

CTO **STREAM**

A graphic consisting of several overlapping, curved lines in shades of blue and green, flowing from the left towards the right, positioned below the 'CTO STREAM' text.

Ethics Approval Expiry Date, Status And Continuing Review

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



Table of Contents

Setting the Provincial Expiry Date.....	3
Study Status	6
Centre Expiry Date	7
Centre Status.....	8
Viewing Study Status, Centre Status and Expiry Dates.....	9
Continuing Review	10
Reminders	10
Lapse/Expiration	10
Reinstating Ethics Approval	11
Drafting the approval letter following a lapse	11



The REB of Record must [set the study-wide expiry date](#) in CTO Stream prior to sending the initial REB approval letter (associated with the Provincial Initial Application, or PIA) and again at the time of each provincial continuing review.

The ethics approval expiry date for each research site is automatically updated when the site’s initial REB approval letter (associated with the Centre Initial Application, or CIA) is sent, and also when the site’s REB approval letter is sent for the Centre Continuing Review application.

The provincial and centre ethics approval expiry dates and study/centre status can be viewed in the [“Centre” tab of the Project View](#).

Setting the Provincial Expiry Date

The provincial expiry date (the end date for the current study-wide ethics approval) must be set prior to sending the initial ethics approval letter (associated with the Provincial Initial Application), and at the time of each provincial continuing review.

To set the provincial expiry date:

1. Access the Project View by clicking on the hyperlink in the Project Title or Project ID (from the timeline view)

Project Title: [RCT comparing A to B](#)

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

Review Reference:

Access the Project View by clicking on the Project Title or Project Id

Project Id:	0904	Applicant Name:	Ms. Erin Bell
Current Committee:	Research Ethics Board	Current Status:	Pending BoR Acceptance
Application Type:	Provincial Initial Application	Meeting:	Unassigned
Clock Status:	Start (0/100) days elapsed.	Assigned Reviewers:	None
Conflicted Users:	None		

2. Click on the “Centres” tab

Project Title: RCT comparing A to B

Project Id: 904 Applicant Name: Ms. Erin Bell

Submissions Tree Documents Data Correspondence **Centres** History

Submissions

Search submissions...

Form Reference	Form name	Submission Date	Review Reference
Provincial Initial Application - RCT comparing A to B - CTO010101 - PA Organization	Provincial Initial Application	16-May-2016	0904-PIA-1

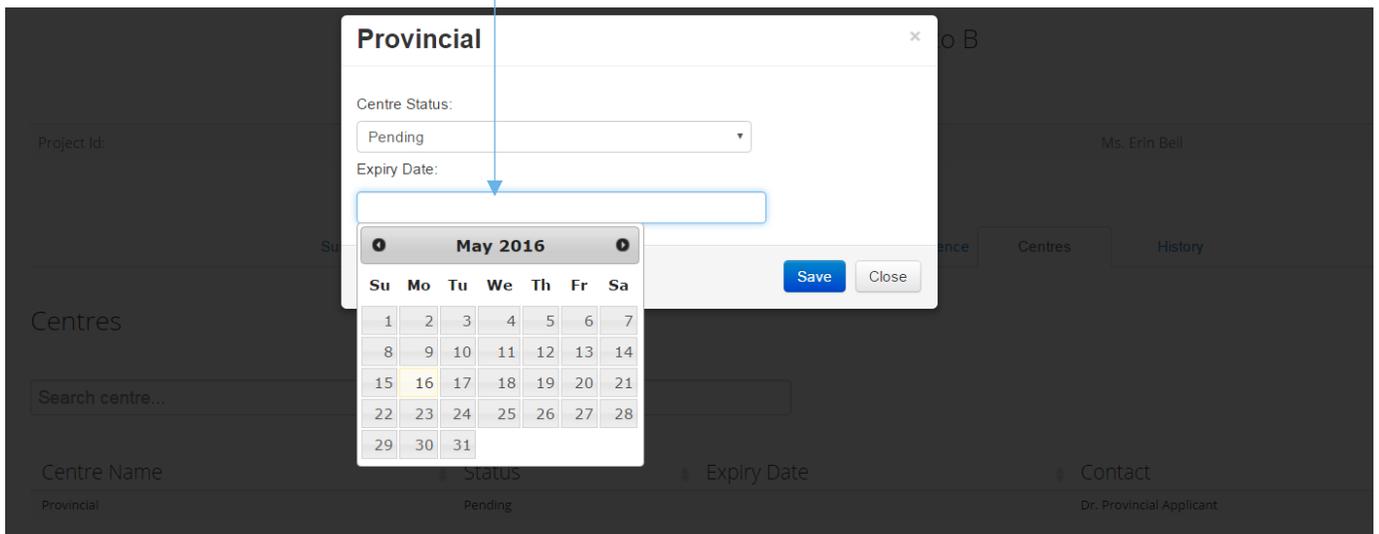
Click on the “Centres” tab

3. Click on the “Provincial” line, and enter the provincial ethics approval expiry date into the “Expiry Date” field in the pop-up window. The calendar will open to the current month/year, so be sure to advance the calendar to the correct expiry date

Do not change the “Centre Status” field; this should remain as “Pending”, as it will be automatically updated once the initial ethics approval letter is sent.

Enter the ethics approval expiry date into the “Expiry Date” field.

(The “Centre Status” field should not be changed and should remain “Pending”)



Provincial

Centre Status: Pending

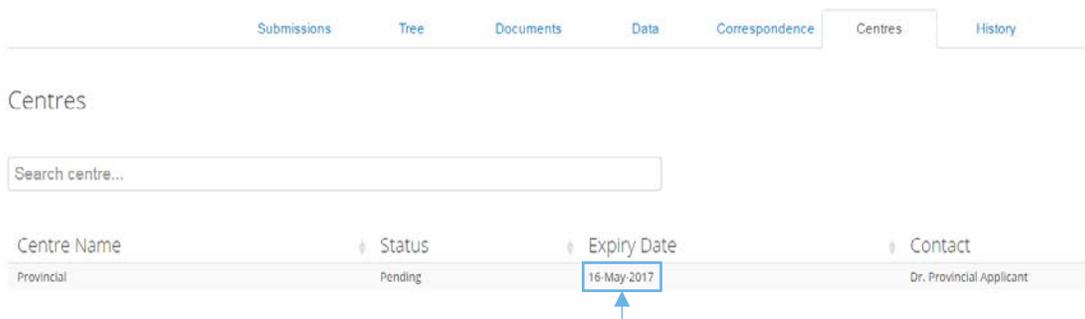
Expiry Date:

May 2016

Su	Mo	Tu	We	Th	Fr	Sa
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Save Close

4. Press the green “Save” button. Once saved, the pop-up window will disappear and the expiry date will be reflected



The screenshot shows the 'Centres' tab in the CTO Stream application. At the top, there are navigation tabs: Submissions, Tree, Documents, Data, Correspondence, Centres, and History. Below the tabs is a search bar labeled 'Search centre...'. Underneath the search bar is a table with the following columns: Centre Name, Status, Expiry Date, and Contact. The table contains one row with the following data: Provincial, Pending, 16-May-2017, and Dr. Provincial Applicant. The 'Expiry Date' cell is highlighted with a blue border, and a blue arrow points to it from below.

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

Once completed, the expiry date
will be reflected

5. To navigate back to the application you were working on, click on the “Submissions” tab (to the left of the “Centre” tab) and then select the application you were working on.

If the “Expiry Date” does not automatically appear in the REB approval letter, please follow the steps above to record the expiry date in CTO Stream.



Study Status

The 'study status' describes the status of the study at all participating Ontario centres. When the PIA is initially submitted, and prior to initial REB approval, the study status will automatically be set to "Pending".

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".

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 will automatically be updated to "Expired". More information on this can be found in the [Lapse/ Expiration](#) section.

If the study has been terminated (e.g., if the study has been completed, withdrawn, or otherwise permanently discontinued), the REB will need to change the status to "terminated". This manual will be amended to add more information about this, and other status, with the next version.

Please consult with CTO prior to manually changing a study status; all fully implemented status features are automatic. Manually changing a status may not result in full functionality.



Centre Expiry Date

Each research site's ethics approval expiry date corresponds with the overall study's 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.

If there is a lapse in ethics approval (e.g., if the approval letter has not been sent prior to the site's ethics approval expiry date), then the original (expired) expiry date will be displayed. This allows the REB and researchers to easily identify centres with expired ethics approval.

The expiry date will be automatically updated for each research site once the approval letter (e.g., the initial approval letter and any continuing ethics approval letter) is sent. There is no action required from the REB.

Each research site's status and expiry date can be viewed via the Project View, as described in steps 1-2 in the ["Setting Provincial Expiry Date"](#) section.



Centre Status

The 'centre status' describes the status of the study at a specific research site. When a CIA is initially created, and prior to initial REB approval, the centre's status will automatically be set to "Pending".

Once the initial REB approval letter is sent for the centre (e.g., the approval letter for the CIA), the centre status will automatically set to "Active".

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 centre's status will automatically be updated to "Expired". More information on this can be found in the [Lapse/Expiration](#) section.

If the centre has been terminated (e.g., if the study has been completed, withdrawn, or otherwise permanently discontinued at a research site), the REB will need to change the status to "terminated". This manual will be amended to add more information about this, and other status, with the next version.

Please consult with CTO prior to manually changing a centre status; all fully implemented status features are automatic. Manually changing a status may not result in full functionality.

Viewing Study Status, Centre Status and Expiry Dates

The REB of Record can view the complete list of statuses and expiry dates for the study and all research sites by accessing the “Centres” tab in the Project View (instructions in steps 1-2 of the [Setting the Provincial Expiry Date](#) section).

The REB of Record will also be able to see which research sites are working on their initial application before the application is submitted, as these will also appear in the list with a “Pending” [centre status](#).

Project Title: RCT comparing A to B

Project Id: 904 Applicant Name: Ms. Erin Bell

[Submissions](#) [Tree](#) [Documents](#) [Data](#) [Correspondence](#) **[Centres](#)** [History](#)

Centres

Search centre...

The “Centres” tab in the Project View lists the study status and expiry date (in the “Provincial” line) and each research site’s Status and Expiry Date

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

Continuing Review

When a study's expiry date is coming up, the REB of Record can expect to receive the Provincial Continuing Review (PCR) form from the PA, as well as a Centre Continuing Review (CCR) form for each research site. Each research site is able to submit their own CCR form even if the PCR has not yet been submitted.

Although the CCR will likely be reviewed via a delegated review mechanism (providing this is in accordance with the REB of Record's Standard Operating Procedures), CTO asks research teams to submit the PCR and the CCR 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.

Continuing ethics approval for each research site is dependent on the continuing ethics approval for the study overall. As a result, the PCR form must be approved before any CCR forms can be approved.

The REB of Record must review the PCR form, set the provincial expiry date, and issue the REB approval letter for the PCR prior to processing any Centre Continuing Review (CCR) applications.

Reminders

The Provincial Applicant (PA) and their main contact are sent reminders 45 days prior to the provincial expiry date, and asked to submit the PCR form prior to the submission deadline for the applicable REB meeting. Similarly, each research site's Principal Investigator (PI) and their main contact are sent a reminder 45 days prior to the ethics expiry date (reminder: each site's expiry date is the same as the study-wide ethics expiry date), and also asked to submit the CCR form prior to the submission deadline for the applicable REB meeting.

The PA/PI are also reminded to submit the PCR/CCR 30 days prior to expiry.

The provincial expiry date and each centre's expiry date, along with the study/centre status, are always displayed to users on the applicant side of the system.

Lapse/Expiration

Within CTO Stream, a lapse 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. This means that the approval letter for the PCR and the approval letter for each CCR must be sent prior to the expiry date in order to avoid a lapse in ethics approval within CTO Stream. Similarly, if provincial ethics approval expires, ethics approval for all research sites is automatically considered to have lapsed as well.



The PA/PI and their main contact are automatically notified of a lapse in ethics approval. If a lapse in ethics approval for a research site should occur, the Department Head and Institutional Representative are also automatically notified (among other recipients). The PA/PI are instructed to cease all research-related activities, including the enrollment of new participants. 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 the study or centre ethics approval remains expired more than 10 days past the expiry date, another notification is sent. The REB of Record operations personnel is blind copied on the email notice of expiry (provincial and centre) and 10 day follow-up notice.

If a lapse should occur, the study 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 within CTO Stream, the PA/PI must submit a PCR/CCR form and the form must receive approval from the REB of Record.

Provincial ethics approval

Prior to issuing the REB approval letter for the PCR, the REB of Record must update the [provincial expiry date](#). Once the provincial continuing ethics approval letter is issued, the study status will automatically update to “Active”.

Approval of the PCR does not automatically update each centre’s expiry date/status; each site is still required to submit and obtain approval for their Centre Continuing Review form.

Centre ethics approval

Once the REB approval letter is issued for the CCR, the centre’s expiry date will automatically update to match the provincial expiry date, and the centre’s status will update to “Active”.

[Drafting the approval letter following a lapse](#)

At this point in time, should a lapse in ethics approval occur, the REB of Record will need to manually update the template letter to reflect the period of expired approval in accordance with their SOPs.