

## Revision History

Version Date	Key Changes
February 28, 2018	CTO application form version 16 - original
May 1, 2019	CTO application form version 20 <ul style="list-style-type: none"><li>• Help text (in green) was added to several questions</li><li>• Questions 1.1 to 1.5: Provincial Applicant (PA), sponsor and CRO contact details were removed and questions were renumbered as a result</li><li>• Q2.8 added to ask about centre study closures.<ul style="list-style-type: none"><li>○ OCREB guidance notes added to instruct the applicant to submit a PSC only after all centres have closed.</li></ul></li><li>• Q 4.2 added to allow a delegate to sign off on resubmissions</li></ul>

## CTO Clinical Trial Provincial Study Closure Form

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

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

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

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.

**Help Text:** If this is the **FIRST TIME** this application is being submitted, please select "No". If this is a re-submission for modifications requested by the REB please select "Yes".

← **1.1** \* Please enter the complete study title:

← **1.2** Please enter the Study ID/Number if applicable:

← **1.3** \*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)

## 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': 2.2.1 \*Provide the reason(s) (Select all that apply):**

Recruitment issues

Safety issues

Efficacy issues

Product/health product/device approved

Other

**If 'Recruitment Issues': 2.2.1.1 \*Please describe the recruitment issues:** Click here to enter text.

**If 'Safety Issues': 2.2.1.2 \*Please describe the safety issues:** Click here to enter text.

**If 'Efficacy Issues': 2.2.1.3 \*Please describe the efficacy issues:** Click here to enter text.

**If 'other': 2.2.1.4 \*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 - Document Type: Sponsor Correspondence/ Newsletter**

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': 2.6.1 \*Please specify:** Click here to enter text.

**If 'Yes': 2.6.2 Upload any abstracts, presentations or publications (if applicable):**

**Upload Document - Document Type: Abstracts/Presentation/Publications**

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

Yes

No

**If 'No': 2.7.1 \*Please Describe:** Click here to enter text.

2.8 **\*Have all centre study closure forms been submitted for REB review?**

Yes

No

**If 'No': 2.8.1 \*Please describe:** Click here to enter text.

Q2.8: If "No", do NOT submit the PSC until all Centres have closed.

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.*

This page appears only when in Q1.0 is answered "Yes".

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 text box.

- 3.1 Upload Provincial Applicant Response to REB request for modification letter (if applicable):**  
**Upload Document - Document Type: Response to REB Letter**
- 3.2 Upload any additional materials requested by the REB (if applicable):**  
**Upload Document - Document Type: Tracked Changes Version Documents**
- 3.3 Please provide any additional comments for the REB to consider (if applicable):** [Click here to enter text.](#)

## SECTION 4.0 – ATTESTATIONS AND SIGNATURES

***If 1.0 = No, 4.1 appears:***

### **4.1 \*Provincial Applicant**

- I confirm that all trial-related activity in Ontario is now complete;
- I request that the REB file for this trial be officially closed;
- 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.

**Signature Type: Provincial Applicant**

***If 1.0 = Yes***

### **4.2 \* Provincial Applicant 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 Provincial Applicant, I attest that the delegation of this responsibility has been documented.

**Signature Type: PA or Delegate**