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# Institution Representatives and the CTO Streamlined System

*This document explains how Institution Representatives will interact with the CTO Streamlined System, including email notifications, signature requirements, and access to CTO Stream.*

## Contents



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## Glossary

**CTO Stream** is the web-based system that manages the research ethics review of all research studies submitted through the CTO Streamlined System.

**Centre Initial Application** (CIA) is the initial site-specific application submitted by each participating site intending to join the study. This brief application form contains only information relating to the conduct of the study at that particular site.

**Institution Representative** (IR) is/are identified by each Participating Organization. The IR receives automated notification of certain events through CTO Stream and has visibility to studies/applications within CTO Stream (based on their site's role in the study). The Primary Institution Representative is responsible for electronically signing Centre Initial Applications from their site before they are submitted to the REB of Record.

**Participating Organization** (PO) may be an REB Host Institution, and/or the legal entity of a Provincial Applicant or participating site.

**Participating site** is an Ontario site where research is being conducted and for which research ethics review is provided through the CTO Streamlined System.

**Principal Investigator** (PI) is the lead researcher at each participating site, responsible for submitting all site-specific information that applies to the local conduct of the study to the REB of Record.

**Provincial Initial Application** (PIA) is the initial study-wide application submitted by the Provincial Applicant. It contains all the information relevant to the conduct of the study at all participating sites (including, for example, the protocol).

**Provincial Applicant** (PA) is the lead researcher responsible for submitting all study-specific information that applies to the overall research project to the REB of Record.

**REB of Record** is the single *CTO Qualified* REB that provides ethics review and continuing ethics oversight of the research project on behalf of multiple participating sites.

**REB Host Institution** is the Participating Organization whose REB has been qualified by CTO and is acting as the REB of Record for a specific study through the CTO Streamlined System.

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## Institution Representative(s)

The Institution Representative(s) (IR) are initially identified by the Participating Organization (PO) after the Participation Agreement is executed, but the PO may update these as needed. A Primary Institution Representative (pIR) must be identified by the PO; the PO may also designate a Secondary Institution Representative (sIR) if they wish.

The IR may or may not be the same person who signs the REB of Record Study Agreement, at the PO's discretion.

The IR(s) will receive notifications/emails, have visibility to CTO Stream and electronically sign Centre Initial Applications as applicable to their site's role in the study, as outlined below.

A list of the designated IR for each institution (including each affiliated research site, as applicable) will be maintained by CTO. The PO can contact CTO should they need to update the information.

## REB Host Institution – Notification from CTO Stream

The pIR and sIR (if applicable) for the REB Host Institution will receive an email notification when:

- The PO's REB is asked to act as the REB of Record for a study using the Streamlined System
- The REB accepts or declines to act as the REB of Record for the study
- Approval of the PIA, or rejection if applicable
- Provincial ethics approval lapses, is terminated, or is suspended
- Approval of each CIA, or rejection if applicable
- The study is completed/terminated

The pIR and sIR for the REB Host Institution do not have access to CTO Stream unless the PO is also involved in the study as a PA or participating site.

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# Provincial Applicant and Participating Site – Access to and Notification from CTO Stream

## Provincial Applicant site

The pIR and sIR (if applicable) for the Provincial Applicant's site will be identified in the Provincial Initial Application (PIA) form.

The pIR and sIR (if applicable) for the PA site will have access to view all provincial submissions (including associated documents and REB correspondence).

The pIR and sIR (if applicable) will also receive an email notification when:

- The PIA is submitted to CTO
- Approval of the PIA, or rejection if applicable
- Provincial ethics approval lapses, is terminated, or is suspended
- The study is completed/terminated

The PA's team is required to provide access to CTO Stream to the pIR and sIR (if applicable) of their site. CTO will ensure that this has occurred as part of the PIA screening process.

## Participating Site

The pIR and sIR (if applicable) for the Principal Investigator's (PI) site will be identified in the CIA form.

The pIR for the participating site (along with the Department Head/Departmental Approver) must electronically sign the CIA before this form can be submitted to the REB of Record. The pIR must also sign electronically in CTO Stream if the PI changes at a participating site. The corresponding attestations are in Appendix 1.

The pIR and sIR (if applicable) for the PI's site will have access to view all provincial submissions (including associated documents and REB correspondence) and all the submissions from their site (including associated documents and REB correspondence).

The pIR and sIR (if applicable) will also receive email notifications from CTO Stream at the following time points:

- Submission of the CIA to REB of Record
- Approval of the CIA, or rejection if applicable
- Submission of a reportable event (local unanticipated problem, participant complaint, protocol deviation/violation, privacy breach, or audit/inspection report) by that site
- Provincial ethics approval lapses, is terminated, or is suspended
- Ethics approval lapses, is terminated, or is suspended at that site
- The study is completed/terminated at that site

The PI's team is required to provide access to CTO Stream to the pIR and sIR (if applicable) of their site. CTO will ensure that this has occurred as part of the CIA screening process.

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# Appendix 1 – IR Attestations in CTO Stream

## Centre Initial Application

- I attest that the Principal Investigator (and Co-Investigator, if applicable) is a researcher in good standing with this institution, and is appropriately qualified to act as the Principal Investigator (or Co-Investigator, if applicable) for the conduct of this study at this institution;
- I confirm that the Principal Investigator has access to the resources necessary to conduct the study;
- I attest that the Principal Investigator (and Co-Investigator, if applicable) has completed any mandatory clinical research training required at this institution, if applicable and, if a physician, has been appropriately credentialed;
- I attest that this institution has entered (or will enter) into appropriate contractual agreements with funders, sponsors and/or other institutions and that the study budget has been (or will be) reviewed and financial conflict of interest has been (or will be) addressed;
- I attest that this institution will notify the REB of Record if institutional approval is suspended or terminated for this study.

### Change in Principal Investigator

- I attest that the Principal Investigator is a researcher in good standing with this institution, and is appropriately qualified to act as the Principal Investigator for the conduct of this study at this institution;
- I confirm that the Principal Investigator has access to the resources necessary to conduct the study;
- I attest that the Principal Investigator has completed any mandatory clinical research training required at this institution, if applicable and, if a physician, has been appropriately credentialed.