CTO Provincial 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)

SECTION 1.0 - GENERAL INFORMATION

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

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

The questions below reflect the information 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 specify the type of review requested:**

☐Full Board
☐Delegated
☐Not specified

SECTION 2.0 - STUDY DETAILS

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

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

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

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

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

"Specify": the study is OPEN to enrollment

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

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

☐Yes
☐No

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

If 'Not yet activated' is selected in Q2.1, 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 overall (globally): Click here to enter text.

Responses to Q2.4 and 2.5 generally require sponsor input.

2.5 *What is the total number of participants enrolled globally to date? Click here to enter text.

SECTION 3.0 - DATA AND SAFETY MONITORING

3.1 ***Has there been a safety monitoring event (e.g., DSMB/C meeting, interim analysis, or steering committee meeting) since the previous continuing review (or initial review, if this is the first continuing review application)?**

☐Yes
☐No

If 'yes' to 3.1, questions 3.2-3.4 appear:

3.2 ***Please provide the date of the last safety monitoring event (e.g., DSMB/C meeting, interim analysis, or steering committee meeting):** Click here to enter text.

3.3 ***Please describe the outcome or recommendations of the safety monitoring of the study:**
Click here to enter text.

3.4 ***Have the associated documents (e.g., DSMB/C report, sponsor correspondence), been previously submitted to the REB using a Provincial Reportable Event Form?**

☐Yes
☐No

***If 'Yes':** ***Please provide the Review Reference # of the Provincial Reportable Event Form in which the documents were previously submitted:** Click here to enter text.

***If 'No':** **Please upload any associated documents (e.g., DSMB/C report, sponsor correspondence), if applicable:**

Upload Document

Q3.4: if "No", submit a provincial reportable event with the DSMB/C report information. DSMB/C reports that are uploaded to this PCR will not be acknowledged with the PCR.

SECTION 4.0 - RESEARCH FINDINGS AND RESULTS

4.1 *Is there any new information in the literature or from other recent studies that would change the rationale or risk/benefit ratio for this study? (e.g., changes in standard of care, approval of another treatment for this indication, new information about side effects)

☐Yes
☐No
***If 'Yes':* *Please specify:** Click here to enter text.

4.2 *Have any results from this research been published, submitted for publication, or presented at a meeting or seminar?

☐ Yes
☐ No
***If 'Yes':* *Please Specify:** Click here to enter text.
***If 'Yes':* Upload any abstracts, presentations or publications (if applicable):**
Upload Document

4.3 *Have all provincial amendments and provincial reportable events been submitted for REB review?

☐ Yes
☐ No
***If 'No':* *Please describe:** Click here to enter text.

SECTION 5.0 - 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.

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

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

5.3 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 5.3.

6.1 Provincial Applicant Signature

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- As the Provincial Applicant, I will continue to promptly report to the REB, through the Clinical Trials Ontario Streamlined Research Ethics Review System, trial-wide (provincial):
    - proposed modifications or amendments, including but not limited to, changes to the protocol, to the consent form, to the participant materials, to the recruitment materials, to the provincial application, or to the Investigator Brochures or Product Monographs;
    - reportable events that meet the REB reporting criteria, including but not limited to DSMB/C reports, interim analysis reports and any new information that might adversely affect the safety of the participants or significantly affect the conduct of the trial;
    - trial progress report (renewal/ continuing review form), annually or as often as requested by the REB;
    - Trial completion or termination
- After the initial submission of this Provincial Continuing Review, I authorize the main provincial trial contact, or other delegated members of the research team, to submit any further edits to this application on my behalf.