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 9.2 was added to allow a delegate to sign off on resubmissions

CTO Clinical Trial Provincial Reportable Events 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)**

1.4 ***Type of event:**
Choose an item.

Help Text: DSMB/DSMC is an acronym for Data and Safety Monitoring Board and Data and Safety Monitoring Committee. The DSMB/DSMC is an independent group of experts that on a periodic basis, reviews and evaluates the accumulated study data for participant safety, study conduct and progress, and, when appropriate, efficacy, and makes recommendations to the study sponsor concerning the continuation, modification, or termination of the study.

AE refers to Adverse Event
Non-local AE refers to those adverse events experienced by research participants enrolled by investigator(s) at other centres/institutions outside the REB's jurisdiction.

SUSAR refers to Suspected Unexpected Serious Adverse Reaction.

Periodic external (non-local) AE or SUSAR report refers to a summary report, created by the sponsor, listing all of the suspected unexpected serious adverse events that have occurred in that reporting period and that also includes a concise summary highlighting the main points of concern and the evolving safety profile of the investigational product.

Single External (non-local) Adverse Event refers to adverse events experienced by research participants enrolled by investigator(s) at other centres/institutions outside the REB's jurisdiction.

If 'Other': **1.4.1 *Specify other type of event:** Click here to enter text.

1.5 ***Is this application associated with or related to a previously submitted Provincial Reportable Event or Provincial Amendment?**

☐Yes ☐No

If 'Yes': **1.5.1 *Please enter the Review Reference # of the corresponding Provincial Reportable Event Form/Provincial Amendment Form:** 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.

1.6 *Please provide a label for this Reportable Event (e.g., an event identifier/description) that will appear in the project tree to help distinguish between events: 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 events. The type of event (from question 1.4) will appear in the project tree automatically. This information will not appear in the REB approval letter.

SECTION 2.0 – DATA SAFETY AND MONITORING BOARD/COMMITTEE REPORT

If "DSMB/C Report" is selected in Q1.4, the following questions appear:

2.1 ***Date of the DSMB/DSMC meeting:** Click here to enter text.

Q2.1: if more than one DSMB report is available for submission, multiple dates may be entered in this text field.

2.2 ***DSMB/DSMC meeting outcome/recommendations:** Click here to enter text.

2.3 **Please upload any associated documents (e.g., DSMB/C report, sponsor correspondence), if available:**
Upload Document - Document Type: DSMB/C or Correspondence

Q2.2 and 2.3: if more than one report is being referenced or uploaded, include the recommendations of each report separately.

2.4 ***Does the information suggest that the research puts participants at greater risk of harm than previously known or recognized?**

☐Yes ☐No

Help Text: Greater risk of harm refers to an elevated likelihood of a similar event occurring to other participants in the study including physical, psychological, economic ethical or social harm than was previously known or recognized.

2.5 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken by the lead researcher/group/sponsor and/or PIs in response to the event (select all that apply):**

☐No action required
☐Suspend study enrollment
☐Revise the study protocol
☐Revise the consent/assent forms
☐Immediately implement changes to reduce/eliminate hazards to current participants
☐Immediately notify research participants (i.e., orally)
☐Other

If 'Other': **2.5.1** ***Specify Other:** Click here to enter text.

Q2.5: select "Other" only if the event does not fall under any of the other available categories.

If 'immediately notify research participants (i.e., orally)' is selected in 2.5, question 2.6 appears:

2.6 **Please upload the oral script, if required:**
Upload Document - Document Type: Oral Script

Help Text: An oral script identifies any information that is to be verbally communicated to participants.

If participants require urgent notification of new information, to prevent an immediate hazard, please upload the proposed oral script along with responses to the following:

1. Confirmation that the new information is a safety risk, and the rationale for its immediate implementation;
2. Confirmation that the sponsor is recommending urgent provision of this information to study participants to prevent an immediate hazard;
3. Confirmation that the PI has reviewed the information and is recommending urgent provision of this information to study participants;
4. The recommended process for disseminating the information (e.g., by phone, recall). If the information is urgent then there must be a process for reaching all participants immediately to ensure that urgent information is transmitted;
5. The proposed content of the information (script or text) that will be provided orally to the study participants and its implications for their ongoing participation.

SECTION 3.0 - INTERIM ANALYSIS RESULTS

If 'Interim Analysis Results' is selected in Q1.4, the following questions appear:

3.1 ***Date of interim analysis:** Click here to enter text.

3.2 ***Description of interim analysis results or findings:** Click here to enter text.

3.3 **Please upload any associated documents (e.g., interim analysis report, sponsor correspondence)**
Upload Document - Document Type: Interim Analysis/Correspondence

3.4 ***Does the information suggest that the research puts participants at greater risk of harm than previously known or recognized?**
☐Yes ☐No

Help Text: Greater risk of harm refers to an elevated likelihood of a similar event occurring to other participants in the study including physical, psychological, economic ethical or social harm than was previously known or recognized.

3.5 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):**

☐No action required
☐Suspend study enrollment
☐Revise the study protocol
☐Revise the consent/assent forms
☐Immediately implement changes to reduce/eliminate hazards to current participants
☐Immediately notify research participants (i.e., orally)
☐Other

If 'Other': **3.5.1** ***Specify other:** Click here to enter text.

If 'immediately notify research participants (i.e., orally)' is selected in 3.5, question 3.6 appears:

3.6 **Please upload the oral script, if required:**
Upload Document - Document Type: Oral Script

Help Text: An oral script identifies any information that is to be verbally communicated to participants.

If participants require urgent notification of new information, to prevent an immediate hazard, please upload the proposed oral script along with responses to the following:

1. Confirmation that the new information is a safety risk, and the rationale for its immediate implementation;
2. Confirmation that the sponsor is recommending urgent provision of this information to study participants to prevent an immediate hazard;
3. Confirmation that the PI has reviewed the information and is recommending urgent provision of this information to study participants;
4. The recommended process for disseminating the information (e.g., by phone, recall). If the information is urgent then there must be a process for reaching all participants immediately to ensure that urgent information is transmitted;
5. The proposed content of the information (script or text) that will be provided orally to the study participants and its implications for their ongoing participation.

SECTION 4.0 - SAFETY NOTICE/UPDATE

If 'Safety Notice/Update (e.g., action letter)' is selected in Q1.4, the following questions appear:

4.1 ***Date of Notice/Update:** Click here to enter text.

4.2 ***Description of Safety Notice/Update:** Click here to enter text.

4.3 ***Does the information suggest that the research puts participants at a greater risk of harm than previously known or recognized?**

☐Yes ☐No

Help Text: Greater risk of harm refers to an elevated likelihood of a similar event occurring to other participants in the study including physical, psychological, economic ethical or social harm than was previously known or recognized.

4.4 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):**

☐No action required
☐Suspend study enrollment
☐Revise the study protocol
☐Revise the consent/assent forms
☐Immediately implement changes to reduce/eliminate hazards to current participants
☐Immediately notify research participants (i.e., orally)
☐Other

If 'No action required': **4.4.1 *Justify no action required:** Click here to enter text.
If 'Other': **4.4.2 *Specify Other:** Click here to enter text.

4.5 **Please upload the Safety Notice/Update and any associated documents (e.g., sponsor correspondence):**
Upload Document - Document Type: Safety Update/Notice

Help Text: A Safety Notice/Update could include, for example, an Action Letter, or a safety letter issued by Health Canada.

If 'immediately notify research participants (i.e., orally)' is selected in 4.4, question 4.6 appears:

4.6 **Please upload the oral script, if required:**
Upload Document - Document Type: Oral Script

Help Text: An oral script identifies any information that is to be verbally communicated to participants.

If participants require urgent notification of new information, to prevent an immediate hazard, please upload the proposed oral script along with responses to the following:

1. Confirmation that the new information is a safety risk, and the rationale for its immediate implementation;
2. Confirmation that the sponsor is recommending urgent provision of this information to study participants to prevent an immediate hazard;
3. Confirmation that the PI has reviewed the information and is recommending urgent provision of this information to study participants;
4. The recommended process for disseminating the information (e.g., by phone, recall). If the information is urgent then there must be a process for reaching all participants immediately to ensure that urgent information is transmitted;
5. The proposed content of the information (script or text) that will be provided orally to the study participants and its implications for their ongoing participation.

SECTION 5.0 - PERIODIC EXTERNAL (NON-LOCAL) AE/SUSAR SUMMARY REPORT

If Periodic External (Non-local) AE/SUSAR Summary Report is selected in Q1.4

ENSURE THAT THE NON-LOCAL AE/SUSAR MEETS REB REPORTING REQUIREMENTS. THE APPLICANT WILL BE REQUIRED TO WITHDRAW SUBMITTED REPORTS THAT DO NOT MEET REPORTING REQUIREMENTS.

Refer to OCREB SOP 404. Submit the PRE ONLY if "Yes" is the appropriate answer to questions 5.1 to 5.4, AND there is or will be a corresponding change to the protocol or consent.

5.1 ***Does this report contain any events that are serious?**

☐Yes ☐No

Help Text: Serious refers to a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

5.2 ***Does this report contain any events that are unexpected in terms of nature, severity or frequency?**

☐Yes ☐No

Help Text: Unexpected refers to a drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug.

5.3 ***Does this report contain any events that are related or possibly related to participation in the research?**

☐Yes ☐No

Help Text: Related or possibly related refers to related or possibly related to participation in the research. Related or possibly related means that there is certainty or a reasonable possibility that the incident, experience, or outcome was or may have been caused by the investigational product(s) or procedures involved in the research.

5.4 ***Does the report suggest that the research puts participants at greater risk of harm than previously known or recognized?**

☐Yes ☐No

Help Text: Greater risk of harm refers to an elevated likelihood of a similar event occurring to other participants in the study including physical, psychological, economic ethical or social harm than was previously known or recognized.

If 'Yes': **5.4.1 *Please describe:** Click here to enter text.

5.5 ***Date of Report:** Click here to enter text.

5.6 ***Summary of Findings:** Click here to enter text.

5.7 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):**

☐No action required

☐Suspend study enrollment

☐Revise the study protocol
☒Revise the consent/assent forms
☐Immediately implement changes to reduce/eliminate hazards to current participants
☐Immediately notify research participants (i.e., orally)
☐Other

If 'No action required': **5.7.1 *Justify no action required:** Click here to enter text.
If 'Other': **5.7.2 *Specify other:** Click here to enter text.

5.8 Please upload the report and any associated documents (e.g., sponsor correspondence):
Upload Document - Document Type: Sponsor Correspondence

If 'immediately notify research participants (i.e., orally)' is selected in 5.7, question 5.9 appears:

5.9 Please upload the oral script, if required:
Upload Document - Document Type: Oral Script

Help Text: An oral script identifies any information that is to be verbally communicated to participants.

SECTION 6.0 - SINGLE EXTERNAL (NON-LOCAL) ADVERSE EVENT

If 'Single External (Non-local) Adverse Event' is selected in Q1.4, the following appear:

ENSURE THAT THE NON-LOCAL AE MEETS REB REPORTING REQUIREMENTS.
THE APPLICANT WILL BE REQUIRED TO WITHDRAW SUBMITTED REPORTS THAT DO NOT MEET REPORTING REQUIREMENTS.

Refer to OCREB SOP 404. Submit the PRE ONLY if "Yes" is the appropriate answer to questions 5.1 to 5.4, AND there is or will be a corresponding change to the protocol or consent.

6.1 ***Is the event serious?**

☐Yes ☐No

Help Text: Serious refers to a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

6.2 ***Is the event unexpected in terms of nature, severity or frequency?**

☐Yes ☐No

Help Text: Unexpected refers to a drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug.

6.3 ***Is the event related or possibly related to participation in the research?**

☐Yes ☐No

Help Text: Related or possibly related refers to related or possibly related to participation in the research and means that there is certainty or a reasonable possibility that the incident, experience, or outcome was or may have been caused by the investigational product(s) or procedures involved in the research.

6.4 ***Does the information suggest that the research puts participants at greater risk of harm than previously known or recognized?**

☐Yes ☐No

Help Text: Greater risk of harm refers to an elevated likelihood of a similar event occurring to other participants in the study including physical, psychological, economic ethical or social harm than was previously known or recognized.

If 'Yes': **6.4.1** ***Please describe:** Click here to enter text.

6.5 ***Date of event:** Click here to enter text.

6.6 ***Adverse event description:** Click here to enter text.

6.7 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):**

☐No action required
☐Suspend study enrollment
☐Revise the study protocol
☐Revise the consent/assent forms

☐Immediately implement changes to reduce/eliminate hazards to current participants
☐Immediately notify research participants (i.e., orally)
☐Other
If 'No action required': **6.7.1 *Justify no action required:** Click here to enter text.
If 'Other': **6.7.2 *Specify other:** Click here to enter text.

6.8 Please upload the report and any associated documents (e.g., sponsor correspondence):
Upload Document - Document Type: Sponsor Correspondence

If 'immediately notify research participants (i.e., orally)' is selected in 6.7, question 6.9 appears:
6.9 Please upload the oral script, if required:
Upload Document - Document Type: Oral Script

Help Text: An oral script identifies any information that is to be verbally communicated to participants.

If participants require urgent notification of new information, to prevent an immediate hazard, please upload the proposed oral script along with responses to the following:

1. Confirmation that the new information is a safety risk, and the rationale for its immediate implementation;
2. Confirmation that the sponsor is recommending urgent provision of this information to study participants to prevent an immediate hazard;
3. Confirmation that the PI has reviewed the information and is recommending urgent provision of this information to study participants;
4. The recommended process for disseminating the information (e.g., by phone, recall). If the information is urgent then there must be a process for reaching all participants immediately to ensure that urgent information is transmitted;
5. The proposed content of the information (script or text) that will be provided orally to the study participants and its implications for their ongoing participation.

SECTION 7.0 - OTHER REPORTABLE EVENT

If 'Other' is selected in Q1.4, the following questions appear:

Will appear only if "Other" in Q2.5 was selected. Other should be used only if the event does not fall under any of the available categories of Provincial Reportable events. **DO NOT** use this category to submit Centre Reportable Events (CREs). There is a separate CRE form.

7.1 ***Type of reportable event:** Click here to enter text.

7.2 ***Date of reportable event:** Click here to enter text.

7.3 ***Description of event:** Click here to enter text.

7.4 ***Is the event serious?**

☐Yes ☐No

Help Text: Serious refers to a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

7.5 ***Is the event unexpected in terms of nature, severity or frequency?**

☐Yes ☐No

Help Text: Unexpected refers to a drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug.

7.6 ***Is the event related or possibly related to participation in the research?**

☐Yes ☐No

Help Text: Related or possibly related refers to related or possibly related to participation in the research and means that there is certainty or a reasonable possibility that the incident, experience, or outcome was or may have been caused by the investigational product(s) or procedures involved in the research.

7.7 ***Does the information suggest that the research puts participants at greater risk of harm than previously known or recognized?**

☐Yes ☐No

Help Text: Greater risk of harm refers to an elevated likelihood of a similar event occurring to other participants in the study including physical, psychological, economic ethical or social harm than was previously known or recognized.

7.8 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken in response to the event (select all that apply):**

☐No action required
☐Suspend study enrollment
☐Revise the study protocol
☐Revise the consent/assent forms
☐Immediately implement changes to reduce/eliminate hazards to current participants

☐Immediately notify research participants (i.e., orally)
☐Other
If 'No action required': **7.8.1 *Justify no action required:** Click here to enter text.
If 'Other': **7.8.2 *Specify other:** Click here to enter text.

7.9 Please upload any associated documents (e.g., sponsor correspondence) if applicable:
Upload Document - Document Type: Sponsor Correspondence

If 'immediately notify research participants (i.e., orally)' is selected in 7.8, question 7.10 appears:

7.10 Please upload the oral script, if required:
Upload Document - Document Type: Oral Script

Help Text: An oral script identifies any information that is to be verbally communicated to participants.

If participants require urgent notification of new information, to prevent an immediate hazard, please upload the proposed oral script along with responses to the following:

1. Confirmation that the new information is a safety risk, and the rationale for its immediate implementation;
2. Confirmation that the sponsor is recommending urgent provision of this information to study participants to prevent an immediate hazard;
3. Confirmation that the PI has reviewed the information and is recommending urgent provision of this information to study participants;
4. The recommended process for disseminating the information (e.g., by phone, recall). If the information is urgent then there must be a process for reaching all participants immediately to ensure that urgent information is transmitted;
5. The proposed content of the information (script or text) that will be provided orally to the study participants and its implications for their ongoing participation.

SECTION 8.0 – 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.

8.1 Upload Provincial Applicant response to REB request for modification letter (if applicable):

Upload Document - Document Type: Response to REB letter

8.2 Upload any additional materials requested by the REB (if applicable):

Upload Document - Document Type: Other materials

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

This page appears only when "Yes" is the response 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 the OCREB's review of this application should be entered into 8.3.

SECTION 9.0 – ATTESTATIONS AND SIGNATURES

If 1.0 = No, then 9.1 appears

9.1 *Provincial Applicant

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- 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, then 9.2 appears

9.2 * 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