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 • Section 1: new shared questions appear to display information previously submitted to the REB – for reference only • Q1.5 added to include the year of the renewal • Q2.1: overall study status options were revised • Q2.6 added to include information about a lapse in approval • Q6.2 added to allow a delegate to sign off on resubmissions

CTO Clinical Trial Provincial 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".

1.1 ***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 the REB letters.)**

1.4 ***Please specify the type of review requested:**
☐Full Board
☐Delegated
☐Not specified

Help Text: Type of review refers to the type of ethics review that will be used by the REB. While the sponsor or investigator may propose the type of review, the REB makes the final decision regarding whether the submission will undergo delegated review (by one or more REB members) or full Board review (at a convened meeting of the REB).

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.

Regulatory Information: The questions below reflect the information that has previously been provided to the REB and are here for reference purposes only.

***Does this submission require an application to Health Canada under the Food and Drugs Act (e.g., a Clinical Trial Application or Investigational Testing Application)?**

☐ Yes – a Clinical Trial Application (CTA) under the Food and Drug Regulations
☐ Yes – a Clinical Trial Application (CTA) under the Natural Health Product Regulations
☐ Yes – an Investigational Testing Application (ITA) under the Medical Device Regulations
☐ No

***Has this study been submitted to the US Food and Drug Administration (FDA) under an Investigational New Drug (IND), Investigational Device Exemption (IDE), or Pre-Market Approval (PMA) Application?**

☐ Yes ☐ No

***Is this research supported by the United States federal government?**

☐ Yes ☐ No

SECTION 2.0 - STUDY DETAILS

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

☐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

Help Text: Participating sites in Ontario refers to any/all of the Ontario sites using the CTO Streamlined Research Ethics System.

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 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.

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.

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

Responses to Q2.4 and 2.5 generally require sponsor input

2.6 ***Has the Provincial ethics approval lapsed?**

☐Yes
☐No

If 'Yes':

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

☐Yes

☐No

***If 'Yes'*:**

2.6.2 *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 - 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': **3.4.1** ***Please provide the Review Reference # of the Provincial Reportable Event Form in which the documents were previously submitted:** Click here to enter text.
Help Text: The Review Reference # refers to the number that was assigned to the submission of the corresponding Provincial Reportable Event Form/Provincial Amendment Form. The Review Reference Number can be found by selecting the form within the project. For more information please consult Section 1 in the Application Features Manual.
If 'No': **3.4.2 Please upload any associated documents (e.g., DSMB/C report, sponsor correspondence), if applicable:**
Upload Document - Document Type: DSMB/C or Correspondence

Q3.4: if "No", submit the associated reports here, which will be acknowledged in the PCR approval letter.

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., unexpectedly high number of reportable events, changes in standard of care, approval of another treatment for this indication, new information about side effects)**

☐Yes

☐No

If 'Yes': **4.1.1 *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 to date?**

☐ Yes

☐ No

If 'Yes': **4.2.1 *Please Specify:** Click here to enter text.

If 'Yes': **4.2.2 Upload any abstracts, presentations or publications (if applicable):**

Upload Document - Document Type: Abstracts/Presentation/Publications

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

☐ Yes

☐ No

☐ Not applicable – no amendments or provincial reportable events to date

If 'No': **4.3.1 *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 - Document Type: Response to REB letter

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

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.

SECTION 6.0 – ATTESTATIONS AND SIGNATURES

If 1.0 = No, then 6.1 appears

6.1 *Provincial Applicant

- 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
- 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, then 6.2 appears

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

Signature Type: PA or Delegate