Clinical Trials Ontario

Streamlined Research Ethics Review System

Post-Approval Submissions

CLINICAL TRIALS ONTARIO

Overview

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Post-Approval Provincial Submissions

What is a Post-Approval Submission?

- Ethics submissions which occur after the project has received initial ethics approval, or after the Provincial application has been submitted
- Responsibility of the Provincial Applicant (PA) team
- Once approved, the approval applies to all of the sites*

**Exception: Provincial Amendments involving change to provincial consent materials*

Provincial Information	Centre Information
Initial Application (study-wide information)	**Initial Application** (centre-specific information)
Amendments: • Changes to protocol • Changes to consent/assent form(s) • Changes in other participant materials • Updated IB/PM • Translation of Provincial Materials • Other changes in previously submitted information	**Amendments:** • Changes to local consent/assent form(s) • Translation of centre-specific material • Changes in other centre-specific participant materials • Other changes in previously submitted centre-information
Continuing Review (study-wide information)	**Continuing Review** (centre-specific information)
Reportable Events • DSMB/C Report • Interim Analysis Results • Safety Notice/Update (e.g., Action Letter), Periodic External (non-local) AE/SUSAR Summary Report, Single External (non-local) Adverse Event meeting reporting definition	**Reportable Events** • Local (internal) Serious Adverse Event meeting reporting definition • Protocol Deviation/Violation • Privacy Breach • Audit/Inspection Report • Participant Complaint
Study Completion/Termination (all centres)	**Study Completion/Termination** (centre-specific information)

Post-Approval Provincial Submissions

Reminders

- Post-approval forms are *sub-forms* of the Provincial Initial Application (PIA)
- Provincial Applicant/lead PI, Provincial Co-Applicant, Provincial Study Staff and Sponsor/CRO-full access Roles are able to create these forms
- Post-approval application forms go directly to the REB of Record upon submission
- Provincial and Centre collaborators are notified at the time of submission and when the REB sends a letter (e.g. a review, acknowledgment or approval letter) for each provincial submission

Post-Approval Provincial Forms - Types

Provincial Amendment Form (PAM)

- Amendments submitted through PAM
- Only updated materials/documents should be included in the PAM form

Provincial Continuing Review (PCR)

- Provincial Applicant (PA) will submit PCR by submission deadline for the full board meeting occurring prior to expiry
- Centres can submit their Centre Continuing Review (CCR) forms even if the PCR form hasn't yet been submitted
- Lapse in provincial ethics approval will simultaneously result in a lapse at all participating sites

Post-Approval Provincial Forms – Types (continued)

Provincial Reportable Events (PRE)

- Include DSMB/C reports, Interim analysis results, safety notices/update and any external (non-local) adverse events **that meet the REB of Record's reporting requirements**

Provincial Study Closure Form (PSC)

- Once all participating sites have submitted their centre study closure forms, the study can be closed by the PA by submitting the PSC

Signature Requirements

- PA must sign each post-approval application when it is **first** submitted
  - A delegate may sign any re-submissions of the form

Post-Approval Centre Submissions

What is a Post-Approval Submission?

- Ethics submissions which occur after the project has received initial ethics approval, or after the centre application has been submitted
- Responsibility of the Centre Applicant team (local site PI team)

Provincial Information	Centre Information
Initial Application (study-wide information)	**Initial Application** (centre-specific information)
Amendments: • Changes to protocol • Changes to consent/assent form(s) • Changes in other participant materials • Updated IB/PM • Translation of Provincial Materials • Other changes in previously submitted information	**Amendments:** • Changes to local consent/assent form(s) • Translation of centre-specific material • Changes in other centre-specific participant materials • Other changes in previously submitted centre-information
Continuing Review (study-wide information)	**Continuing Review** (centre-specific information)
Reportable Events • DSMB/C Report • Interim Analysis Results • Safety Notice/Update (e.g., Action Letter), Periodic External (non-local) AE/SUSAR Summary Report, Single External (non-local) Adverse Event meeting reporting definition	**Reportable Events** • Local (internal) Serious Adverse Event meeting reporting definition • Protocol Deviation/Violation • Privacy Breach • Audit/Inspection Report • Participant Complaint
Study Completion/Termination (all centres)	**Study Completion/Termination** (centre-specific information)

Post-Approval Centre Submissions

Reminders

- Are sub-forms of the Centre Initial Application (CIA)
- Centre PI, Co-Investigator, Centre Study Staff and Sponsor/CRO-full access Roles are able to create these forms
- Post-approval applications go directly to the REB of Record upon submission
- Centre applicant team is notified at the time of submission and when the REB sends a letter (e.g., a review, acknowledgment or approval letter) for each centre submission

Post-Approval Centre Form - Types

Centre Amendment Form (CAM)

- Site-specific amendments submitted through CAM
- Only updated materials/documents should be included in the CAM form

Reminder:

Sites are not required to submit non-consent participant facing materials when the only change to the provincially approved version is the insertion of site-specific contact information and/or letterhead

Post-Approval Centre Form – Types (continued)

Changes to Provincial Consent Template

- When a Provincial Amendment is approved that involves **a change to the consent materials,** sites must submit a Centre Amendment (CAM) form for their new ICF
  - Each site will create their new site-specific ICF **reflecting changes in the new Provincially approved ICF template** and submit for REB approval using the CAM form
- **OCREB Users – Please note this is not required for OCREB studies*

Post-Approval Centre Form – Types (continued)

Centre Continuing Review (CCR)

- Centre applicant (CA) will submit CCR form by submission deadline for full board meeting occurring prior to expiry date
- Centres can submit their CCR forms even if PCR form hasn't been submitted
- Provincial Applicant must also submit a CCR for their own site (in addition to the PCR form)

Centre Reportable Events (CRE)

- Centre reportable events include only local (internal) SAEs, protocol deviations, privacy breaches, audit/inspection reports and participant complaints occurring at the centre **that meet the REB of Record's reporting requirements**

Post-Approval Centre Form – Types (continued)

Centre Study Closure (CSC)

- When study is completed at an individual research site (e.g., there is no further participant involvement, all new data collection is complete, and the sponsor close-out activities at the site have been completed, if applicable), each site will submit a CSC form
- Each participating site (including the PA's site) must submit a CSC form before study can be closed out overall (e.g., at the provincial level)

Signature Requirements

- PI must sign each post-approval application when it is **first** submitted
  - A delegate may sign any re-submissions of the form

Continuing Review Reminders

- Single ethics expiry date for the entire study and all participating sites
- Reminders are sent 45, 30 and 15 days prior to the expiry date – submit for the Full-Board meeting prior to your expiry date
- Provincial Continuing Review (PCR) form must be submitted by the Provincial Applicant (PA) team, and each research site (including the PA site) must submit a Centre Continuing Review (CCR) form
- A lapse in ethics approval occurs if the continuing review is not approved prior to the ethics approval expiry date
- If provincial ethics approval expires, ethics approval for all research sites is automatically considered to have expired as well.

CTO Stream Help Desk

Main: 1-877-715-2700
Email Support: streamline@ctontario.ca

Scott Tomlinson, CTO Stream Navigator
scott.tomlinson@ctontario.ca

Lynn Nowoselski Coordinator, Streamlined Research Ethics Review
lynn.nowoselski@ctontario.ca

Ranuka Srinivasan Program Manager
ranuka.srinivasan@ctontario.ca