CTO REB Centre 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)

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.

Study Information: The questions below reflect the information most recently provided to the REB as part of a Provincial submission.

1.1 ***Please complete the Provincial Applicant (PA) details:**
*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

NOTE. You may notice discrepancies in this section when compared to earlier approved submissions. This is because 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.

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

If 'Yes': ***Please complete the Provincial Co-Applicant details:**
*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

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:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.4 ***Please complete the Main Sponsor Contact details:**

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
*Email:

1.5 ***Are the Main CRO Contact details available?**

Yes No No CRO

***If 'Yes':* *Please enter the Main CRO Contact details:**

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.6 ***Complete Study Title: (Enter exactly as written in protocol)**

1.7 **Please enter the Sponsor's Study ID/Number:**

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.)**

Centre Information: 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 below to reflect the changes being made with this amendment.

1.9 ***Please complete the Centre Principal Investigator (PI) details:**

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

NOTE. Changes to any contact details in this section take effect in all new or open centre applications as soon as the change is made in a CAM in Pre Submission. This includes a change to the PI without the PI accepting the role, or the DA or IR authorizing the new Centre PI, or REB approval of the incoming PI.

Please complete and submit a CAM involving a change in PI as quickly as possible.

1.10 ***Is there a Centre Co-Investigator (Co-I)?**

☐Yes ☐No

If 'Yes': ***Enter the contact details of the Centre Co-Investigator:**

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

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

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

1.11 ***Please complete the Centre 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.

1.12 *Please complete the Primary Institutional Representative details:

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

1.13 Please complete the Secondary Institutional Representative details:

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

SECTION 2.0 - AMENDMENT DETAILS

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

☐Centre-specific changes to the consent/assent form(s) used at this centre (not related to/associated with a provincial amendment)
☐Changes in the informed consent/assent process at this centre
☐Centre-specific translation of approved material(s)
☐Changes in recruitment methods and/or recruitment material(s) (e.g., telephone, web or email scripts, flyers, brochures, etc.) used at this centre
☐Changes to other centre-specific material(s) that will be given to study participants (including surveys/questionnaires/scripts, diaries and wallet cards)
☐Changes to how personal information or personal health information is being accessed, collected, used, stored or transferred at this centre
☐Changes in the conflict of interest information previously provided to the REB for any of the investigators, study staff or members of their immediate families
☐Changes in participant reimbursement and/or communication of study results
☐Changes in centre-specific study conduct (including location of visits/procedures, standard of care, and protocol implementation)
☐Change in name/contact information (Principal Investigator/Co-Investigator/centre main study contact)
☐Other changes

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

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

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

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

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

☐Consent Form(s)

☐Assent Form(s)

If 'Consent Form(s) is selected in question 3.2, Q3.3-3.4 appear:

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

Upload Document

3.4 ***Please upload the "clean" version(s) of the revised consent form(s) (i.e., with the changes accepted):**

Upload Document

If 'Assent Form(s) is selected in question 3.2, Q3.5-3.6 appear:

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

Upload Document

3.6 ***Please upload the "clean" version(s) of the revised assent form(s) (i.e., with the changes accepted):**

Upload Document

SECTION 4.0 – CHANGES IN THE INFORMED CONSENT/ASSENT PROCESS AT THIS CENTRE

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

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

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

SECTION 5.0 – CENTRE-SPECIFIC TRANSLATION OF APPROVED MATERIALS

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

5.1 ***Please upload all centre-specific translated material(s):**
Upload Document

5.2 **Please upload all corresponding translation certification(s) (if applicable):**
Upload Document

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

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

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

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

☐Change(s) in recruitment methods at this centre

☐Change(s) in centre-specific recruitment material(s)

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

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

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

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

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

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

☐Changes to previously approved centre-specific recruitment materials

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

6.5 *Upload any new centre-specific recruitment material(s):

Upload Document

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

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

6.7 *Please upload the revised centre-specific recruitment material(s) showing the changes from the currently approved version (i.e., with the changes tracked):

Upload Document

6.8 *Please upload the "clean" version(s) of the revised centre-specific recruitment material(s) (i.e., with the changes accepted):

Upload Document

SECTION 7.0 - Changes TO CENTRE-SPECIFIC PARTICIPANT MATERIALS

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

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

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

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

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

7.2 ***Please upload the new other centre-specific material(s) that will be given to study participants:**

Upload Document

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

Add Another

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

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

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

Upload Document

7.6 ***Please upload the "clean" version(s) of the revised other centre-specific material(s) that will be given to study participants (i.e., with the changes accepted):**

Upload Document

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

Add Another

SECTION 8.0 - CHANGES TO HOW PERSONAL INFORMATION OR PERSONAL HEALTH INFORMATION IS BEING ACCESSED, COLLECTED, USED, STORED OR TRANSFERRED AT THIS CENTRE

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

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

☐Change in the Personal Information (PI) or Personal Health Information (PHI) that this centre is authorized to disclose on the data collection tools leaving the institution

☐Change in the Personal Information (PI) or Personal Health Information (PHI) that is collected and retained locally for the purposes of the study (e.g., recruitment tools, recruitment or screening logs)

☐Change in how data is accessed, collected, used, stored or transferred at this centre

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

If 'Change in the Personal Information or Personal Health Information that this centre is authorized to disclose on the data collection tools leaving the institution' is selected in question 8.1:

***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).**

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

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

Q8.2: this question appears in all amendments regardless of what is selected in 2.1 (**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 Q2.1. OCREB will not review Q8.2 unless "*Changes to how personal information or personal health information is being accessed, collected, used, stored or transferred at this centre*" is selected in 2.1.

This question is shared with the CIA and displays the identifiers selected in the approved CIA. Unless you have a centre-specific, OCREB pre-approved change to support restrictions to the disclosure of the identifiers approved in the PIA, do not make any changes to this section.

☐Voice/Audio Recording
☐Other
***If 'Other':* *Specify:** Click here to enter text.

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

8.3 *What PI or PHI do you need to collect and retain locally for the purposes of this study (e.g., recruitment tools, recruitment or screening logs)?

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

Q8.3: for some reason this question appears in all amendments even when "*Changes to how personal information or personal health information is being accessed, collected, used, stored or transferred at this centre*" is not selected in question 2.1 (**Type of Amendment**). This refers to the identifiable participant information that is retained onsite to manage the study and study participants. This does not refer to any identifiers sent outside the institution. OCREB does not review this section thus any changes to not need to be submitted. Study personnel are expected to comply with institutional privacy policies with respect to collecting and retaining identifiers in the study files.

***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 '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 'Address':*** ***Justify address:** 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 'Telephone Number':*** ***Justify telephone number:** Click here to enter text.
- ***If 'Email Address':*** ***Justify Email address:** Click here to enter text.
- ***If 'Fax Number':*** ***Justify fax number:** Click here to enter text.
- ***If 'Ontario Health Card Number':*** ***Justify Ontario health card number:** Click here to enter text.
- ***If 'Medical Record Number':*** ***Justify medical record number:** 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 'Date of Death':*** ***Justify date of death:** 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 'Driver's License Number':*** ***Justify driver's license number:** Click here to enter text.
- ***If 'Voice/audio recording':*** ***Justify voice/audio recording:** Click here to enter text.
- ***If 'Full face photograph':*** ***Justify full face photograph:** Click here to enter text.

If 'change in how data is accessed, collected, used, stored or transferred' is selected in question 8.1, question 8.4-8.5 will appear:

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

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

If 'Linking of data with any other data sets, databases or registries' is selected in question 8.1, question 8.6-8.11 will appear:

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

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

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

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

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

8.11 ***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 9.0 - CHANGES IN THE CONFLICT OF INTEREST INFORMATION PREVIOUSLY PROVIDED TO THE REB FOR ANY OF THE INVESTIGATORS, STUDY STAFF OR MEMBERS OF THEIR IMMEDIATE FAMILIES

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

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

☐Personal financial benefit in connection with this study

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

☐Community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research

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

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

☐Association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, board member, employee, director, etc.)

☐Other real, potential or perceived conflict of interest

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

9.2 *Will the investigator or sub-investigators or anyone connected to them though their interpersonal relationship (including their partners, family members, or their former or current professional associates) receive any personal financial benefit in connection with this study?

☐Yes ☐No

***If 'Yes':* *State how much money (in Canadian dollars) is paid by the funder and to whom it is being paid, over and above the direct cost of conducting this study (e.g., recruitment incentives consulting fees, advisor fees):** Click here to enter text.

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

***In the last three years, how much money (in Canadian dollars) or other benefits has the investigator or sub investigator or anyone connected to them through their interpersonal relationship including their family members, friends, or their former or current professional associates (or any company owned or managed by the investigator or sub investigator or anyone connected to them through their interpersonal relationships) received from the sponsor and/or funder?** Click here to enter text.

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

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

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

9.3 *Will the investigator or sub-investigators or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current

professional associates) receive any personal [financial or otherwise] benefits including patent or intellectual property rights, royalty income, employment, share ownership, stock options, etc?

☐Yes ☐No

If 'Yes': ***Please describe the benefits:** Click here to enter text.

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

If 'Community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research' is selected in 9.1, question 9.4 appears:

9.4 ***Is the investigator or sub-investigator aware of any other community relationships, academic interests, financial partnerships, or economic interests (e.g., spin-off companies in which researchers have stakes or private contract research outside of the academic realm) or any other incentives that may compromise their integrity, independence or ethical duties in the conduct of the research?**

☐Yes ☐No

If 'Yes': ***Describe the relationships, interests or incentives:** Click here to enter text.

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

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

9.5 ***Is the investigator or sub-investigator(s) aware of any institutional conflicts of interest (financial or non-financial) that may have an impact on the research?**

☐Yes ☐No

If 'Yes': ***Describe the institutional conflicts of interest:** Click here to enter text.

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

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

9.6 ***Does the Investigator or sub-investigator or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any proprietary interest in the product under study or in any entity that is sponsoring or otherwise supporting the conduct of the study?**

☐Yes ☐No

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

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

If 'Association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study? (e.g., consultant, advisor, Board member, employee, director, etc.)' is selected in 9.1, question 9.7 appears:

9.7 ***Will or does the Investigator or sub-investigator or anyone connected to them through their interpersonal relationships (including their family members, friends, or their former or current professional associates) have any association or connection with an entity that is sponsoring or otherwise interested in the outcome of the study (e.g., consultant, advisor, board member, employee, director, etc.)?**

☐Yes ☐No

If 'Yes': ***Describe the association or connection:** Click here to enter text.

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

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

☐Yes ☐No

If 'yes': ***Specify:** Click here to enter text.

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

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

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

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

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

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

☐Participant reimbursement
☐Communication of study results to participants

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

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

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

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

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

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

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

☐Individual debriefing at end of test session
☐Group debriefing
☐End of study letter
☐Publication
☐Other

If 'Individual debriefing at end of test session, Group Debriefing and/or End of study letter' is selected in 10.6, 10.7 appear:

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

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

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

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

10.9 Please upload the "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 10.6, 10.10 appear:

10.10 Please upload the "clean" version(s) of the end of study letter (i.e., with the changes accepted, if applicable):

Upload Document

SECTION 11.0 - CHANGES IN CENTRE-SPECIFIC STUDY CONDUCT

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

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

Q11.1: include the addition or changes to satellite sites for pediatric studies; or the addition or change in location of any study visits or procedures/tests that will be done outside of the institution.

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

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

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

☐Variation in protocol implementation at this centre (e.g., compared to that described in provincial applications)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 12 - CHANGE IN NAME/CONTACT INFORMATION (PRINCIPAL INVESTIGATOR/CO-INVESTIGATOR/CENTRE MAIN STUDY CONTACT)

If 'Change in contact information' is selected in question 2.1, the following section appears:

12.1 *The updated contact information pertains to the following individual(s) (select all that apply):

- ☐Principal Investigator (PI)
- ☐Co-Investigator (Co-I)
- ☐Centre Main Study Contact

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

SECTION 13 – OTHER CHANGES

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

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

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

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

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

SECTION 14 – 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.

14.1 Upload Principal Investigator Response to REB request for modification letter (if applicable):
Upload Document

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

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

This page appears only when "Yes" is answered in Q1.0. If you do not have a place to upload a response letter, or comments in response to REB queries, or additional requested materials, ensure that Q1.0 is answered "Yes". Any additional information that would assist in the OCREB review of this application should be entered into 14.3.

15.1 Centre Principal Investigator Signature for CAMs not involving a change in PI

- 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 Centre Amendment, I authorize the main centre trial contact, or other delegated members of the research team, to submit any further edits to this application on my behalf.

Signatures for CAMs involving a change in PI

15.3 Principal Investigator Signature - attestation

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- I attest that I am appropriately qualified to conduct this study in accordance with my institutional requirements;
- After the initial submission of this Centre Amendment, I authorize the main centre trial contact, or other delegated members of the research team, to submit any further edits to this application on my behalf.
- As the Centre PI:
    - I assume responsibility for the scientific and ethical conduct of the study at this institution
    - I agree to conduct this study in compliance with TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND with all other applicable laws, regulations or guidelines;
    - I attest that I have sufficient space, time and resources to conduct this study;
    - I attest that all members of the research team at this site will conduct the study as approved by, and in accordance with any limitations set by, the REB of Record. No changes will be made to study conduct prior to seeking approval from the REB of Record unless required to eliminate an immediate safety hazard to participants;
    - I attest that the Co-Investigator listed in this application (if applicable) is appropriately qualified to assume my responsibilities in the event that I am unable to do so;
    - I certify that all Co-investigators, researchers and other personnel (research team) involved in this study at this institution are appropriately qualified and experienced, or will undergo appropriate training to fulfill their role in this project;
- I acknowledge that I am responsible for promptly notifying the REB of Record through CTO Stream of applicable site-specific information, including proposed changes to the conduct of the research at this site (centre amendments), reportable events, continuing review applications and the completion or termination of this study at this site
- I attest that REB of Record approval and all external and local institutional approvals will be obtained before beginning the study at this site;
- I have reviewed the current REB-approved provincial materials (e.g., REB approved provincial application forms including attachments);
- I will ensure that all provincial changes approved by the REB of Record will be implemented at my site, when relevant.

<u>Privacy and Security Acknowledgement:</u>

- On behalf of all members of my research team, I am aware of my obligations in maintaining the importance of maintaining the confidentiality of personal health information and the privacy of individuals with respect to that information;

- I will ensure that the personal (health) information is used only as necessary, to fulfill the specific study objectives and related study questions described in the application approved by the REB of Record. This includes all conditions and restrictions imposed by the REB of Record and the institution in which the study is being conducted, governing the use, security, disclosure, return or disposal of participants' personal health information;
- I agree to take any further steps required by the REB of Record or the institution to ensure that the confidentiality and security of the personal health information is maintained in accordance with the Personal Health Information Protection Act (PHIPA), its accompanying regulations, and the Tri-Council Policy Statement.

15.5 *Department Approver/Department Head - attestation

- I attest that the new Principal Investigator is qualified and has the experience and expertise to conduct this study.

15.6 *Institutional Representative - attestation

- I attest that the new Principal Investigator is a researcher in good standing with this institution, and is appropriately qualified to act as the Principal Investigator for the conduct of this study at this institution;
- I confirm that the Principal Investigator has access to the resources necessary to conduct the study;
- I attest that the Principal Investigator has completed any mandatory research training required at this institution, if applicable;