

CTO Stream

Tips for Advanced Users

This guide provides additional tips and suggestions to help navigate and manage CTO Stream submissions.

CTO Informed Consent Form (ICF) Templates

When creating the Provincial ICF(s), Provincial Applicant teams **must** use the CTO Informed Consent Form Template. The CTO templates have been accepted by all the CTO Qualified REBs and facilitate the review process for studies submitted through CTO Stream. The template can be found on the CTO Website at:

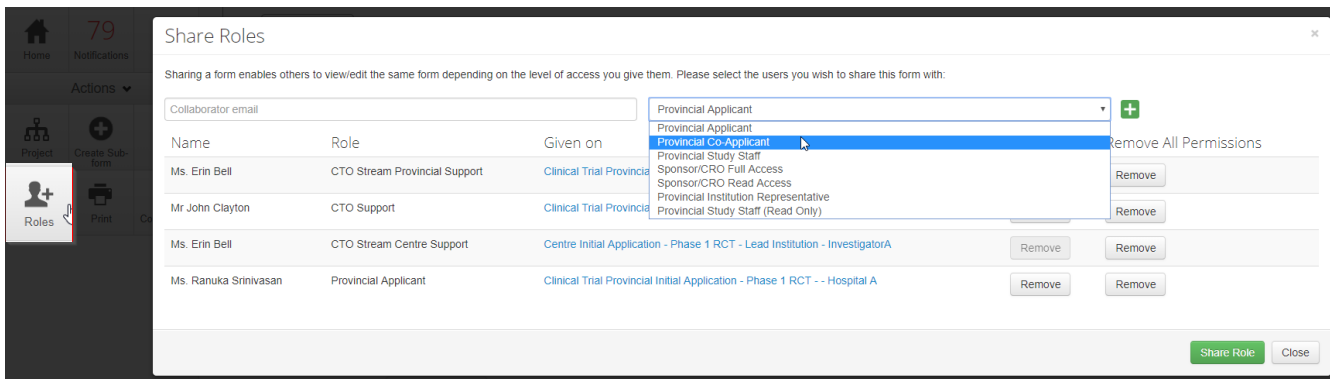
<http://www.ctontario.ca/streamlined-research-ethics-review-system/cto-stream/cto-stream-overview/>

(Note – this is not applicable to OCREB studies)

Co-Investigator/ Provincial Co-Applicant

Listing a Co-Investigator (or Provincial Co-Applicant) on the application forms is optional. Including their name on the form does not give automatic access to the study in CTO Stream, nor will they be listed in the REB approval letters. If a Co-Investigator/Co-Applicant is listed in the form they must also sign-off on the application prior to submission.

Any number of Co-Investigator(s)/Co-Applicants can be given access to the study simply by assigning them a Role using the Roles button.



[CTO Online Helpdesk – support.ctontario.ca](http://support.ctontario.ca)


Abbreviations:

CA – Centre Applicant	PAM – Provincial Amendment Form
CIA-Centre Initial Application	PI – Principal Investigator
PA – Provincial Applicant	PIA – Provincial Initial Application

Naming Documents

The Document Name, Version Date and Version will appear in the REB approval letter exactly as displayed in CTO Stream.

When uploading documents in CTO Stream, the Document Name automatically defaults to the File Name of your document. The Document Name can be changed by users when the document is uploaded. Changing the Document name in CTO Stream does not change the File Name. Document Name (and version date/version) should match the what is written on the document, as this is what will appear in the REB approval letter.

2.18.2 *Please indicate which of the following document(s) were submitted to Health Canada for the product(s) covered under the Clinical Trial Application (CTA) (select all that apply)? 

Investigator Brochure (IB)
 Product Monograph (PM)

*Please upload Investigator Brochure (IB):

Type	Document Name	File Name	Version Date	Version	Size	View	Delete
Investigator Brochure	IB (Drug 123)	IB for CTO Test.docx	03-Jan-2018	1.1	11.5 KB	Download	Delete

Centre Initial Applications

The Centre Initial Applications (CIA) can be created (but not submitted) as soon as the Provincial Initial Application (PIA) has been created. Creating the CIA form ensures institution representatives get early access to documents and information in CTO Stream and can facilitate any local review processes.

Centre Name

To view the name of the research site as it will appear on all REB approval letters, click on the Centre tab of your CIA (below the Project Tree). If the Centre listed here is incorrect, users can change it before submitting the application by clicking on *+ Change Centre*.

Users should check this tab before working on the CIA to verify the site name (as it will appear in the REB approval letters). It is especially important for users with a provincial role to check the centre name to ensure they are working on the CIA for their own site, as they have the ability to view the CIA for each participating site.

Tip: Members of the Provincial Applicant team who are assigning Roles to staff at other sites will want to check the Centre tab to ensure they assign the Role on the correct CIA. For example, if you are assigning a Centre Study Staff role to someone from Mt. Sinai Hospital, ensure that you have selected the CIA for Mt. Sinai Hospital by checking the Centre tab. The name of the centre does not appear in the Project Tree until the PI's Organization name has been entered in section 1 of the CIA. When planning to create multiple CIAs, users may want to type in the PI organization

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name before creating the next one, so they can be distinguished in the Project Tree. The local research staff can update the PI organization name as they fill out the application.

Project Tree ▾

- Example Study Title
 - Clinical Trial Provincial Initial Application - Example Study Title -- Lead Organization
 - Centre Initial Application - Example Study Title --

Form Status	Review Reference	Date Modified
Not Submitted	N/A	08-Mar-2018 15:13

Navigation Documents Signatures Collaborators Submissions Correspondence **Centre** History

Centre + Change Centre

Centre Name	Status	Expiry Date
Test Centre	Pending	

Checking the Status of an Application Form

Users can quickly check the status of any form by highlighting the form in the Project Tree and scrolling down to the Form Status row below the Project Tree.

Project Tree ▾

- Short Title 2
 - Clinical Trial Provincial Initial Application - Short Title 2 -- PA Organization
 - Centre Initial Application - Short Title 2 --

Form Status	Review Reference	Date Modified
Submitted by Applicant	1249-PIA-Jan/2018-1308	12-Jan-2018 14:40

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

Project Documents Tab

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- | | |
|--------------------------------|--------------------------------------|
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Users can quickly view and access all the current, REB approved/acknowledged study documents through the Project Documents tab. To access this tab, click on the Short Study Title at the very top of the Project Tree OR click on the Project button in the Actions toolbar.



This view allows users to easily access the current REB approved documents (Provincial and Centre) without having to navigate through individual applications in the Project Tree. The Project Documents tab includes a search bar and each column can be sorted to help users find relevant documents.

Document Name	Document Date	Document Version	Document Category	Download Submission	Centre Name
Consent Form- clean	12-Feb-2018	1	Approved	Download	Provincial
DSMC Report	12-Feb-2018	1	Acknowledged	Download	Provincial
IB for CTO Test	15-Feb-2018		Acknowledged	Download	Provincial
Investigator Brochure	12-Feb-2018	1	Acknowledged	Download	Provincial

Displaying Amendment Identifiers/Reference Numbers in the Project Tree

To make it easier to identify an amendment in the Project Tree, users may enter an amendment reference number/ID when filling out the Provincial Amendment Form (PAM) form (question 2.5 of the Clinical Trial PAM or 2.4 of the Observational PAM).

Signature Request Reminders

CTO Stream does not send out reminders for a pending signature request, however users can cancel and then re-request a signature which will send a new email notification to that individual. Please note, only the person who requested the original signature can cancel their signature request.

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Translated Materials – Provincial vs. Centre level submissions

If the translated materials are study-wide documents meant to be used by any site, they should be submitted by the Provincial Applicant (on the appropriate form, PIA or PAM).

If the translated material is a site-specific document (a site-specific, translated ICF for example), this should be submitted by the Centre Applicant (on the appropriate form, CIA or CAM).

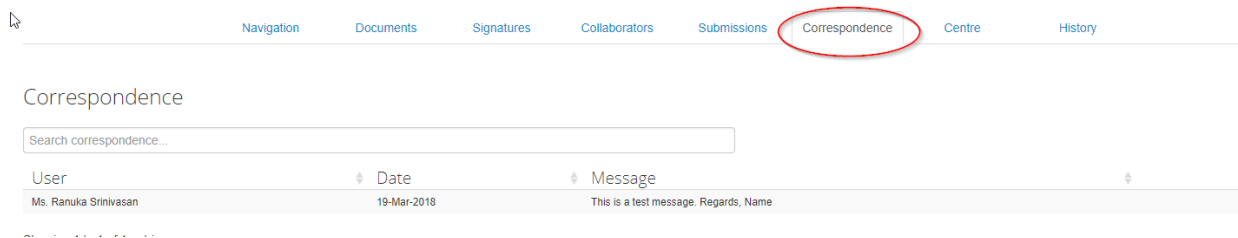
Contacting the REB

Users can contact the REB through CTO Stream for questions by highlighting the application in the Project Tree and sending a Correspondence message using the Correspond button in the Actions toolbar.



Users can attach a document (if applicable) and the correspondence messages will be visible through the Correspondence tab.

Note: The Correspond button cannot be used to upload documents for REB approval.



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