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 • Question 1.5 was added to include the year of the renewal • Questions 1.9 to 1.11: Centre contact details were removed and questions were renumbered as a result • Question 2.5 was added to include information about a lapse in approval • Question 5.2 added to allow a delegate to sign off on resubmissions

CTO Clinical Trial Centre Continuing Review 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".

1.2 ***Complete Study Title: (Enter exactly as written in protocol)**

1.3 **Please enter the Sponsor's Study ID/Number:**

1.4 ***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.)**

1.5 ***Please provide a label for this continuing review (e.g., the year of renewal) that will appear in the project tree to help distinguish between continuing review applications:** Click here to enter text.

HELP TEXT: The information entered into this field will appear in the project tree and is used to easily distinguish between continuing reviews. This information will not appear in the REB approval letter.

SECTION 2.0 - STUDY STATUS

2.1 *What is the current study status at this site?

☐Not yet activated
☐Activated, but no participants enrolled to date
☐Activated/open to enrollment, participants have been enrolled but none are currently receiving study treatment/intervention
☐Activated/open to enrollment with 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':* 2.1.1 *Specify:** Click here to enter text.

***If 'prematurely terminated':* 2.1.2 *Please provide details:** Click here to enter text.

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':* 2.2.1 *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 this site: Click here to enter text.

Help Text: Progress of the study refers to a report on how the study is progressing overall since the time of the last progress report (continuing review application) submitted to the REB. The REB requires the submission of regular study progress reports, at a minimum of annually.

Q2.4: Include details to describe the study progress, for example: screening/recruitment is ongoing or the enrollment target has been met; number of participants who have consented and are not yet randomized/or on treatment; any recruitment issues.

2.5 *Has the Centre ethics approval lapsed?

☐Yes
☐No

If 'Yes':

2.5.1 *Was there a need to continue research activity or treatment of current research participants for their safety and well-being?

☐Yes
☐No

***If 'Yes'*:**

2.5.2 *Provide the reason for the lapse and describe all actions taken to prevent a lapse from occurring in the future: Click here to enter text.

SECTION 3.0 - SITE DETAILS

THE FOLLOWING QUESTIONS RELATE TO THE OVERALL CONDUCT OF THE STUDY TO DATE:

3.1 ***How many participants are enrolled in the study at this site to date?** Click here to enter text.

Help Text: Enrolled refers to a participant who signed a consent form, completed all study-specific eligibility procedures, qualified to enter the study and was registered or randomized into the study.

THE FOLLOWING QUESTIONS RELATE TO THE CURRENT CONDUCT OF THE STUDY:

3.2 ***How many participants have agreed to take part in this study during this review period (i.e., new participants enrolled since last continuing review)?** Click here to enter text.

Include only those who were enrolled i.e. signed consent and randomized or received intervention (do not include screen failures)

3.3 ***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': **3.3.1 *How many?**

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

Q3.4 refers to screen failures – i.e., those who signed a consent but were not eligible.

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

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

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

Q.3.7 Include participants who died during the study.

3.8 ***Have any participants withdrawn consent (not including any participant(s) who withdrew prior to being enrolled in the study) during this review period?**

☐ Yes
☐ No
☐Not applicable

Q3.8 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?"

If 'Yes': **3.8.1 *How many participants have withdrawn consent?** Click here to enter text.)
If 'Yes': **3.8.2 *Please provide details for each participant:** Click here to enter text.

3.9 ***Have any participants been taken off the study prematurely (for example, by a local investigator or lead group/sponsor) during this review period?**

☐ Yes

☐ No

If 'Yes': **3.9.1 *How many participants have been taken off-study prematurely:** Click here to enter text.

If 'Yes': **3.9.2 *Please provide details for each participant:** Click here to enter text.

3.10 ***Have there been any participant complaints about the study during this review period?**

☐Yes

☐No

If 'Yes': **3.10.1 *Please provide details of each complaint:** Click here to enter text.

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

☐Yes

☐No

☐N/A

Help Text: Reportable events includes anything that could significantly impact the conduct of the study or alter the REB's approval or favourable opinion to continue the study. Reportable events are submitted at the provincial or at the site level, as applicable. Reportable events that meet the criteria for reporting to the REB would be reported in one of the following categories, as applicable:

Provincial:

- DSMB/C Report;

- Interim Analysis Results;

- Safety Notice/Update (e.g., Action Letter);

- Other.

Site:

- Local Serious Adverse Event (SAE);

- Protocol Deviation;

- Summary report of inspection or audit;

- Privacy Breach;

- Other.

If 'Yes': **3.11.1 *Please describe:** Click here to enter text.

3.12 ***Have any of the following formal inspections or audits been conducted (select all that apply) during this review period?**

☐Health Canada inspection

☐FDA audit

☐'for cause' audit (not including standard monitoring visits)

☐Internal institutional audit (e.g., QA)

☐Other

☐None

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

If 'Other': **3.12.1 *Please describe:** Click here to enter text.

If 'Health Canada inspection', 'FDA audit', 'for cause audit (not including standard monitoring visits)', 'internal institutional audit', 'other' are selected in 4.3:

3.12.2 *Please describe the outcome (e.g., findings, issues, concerns): Click here to enter text.

3.13 *Have all site amendments and site reportable events been submitted for REB review?

☐Yes

☐No

***If 'No':* 3.13.1 *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.

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.

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, 8.1 will appear:

5.1 * Principal Investigator

- 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 Coinvestigator (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
- 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