CTO Centre Reportable Events Form

Orange text *indicates an upload or action feature*
Red/italics/bold *indicates question/feature dependencies*
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.

Always answer 'YES" to Q1.0 if this is not the FIRST time the application is being submitted – i.e., if the application is being re-submitted with changes requested by the REB or by the REB office.

The questions below reflect the information most recently provided to the REB.

1.1 *Please complete the Provincial Applicant (PA) details
*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.2 *Is there a Provincial Co-Applicant?
Yes No
***If 'Yes':* *Please complete the Provincial Co-Applicant details:**
*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.3 *Are the contact details for the Main Study Contact different than the Provincial Applicant named above?
Yes No
***If 'Yes':* *Please complete the Main Study Contact details:**

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.4 *Please complete the Main Sponsor Contact details:

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
*Email:

1.5 *Are the Main CRO Contact details available?

Yes No No CRO

***If 'Yes':* *Please enter the Main CRO Contact details:**

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

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

1.7 Please enter the Sponsor's Study ID/Number:

1.8 *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.)

1.1 *Please complete the Centre Principal Investigator (PI) details:

*Title:
*First Name:

*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.2 *Is there a Centre Co-Investigator (Co-I)?

Yes No

***If 'Yes':* *Enter the contact details of the Centre Co-Investigator:**

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

***If 'No':* AT ALL TIMES, there must be oversight of research participants by an appropriately trained, qualified and designated individual.**

***Please outline the management plan to ensure an appropriately trained, qualified and designed individual will always be available to ensure oversight of research participants:**

1.3 *Please complete the Centre Main Study Contact details:

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:
*Province/State:
*Postcode/Zip:
*Telephone:
Fax:
*Email:

1.4 *Please complete the Primary Institutional Representative details:

*Title:
*First Name:
*Surname:
*Organization:
*Address:
*City:

*Province/State:
*Postcode/Zip:
*Telephone:
*Email:

1.5 Please complete the Secondary Institutional Representative details:

Title:
First Name:
Surname:
Organization:
Address:
City:
Province/State:
Postcode/Zip:
Telephone:
Email:

Reportable Event Information:

1.14 *Type of Event

Choose an item.

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

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

If 'Local (Internal) Serious Adverse Event (SAE)' is selected in question 1.9, 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.

NOTE. You must submit a new CRE to update a previously submitted local AE. For AE updates, please reference the previous CRE reference number(s) in "Follow-up report number" section in Q 2.1 or in Q2.7.

2.1 *Report Type:

☐Initial
☐Follow Up
☐Final

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

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.

2.2 *Is the event serious?

☐Yes ☐No

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

☐Yes ☐No

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

☐Yes ☐No

2.5 *Is the event suggesting that the research puts participants at greater risk of harm than previously known or recognized??

☐Yes ☐No

***If 'Yes':* *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.

Q2.11: including sex and age is not required by OCREB as these are considered identifiers. OCREB prefers the use of 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. OCREB will follow-up with the PI if additional information is required.

2.11 *Sex/gender:

☒Male
☒Female

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

2.15 *Will any additional corrective action be taken by the PI locally:
☐Yes ☐No
If 'yes': ***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': **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': ***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

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. Include only the participant study ID.

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

SECTION 3.0 - PROTOCOL DEVIATION/VIOLATION

If 'Protocol Deviation/Violation' selected in question 1.9, 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 approved by sponsor
☐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':** ***Specify Other:** Click here to enter text.

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

Q3.3: choose "Other" if there were deviations in the consent process or documentation: e.g. incorrect version

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

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

***Upload the sponsor's approval of the waiver:**
Upload Document

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.

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

Q3.7: this question is not mandatory. Applicants may choose not to upload the report or to upload correspondence with the sponsor. Uploading the deviation reporting form is mandatory in Q3.11

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

☐Yes ☐No

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

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

☐Yes ☐No

***If 'No':** ***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:**
Upload Document

SECTION 4.0 - PRIVACY BREACH

If 'privacy breach' selected in question 1.9, 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':** ***Describe the privacy officer's response and recommendations:** Click here to enter text.

***If 'Yes':** **Upload copies of the correspondence and recommendations of the privacy officer:**

Upload Document

***If 'No':** ***Explain why the privacy officer has not been notified:** Click here to enter text.

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 1.9, the following questions appear:

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

☐Health Canada inspection
☐Sponsor 'for cause' audit (do not include standard sponsor monitoring visits)
☐FDA audit
☐Internal institutional audit (e.g., QA)
☐Other
If 'Other': ***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': ***Describe the increased risk:** Click here to enter text.
If 'Yes': ***Describe the proposed corrective action(s) taken or to be taken by the sponsor and/or PI 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': **Describe:** Click here to enter text.

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

Upload Document

SECTION 6.0 – STUDY PARTICIPANT COMPLAINT

If 'Other' selected in question 1.9, the following questions appear:

DO NOT INCLUDE ANY INDIVIDUAL IDENTIFYING INFORMATION

6.1 ***Study Participant unique study ID number/code:** 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':** ***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.

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

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

7.3 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 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.

8.1 Centre Principal Investigator Signature

- I attest that, to the best of my knowledge, the information in this application is complete, current and accurate;
- After the initial submission of this Centre Reportable Event, I authorize the main centre trial contact, or other delegated members of the research team, to submit any further edits to this application.