

CTO Stream – Centres, Status, Expiry Dates and Continuing Review

Table of Contents

Selecting the Centre.....	2
Study Status and Expiry Date	4
Centre Status and Expiry Date	5
Viewing Study Status, Centre Status and Expiry Dates.....	5
Continuing Review – Reminders and Process.....	6
Reminders	6
Lapse/Expiration	6
Reinstating Ethics Approval	6

CTO Helpdesk: 1 (877) 715-2700
streamline@ctontario.ca

Making Ontario a preferred location for Global Clinical Trials, while maintaining the highest ethical standards.

Prior to filling out a Centre Initial Application (CIA), the research team must select the applicable centre (where the research is being conducted and to which the approval will apply) from the new “Centres” tab.

If the research team should need to submit an Implementation of Provincial Amendment (IPA) form, the corresponding centre will need to be selected again. For all other forms (e.g., sub-forms of the CIA), the centre will automatically be selected and no additional action is required.

CTO Stream will not permit a form to be submitted if the centre has not been identified in the “Centre” tab.

Please contact CTO (877-715-2700 or streamline@ctontario.ca) if you do not see your centre listed amongst the options in the “centres” tab.

The Provincial Initial Application (PIA) will automatically default to the “Provincial” centre, and should not be changed by the research teams.

NOTE: The centre will be automatically updated for PIA, CIA and IPA submitted prior to the feature implementation date. Research teams will need to select the appropriate centre for CIA/IPA that have been created but not yet submitted and all new CIA forms prior to submitting to the REB of Record.

Selecting the Centre

As part of the process of creating a Centre Initial Application (CIA) and for any IPA form, the research team must select the applicable centre (where the research is being conducted and to which the approval will apply) from the new “Centre” tab.

1. Click the “Centre” tab from the Table of Contents view for the CIA/IPA.

RCT comparing A to B

Project Tree ▼

- RCT comparing A to B
 - Provincial Initial Application - RCT comparing A to B - CTO010101 - PA Organization
 - Centre Initial Application - RCT comparing A to B - -

Form Status	Review Reference	Date Modified
Not Submitted	N/A	17-May-2016 08:40

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

Click on the “Centre” tab from the Table of Contents view.

2. Click on the “+ Centres” button.

RCT comparing A to B

Project Tree ▼

- RCT comparing A to B
 - Provincial Initial Application - RCT comparing A to B - CTO010101 - PA Organization
 - Centre Initial Application - RCT comparing A to B - -

Form Status	Review Reference	Date Modified
Not Submitted	N/A	17-May-2016 08:40

Navigation Documents Signatures Collaborators Submissions Correspondence Centre History

Centre + Centre ← Click on the “+ Centre” button

Note: You do not have a centre assigned to this form.

3. Select the appropriate centre from the drop-down menu. Once selected, press the green “Save” button.

Select the appropriate centre from the drop-down menu

Once selected, press the green “Save” button

4. Once completed, the site name will be displayed, along with the [centre status](#) and [expiry date](#).

Project Tree ▼

- RCT comparing A to B
 - Provincial Initial Application - RCT comparing A to B - CTO010101 - PA Organization
 - Centre Initial Application - RCT comparing A to B - -

Form Status	Review Reference	Date Modified
Not Submitted	N/A	17-May-2016 08:40

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

Centre + Change Centre

Centre Name	Status	Expiry Date
Sunnybrook	Pending	

The site to which the CIA belongs is indicated in the “Centre” tab, along with the status and ethics approval expiry date (updated following initial ethics approval)

Please contact CTO (877-715-2700 or streamline@ctontario.ca) if you do not see your centre listed amongst the options in the “Centre” tab.

Study Status and Expiry Date

The ‘study status’ describes the status of the study at all participating Ontario centres. The ‘study expiry date’ is the ethics approval expiry date for the entire study, and is determined by the REB of Record at the time of initial approval and revised with each continuing review.

The study status and expiry date can be viewed in the Project View (see the [Viewing Study Status, Centre Status and Expiry Dates](#) section), and is displayed in the “Provincial” centre line.

When the PIA is created, and prior to initial REB approval, the study status will automatically be set to “Pending” and the expiry date will be blank.

Once the initial REB approval letter (e.g., the approval letter for the PIA) is sent for the study, the study status will automatically change to “Active” and the study-wide ethics approval expiry date will be displayed. The updated expiry date will be displayed when the REB approval letter is sent at the time of continuing review.

If there is a lapse in study-wide ethics approval (e.g., if the REB approval letter has not been sent for the Provincial Continuing Review form prior to the provincial ethics approval expiry date), the study status and the status of all research sites will automatically be updated to “Expired”.

Centre Status and Expiry Date

The ‘centre status’ describes the status of the study at a specific research site. Each research site’s ethics approval expiry date corresponds with the study-wide expiry date, regardless of when that site was initially approved to join the study. This means that a research site may be required to submit their first Centre Continuing Review form less than a year from when they received initial REB approval.

When a CIA is created, and prior to initial REB approval, the centre’s status will automatically be set to “Pending” and the expiry date will be blank.

Once the initial REB approval letter is sent for the research site (e.g., the approval letter for the CIA), the centre status will automatically set to “Active” and the expiry date will be displayed. The updated expiry date will be displayed when the REB approval letter is sent for each site’s continuing review.

If there is a lapse in the site’s ethics approval (e.g., if the REB approval letter has not been sent for the Centre Continuing Review form prior to the centre ethics approval expiry date), the site’s status will automatically be updated to “Expired”.

Viewing Study Status, Centre Status and Expiry Dates

Research teams can view the complete list of statuses and expiry dates for a study via the “Centres” tab in the Project View.

To access to Project View, click on the box containing the short study title in the project tree. Click on the “Centres” tab to view information about study/centre status and expiry dates.

Project Overview - RCT comparing A to B

Project Tree ▼

- RCT comparing A to B
- Provincial Initial Application - RCT comparing A to B - CTO010101 - PA Organization
- Centre: Initial Application - RCT comparing A to B - -

1. Access the Project View by clicking on the short study title in the project tree

2. Click on the “Centres” tab to see the study status and expiry date, along with a complete list of research sites, their status, and their expiry dates.

Forms Submitted Documents Transfers Centres History Project Documents

Centres

Search centre...

Centre Name	Status	Expiry Date	Contact
Sunnybrook	Pending		
Provincial	Active	16-May-2017	Dr. Provincial Applicant

Continuing Review – Reminders and Process

When a study's expiry date is coming up, the Provincial Continuing Review (PCR) form must be submitted by the Provincial Applicant (PA) team, and each research site must submit a Centre Continuing Review (CCR) form. Each research site is able to submit their own CCR form even if the PCR has not yet been submitted.

CTO asks that the PCR and the CCR be submitted by the submission deadline for the applicable full board meeting date so that the REB of Record will have access to all the centre information when reviewing the study-wide information. Please submit by the full board submission deadline even if you think that the application(s) will undergo delegated review.

Reminders

The PA and their main study contact are sent reminders 45 days prior to the provincial expiry date. Similarly, each research site's Principal Investigator (PI) and their main centre contact are sent a reminder 45 days prior to the centre's ethics expiry date (reminder: each site's expiry date is the same as the study-wide ethics expiry date). The PA/PI and main contact are also reminded to submit the PCR/CCR 30 days prior to expiry. These are courtesy reminders only, and the PA/PI are expected to submit the application on time regardless of whether they receive the reminder.

Lapse/Expiration

A lapse in ethics approval is considered to occur if the continuing ethics approval letter (provincial or centre, as applicable) has not been sent prior to the ethics approval expiry date.

If provincial ethics approval expires, ethics approval for all research sites is automatically considered to have expired as well.

The PA/PI and their main contact are automatically notified of a lapse in ethics approval. The Department Head and Institutional Representative are also automatically notified (among other recipients) if a lapse in ethics approval for a research site should occur. The PA/PI are instructed to cease all research-related activities, including the enrollment of new participants, when ethics approval is expired. They are also instructed to notify the REB of Record via the correspondence feature in CTO Stream if there is a need to continue the research intervention to ensure the rights, safety or well-being of participants enrolled prior to the lapse in approval.

If a lapse should occur, the study and/or centre status will automatically be updated to "Expired". See [Study Status](#) or [Centre Status](#) sections for further status information.

Reinstating Ethics Approval

To resolve a lapse in ethics approval, the PA/PI must submit a PCR/CCR form and the form must receive approval from the REB of Record.