



**CTO Stream**  
Tips for Advanced Users

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

**CTO Informed Consent Form (ICF) Templates**

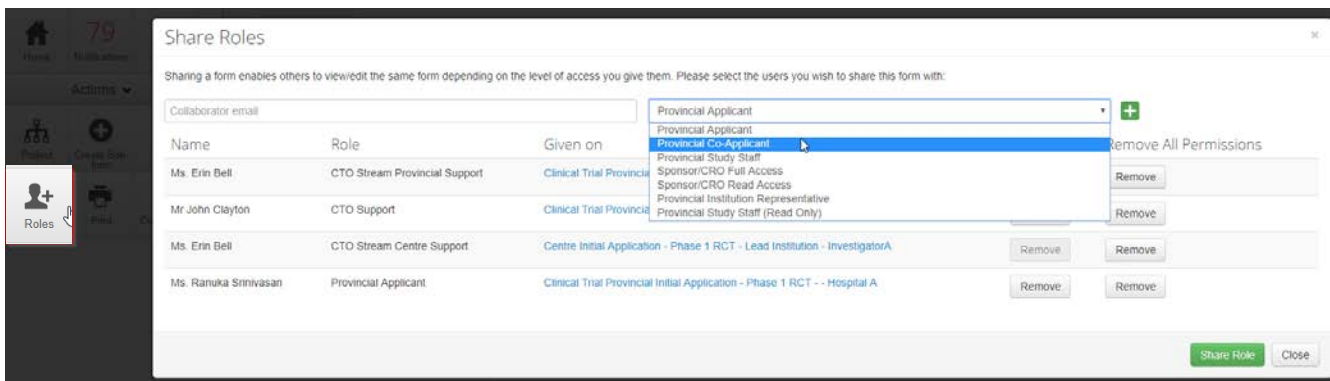
When creating the Provincial ICF(s), Provincial Applicant teams **must** use the CTO Informed Consent Form Template. The CTO templates have been accepted by all the CTO Qualified REBs and facilitate the review process for studies submitted through CTO Stream. The template can be found on the CTO Website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

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

**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.

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



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**Abbreviations:**

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

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)? i

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	<a href="#">Download</a>	<a href="#">Delete</a>

## 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 should 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 the CIA for their own site, as they can see 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.

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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

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[Submissions](#)
[Correspondence](#)
Centre
[History](#)

Centre + Change Centre

Centre Name	Status	Expiry Date
<span style="border: 1px solid red; border-radius: 50%; padding: 2px;">Test Centre</span>	Pending	

### Research Site Name in the Project Tree

The name of the research site will appear in the Project Tree when the site PI’s organization is typed into the CIA. The Project Tree will remain blank until this information is entered. We encourage users to enter this information as soon as they get access to the CIA. If you see multiple CIAs in the Project Tree and cannot tell which site they belong to, simply highlight the CIA in the Project Tree, click on the Centre tab, and the Centre name can be viewed.

### 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

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**Abbreviations:**

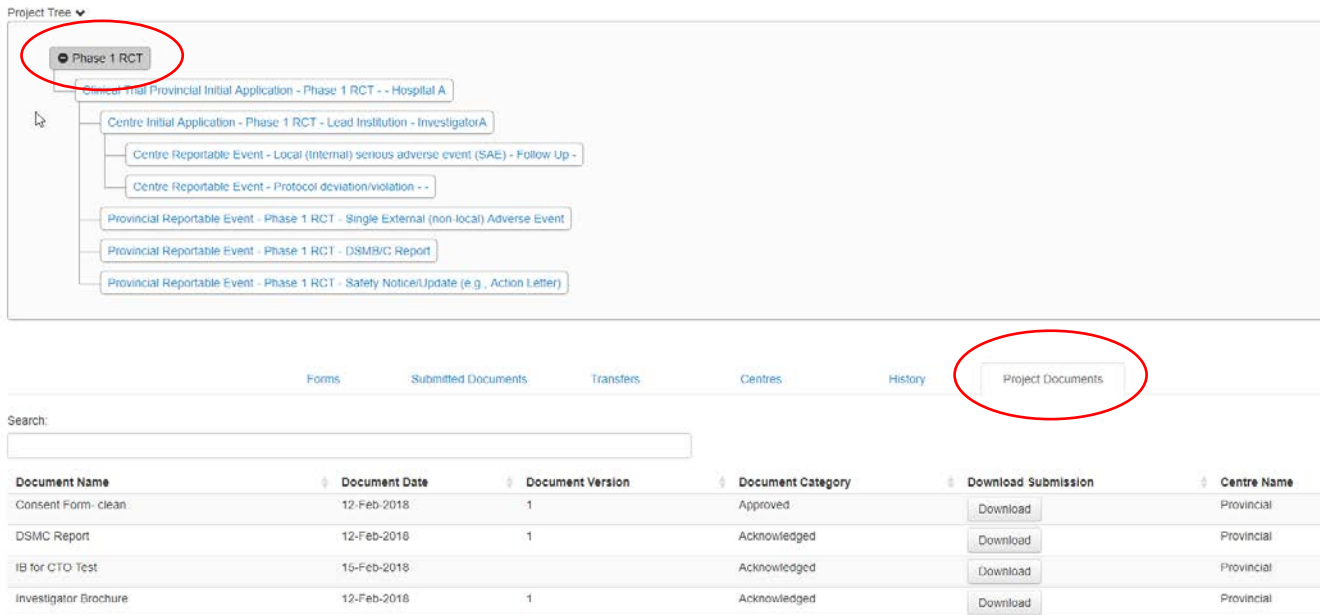
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## Project Documents Tab

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	<a href="#">Download</a>	Provincial
DSMC Report	12-Feb-2018	1	Acknowledged	<a href="#">Download</a>	Provincial
IB for CTO Test	16-Feb-2018		Acknowledged	<a href="#">Download</a>	Provincial
Investigator Brochure	12-Feb-2018	1	Acknowledged	<a href="#">Download</a>	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.

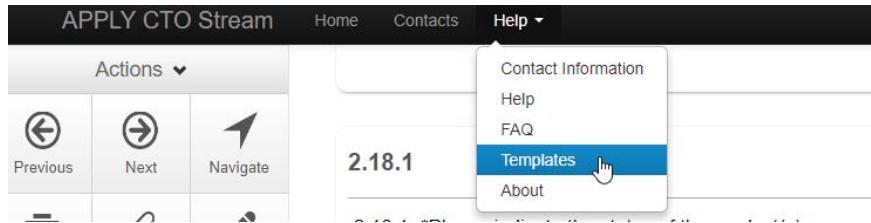
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## CTO Stream User Guides

User guides can be accessed through the CTO Website or directly through the Help Menu bar in CTO Stream, under Templates.



## 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).

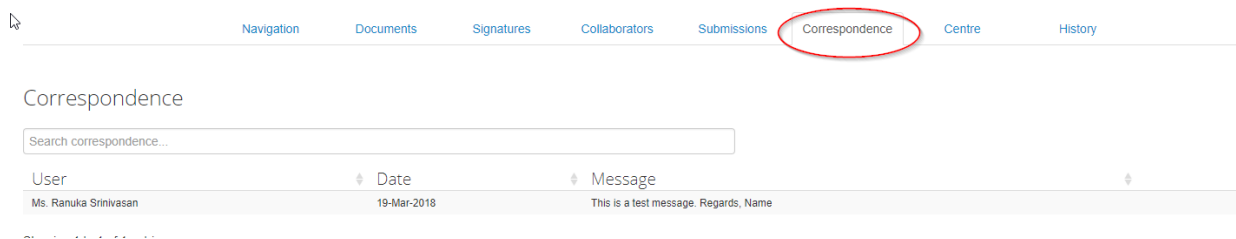
## Contacting the REB

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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