

Notification of Update to CTO Stream

To: All Applicants Submitting Ethics Applications Through CTO Stream

CTO is pleased to announce we have made several improvements to CTO Stream based on the feedback received from study teams and REBs.

The update will go live on February 18th, 2019. To avoid any downtime, CTO will be making changes to system settings in the back-end between now and the release date. These changes will not affect your normal day to day operations through CTO Stream. In the event you experience any abnormal system interruptions or errors during this time, please contact CTO. If any unforeseen circumstances cause a delay of the release, CTO will notify all Applicants of the revised release date as soon as possible.

Below is a description of the new features included with this update, along with a few important notices for Applicants:

1) New Restrictions on Form Creation

We will be introducing new restrictions which prevent study teams from creating new post-approval application forms (i.e., amendments) if there is already a form of the same type under review with the REB or unsubmitted.

Currently in CTO Stream, researchers at the Provincial and Centre levels can create and submit more than one amendment or continuing review form simultaneously. This can lead to duplicate or incorrect information being submitted, leading to confusion for REBs and study teams. To prevent this issue, CTO will be adopting new form restrictions that prevent users from creating an amendment or continuing review form if they have one already created but not submitted, or one currently under review.

2) Improvements to Logic in Application Form Questions

We are excited to announce that application forms are 'smarter' with improvements to the underlying conditional logic of the questions in our forms. This added flexibility ensures that applicants will only need to answer questions or upload documents which are relevant to their research and that all irrelevant questions will be hidden from the form. With this improved question logic, applicants will no longer see duplicated questions on the form.

3) Changes to Signature Requirements

Signature Changes

The Initial submission of all forms (initial application, amendment, reportable event, continuing review, closure) must be signed by the Provincial Applicant (PA, provincial forms) or PI (centre forms). The signature attestations will reflect that the PA/PI is ultimately responsible and that there is appropriate documentation of any delegation.

Exception: A member of the study team may sign Amendment forms where **the only change** is to correct contact details for the PA/PI/Co-Applicant/Co-Investigator or the name/contact details for the main contact/Institution Representative(s).

Re-submissions of All Forms: These applications can be signed by a member of the study team. The PA/PI will receive an email notification when the application is submitted. Delegation is optional; the PA/PI may elect to sign all submissions.

The REB of Record may still require that an application be signed by the PA/PI (e.g. in cases where significant changes are requested by/re-submitted to the REB). This requirement must be specified in the REB review letter outlining the requested revisions.

Attestation Changes

To reflect the updated signature requirements, the following language has been added to the Provincial Applicant/Principal Investigator attestation for the initial submission of ALL forms:

“Following the initial submission of this application form, a member of the research team may submit edits to this application on my behalf. I acknowledge that I remain ultimately responsible for REB submissions and the overall conduct of the study. I attest that, should a designate sign on my behalf, the responsibility for corresponding with the REB has been appropriately delegated, and the delegation has been documented.”

When a form is re-submitted in response to a request for modifications by the REB or CTO the Provincial Applicant/Principal Investigator or Delegate attestation will appear with the following additional language added:

“I confirm that I have obtained any authorizations as applicable to make changes to this application. If signing on behalf of the Principal Investigator/Provincial Applicant, I attest that the delegation of this responsibility has been documented.”

4) Removal of Implementation of Provincial Amendment (IPA) Form*

Due to the changes being made with this update, the IPA form is being retired. When a Provincial Amendment involving changes to the participant consent/assent materials is approved, sites must use the Centre Amendment Form (CAM) to submit their revised site-specific consent/assent changes to the REB of Record*. A question has been added to the CAM to specify if the form is being submitted in response to an approved PAM.

*Not applicable to studies reviewed by OCREB

5) Important - Mandatory Update for All Projects in CTO Stream

After the update goes live CTO will be releasing an updated set of forms on February 18th. It will be mandatory for ALL projects to be updated to the latest version of our application forms (Version 20).

Project Owners will be given one work week to update their studies in CTO Stream, it is mandatory that all projects be updated. As of end of day 5:00 pm EST Friday, February 22nd, CTO Stream will not accept submissions for projects that are using older versions of the forms. A second reminder will be sent to all Project Owners before the update goes live.

Note: Updating a project will invalidate signatures/signature requests on unsubmitted forms.

If your project is using an older version of the forms, the following message will appear at the top of the screen:

Note: There is a newer version of the project. (Please contact the project owner to update this form).

The Project Owner is the only user with permissions to update the forms for a given study. You can find out who the Project Owner is for your study by clicking on the 'Collaborators tab' with any form highlighted in the project tree.

Project Tree ▾

- Scott's Study
 - Clinical Trial Provincial Initial Application
 - Centre Initial Application

Form Status	Review Reference	Date Modified
Not Submitted	N/A	18/Dec/2018 14:48

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Collaborators

Name	Access	Edit Permissions
Mr. Scott Tomlinson	Read, Write, Submit, Share, Create all sub forms, Receive notifications	Edit Permissions
Mr. Craig Proulx	Read, Write, Share, Create all sub forms, Receive notifications	Edit Permissions
Ms. Ranuka Srinivasan	Read, Write, Share, Create all sub forms, Receive notifications	Edit Permissions
Ms. Lynn Nowoselski	Read, Write, Share, Create all sub forms, Receive notifications	Edit Permissions
Dr. Provincial Applicant	Project Owner and Form Owner	Edit Permissions

A user manual with instructions for updating a study is located here:
<http://apply.ctostream.ca/Personalisation/DownloadTemplate/29>

If you are unable to reach the Project Owner or they have left the study, please contact CTO Stream Help Desk at streamline@ctontario.ca.

Please feel free to contact CTO with any questions or feedback.

Streamline@ctontario.ca
 1-877-715-2700