CTO Centre Continuing Review 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)

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.

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.

The questions below reflect the information most recently provided to the REB.

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

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.)**

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

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

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

Yes No

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

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

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:**

1.11 ***Please complete the Centre Main Study Contact details:**

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

Fax:
*Email:

1.12 *Please complete the Primary Institutional Representative details:

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

1.13 Please complete the Secondary Institutional Representative details:

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

SECTION 2.0 - STUDY STATUS

2.1 *What is the current study status at your centre?

☐Not yet activated
☐Activated, but no participants enrolled to date
☐One or more study participant(s) receiving study treatment/intervention
☐Permanently closed to enrolment, one or more study participant(s) receiving treatment/intervention
☐Permanently closed to enrolment, no participants are receiving treatment/intervention, and all study participants are in long term follow up or data collection continues
☐Study completed (i.e., no further involvement of study participants and no further data collection)
☐Prematurely terminated
☐Other

If 'Other': *Specify: (Text Field)
If 'prematurely terminated': *Please provide details: Click here to enter text.

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

"Specify": the study is OPEN to enrollment

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

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

☐Yes
☐No

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

If 'Not yet activated' is selected in 2.1, question 2.3 appears:

2.3 *Explain why it has not yet been activated: Click here to enter text.

2.4 *Summarize the progress of the study to date at your centre: Click here to enter text.

SECTION 3.0 - CENTRE DETAILS

COMPLETE EACH OF THE FOLLOWING WITH REGARDS TO THE NUMBERS OF RESEARCH PARTICIPANTS AT YOUR CENTRE SINCE THE STUDY STARTED AT YOUR CENTRE:

As per the CTO form guidance text, Q3.1 refers to all those who signed the consent form, met the eligibility criteria and were randomized or registered in the study.

3.1 ***How many participants are enrolled in the study at your centre?**
Click here to enter text.

3.2 ***Are any of these enrolled participants individuals who are involved in the study but not directly receiving the treatment or intervention (for example, a caregiver(s), parent(s), or guardian(s))?**

☐Yes
☐No
If 'Yes': ***How many?** Click here to enter text.

3.3 ***How many participants agreed to take part (e.g., signed a consent/assent form) but were subsequently deemed ineligible?**
Click here to enter text.

Q3.3 refers to screen failures – i.e., those who signed a consent but were not eligible.

PLEASE PROVIDE THE FOLLOWING DETAILS FOR PARTICIPANTS ENROLLED AT YOUR CENTRE:

3.4 ***How many participants are currently receiving study intervention?** Click here to enter text.

3.5 ***How many participants are currently in the post-intervention period?** Click here to enter text.

3.6 ***How many participants have completed the study with no further planned contact for study purposes?** Click here to enter text.

3.7 ***Have any participants withdrawn consent (not including any participant(s) who withdrew prior to being enrolled in the study)?**

☐ Yes
☐ No
If 'Yes': ***How many participants have withdrawn consent?**
Click here to enter text.)
If 'Yes': ***Please provide details for each participant:** Click here to enter text.

Q3.7 Disregard information in brackets. Answer "Yes" if any participants withdrew consent after being enrolled (see definition Q3.1). This question could be read as "Did any participants withdraw consent after they were enrolled in the study?"

3.8 ***Have any participants been taken off the study prematurely (for example, by a local investigator or sponsor)?**

☐ Yes
☐ No
If 'Yes': ***How many participants have been taken off-study prematurely:** Click here to enter text.
If 'Yes': ***Please provide details for each participant:** Click here to enter text.

3.9 ***Have there been any participant complaints about the study?**

☐Yes

☐No

If 'Yes': *Please provide details of each complaint: Click here to enter text.

3.10 *In the opinion of the Principal Investigator, is there a concern or a trend in the reportable events that have occurred at this centre?

☐Yes
☐No
☐N/A

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

3.11 *Have any of the following formal inspections or audits been conducted (select all that apply)?

☐Health Canada inspection
☐FDA audit
☐Sponsor audit (not including standard monitoring visits)
☐Internal quality assurance audit
☐Other
☐None

3.11 refers to any inspections or audits since the last Continuing Review application was submitted to OCREB.

If 'Other': *Please describe: Click here to enter text.

If 'Health Canada inspection', 'FDA audit', 'sponsor audit (not including standard monitoring visits)', 'internal quality assurance audit', 'other' are selected in 4.3: *Please describe the outcome (e.g., findings, issues, concerns): Click here to enter text.

3.12 *Have all centre amendments and centre reportable events been submitted for REB review?

☐Yes
☐No

If 'No': *Please Describe: Click here to enter text.

SECTION 4.0 - RE-SUBMISSION INFORMATION

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

4.1 Upload Provincial Applicant response to REB request for modification letter (if applicable):
Upload Document

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

4.3 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 4.3.

5.1 Centre Principal Investigator Signature - attestation

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- As the Centre PI, I will continue to conduct this trial in compliance with TCPS2 (2nd edition of Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans); AND with the provisions of the Ontario Personal Health Information Protection Act and its applicable Regulations; AND with all other applicable laws, regulations or guidelines (e.g., Food and Drugs Act and applicable Regulations; International Conference on Harmonization Guidance E6: Good Clinical Practice);
- As the Centre PI, I agree to promptly report to the Research Ethics Board (REB), through the Clinical Trials Ontario Streamlined Research Ethics Review System, any centre-specific:
    - modifications or amendments, such as changes in Centre Principal Investigator, changes in Centre Co-investigator (if applicable), centre-specific required changes to the consent form, etc.;
    - local reportable events that meet the REB reporting criteria, including but not limited to local unexpected, serious adverse events (SAEs), privacy breaches, protocol deviations and any new information that may adversely affect the safety of the participants or significantly affect the conduct of the trial;
    - trial progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - trial completion or termination
- After the initial submission of this Centre Continuing Review, I authorize the main centre trial contact, or other delegated members of the research team, to submit any further edits to this application.