Revision History

Version Date	Key Changes
February 28, 2018	CTO application form version 16 - original
May 1, 2019	CTO application form version 20 • Help text (in green) was added to several questions • Questions 1.1 to 1.5: Provincial Applicant (PA), sponsor and CRO contact details were removed and questions were renumbered as a result • Questions 1.9 to 1.11: Centre contact details were removed and questions were renumbered as a result • Question 5.2 added to allow a delegate to sign off on resubmissions

CTO Clinical Trial Centre 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:**

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 the study was terminated or completed at this site:** Click or tap here to enter text.

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

☐Yes
☐No

If 'Yes': **2.2.1 *Provide the reason(s) (Select all that apply)*:**

☐ Funding issues at this site only
☐ Recruitment issues at this site only
☐ Safety issues at this site only
☐ Terminated by Principal Investigator at this site
☐ Terminated by study sponsor/lead group
☐ Other

If 'Funding Issues at this site only': **2.2.1.1 *Please describe the funding issues:** Click or tap here to enter text.

If 'Recruitment Issues at this site only': **2.2.1.2 *Please describe the recruitment issues:** Click or tap here to enter text.

If 'Safety Issues at this site only': **2.2.1.3 *Please describe the safety issues:** Click or tap here to enter text.

If 'Terminated by Principal Investigator at this site: **2.2.1.4 *Please explain why the study was terminated by the Principal Investigator:** Click or tap here to enter text.

If 'Terminated by study sponsor/lead group': **2.2.1.5 *Please explain why the study was terminated by the study sponsor:** Click or tap here to enter text.

If 'other': **2.2.1.6 *Please describe:** Click or tap here to enter text.

2.3 ***Have all of the study closeout procedures been completed at your site?**

☐Yes
☐No
☐N/A

SECTION 3.0 – PARTICIPANT INFORMATION

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

3.2 ***Were any of these enrolled participants individuals who were 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': **3.2.1 *How many?** Click here to enter text.

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

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 ineligible.

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

☐ Yes
☐ No

If 'Yes': **3.4.1 *How many participants withdrew consent?** Click here to enter text.

If 'Yes': **3.4.2 *Please provide details for each participant:** Click here to enter text.

Q3.4 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?" – i.e., signed the consent, met the eligibility criteria and were randomized or registered in the study

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

☐ Yes
☐ No

If 'Yes': **3.5.1 *How many participants were taken off-study prematurely?** Click here to enter text.

If 'Yes': **3.5.2 *Please provide details for each participant:** Click here to enter text.

3.6 ***Were there any participant complaints about the study at this site?**

☐Yes
☐No

If 'Yes': **3.6.1 *Please provide details of each complaint:** Click here to enter text.

3.7 ***Have reports of all formal inspections or audits been submitted for REB review?**

☐Yes
☐No

If 'No': **3.7.1 *Please describe:** Click here to enter text.

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

☐Yes

☐No

If 'No': **3.8.1 *Please describe:** Click here to enter text.

3.9 *Have or will the study participants at this site be provided with the research results?

☐Yes

☐No

If 'Yes': **3.9.1 *Please describe how the results have been or will be provided:** Click here to enter text.

If 'No': **3.9.2 *Please justify why they will not be disseminated:** Click here to enter text.

NOTE. Centre closures are acknowledged, not approved.

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.

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 4.3.

4.1 **Upload Principal Investigator Response to REB request for modification letter (if applicable)**:
Upload Document - Document Type: Response to REB letter

4.2 **Upload any additional materials requested by the REB (if applicable):**
Upload Document - Document Type: Other Materials

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

SECTION 5.0 – ATTESTATIONS AND SIGNATURES

If 1.0 = No, 5.1 will appear:

5.1 * Principal Investigator

- I confirm that there is no further participation at this centre, all data collection, clarification and transfer is complete (including access to the participants' medical record), and that the final sponsor closeout procedures (if applicable) have taken place;
- I certify that trial data will be retained according to applicable guidelines and regulations;
- I request that the REB file for this centre 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: Principal Investigator

If 1.0 = Yes, 5.2 will appear:

5.2 * Principal Investigator or 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 Principal Investigator, I attest that the delegation of this responsibility has been documented.

Signature Type: PI or Delegate