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

CTO Clinical Trial Centre 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:**

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))**

Reportable Event Information:

1.4 ***Type of Event**
Choose an item.
If 'Other': **1.4.1 *Specify:** Click here to enter text.

1.5 ***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 1.14) will appear in the project tree automatically. This information will not appear in the REB approval letter.

SECTION 2.0 - LOCAL (INTERNAL) SERIOUS ADVERSE EVENT (SAE)

If 'Local (Internal) Serious Adverse Event (SAE)' is selected in question 1.4, the following questions appear:

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

Refer to OCREB SOP 404. Complete and submit this CRE ONLY if "Yes" is the appropriate answer to questions 2.2 to 2.5 AND there is or will be a corresponding change to the protocol or consent.

2.1 *Report Type:

☐Initial
☐Follow Up
☐Final

Help Text: Subsequent reports (e.g., follow-up reports) that are associated with a previously reported event must be submitted to the REB by revising the application form in which the event was first reported.

NOTE. CRE updates only apply to **local serious adverse events.**

If this is a follow-up or final report of an event that was previously submitted to the REB, please unlock the initial reporting form and update the report type in this question. Once you have selected the report type, please update the remaining content of that application and submit it to the REB.

If 'Follow-up': **2.1.1 *Follow-up report number:** Click here to enter text.

2.2 *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.

2.3 *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.

2.4 *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.

2.5 *Is the event suggesting 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': **2.5.1 *Please describe:** Click here to enter text.

2.6 ***Name or medical term of adverse event:** Click here to enter text.

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

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

2.9 ***Date that PI or study team became aware of event:** Click here to enter text.

2.10 ***Participant study ID number:** Click here to enter text.

2.11 ***Sex and/or gender:**

☒Male
☒Female
☐ Not available or not applicable to unanticipated problem being reported

Q2.11 & 2.12: Sex and age are not required by OCREB as these are considered identifiers. OCREB requires only the participant's study ID. However, these are mandatory fields that require a response. The applicant may choose to answer these questions accurately or select both male and female for 2.11 and enter "0" for age.

2.12 ***Age at the time of event:** Click here to enter text.

2.13 ***Action taken (select all that apply):**

☐None
☐Hospitalization (initial or prolonged)
☐Study treatment/intervention temporarily altered
☐Study treatment/intervention permanently altered
☐Study treatment/intervention temporarily stopped
☐Study treatment/intervention permanently stopped
☐Study blind broken
☐Other

If 'Other': **2.13.1 *Specify Other:** Click here to enter text.

2.14 ***Outcome of event:**

☐Complete resolution
☐Ongoing/unresolved
☐Partial recovery
☐Disability or impairment
☐Death
☐Other

If 'Other': **2.14.1 *Specify Other:** Click here to enter text.

2.15 ***Will any additional corrective action be taken by the PI locally:**

☐Yes ☐No

If 'yes': **2.15.1 *Describe:** Click here to enter text.

2.16 ***Is it expected that this local (internal) SAE will result in a provincial corrective action (e.g., changes to the protocol or consent/assent form(s))?**

☐Yes ☐No ☐Unknown

If 'yes':

2.16.1 Which of the following types of corrective action are anticipated (select all that apply)?

☐Suspension of study enrollment and further investigation

☐Revisions to the protocol

☐Revisions the consent/assent form(s)

☐Immediate notification of research participants (i.e. orally)

☐Other:

If 'Other': **2.16.1.1 *Specify:** Click here to enter text.

2.17 Upload a copy of the serious adverse event reporting form that was submitted to the sponsor and any sponsor analysis of the event, if available: (ALL DOCUMENTS MUST BE DE-IDENTIFIED. DO NOT APPEND COPIES OF ANY MEDICAL RECORDS, NOTES, REPORTS OR ANY INDIVIDUAL IDENTIFYING INFORMATION)

Upload Document - Document Type: SAE Reporting Form

Q2.17: do not include any clinic notes, medical record information or reports. **All identifiers must be removed** from the sponsor's AE report prior to uploading. Only the participant study ID should be retained.

If 'immediately notify research participants (i.e., orally)' is selected in 2.16, question 2.18 appears:

2.18 Please upload the oral script, if required:

Upload Document - Document Type: Oral Script

SECTION 3.0 - PROTOCOL DEVIATION/VIOLATION

If 'Protocol Deviation/Violation' selected in question 1.4, the following questions appear:

3.1 ***Description/summary of the protocol deviation/violation:** Click here to enter text.

3.2 ***Date the protocol deviation/violation occurred:** Click here to enter text.

3.3 ***Does the protocol deviation/violation include any of the following (select all that apply)?**

☐Eligibility (inclusion/exclusion criteria) waiver
☐Increased risk or possibility of risk for the research participant(s)
☐Compromises the scientific integrity (study efficacy or data integrity) of the study
☐Other

If 'Other': **3.3.1 *Specify Other:** Click here to enter text.

Q3.3: if one or more of the first 3 responses is selected, the deviation must be submitted. Refer to OCREB protocol deviation guidelines at https://ocreb.ca

Q3.3.1 : choose "Other" if there were deviations in the consent process or documentation: e.g. incorrect version; inadequate consenting

If 'eligibility (inclusion/exclusion criteria) waiver' is selected in question 3.3, question 3.4 will appear:

3.4 ***Please describe eligibility (inclusion/exclusion criteria) waiver:** Click here to enter text.

3.4.1 Upload the approval of the waiver (if applicable):
Upload Document - Document Type: Sponsor's Approval of Waiver

If 'Increased risk or possibility of risk for the research participant(s)' is selected in question 3.3, question 3.5 will appear:

3.5 ***Please describe increased risk or possibility of risk for the research participant(s):** Click here to enter text.

If 'Compromises the scientific integrity (study efficacy or data integrity) of the study' is selected in question 3.3, question 3.6 will appear:

3.6 ***Please describe how the deviation compromises the scientific integrity (study efficacy or data integrity) of the study?** Click here to enter text.

Help Text: Scientific integrity refers to maintaining the quality and objectivity of research activities.

3.7 **Upload the deviation/violation (e.g., report/notice/correspondence) issued by or submitted to the Lead group/Sponsor/CRO/Monitor, if applicable:**
Upload Document - Document Type: Protocol Deviation

Q3.7: Although not mandatory, please upload the report or correspondence with the sponsor regarding the deviation if one is available.

3.8 ***Were study participant(s) adversely affected by the deviation/violation?**

☐Yes ☐No

If 'Yes': **3.8.1 *Describe:** Click here to enter text.

3.9 ***Were study participant(s) informed of the deviation/violation?**

☐Yes ☐No

If 'No': **3.9.1 *Explain why participant(s) were not informed:** Click here to enter text.

3.10 ***Describe what measures have been, or will be, taken to reduce the likelihood that similar deviations will occur in the future:** Click here to enter text.

3.11 **Upload the protocol deviation/violation form that was submitted to the sponsor, if applicable: Upload Document - Document Type: Protocol Deviation**

SECTION 4.0 - PRIVACY BREACH

If 'privacy breach' selected in question 1.4, the following questions appear:

4.1 ***Date of the privacy breach:** Click here to enter text.

4.2 ***Please describe the privacy breach, including nature of information that was released:** Click here to enter text.

4.3 ***How many research participants are affected?** Click here to enter text.

4.4 ***Has the institution's privacy officer been notified of the breach?**
☐Yes ☐No
If 'Yes': **4.4.1** ***Describe the privacy officer's response and recommendations:** Click here to enter text.
If 'No': **4.4.2** ***Explain why the privacy officer has not been notified:** Click here to enter text.
If 'Yes': **4.4.3 Upload copies of the correspondence and recommendations of the privacy officer:**
Upload Document - Document Type: Correspondence & Recommendations – Privacy Officer

4.4.3
Remove any participant identifiers from any reports or summaries uploaded. Include only the participant study ID.

4.5 ***Describe what measures have been, or will be, taken to reduce the likelihood that similar breaches will occur in the future:** Click here to enter text.

SECTION 5.0 - AUDIT/INSPECTION REPORT

If 'audit/inspection report' selected in question 1.4, the following questions appear:

5.1 ***Select the type of audit or inspection that was conducted:**

☐Health Canada inspection
☐'For cause' audit (do not include standard monitoring visits)
☐FDA audit
☐Internal institutional audit (e.g., QA)
☐Other

Help Text: Audit or inspection refers to a systematic and independent examination of trial-related activities and documents to determine whether the evaluated trial-related activities were conducted, and the data were recorded, analyzed, and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), good clinical practice (GCP), and the applicable regulatory and ethical requirement(s).

If 'Other': **5.1.2** ***Specify:** Click here to enter text.

5.2 ***Description/summary of the findings:** Click here to enter text.

5.3 ***Are there findings that suggest that the research participants are at greater risk of harm than was previously known or recognized?**

☐Yes ☐No

If 'Yes': **5.3.1** ***Describe the increased risk:** Click here to enter text.

If 'Yes': **5.3.2** ***Describe the proposed corrective action(s) taken or to be taken in response (select all that apply):**

☐Suspend study enrollment at this site and investigate further
☐Implement immediate changes to reduce/eliminate hazards to current participants
☐Other

If 'Other': **5.3.2.1 Describe:** Click here to enter text.

5.4 **Upload any relevant document (e.g., correspondence, inspection/audit report or summary), if available:**

Upload Document - Document Type: Correspondence, inspection/audit report or summary

SECTION 6.0 – STUDY PARTICIPANT COMPLAINT

If 'Other' selected in question 1.4, the following questions appear:

DO NOT INCLUDE ANY INDIVIDUAL IDENTIFYING INFORMATION

6.1 **Participant study ID number/code (if known):** Click here to enter text.

6.2 ***Please indicate who the complaint was made by:**

☐The study participant
☐A family member of the study participant
☐A friend of the study participant
☐Other

If 'Other': **6.2.1** ***Please provide the relationship to the study participant:** Click here to enter text.

6.3 ***Date of complaint:** Click here to enter text.

6.4 ***Please describe the nature of the complaint including to whom the complaint was made:** Click here to enter text.

6.5 ***Please describe how the complaint was handled, including who was involved in reviewing the complaint:** Click here to enter text.

6.6 ***Please describe any corrective actions taken:** Click here to enter text.

6.7 ***Is any REB follow-up with the study participant being requested?** Click here to enter text.

6.8 **Any additional comments:** Click here to enter text.

SECTION 7.0 – 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 OCREB's review of this application should be entered into 7.3.

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

7.2 Upload any additional materials requested by the REB (if applicable):
Upload Document - Document Type: Track Changes Version Documents

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

SECTION 8 – ATTESTATIONS AND SIGNATURES

If 1.0 = No, question 8.1 will appear:

8.1 * Principal Investigator

- 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, question 8.2 will appear:

8.2 * 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