

# Post-Approval Centre Submissions in CTO Stream

Once a centre initial application (CIA) is approved, the Centre Applicant team may create relevant post-approval centre-specific applications (e.g., amendments, reportable events, etc.) for submission to OCREB.

## Tips

- CTO Stream can be accessed via [apply.ctostream.ca](http://apply.ctostream.ca) (do not add “www” in front of the address);
- CTO Stream works with current versions of all browsers. However, Internet Explorer (IE) is not as highly recommended;
- When re-submitting an application, applicants must answer “Yes” to question 1.0 “is this a resubmission in response to a request from the Research Ethics Board to make changes to your application?”;
- Centre post-approval applications are sub-forms of the Centre Initial Application (CIA). Click on the CIA in the project tree and press the “Create Sub-forms” button in the left-hand actions toolbar to see a list of available sub-forms;
- Any user with ‘write’ permissions for that centre (including the Principal Investigator, Co-Investigator, Centre Study Staff and Sponsor/CRO-full access) is able to create a sub-form;
- Post-approval applications go directly to OCREB on submission.

## Post-Approval Form Differences

### *Centre Amendments*

- Site-specific amendments (e.g., change in Principal Investigator (PI), translation of approved materials) are submitted through the Centre Amendment form (CAM)
- Only updated materials/documents should be included in the CAM form – previously approved materials that remain unchanged should not be re-submitted;
- The submission of an amendment for centre-specific ICF changes that meet the definition of administrative changes or that are pre-approved, centre-specific ICF changes is not required. No other changes to the consent documents should be made at the centre level.
- There may be very rare occasions when a centre amendment is required following centre initial approval. However, in these instances, please contact OCREB for further information prior to preparing the CAM.

### *Implementation of Provincial Amendment (IPA) form*

- This form is not required for OCREB studies;
- OCREB will continue to follow its existing policy for consent form review, thus OCREB sites will not need to submit the IPA form. The provincial amendment approval letter will continue to note that all provincial materials (including consents) are approved for implementation by all approved participating sites.

### *Centre Continuing Review*

- The centre applicant (CA) team (those with Principal Investigator, Co-Investigator, Centre Study Staff and Sponsor/CRO-full access roles) will receive reminder emails 45 and 30 days prior to expiry of centre ethics approval;
- The CA will submit a Centre Continuing Review (CCR) form by the submission deadline for the full board meeting occurring prior to the expiry date (just like before);
- Failure to submit the application by the deadline will result in a lapse of approval for the site;
- Centres can submit their CCR forms even if the Provincial Continuing Review form hasn’t been submitted.

### *Centre Reportable Events*

- Centre reportable events include only local (internal) serious adverse events, protocol deviations, privacy breaches, audit/inspection reports and participant complaints occurring at the centre **that meet the OCREB reporting requirements**;
- If there is a follow-up to a previously submitted reportable event (specifically for SAEs), a new Reportable Event form must be submitted. Please reference the previous CRE reference number(s) in the “Follow-up report number” section in Q 2.1 or in Q2.7.

### *Centre Study Closure*

- When the study is completed at an individual research site (e.g., when there is no further participant involvement, all new data collection is complete, and the sponsor's close-out requirements for the site have been completed), the site will submit a Centre Study Closure (CSC) form;
- Each participating site (including the Provincial Applicant's site) must submit a CSC form before the study can be closed at the provincial level.

### **Signature Requirements and Notifications**

- The Principal Investigator must sign each post-approval application when it is first submitted. However, the main study contact may sign any re-submissions of the form;
- The CA team is notified at the time of the submission of an application and when the REB sends a letter (e.g., a review, acknowledgment or approval letter) in response to each centre submission.