

CTO Provincial Study Closure 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?

Yes No

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.)**

SECTION 2.0 – STUDY INFORMATION

2.1 ***Date that the study was completed or terminated:** [Click here to enter text.](#)

2.2 ***Was this study terminated prematurely?**

Yes

No

If 'Yes': *Provide the reason(s) (Select all that apply):

Recruitment issues

Safety issues

Efficacy issues

Product/health product/device approved

Other

If 'Recruitment Issues': *Please describe the recruitment issues: [Click here to enter text.](#)

If 'Safety Issues': *Please describe the safety issues: [Click here to enter text.](#)

If 'Efficacy Issues': *Please describe the efficacy issues: [Click here to enter text.](#)

If 'other': *Please describe other: [Click here to enter text.](#)

2.3 ***Summarize the progress of the study overall globally:** [Click here to enter text.](#)

2.4 **Upload any documents relevant to the study closure (e.g., sponsor correspondence, newsletter):**

[Upload Document](#)

2.5 ***How many participants were enrolled globally?** [Click here to enter text.](#)

2.6 ***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](#)

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

Yes

No

If 'No': *Please Describe: [Click here to enter text.](#)

NOTE. Study closures are acknowledged, not approved.

SECTION 3.0 - 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.

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

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

3.3 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 to provide additional requested materials, ensure that Q1.0 is answered "Yes". Any additional information that would assist in OCREB's review of this application should be entered into 3.3.

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.