CTO Provincial 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.)**

1.9 ***Type of event:**

Choose an item.

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

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

☐Yes ☐No

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

SECTION 2.0 – DATA SAFETY AND MONITORING BOARD/COMMITTEE REPORT

If "DSMB/C Report" is selected in Q1.8, the following questions appear:

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

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

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

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

2.5 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken by the 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':** ***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

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 Q1.8, 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

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

3.5 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken by the 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':** ***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

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 Q1.8, 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

4.4 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken by the 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 'No action required':** ***Justify no action required:** Click here to enter text.
***If 'Other':** ***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

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

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 Q1.8

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

5.2 *Does this report contain any events that are unexpected in terms of nature, severity or frequency?
☐Yes ☐No

5.3 *Does this report contain any events that are related or possibly related to participation in the research?
☐Yes ☐No

5.4 * Does the report suggest 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.

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

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

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

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

If 'Single External (Non-local) Adverse Event' is selected in Q1.8, 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 6.1 to 6.4 AND there is or will be a change to protocol or consent.

6.1 *Is the event serious?
☐Yes ☐No

6.2 *Is the event unexpected in terms of nature, severity or frequency?
☐Yes ☐No

6.3 *Is the event related or possibly related to participation in the research?
☐Yes ☐No

6.4 *Does the information suggest 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.

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

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

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

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 Q1.8, 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.

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

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

☐Yes ☐No

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

☐Yes ☐No

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

☐Yes ☐No

7.8 ***Describe the corrective action(s) taken or the proposed corrective action(s) to be taken by the 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 'No action required':** ***Justify no action required:** Click here to enter text.

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

7.9 **Please upload any associated documents (e.g., sponsor correspondence) if applicable:**
Upload Document

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

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

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

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.

9.1 Provincial Applicant Signature - attestation

- 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 Provincial Reportable Event, I authorize the main provincial trial contact, or other delegated members of the research team, to submit any further edits to this application on my behalf.