CTO Centre Study Closure 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?**
Yes No

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

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

1.10 ***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:**

1.11*Please complete the Centre Study Contact details:

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

Fax:
*Email:

SECTION 2.0 – STUDY INFORMATION

2.1 ***Date the study was terminated or completed at your centre:** (Text Field)

2.2 ***Was this study terminated prematurely at your centre?**

☐Yes
☐No

***If 'Yes':* *Provide the reason(s) (Select all that apply)**:

☐ Funding issues
☐ Recruitment issues
☐ Safety issues
☐ Terminated by centre PI
☐ Terminated by study sponsor
☐ Other

***If 'Funding Issues':* *Please describe the funding issues:** (Text Field)
***If 'Recruitment Issues':* *Please describe the recruitment issues:** (Text Field)
***If 'Safety Issues':* *Please describe the safety issues:** (Text Field)
***If 'Terminated by centre PI':* *Please explain why the study was terminated by the centre PI:** (Text Field)
***If 'Terminated by study sponsor':* *Please explain why the study was terminated by the study sponsor:** (Text Field)
***If 'other':* *Please describe:** (Text Field)

2.3 ***Have all of the sponsor closeout procedures been completed at your centre?**

☒Yes
☐No
☐N/A

SECTION 3.0 – PARTICIPANT INFORMATION

3.1 ***How many participants were enrolled in the study at your centre?**
Click here to enter text.

As per the CTO form guidance text, Q3.1 refers to all those enrolled – i.e., who signed the consent, met the eligibility criteria and were randomized or registered in the study.

3.2 ***Were any of these enrolled participants individuals who were involved in the study but not directly receiving the treatment or intervention (for example, a caregiver(s), parent(s), or guardian(s))?**

☐Yes
☐No

***If 'Yes':* *How many?** Click here to enter text.

3.3 ***How many participants agreed to take part (e.g., signed a consent/assent form) but were subsequently deemed ineligible?**
Click here to enter text.

Q3.3 refers to screen failures – i.e., those who signed a consent but were ineligible.

3.4 *** Have any participants withdrawn consent (not including any participant(s) who withdrew prior to being enrolled in the study)?**

☐ Yes

☐ No

If 'Yes': ***How many participants withdrew consent?** Click here to enter text.

If 'Yes': ***Please provide details for each participant:** Click here to enter text.

Q3.4 Disregard information in brackets. Answer "Yes" if any participants withdrew consent after being enrolled (see definition Q3.1). This question could be read as "Did any participants withdraw consent after they were enrolled in the study?" – i.e., signed the consent, met the eligibility criteria and were randomized or registered in the study

3.5 ***Were any participants taken off the study prematurely (for example, by a local investigator or sponsor)?**

☐ Yes

☐ No

If 'Yes': ***How many participants were taken off-study prematurely?** Click here to enter text.

If 'Yes': ***Please provide details for each participant:** Click here to enter text.

3.6 ***Were there any participant complaints about the study at your centre?**

☐Yes

☐No

If 'Yes': ***Please provide details of each complaint:** Click here to enter text.

3.7 ***Have reports of all formal inspections or audits been submitted for REB review?**

☐Yes

☐No

If 'No': ***Please describe:** Click here to enter text.

3.8 ***Have all centre amendments and centre reportable events been submitted for REB review?**

☐Yes

☐No

If 'No': ***Please describe:** Click here to enter text.

3.9 ***Have or will the study participants at your centre be provided with the research results?**

☐Yes

☐No

If 'Yes': ***Please describe how the results have been or will be provided:** Click here to enter text.

If 'No': ***Please justify why they will not be disseminated:** Click here to enter text.

NOTE. Centre closures are acknowledged, not approved.

SECTION 4.0 - 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.

4.1 Upload Provincial Applicant Response to REB request for modification letter (if applicable):
Upload Document *(Document Name, Document Date, Version)*

4.2 Upload any additional materials requested by the REB (if applicable):
Upload Document *(Document Name, Document Date, Version)*

4.3 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 in OCREB's review of this application should be entered into 4.3.

5.1 Centre Principal Investigator Signature

- I confirm that there is no further participant involvement at this centre, all data collection, clarification and transfer is complete (including access to the participants' medical record), and that the final sponsor closeout procedures (if applicable) have taken place
- I certify that trial data will be retained according to applicable guidelines and regulations;
- I request that the REB file for this centre be officially closed;
- After the initial submission of this Centre Study Closure, I authorize the main Centre trial contact, or other delegated members of the research team, to submit any further edits to this application on my behalf.