

Revision History

Version Date	Key Changes
February 28, 2018	CTO application form version 16 - original
May 1, 2019	<p>CTO application form version 20</p> <ul style="list-style-type: none"> • 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 • Q2.8 added to ask about centre study closures. <ul style="list-style-type: none"> ○ OCREB guidance notes added to instruct the applicant to submit a PSC only after all centres have closed. <p>Q 4.2 added to allow a delegate to sign off on resubmissions</p>
August 20, 2020	<p>CTO application form version 21</p> <ul style="list-style-type: none"> • Question 1.0: Instructions about the PI response letter added. • Question 1.0.1: New question about the Canadian Collaboration for Child Health (CHEER) study. • Question 2.9 : New question about the final disposition of data/biospecimens added. • Question 2.10 : New question about the destruction of data/biospecimens added. • Question 4.1: Instructions revised to indicate that the PI signature will appear if “NO” is selected in question 1.0. • Question 4.2: Instructions revised to indicate that this question will appear if “YES” is selected in question 1.0.


CTO Clinical Trial Provincial Study Closure/CHEER Study Closure

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/CHEER 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".


If 'Yes' to question 1.0:

If required, please ensure that you upload a response letter in question 3.1, outlining how each comment/question from the REB has been addressed in this re-submission.

 **1.0.1** ***Is this a Canadian Collaboration for Child Health (CHEER) study?**
 Yes No

 **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/CHEER Amendments and Provincial Reportable Events/CHEER 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.

If 'Yes' is selected in question 1.0.1, question 2.9 and 2.10 appear:

2.9 *Describe plans for the final disposition of the data/biospecimens. Include, as applicable, how long the study data/biospecimens will be retained and where, and what plans there are for future use of the data/biospecimens (if any) including who will have access to the data/ biospecimens in the future and for what purpose. [Click here to enter text.](#)

Help Text:

Please note that under UBC Policy #85, the PI must ensure that all study data is retained for at least 5 years within a UBC-affiliated facility. For Clinical Trials, in accordance with Health Canada the retention period is at least 25 years. The applicable retention period must be confirmed in the response to 5.1.

2.10 If the data/biospecimens will be destroyed, indicate the planned method for erasure/destruction of the data/biospecimens, including when they will be destroyed. [Click here to enter text.](#)

SECTION 3.0 - RE-SUBMISSION INFORMATION

If 'Yes' to question 1.0 'Is this a resubmission in response to a request from the Research Ethics Board to make changes to your application', questions 3.1 – 3.3 will appear:

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/CHEER 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 – AGREEMENT & APPROVAL AND SIGNATURES

If 'No' to question 1.0, the Provincial Applicant/CHEER Applicant signature appears:

4.1 *Provincial Applicant/CHEER Applicant

- I confirm that all trial-related activity for sites submitted through the Clinical Trials Ontario Streamlined Research Ethics Review System 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 'Yes' is selected to question 1.0, the Provincial Applicant/CHEER Applicant or Delegate signature appears:

4.2 *Provincial Applicant/CHEER 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/CHEER Applicant, I attest that the delegation of this responsibility has been documented

SIGNATURE TYPE: PA OR DELEGATE