Application Features

CTO Helpdesk:
support.ctontario.ca

1. Contents

1. Project Tree Page

All application forms in the project have the following information displayed when selected in the project tree:

- **Action Required** – Indicates whether any mandatory questions on the form still need to be completed.
- **Form Status** – The current status of the submitted form within the REB review process.
- **Review Reference** – Each form receives a Review Reference once it is submitted to the REB. If the form has not yet been submitted, this will show as "N/A".
- **Date Modified** - The last date the form was edited.

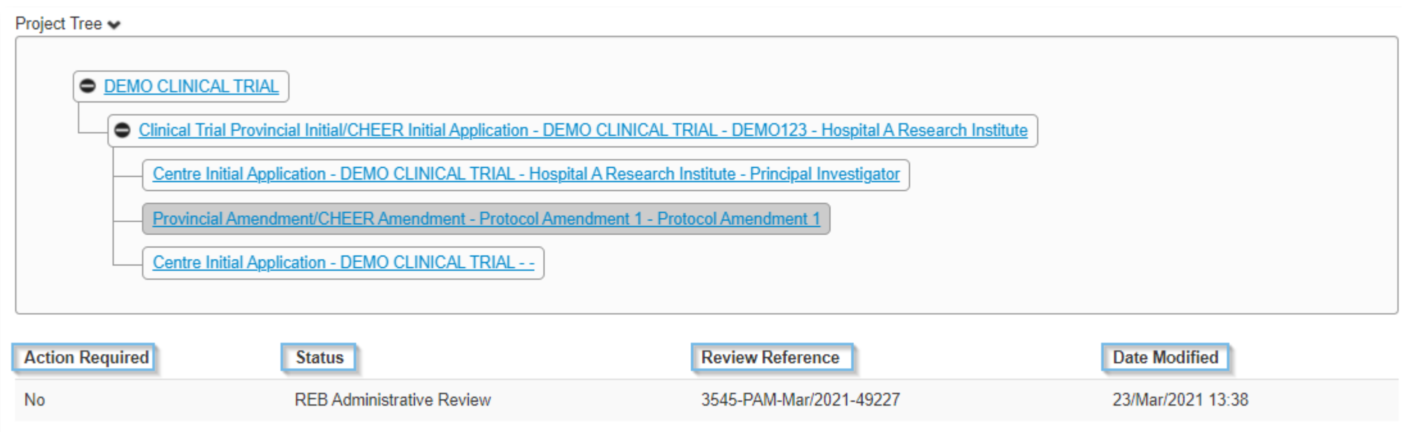


Figure 1.1 – Form Status Bar

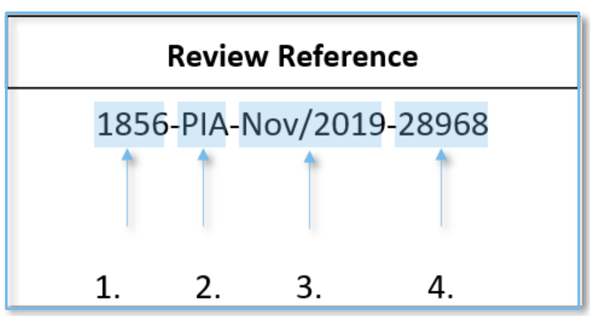


Figure 1.2 – Review Reference Number

1. Project ID number for study in CTO Stream
2. The three-letter designations for our clinical trial application forms* (definitions below):

PIA – Provincial Initial Application
CIA – Centre Initial Application
PAM – Provincial Amendment Form
CAM – Centre Amendment Form
PRE – Provincial Reportable Event
CRE – Centre Reportable Event
PCR – Provincial Continuing Review Form
CRE – Centre Continuing Review Form
PSC – Provincial Study Closure
CSC – Centre Study Closure

Note: Observational application forms have the same three letter codes, but with an "O" added to the beginning as a prefix (i.e., OPIA – Observational Provincial Initial Application).

3. The date the form was submitted to the REB
4. This is a unique, sequential numeric identifier for each form submission. This number allows you to directly communicate with the REB about a specific form submission

2. Actions Menu from the Project Tree Page

The **'Actions Menu'** (*Figure 2.0*) displays the various actions that can be performed in CTO Stream with each action represented by a unique icon. The menu is 'dynamic', meaning the buttons appearing at any given point in time may change, depending which page is currently open (Work Area, Project Tree, etc.). *Figure 2.0* shows what action buttons are visible while on the Project Tree Page. This section describes the function of each action button.

The buttons displayed in the Action Menu change depending which page is currently open

Figure 2.0 - The Action Menu on the Project Tree Page

Table 1.0

Action Name	Description
Project	Takes user to the Project Overview page. *(Refer to the Project Overview Guide for more information).*
Create Sub-form	Can be used to create a CIA and/or centre post-approval applications
Roles	Can be used to give a user access to the PIA or CIA of an existing project. Can use to remove a user's access, or to view the list of users that have been given a role.
Completeness Checker	Can be used on a form at any time to see which mandatory questions have not been completed.
Automatic Submission	Can be used to disable/enable Automatic Submission for a specific form within a project. Enabled on all forms by default.
Print	Generates PDF of the current application form which can be downloaded. It may take a few minutes to generate a PDF of larger application forms in the system (i.e., PIA).
Correspond	Once the REB of Record has been selected for the study, this feature allows members of the research team to send a message directly to the REB of Record.

2.1. Roles

The 'Roles' button is used to grant other individuals of the research team access to a project. Once a user is assigned a role, they gain access to all existing application forms in the project any forms created in the future. There are two types of roles that a user can receive:

1. **Provincial-level roles:** Granted on the PIA for the study. Gives access to all application forms that have already been created, PLUS all forms created in the future for this study.
2. **Centre-level roles:** Granted on the CIA for a participating site. Gives access to all existing & future forms for this site, PLUS read-only access to all current & future provincial forms.

Click the 'Roles' button and a pop-up window appears where the email address of the user being given the role can be typed into the 'Collaborator Email' field. Select the type of role to give (Provincial Study Staff, Sponsor, etc.) from the drop-down menu (*Figure 2.1*).

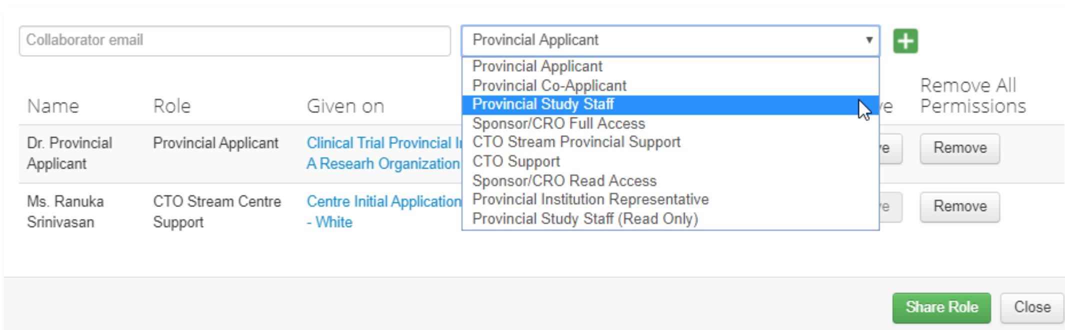


Figure 2.1 – Provincial roles drop-down

When entering the user's email, ensure to use the email associated with their CTO Stream account. If the individual does not have an account a message will appear saying, "User does not exist on the system" when the 'Share Role' button is pressed. A green 'Invite' button will also appear *(Figure 2.2)*, which can be used to send an email with a link to the CTO Stream account registration page where they can self-register for a CTO Stream account (email comes from 'donotreply@infonetica.net'). Please check your spam folder to ensure it has not been misclassified as spam. For more information about using roles, see the *Adding new study team members using Roles* Quick Guide on the CTO website.

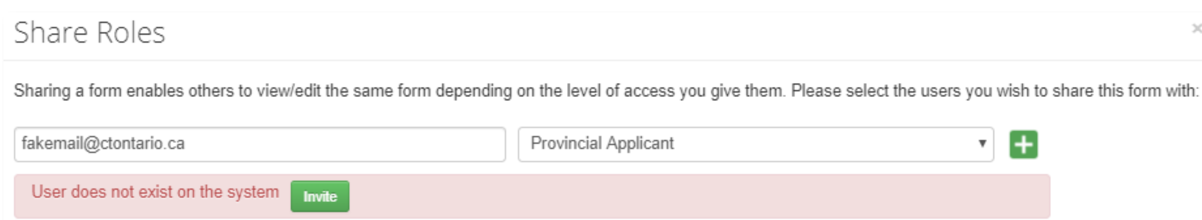
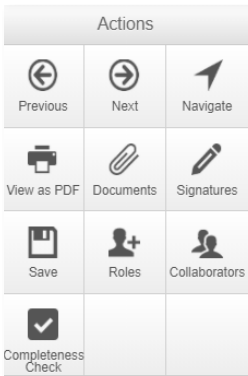


Figure 2.2 – Invalid collaborator email

3. Actions Menu – Inside the Application

This section describes the Action buttons available in the "Action Menu" when inside an application form. The buttons in the menu (*Figure 3.0*) appear the same, regardless of the type of application being worked on. Some of the buttons (i.e., Documents, Signatures, etc.) have a corresponding area or 'Tab' which serves the same purpose and is accessible from the Project Tree page.



The Action Menu as it appears from within a section of any application form

Figure 3.0 – Action Menu inside form

3.1. Previous/Next

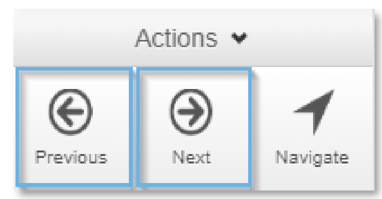


Figure 3.1

The buttons in the Actions Menu shown in *Figure 3.0* are visible from within any section of an application form. Click on **'Next'** or **'Previous'** *(Figure 3.1)* to view subsequent or preceding section, respectively. **Note: all work done on the current section is automatically be saved when 'Next' or 'Previous' is used.**

3.2. Navigate

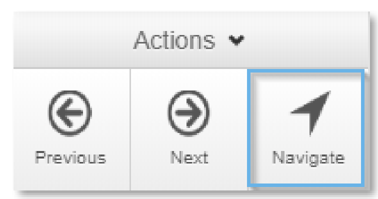


Figure 3.2

Clicking the 'Navigate' button (*Figure 3.2*) takes you back to the Navigation tab (*Figure 3.2.1*) on the Project Tree page. This tab acts as a 'table of contents' for the application, listing the name and number of each section and the number of questions contained within. **Note: The Navigate button also saves all work that has been done on the application up to that point.**

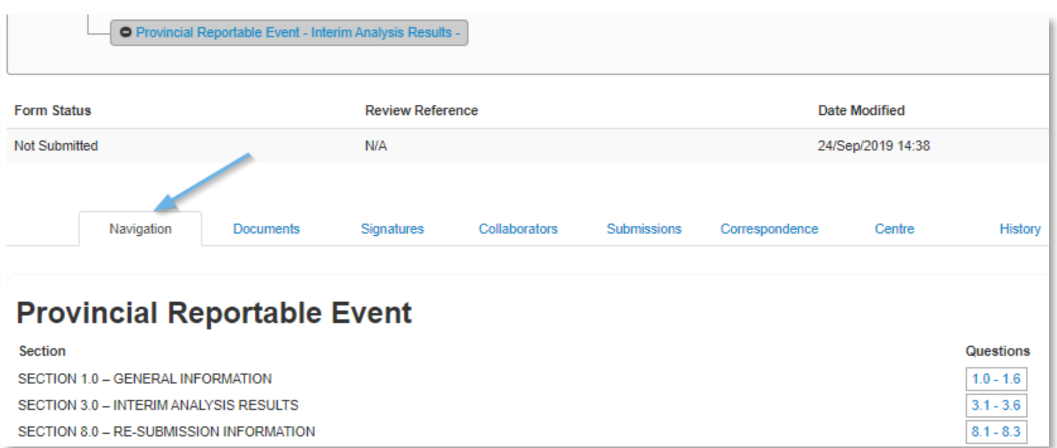


Figure 3.2.1 – Navigation tab

3.3. Documents

The ‘Documents’ button (*Figure 3.3a*) allows users to download or view any document uploaded to the current form, via several methods.

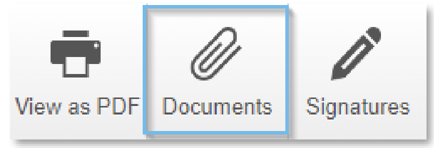
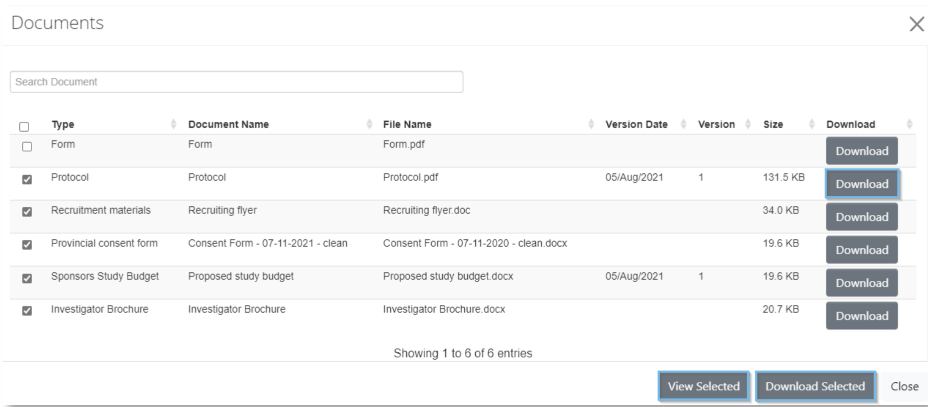


Figure 3.3

a) To download the document in the same file format it was uploaded in (i.e., PDF, MS Word, etc.), click the ‘Download’ button at the far-right side of the window in row of the desired document.

b) Alternatively, you can use the checkboxes in the far-left column to select the desired documents, then click ‘View Selected’ at the bottom of the window to view the documents in a PDF within a new browser tab or click ‘Download Selected’ to download a ZIP folder containing the documents (*Figure 3.3.1*). To view or download the submitted application form, check off the checkbox for the document with filename “Form.pdf”.



Documents

Search Document

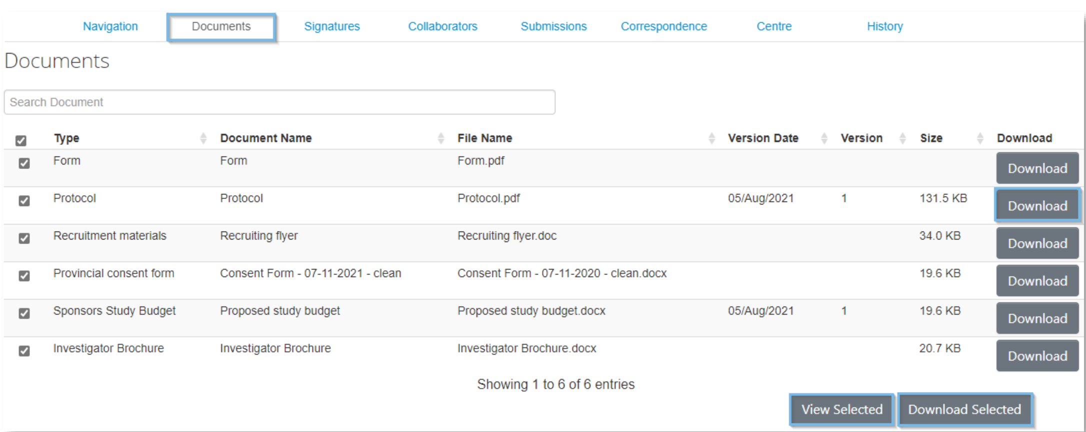
	Type	Document Name	File Name	Version Date	Version	Size	Download
	Form	Form	Form.pdf				Download
	Protocol	Protocol	Protocol.pdf	05/Aug/2021	1	131.5 KB	Download
	Recruitment materials	Recruiting flyer	Recruiting flyer.doc			34.0 KB	Download
	Provincial consent form	Consent Form - 07-11-2021 - clean	Consent Form - 07-11-2020 - clean.docx			19.6 KB	Download
	Sponsors Study Budget	Proposed study budget	Proposed study budget.docx	05/Aug/2021	1	19.6 KB	Download
	Investigator Brochure	Investigator Brochure	Investigator Brochure.docx			20.7 KB	Download

Showing 1 to 6 of 6 entries

View Selected | Download Selected | Close

Figure 3.4.1 – Documents pop-up window

It is also possible to view and/or download any form documents by clicking on the Documents tab with the form selected in the project tree (*Figure 3.3.2*). The same list of documents uploaded to form can be found here, along with the related information shown in Table 1.1.



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

Documents

Search Document

	Type	Document Name	File Name	Version Date	Version	Size	Download
	Form	Form	Form.pdf				Download
	Protocol	Protocol	Protocol.pdf	05/Aug/2021	1	131.5 KB	Download
	Recruitment materials	Recruiting flyer	Recruiting flyer.doc			34.0 KB	Download
	Provincial consent form	Consent Form - 07-11-2021 - clean	Consent Form - 07-11-2020 - clean.docx			19.6 KB	Download
	Sponsors Study Budget	Proposed study budget	Proposed study budget.docx	05/Aug/2021	1	19.6 KB	Download
	Investigator Brochure	Investigator Brochure	Investigator Brochure.docx			20.7 KB	Download

Showing 1 to 6 of 6 entries

View Selected | Download Selected

Figure 3.3.2 – Documents tab

Table 1.1

Documents Tab	
Tab Description	**Available Information**
Displays the documents uploaded to the selected application	**Type** – displays the type of document **Document Name** – displays the name of the document as inputted by the user **File Name** – displays the file name of the document **Date** – displays the version date of the document (if applicable) **Version** – displays the version number of the document (if applicable) **Size** – displays the file size of the document

3.4. Collaborators

To view the complete list of all users with access to the current form (including the Project Owner[1] and Form Owner[2]):

a) clicking the **'Collaborators'** button from within any section of the form *(Figure 3.4)*

b) by clicking the Collaborators tab *(Figure 3.4.1)* while on the project tree page, with the specific form highlighted in the project tree.

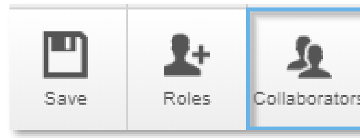


Figure 3.4

[1] **Project Owner**: the user who created the study in CTO Stream or had ownership of the study transferred to them.

[2] **Form Owner**: the user who created the application form within the project or had form ownership transferred to them.

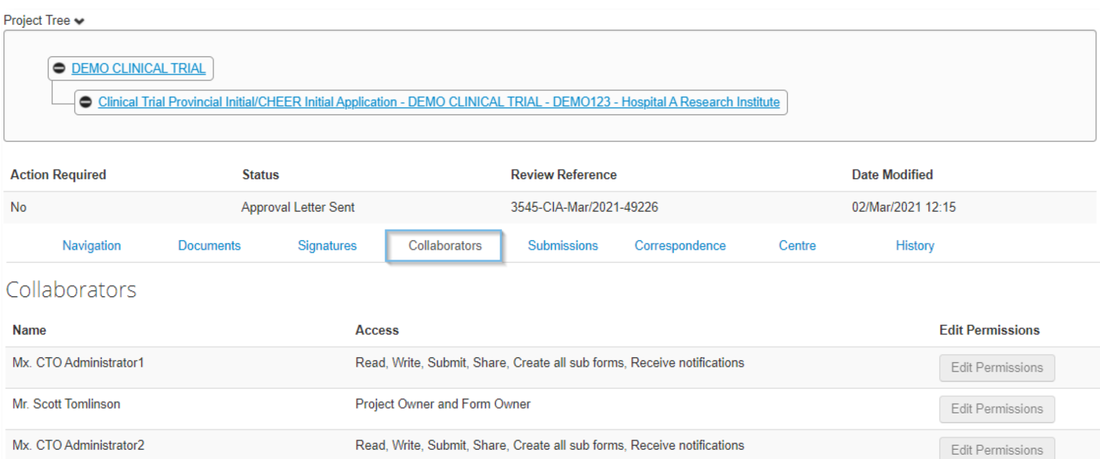


Figure 3.4.1 – Collaborators tab

3.5. Submissions

Each time an application form is submitted, a record of the submission is added under the Submissions tab for the form (*Figure 3.5)*. All submissions of the form can be downloaded to PDF format using the 'View as PDF' button in the right-most column. When a form is submitted to the REB multiple times, the previous submission of the form is automatically archived whenever a new version is submitted.

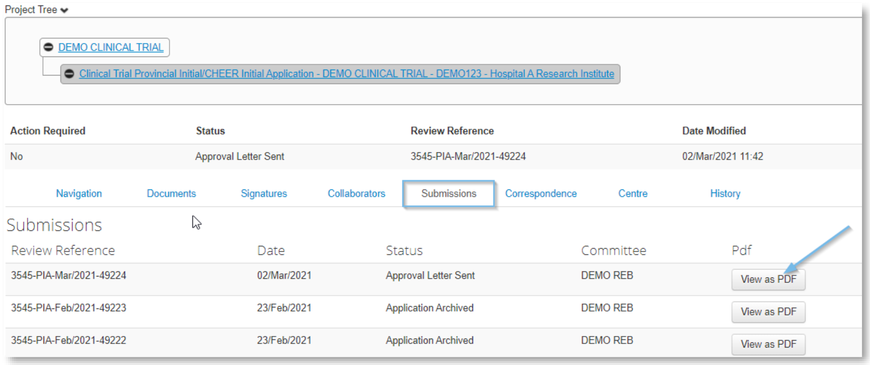


Figure 3.5 – Submissions tab

3.6. History tab

The History tab displays all previous events that have been recorded on the application, since it was created (i.e., signature requests, roles given, status changes, etc.). The events are listed in chronological order by default, but the table can be sorted by any column. Certain events will have an accompanying attachment *(Figure 3.6)* which can be downloaded in PDF format by pressing the 'Download' button in the column on the far-right.

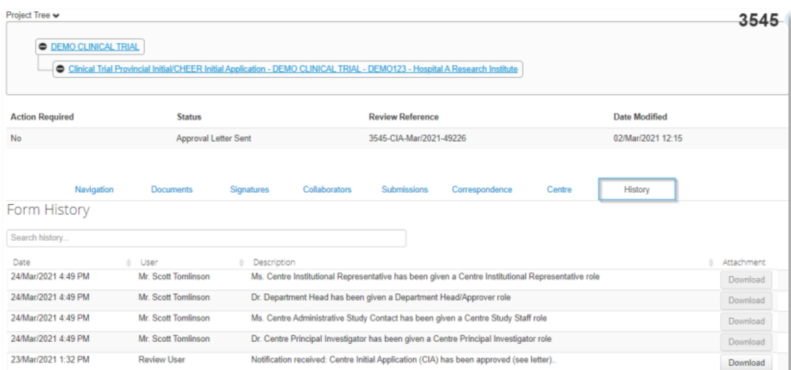


Figure 3.6 – History tab

3.7. Signatures

Each application must be signed electronically. To view a list of all current/previous signatures or signature requests for an application:

a) Press the 'Signatures' button (*Figure 3.7a*) from within any section of the form, or
b) Click on the 'Signatures' tab (*Figure 3.7b*) with the application selected in the project tree.

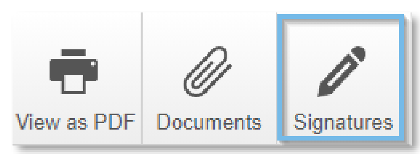


Figure 3.7a

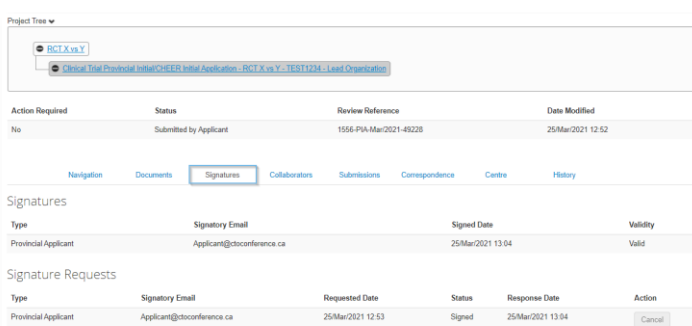


Figure 3.7b – Signatures tab

Table 1.3

Signatures Tab	
Description	**Available Information**
Displays current and previous signatures/signature requests on the form	**Type** – displays the role of the signatory (i.e., Principal Investigator, Department Head, etc.) **Signatory Email** – displays the email of the person who signed the form **Signed Date** – displays the date the person signed the form **Validity** - forms automatically become locked once a signature is applied, preventing any further changes from being made. The validity of all signatures initially appears as 'valid', however if the form is unlocked, any signatures/requests will become 'invalid' *(Figure 3.7c)*. Signatures will also display as invalid if the form is sent back for changes by the REB or CTO.

3.7.1. Signing a Form Directly

Users can apply their signature to the application from the final section of the form called "Agreement & Approval". This section is where electronic signatures are recorded for each person required to sign the form (i.e., Principal Investigator, Department Head, etc.).

Underneath each signature question is a blue 'Sign' button *(Figure 3.7.1)* which users can press to sign the form directly, without a signature request.

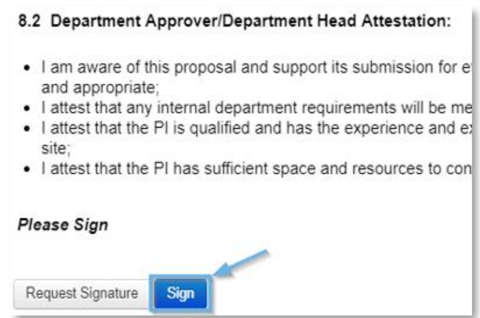


Figure 3.7.1

Click the 'Sign' button and a pop-up window will appear where the user can re-enter their username and password. Then press the green 'Sign' button at the bottom of the pop-up window to complete the signing process *(Figure 3.7.1.1)*.

Note: The button will not be available if the signature has already been requested.

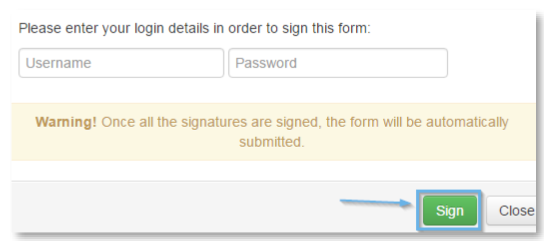


Figure 3.7.1.1

3.7.2. Requesting a Signature

If completing an application but not authorized to sign, use the 'Request Signature' button *(Figure 3.7.2)* to request the signature of the appropriate individual.

Figure 3.7.2

This will bring up a pop-up window (*Figure 3.7.2.1*) where the email address of the signature recipient can be entered along with an optional message. Click the 'Request' button to complete the signature request. For more information about requesting a signature, see the [Requesting Signatures (3:18)]() video tutorial or the [Responding to a Signature Request]() Quick Guide.

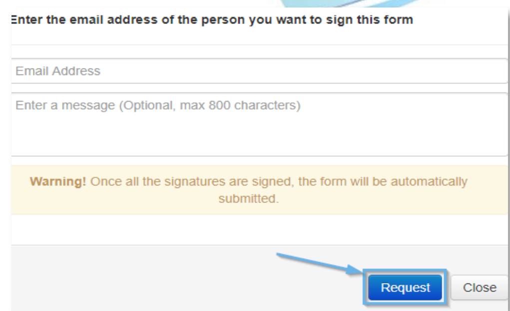


Figure 3.7.2.1

3.7.3. Signing a Form (responding to a signature request)

When a user's signature is requested on the form, an email notification (and an in-system notification) is automatically sent to the user. The email includes a link to the application in CTO Stream where the 'Sign' button *(Figure 3.7.3)* is visible under the Actions Menu. **Note: The 'Sign' button is also available in the Actions Menu while inside the application.** For more information on responding to a signature request, [Responding to a Signature Request (3:25)]() video tutorial or the [Responding to a Signature Request]() QuickGuide on the CTO website.

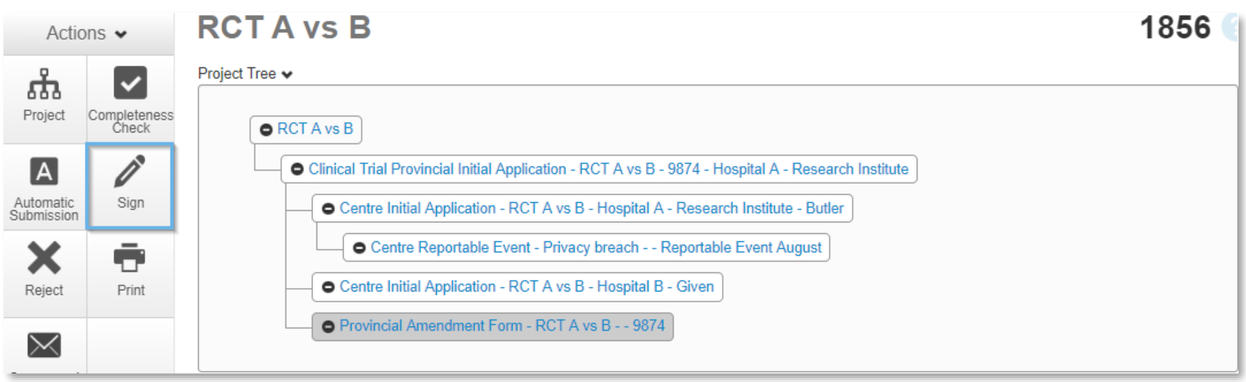


Figure 3.7.3 – Sign button

3.8. Rejecting a Signature Request

If required, a signature request can be **rejected** pressing the 'Reject' button instead (*Figure 3.7.3*). A pop-up window will appear where your CTO Stream login credentials and a reason for rejecting the signature request (*Figure 3.7.4.1*) are required to be provided. **Note: It is mandatory to provide a reason when rejecting a signature request.**

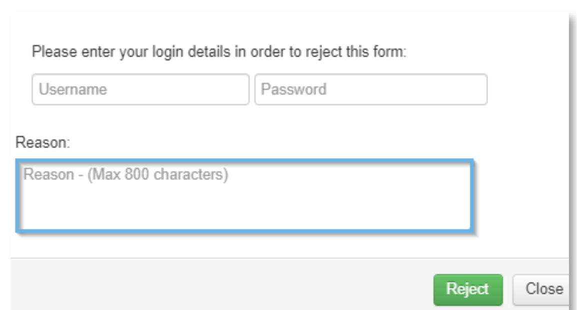


Figure 3.7.4.1 – Reject signature pop-up window

3.9. Submitting an Application

Application forms are automatically submitted to the REB once the final required signature has been applied to the form. **Note: An email notification is sent once the form has been successfully submitted.**

4. Completing an Application

4.1. Smart Questions

The application forms in CTO Stream use ‘smart’ forms, which means a response to one question causes later questions to become visible or remain hidden when not applicable. While working through a form, you may notice some questions or complete sections, are skipped. This is a result of the smart question functionality.

4.2. Panel Comments

Any user with access to form in CTO Stream can add their own ‘Panel’ comments. These comments will be visible to other any other members of the study with access to the form. They are NOT visible to the REB, even after the application has been submitted. To add a new panel comment, click on the speech bubble icon in the top right-hand corner of the any panel while inside any section of the form (*Figure 4.2*).

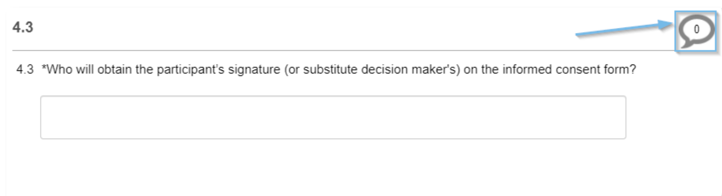


Figure 4.2

A pop-up window will appear displaying all the panel comments made previously (if there have been no comments a message will appear like in *Figure 4.2.1)*. To add a comment, press ‘+Add Comment’ then type your comment into the text box. Once finished press ‘Save’ and the comment will be recorded.

Figure 4.2.1- Panel comments pop-up window

4.3. Help Text

Some questions within CTO Stream have help text available, which helps to provide clarification of the question being asked. To view the help text, click on blue icon (*Figure 4.3*) and the help text will appear in a pop-up window (*Figure 4.3.1)* To close the help text, click anywhere outside the pop-up window.

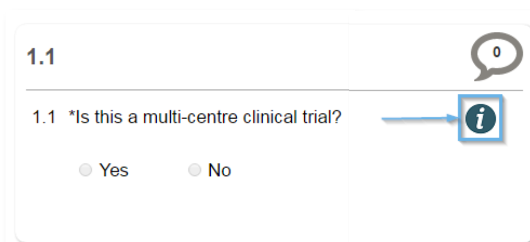


Figure 4.3

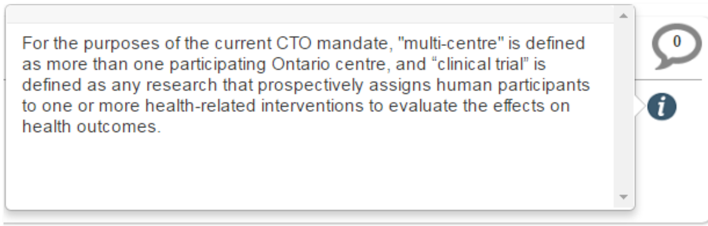


Figure 4.3.1 – Help text pop-up window

4.4. Mandatory Questions

All questions labeled with an asterisk (*) are mandatory questions and must be completed to sign and submit the application *(Figure 4.4)*.

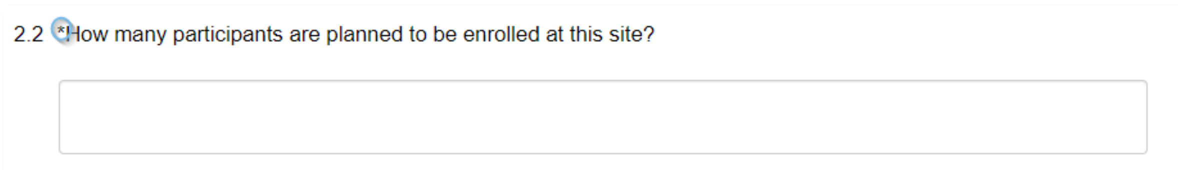


Figure 4.4 – Mandatory question icon

4.5. Document Upload Questions

To can upload documents to the application, click the blue 'Upload Document' button found on all document questions *(Figure 4.5)*. Then click 'Browse' in the pop-up window and locate the file to want to upload. All major file types are supported including word documents, excel documents, text files and PDFs (all files must be < 150 MB.

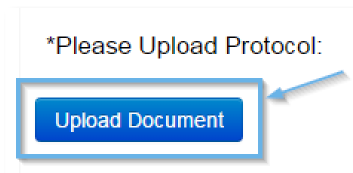


Figure 4.5

Enter a Document Date and Version (not mandatory), then complete the upload process by pressing the 'Upload' button (*Figure 4.5.1)*. All documents must be uploaded with a suitable name to aid the REB in identifying the document. The document name provided will be reflected in the REB approval letter. Multiple documents can be uploaded to document questions whenever necessary. **Note: All Product Monographs and Investigator Brochures should include the name of the drug in the document name. Do not add any underscores or special characters into the document name.**

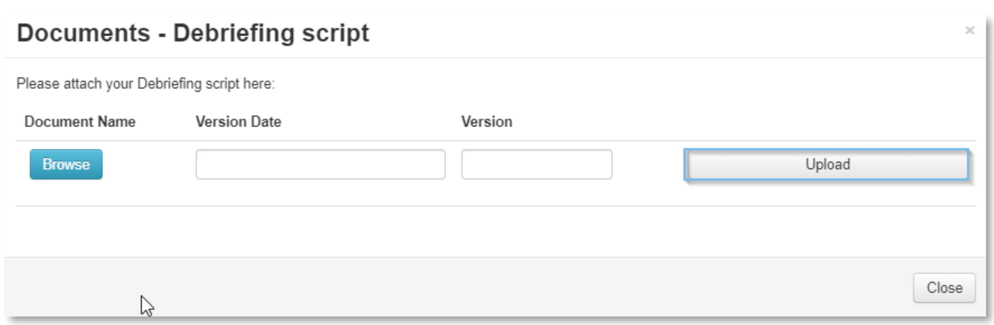


Figure 4.5.1 – Document upload pop-up window

4.6. Save

All data entered into the form can be saved at any time using the ‘Save’ button (*Figure 4.6*) in the Actions Menu (progress is also saved automatically by pressing ‘Next’, ‘Previous’ or ‘Navigate’).

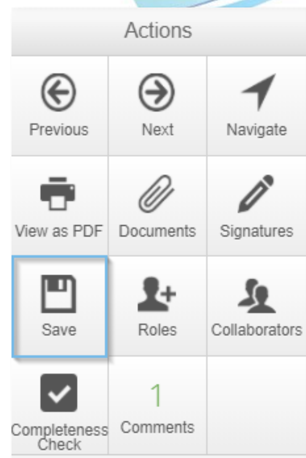


Figure 4.6