Post-Approval Provincial Submissions in CTO Stream

Once a new study (PIA) is approved, the Provincial Applicant team may create relevant post-approval provincial (study-wide) applications (e.g., amendments, reportable events, etc.) for submission to OCREB.

Tips
- CTO Stream can be accessed via 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?";
- Provincial post-approval applications are sub-forms of the Provincial Initial Application (PIA). Click on the PIA 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 at the provincial level, (including the Provincial Applicant/lead PI, Provincial Co-Applicant, Provincial Study Staff and Sponsor/CRO-full access) is able to create a sub-form;
- Post-approval applications go directly to OCREB upon submission.

Post-Approval Form Differences
Amendments
- Amendments are submitted through the Provincial Amendment form (PAM)
- Only updated materials/documents should be included in the PAM form – previously approved materials that remain un-changed should not be re-submitted.

Continuing Review
- The Provincial Applicant (PA) team (those with Provincial Applicant, Provincial Co-Applicant, Provincial Study Staff and/or Sponsor/CRO –full access roles) will receive reminder emails 45 and 30 days prior to the expiry date of the provincial ethics approval;
- The PA will submit a Provincial Continuing Review (PCR) form by the submission deadline for the full board meeting occurring prior to the expiry date (just like before);
- Centres can submit their Centre Continuing Review (CCR) forms even if the PCR form hasn't yet been submitted;
- A lapse in provincial ethics approval will simultaneously result in a lapse at all participating sites, so it is important to ensure that all PCRs and CCRs are submitted and approved before the study expiry date.

Reportable Events
- Provincial reportable events include DSMB/C reports, Interim analysis results, safety notice/updates (e.g., action letters) and any external (non-local) adverse events **that meet the OCREB reporting requirements**;
- If there is a follow-up to a previously submitted reportable event, a new Reportable Event form for the same event will need to be submitted.

Provincial Study Closure
- Once all participating sites have submitted their centre study closure forms (CSC), the study can be closed by the PA by submitting the Provincial Study Closure (PSC) form. Please only submit the PSC once all the Centres are closed.

Signature Requirements and Notifications
- The PA must sign each post-approval application when it is first submitted. However, the main study contact may sign any re-submissions of the forms;
- Provincial and centre collaborators are 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 provincial submission.