdraw banked specimens?

Yes  No

*If 'Yes':*

**4.32.1** \*Describe any limitations to the withdrawal: [Click here](#) to enter text.

**Q#4.32.1** – Please include when participants may withdraw (i.e. anytime). If there are other conditions regarding withdrawal, they should also be noted in this section (e.g. samples have been sent to the lab where they have been anonymized; samples are no longer linked to the participants and therefore cannot be withdrawn).

Please also indicate what will happen to the samples if participants withdraw (e.g. samples will be destroyed or discarded or sent back to the study site where they were collected, if requested).

*If 'No':*

**4.32.2** \*Explain why not: [Click here](#) to enter text.

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

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

**5.1 \*Did the new information require urgent oral communication with current/past participants, to eliminate an apparent/potential immediate hazard?**

Yes  No

**5.2 \*What does this change include?**

- Consent Form(s)
- Assent Form(s)
- Debriefing Material(s)
- Other consent/assent 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.

**Q#5.2 – “Consent Form(s)” should be selected if the study is Active and Open to enrollment.**

“Consent/Assent Update Form(s)” should be selected for studies no longer enrolling new participants but have currently enrolled participants, and the amendment includes Consent changes that would impact their safety and willingness to continue participation . Note that the use of the CONSENT UPDATE FORM is mandatory when reconsenting these participants.

*If 'Consent Form(s)' is selected in 5.2, questions 5.3 and 5.4 will appear:*

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

**UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES DOCUMENT**

**Q#5.3 – Remember to TRACK the most recently APPROVED version of the Study-Wide Consent Form (not the site specific consent).**

**5.4 \*Upload clean versions of the new and/or revised consent form(s):**

**UPLOAD DOCUMENT - DOCUMENT TYPE: STUDY-WIDE CONSENT FORM**

*If 'Assent Form(s)' is selected in 5.2, questions 5.5 and 5.6 will appear:*

**5.5 Please upload the revised assent form(s) showing the changes from the currently approved version ( i.e., with the changes tracked):**

**UPLOAD DOCUMENT - DOCUMENT TYPE: TRACK CHANGES DOCUMENT**

**5.6 \*Please upload clean versions of the new and/or revised assent form(s):**

**UPLOAD DOCUMENT - DOCUMENT TYPE: STUDY-WIDE ASSENT FORMS**

*If 'Debriefing material(s)' is selected in 5.2, questions 5.7 and 5.8 will appear:*

**5.7** Please upload the revised debriefing material(s) showing the changes from the currently approved version (i.e., with the changes tracked):

**UPLOAD DOCUMENT – DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS**

**5.8** \*Upload clean versions of all new and/or revised debriefing material(s):

**UPLOAD DOCUMENT – DOCUMENT TYPE: DEBRIEFING SCRIPT**

*If 'Other consent/assent material(s)' is selected in 5.2, question 5.9 and 5.10 will appear:*

**5.9** Upload the revised other consent/assent material(s) showing the changes from the currently approved version (i.e., with the changes tracked):

**UPLOAD DOCUMENT – DOCUMENT TYPE: TRACK CHANGES VERSION DOCUMENTS**

**5.10** \*Upload clean versions of all proposed other consent/assent material(s):

**UPLOAD DOCUMENT – DOCUMENT TYPE: OTHER CONSENT/ASSENT MATERIAL(S)**

*If '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', 'Permanently closed to enrolment, one or more study participant(s) receiving treatment/intervention', 'Permanently closed to enrolment, no participants are receiving treatment/intervention, and all study participants are in long term follow up or data collection continues', 'Study completed (i.e., no further involvement of study participants and no further data collection)', 'Prematurely terminated', or 'Other' is selected in question 2.1 AND 'Changes to consent forms(s), assent form(s), debriefing material(s), or other consent/assent material(s) is selected in question 2.3, question 5.11 appears:*

**5.11** \*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':*

**5.11** \*Justify: [Click here to enter text.](#)

*If 'Yes' in 5.11, questions 5.12 – 5.14 will appear:*

**5.12** \*Describe how this information will be communicated to participants who are currently enrolled in the study and receiving study treatment or intervention: [Click here to enter text.](#)

**HELP TEXT:**

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

**Q#5.12 – Please use one of the following options:**

- Recall participant immediately to provide consent update form and obtain signature. Document in health record.
- At next visit, provide consent update form. Document in health record.
- At next visit, provide consent update form and obtain signature; if NO immediate visits,
  - o Contact participant (via phone) to provide new information orally (using the approved consent update form). Document in health record, provide consent update form and obtain signature at next visit.

**5.13 \*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.](#)

**Q#5.13 – Please use one of the following options.**

- 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.

**Note: This description may also include other instructions (e.g. For participants who discontinued study treatment within the last xx days/months).**

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

Yes  No

**If 'Yes':**

**5.14.1 \*How do you plan to communicate the updated information to participants?** [Click here to enter text.](#)

**Note: if the participant is no longer being followed for study purposes, the study site staff should NOT be contacting them. Any new information provided to these past participants should be communicated by the treating physician (i.e. personnel within the patient's circle of care). For provision of summary of study results, may select this if initial Consent signed includes information about receiving this summary AFTER they have completed the study.**

**Example: The Consent Update Form will be sent by certified mail. The Consent Update will be accompanied by contact information in case the participant has any questions. This communication process will be documented in the participants health record.**

**If 'Yes' is selected in question 5.11 OR 'Consent/Assent Update Form' is selected in 5.2, questions 5.15 – 5.16 appear:**

**5.15 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: When the amendment is initially submitted, the Consent Update Form is considered a NEW document, and should NOT be tracked from the template or from a previously approved Consent Update Form. If changes are requested to the submitted Consent Update, the tracked changes copy should be uploaded to Q#19.2.**

**5.16 Researchers must ensure to update question 18.19 to reflect the current consent/assent documents being used for the study overall.**

**SECTION 6.0 – RECRUITMENT PLAN AND/OR MATERIALS**

***If 'Changes to recruitment plan and/or materials' is selected in question 2.3, the following questions appear:***

**6.1 \*Identify the revisions to the recruitment material(s) or processes as a result of this amendment (select all that apply):**

- Changes to recruitment methods (i.e., how participants will learn/find out about the study)
- Changes to method(s) of initial contact with participants
- Addition of new recruitment material(s)
- Changes to previously approved recruitment material(s)

**Q#6.1 : Recruitment materials are materials that are intended to be provided to potential participants who are NOT yet in enrolled in the study (i.e. patients who have not yet signed the Consent Form)**

**If the amendment includes Changes to previously approved recruitment material, tracked and clean copies should be included in the application.**

**Please note that OCREB does NOT allow inclusion of Sponsor name and Drug name in these materials.**

***If 'Change to recruitment methods', question 6.2-6.3 appear:***

**6.2 \*Identify the proposed changes to the recruitment methods(s) (i.e., how participants will learn/find out about the study):**

**6.3 Research teams must ensure question 18.22 has been updated as appropriate to reflect any change(s) in recruitment methods (i.e., how participants will learn/find out about the study).**

***If 'Change to methods of initial contact with participants', questions 6.4-6.5 appear:***

**6.4 \*Identify the proposed changes to proposed changes to methods of initial contact with participants:**

**6.5 Research teams must ensure question 18.23 has been updated to reflect the change(s) to methods of how initial contact will be made with participants (for the study overall).**

*If 'Changes to previously approved recruitment material' is selected in 6.1, question 6.6 appears:*

**6.6 \*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**

*If 'Changes to previously approved recruitment material(s)' or 'Addition of new recruitment material(s)' is selected in 6.1, question 6.7 appears:*

**6.7 \*Upload clean versions of the new or revised recruitment material(s) (i.e., with tracked changes accepted):**

**UPLOAD DOCUMENT - DOCUMENT TYPE: RECRUITMENT MATERIALS**

## SECTION 7.0 – PARTICIPANT MATERIALS

*If 'Changes to participant materials' is selected in question 2.3, the following questions appear:*

**7.1 \*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 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 that are not covered in the checkboxes above.**

**“Other materials” does not include:**

- Recruitment material
- Interview or focus group scripts
- Surveys, questionnaires, screen shots
- Consent/assent forms or form updates
- Diaries and wallet cards

*If 'Addition of new survey/questionnaire/interview/focus group' is selected in 7.1, 7.2-7.4 appears:*

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

**7.3 \*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**

**7.4 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 selected in question 7.1, questions 7.5-7.7 appear:*

**7.5 \*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**

**7.6 \*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**

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

**Add Another**

*If 'Addition of new other material to be provided to study participants' is selected in 7.1, question 7.8 appears:*

**7.8 \*Upload all new other material(s) to be provided to study participants:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS**

**Q#7.8 – Other materials may include instructions on how to complete ePROs or documents related to optional reimbursement methods being used in the study (e.g. Greenphire).**

*If 'Changes to previously approved other materials that will be provided to study participants' is selected in 7.1, questions 7.9 and 7.10 appear:*

**7.9 \*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**

**7.10 \*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 7.1, questions 7.11-7.12 appear:*

**7.11 \*Describe the other change(s):** [Click here to enter text.](#)

**7.12 Upload any additional information that will be provided to participants, if applicable:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS**

**SECTION 8.0 - INVESTIGATOR BROCHURE (IB)/ PRODUCT MONOGRAPH (PM)/ INSTRUCTIONS FOR USE (IFU)**

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

**8.1 \*Indicate which of the following document(s) is/are being updated (select all that apply):**

- Investigator Brochure (IB)
- Product Monograph (PM)
- Instructions for Use (IFU)

*If 'Investigator Brochure (IB)', 'Product Monograph (PM)' is selected in 8.1, question 8.2 appears:*

**8.2 \*Upload the updated version of the Investigator Brochure (IB), Product Monograph (PM), or Instructions for Use (IFU):**

**UPLOAD DOCUMENT - DOCUMENT TYPE: IB, PM, OR DEVICE IFU**

**Q#8.2 – Please note that the name of the drug or compound should be included in the document name (e.g. Pembrolizumab IB Ed.26).**

**8.3 \*Has the Lead Applicant reviewed the updated IB/PM/IFU to determine if changes are required to the protocol or study-wide ICF?**

- Yes  No

*If 'Yes':*

**8.3.1 \*Are these changes included within this amendment submission?**

- Yes  No  N/A

*If 'No' in 8.3.1:*

**8.3.1.1 \*When are the corresponding changes expected to be submitted to the REB?** Click here to enter text.

**Q#8.3.1: OCREB's preference is to have the corresponding changes to the ICF, submitted together with the IB, in the same application.**

**SECTION 9.0 – TRANSLATION OF APPROVED MATERIALS**

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

**9.1 \*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**

**Q#9.1 – Only translation from English to another language require submission;  
If Canadian English documents are being submitted, these should be used throughout the study. If US English documents are being submitted, please only use these versions throughout the study.**

**9.2 Upload all translation certificate(s) /supporting documentation for authenticity of the translation, if applicable:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: TRANSLATION CERTIFICATE**

**Q#9.2 – Translation certificates are not required and will not be accepted for validated paper questionnaires (e.g. EQ-5D-5L). Translation certificates are also not required for English US to English CA. All ePRO questionnaires (screenshots) will require a CoT.**

**SECTION 10.0 – 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:*

**10.1 \*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 10.1, question 10.2 and 10.3 appear:*

**10.2 \*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 here to enter text.

**10.3 Research teams must ensure to update question 18.2 to reflect any change(s) to the Personal Information/Personal Health Information collected on the study data collection tools.**

*If 'Change in how data is accessed, collected, used or stored' is selected in question 10.1, questions 10.4-10.5 will appear:*

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

*If 'Linking of data with any other data sets, databases or registries' is selected in question 10.1, questions 10.5-10.6 will appear:*

**10.5 \*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':*

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

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

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

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

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

**10.6 \*Will any of the study data be kept by the lead research/research group/sponsor for future use?**

Yes No

***If 'Yes':***

**10.6.1 \*Specify:** Click here to enter text.

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

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

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

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

## SECTION 11.0 – STUDY FUNDING/REMUNERATION

*If 'Changes in study funding, participant remuneration, 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:*

### 11.1 \*Select the type of change (select all that apply):

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

**If Other:**

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

*If 'Addition of new funder(s) is selected in 11.1, question 11.2 will appear:*

### 11.2 \*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':**

**11.2.1 \*Specify other funder(s):** [Click here to enter text.](#)

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

**11.2.2 \*Name(s) of Industry funder:** [Click here to enter text.](#)

**If 'Government':**

**11.2.3 \*Name(s) of government:** [Click here to enter text.](#)

**If 'Charitable Foundation':**

**11.2.4 \*Name(s) of charitable foundation(s):** [Click here to enter text.](#)

**If 'Tri-Council':**

**11.2.5 \*Name(s) of funding agency/ies:** [Click here to enter text.](#)

**If 'Internal funding':**

**11.2.6 \*Name(s) of internal funding sources:** [Click here to enter text.](#)

**If 'US Federal Funds':**

**11.2.7 \*Name(s) of US federal funder(s):** [Click here to enter text.](#)

*If 'Change in current funder(s)' is selected in 11.1, questions 11.3 will appear:*

**11.3 \*Describe all changes in study funder(s):** [Click here to enter text.](#)

*If 'Change to participant remuneration' is selected in 11.1, questions 11.4 will appear:*

**11.4 \*Describe all changes in participant remuneration:** [Click here to enter text.](#)

**HELP TEXT:**

For additional information about participant expense reimbursement see the [Participant Experience Toolkit](#).

**Q#11.4 – Changes in participant remuneration can include changes to the amount (if this has been disclosed in the CTIA) or changes to what expenses will be reimbursed (e.g. transportation, accommodations/hotels stay, meals etc.**

*If 'Change in provision of or access to agent(s)/devices used in the study' is selected in 11.1, questions 11.5 will appear:*

**11.5 \*Describe all changes in provision/access:** [Click here to enter text.](#)

*If 'Change in financial incentive(s)/pressure(s)' is selected in 11.1, question 11.6 will appear:*

**11.6 \*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':*

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

*If 'No':*

**11.6.2 \*Describe the changes in financial incentive(s)/pressure(s):** [Click here to enter text.](#)

## SECTION 12.0 - COMMUNICATION OF RESULTS

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

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

- Stakeholders
- Participants

**12.2 \*Describe the change/update relating to the communication of results:** [Click here to enter text.](#)

*If 'Participants' is selected in 12.1, questions 12.3-12.4 will appear:*

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

- Debriefing script
- Group debriefing
- End of study letter
- Publication
- Lay language results summary
- Thank you letter
- Other

**HELP TEXT:**

**For additional information about communicating results and thanking participants see the [Participant Experience Toolkit](#).**

**12.4 If the amendment includes change(s) to previously submitted document(s), 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, 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 12.4, question 12.5 will appear:*

**12.5 \*Upload clean version(s) of the debriefing script:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: DEBRIEFING SCRIPT**

*If 'Group debriefing' is selected in 12.4, question 12.6 will appear:*

**12.6 \*Upload clean version(s) of the group debriefing:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: GROUP DEBRIEFING**

*If 'End of study letter' is selected in 12.4, question 12.7 will appear:*

**12.7 \*Upload clean version(s) of the end of study letter:**

**UPLOAD DOCUMENT - DOCUMENT TYPE: END OF STUDY LETTER**

**SECTION 13.0 - US REGULATORY INFORMATION**

***If 'Change in US regulatory information' is selected in question 2.3, question 13.1 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 Research teams must ensure they have updated question 18.3 to reflect any change(s) in the status of the US FDA application.**

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

**13.3 Research teams must ensure they have updated question 18.4 to reflect any change(s) to support from the United States Federal Government.**

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

**13.4 \*Describe the other type of change relating to US regulatory information:** [Click here to enter text.](#)

## SECTION 14.0 – GENERAL STUDY INFORMATION / STUDY TEAM DETAILS

*If 'Change to CONTACT DETAILS ONLY of the Lead Applicant' AND/OR 'Change to the name or contact details for Lead Administrative Contact, Sponsor Contact, or CRO' is selected in question 2.3, question 14.1 appears:*

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

- Contact details for the Lead Applicant
- Name and/or contact details for the Lead Administrative Contact, Sponsor, or CRO

*If 'Name and/or contact details for the Lead Administrative Contact, Sponsor contact or CRO':*

**14.1.1 \*Specify details:** [Click here to enter text.](#)

*If 'Change to current Lead Applicant' or 'Change to study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID)' is selected in question 2.3, question 14.2 appears:*

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

- Change in Lead Applicant
- Study title
- Study acronym/nickname/short title
- Study ID/Number

*If 'Change to study information (i.e., study title, study acronym/nickname/short name, sponsor's study ID)', 'Change to current Lead Applicant', 'Change to CONTACT DETAILS ONLY for the Lead Applicant, or 'Change to the name or contact details for Lead Administrative contact, Sponsor Contact, or CRO' is selected in question 2.3, questions 14.3-14.4 will appear:*

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

- Yes
- No

*If 'Yes' to question 14.3, questions 14.3.1-14.3.3 will appear:*

**14.3.1 Research teams must ensure question 2.3 correctly indicates which study document are being revised.**

**14.3.2 Research teams must ensure they have uploaded the revised study document(s) into the appropriate section(s) of this form.**

**14.3.3 Research teams must ensure they have updated the corresponding information in SECTION 1.0 – GENERAL INFORMATION.**

**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 questions appear:*

**15.1** \*If another REB has refused to approve this study, , 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 – INFORMED CONSENT/ASSENT/DEBRIEFING PROCESS

*If 'Change to informed consent/assent/debriefing process is selected in 2.3, questions 16.1 – 16.2 appear:*

**16.1** \*Describe the proposed change(s) to the informed consent/assent/debriefing process: [Click here to enter text.](#)

**16.2** *Important: Review questions in SECTION 18 (18.5-18.8) showing the current REB approved Informed Consent/Assent or Debriefing Process, and update as necessary based on the description provided in 16.1 above.*

## SECTION 17.0 - OTHER

*If 'Other' is selected in question 2.3, the following questions appear:*

**17.1 \*Describe the 'other' changes made with this amendment:** [Click here to enter text.](#)

**Q#17.1 – When “Other” is selected in section 2.3, it is typically for administrative corrections. These applications are Acknowledged by the RECs (e.g. minor corrections to previously approved documents which could include correction to the footer/version date/pagination of the document).**

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

**17.3 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 Clinical Trial 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.*

### **STUDY LAY SUMMARY:**

**Question 18.1 below should only be updated if the protocol changes have been fully described in SECTION 3.0. If the questions in SECTION 3 are not addressed, any changes made to this question in this amendment will NOT have REB approval.**

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

### **PI/PHI COLLECTED FOR STUDY:**

*Question 18.2 below 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 10.0. If the questions in SECTION 10 are not addressed, any changes made to this question in this amendment will NOT have REB approval.*

- 18.2 \*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 (e.g. first/last only)
- Full date of birth
- Partial date of birth (e.g., year/month only)
- Full date of death
- Partial date of death (e.g., year/month only)
- Age
- Sex
- Gender identity
- Full postal code
- First 3 digits of postal code
- Pathology specimen number
- Medical device identifier

- Admission date
- Discharge date
- Medical record number
- Health card number
- Driver's license number
- Address
- Telephone number
- Fax number
- E-Mail address
- Identifiable photograph (e.g., full face photos, or other photos containing identifiable information)
- Voice/audio recording
- Video recording
- Social Insurance Number (SIN) number
- Device identifier
- Internet Protocol address (IP address)
- Race and/or ethnicity
- Family/caregiver names and/or contact information
- Other

☞ **If 'Other': 18.2.1 \*Specify other information:**

☞ **If 'Other': 18.2.2 \*Justify other information:**

☞ **If 'Full name': 18.2.3 \*Justify full name:**

☞ **If 'Full initials': 18.2.4 \*Justify full initials:**

☞ **If 'Partial initials': 18.2.5 \*Justify partial initials:**

☞ **If 'Full date of birth': 18.2.6 \*Justify full date of birth:**

☞ **If 'Partial date of birth': 18.2.7 \*Justify partial date of birth:**

☞ **If 'Full date of death': 18.2.8 \*Justify full date of death:**

☞ **If 'Partial date of death': 18.2.9 \*Justify partial date of death:**

☞ **If 'Age': 18.2.10 \*Justify age:**

☞ **If 'Sex': 18.2.11 \*Justify sex:**

☞ **If 'Gender identity': 18.2.12 \*Justify gender identity:**

☞ **If 'Full postal code': 18.2.13 \*Justify full postal code:**

☞ **If 'First 3 digits of postal code': 18.2.14 \*Justify first 3 digits of postal code:**

☞ **If 'Pathology specimen number': 18.2.15 \*Justify pathology specimen number:**

☞ **If 'Medical device identifier': 18.2.16 \*Justify medical device identifier:**

☞ **If 'Admission date': 18.2.17 \*Justify admission date:**

☞ **If 'Discharge date': 18.2.18 \*Justify discharge date:**

☞ **If 'Medical record number': 18.2.19 \*Justify medical record number:**

☞ **If 'health card number': 18.2.20 \*Justify Health card number:**

☞ **If 'Driver's license number': 18.2.21 \*Justify driver's license number:**

- ◀▶ If 'Address': 18.2.22 \*Justify address:
- ◀▶ If 'Telephone number': 18.2.23 \*Justify telephone number:
- ◀▶ If 'Fax number': 18.2.24 \*Justify fax number:
- ◀▶ If 'E-Mail address': 18.2.25 \*Justify E-mail address:
- ◀▶ If 'Full face photograph':  
18.2.26 \*Justify Identifiable photographs::
- ◀▶ If 'Voice/audio recording': 18.2.27 \*Justify voice/audio recording:
- ◀▶ If 'SIN number': 18.2.28 \*Justify SIN number:
- ◀▶ If 'Device Identifier': 18.2.29 \*Justify device identifier: Click here to enter text.
- ◀▶ If 'Internet Protocol address (IP address)': 18.2.30 \*Justify internet protocol address (IP address):
- ◀▶ If 'Race and/or ethnicity': 18.2.31 \*Justify race and/or ethnicity: Click here to enter text.
- ◀▶ If 'Family/caregiver names and/or contact information':  
18.2.32 \*Justify family/caregiver names and/or contact information: Click here to enter text.
- ◀▶ If 'Video recording': 18.2.33 \*Justify video recording: Click here to enter text.

**US GOVERNMENT REGULATIONS:**

*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 the question(s) in SECTION 13 are not addressed, any changes made to these questions in this amendment will NOT have REB approval.*

- ◀▶ 18.3 \*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
- ◀▶ 18.4 \*Is this research supported by the United States federal government?  
 Yes  No

**INFORMED CONSENT/ASSENT/DEBRIEFING PROCESS:**

*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 these questions in this amendment will NOT have REB approval.*

- ◀▶ 18.5 \*Will informed consent be obtained from potential participants (select all that apply)?
  - Informed consent will be obtained from some or all participants/substitute decision makers (SDMs)
  - Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)  
**Note: The use of remote consent, use of a substitute decision maker (SDM) or different methods of documenting informed consent (e.g., written, verbal, implied) are NOT considered alterations**
  - Informed consent will not be obtained from some or all participants/authorized third party (a waiver of the requirement to obtain informed consent is being requested for some/all participants)

- This study involves incapacitated patients experiencing a medical emergency and we are seeking authorization to proceed with the research intervention without the prior consent of participants/SDM (if this is your entire study population, select only this option – you do not need to separately select the ‘alteration’ and ‘waiver’ options above)

*If ‘Informed consent will not be obtained from some or all participants/substitute decision makers (SDMs) (a waiver of the requirement to obtain informed consent is being requested for some/all participants)’ is selected in 18.5, then question 18.6 will appear:*

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

- All participants/substitute decision makers (SDMs)  
 Some participants/SDMs

*If ‘Some participants’:*

**18.6.1 \*Describe the circumstances/participant population for whom you are seeking a waiver:**

*If ‘All Participants’ or ‘Some participants’ selected in 18.6, questions 18.7 and 18.8 appear:*

**18.7 \*Explain why the waiver of consent is unlikely to have an adverse effect:** Click here to enter text.

**18.8 \*Why/how it is impossible or impracticable to seek informed consent?** Click here to enter text.

*If ‘Informed consent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)’ is selected in 18.5, questions 18.9 – 18.11 appear:*

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

**18.10 \*Explain why the alteration is unlikely to have an adverse effect:** Click here to enter text.

**18.11 \*Why/how is it impossible or impracticable to conduct the research without the alteration?** Click here to enter text.

*If ‘Informed consent/assent will be obtained but there is a proposed alteration in the consent procedures (e.g., deferred consent, partial disclosure, deception)’ OR ‘Informed consent/assent will not be obtained from some or all participants/substitute decision makers...’ is selected in 18.5, question 18.12 appears:*

**18.12 \*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’:*

**18.12.1 \*Describe the debriefing plan:** Click here to enter text.

*If ‘No’:*

**18.12.2 \*Justify why participants will not be debriefed:** Click here to enter text.

*If ‘Informed consent will be obtained from some or all participants/substitute decision maker (SDM)’ or ‘Informed consent will be obtained but there is a proposed alteration...’ was selected in question 18.4 or ‘Some participants’ was selected in question 18.5, questions 18.12-18.13 appear:*

18.13 \*How will the informed consent discussion be held? (Select all that apply): {CTIA 5.9}

- In person
- Remote
- No discussion proposed

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

18.14 \*Indicate how informed consent from participants/substitute decision makers (SDMs) will be documented (select all that apply):

- Written
- Verbally
- Implied consent
- Other

*If 'Other':*

18.14.1 \*Describe the proposed documentation process: Click here to enter text.

*If 'Written':*

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

- Yes  No

*If 'This study involves incapacitated patients experiencing a medical emergency...' selected in question 18.4, questions 18.15 – 18.18 appear:*

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

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

- In person
- Remote
- No discussion proposed

*If 'No discussion proposed':*

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

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

How will informed consent from substitute decision makers (SDMs) be documented? (select all that apply):

- Written
- Verbally
- Other

*If 'Other':*

18.16.1 \*Describe the proposed documentation process: Click here to enter text.

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

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

- In person
- Remote
- No discussion proposed

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

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

How will this informed consent be documented? (Select all that apply):

- Written
- Verbally
- Other

**If 'Other':**

- 18.18.1 \*Describe the proposed documentation process: [Click here to enter text.](#)

#### **CONSENT/ASSENT FORM(S) OR DEBRIEFING MATERIALS:**

**Question 18.19 below indicates which documents are being used for the study. Any changes made must be fully described in SECTION 5.0. If the questions in SECTION 5 are not addressed, any changes made to this question in this amendment will NOT have REB approval.**

- 18.19 \*Which of the following will be used? (Select all that apply):

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

#### **STUDY SAMPLE SIZE:**

**Question 18.20 below reflects the current REB approved sample size for the study overall. Any changes made must be fully described in SECTION 3.0. If the questions in SECTION 3 are not addressed, any changes made to this question in this amendment will NOT have REB approval.**

- 18.20 \*How many participants will be enrolled in the overall study (i.e., what is the sample size)? [Click here to enter text.](#)

#### **PARTICIPANT RECRUITMENT:**

**Question 18.21 describes the study-wide recruitment materials/methods that currently have REB approval to be used for this study. If making changes to this information with this amendment research teams must**

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**SECTION 6.0. If the questions in SECTION 6 are not addressed, any changes made to this question in this amendment will NOT have REB approval.**

**18.22 \*How will potential participants learn/find out about the study? (Select all that apply):**

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

**If 'Other':**

**18.22.1 \*Specify other:** Click here to enter text.

**Question 18.23 is showing methods of initial contact with participants that currently have REB approval. Study teams making changes to this information ensure they have completed SECTION 6. If the questions in SECTION 6 are not addressed, any changes to this question in this amendment will NOT have REB approval.**

**18.23 \*How will participants initially be contacted by the research team? (select all that apply)?**

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

**If 'Other':**

**18.23.1 \*Describe the other methods of contact:**

**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:*

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

**19.1 Upload Lead Applicant Response to REB request for modification letter (if applicable):**

**UPLOAD DOCUMENT - DOCUMENT TYPE: RESPONSE TO REB LETTER**

**Q#19.1 – If the amendment was reviewed at a Full Board meeting, a PI Response Letter is required upon resubmission of the application. All OCREB requirements and questions should be clearly addressed in the PI response letter. The Response Letter may be signed by the PI or Delegated staff . If multiple review letters are issued, ALL PI response letters must be retained here (i.e. DO NOT remove previously uploaded letters).**

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

**UPLOAD DOCUMENT - DOCUMENT TYPE: OTHER MATERIALS**

**Q#19.2: Please upload TRACKED Protocol document here , if protocol changes were requested as part of the REB review.**

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

**Q#19.3 - Please use this Section to provide information about any additional changes made or to confirm that all requested application changes in the review letter have been made.**

## SECTION 20.0 – AGREEMENT & APPROVAL

**If 'No' to question 1.0 AND Any checkbox besides 'Change(s) to contact details for the Lead Applicant; and/or the name/contact details for the Lead Administrative Contact, Sponsor Contact, or CRO Contact' is selected in question 2.3; the Lead Applicant signature appears:**

### 20.1 Lead 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 Lead 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 Lead Applicant:

- I attest that this application is and all subsequent trial-related 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 in accordance with all applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice; and provincial privacy laws
- I acknowledge that I am responsible for promptly reporting to the REB, through the Clinical Trials Ontario Streamlined Research Ethics Review System, all trial wide:
  - 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, 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 Clinical Trial Initial Application is approved, I am aware that if I also am a site PI on this trial, I must submit, through the Clinical Trials Ontario Streamlined Research Ethics Review System, a Participating Site Initial Application Form for approval to conduct the trial at my site;
- I am aware that the REB review materials (e.g., study-wide forms including attachments, review letters, other correspondence, approval letters, etc.) will be shared with all sites participating in this trial through the Clinical Trials Ontario Streamlined Research Ethics Review System;
- I am aware that the following trial information will be made available to all sites participating in this trial: Project I.D. #, Sponsor Name, Sponsor Protocol I.D. #, Trial Title, REB review status, name of Lead Applicant, and the names of the participating sites and PIs.

**SIGNATURE TYPE: LEAD APPLICANT**

**Q#20.1 : Application for change in PI should be signed by the NEW or INCOMING PI .**

*If 'No' to question 1.0 AND/OR 'Change(s) to contact details for the Lead Applicant; and/or the name/contact details for the Lead Administrative Contact, Sponsor Contact, or CRO Contact' is exclusively selected in question 2.3; the Lead Applicant or Delegate signature appears:*

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

**SIGNATURE TYPE: LA OR DELEGATE**

**Q#20.2: PI Delegate or Study Staff can sign Resubmissions**