

REB User Manual: Ethics Approval Expiry Dates

Stream Helpdesk:

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1. Study Status and Expiry Date

The REB of Record can view the ethics approval status and expiry date for both the overall study and all participating research sites by navigating to the **Sites tab** on the **Project Overview** page.

This tab also identifies research sites that are in the process of completing their initial application but have not yet submitted it. These sites are displayed with a status of **Pending**.

1.1 Accessing the Sites Tab

- a) REB Staff can use the **Sites tab** to view the ethics approval status for both the overall study and each participating site. The study-wide expiry date is also displayed here. The ethics approval status for the overall study is shown in the row labeled "Study-Wide."
- b) To access the Sites tab, click on the Project Title (*Figure 1*) from the Submission Timeline Page of any submission for the project. This will open the **Project Overview Page**, where the Sites tab is located.

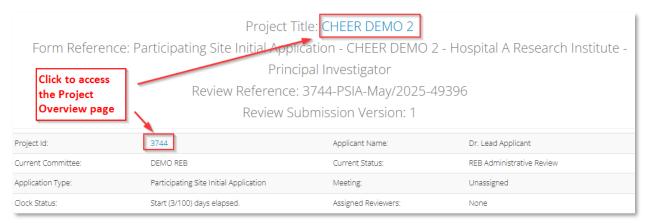


Figure 1

c) From the Project Overview page, click on the **Sites Tab** (*Figure 2*) to view the expiry date and ethics approval status for the overall study. As mentioned previously, this information is displayed in the row containing the site name, "Study-Wide".

Important: All projects in Stream have a single expiry date shared by all participating sites.



Figure 2



1.2 Study Status

Upon submission of the Clinical Trial Initial Application (CTIA) or Observational Study Initial Application (OSIA) by the Lead Applicant study team, the ethics approval status for the overall study is set to **Pending**.

Once the REB grants approval, the status automatically updates to **Active** (See Figure 3 below). If ethics approval lapses at any point, the status changes to **Expired**.

When the REB approves the Study-Wide Closure (SWCL) application for the study, the status updates to **Completed**.

In cases where the REB suspends or terminates ethics approval, the status will reflect **Suspended** or **Terminated**, respectively.

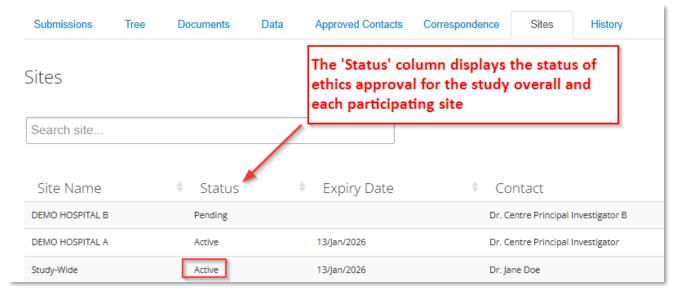


Figure 3

1.3 Setting the Study-Wide Expiry Date

The REB is required to set the ethics approval expiry date for a study before issuing the approval letter for either a Clinical Trial Initial Application (CTIA) or an Observational Study Initial Application (OSIA). Similarly, the expiry date must be set prior to issuing the approval letter for a Study-Wide Continuing Review (SWCR) application.

Setting the expiry date is a mandatory step in the REB review workflow and must be completed by REB Staff when processing either type of application.

1.4 Correcting the Study-Wide Expiry Date

If an incorrect expiry date was set during the approval of a CTIA, OSIA, or SWCR application (i.e., due to an error in the selected date), it can be corrected manually.

To do this, navigate to the Sites tab and click on the expiry date listed for the "Study-Wide" site (see *Figure 4*). A pop-up window will appear, allowing REB staff to enter a new expiry date.

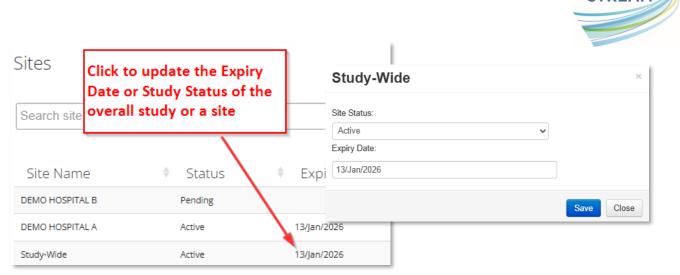


Figure 4

Tip: If the study-wide ethics approval has expired and needs to be corrected (e.g., it should still be active but an error in the expiry date caused it to lapse), the following steps must be taken.

- a) **Update the Expiry Date** Manually correct the expiry date by navigating to the <u>Sites tab</u> and clicking on the expiry date for the "Study-Wide" site. Enter the correct date in the pop-up window.
- b) **Update the Site Status** After correcting the expiry date, you must also change the Site Status to "Active" for the "Study-Wide" site and any other affected sites.
- c) **Review Other Sites** Updating the expiry date for one site does not automatically update the expiry dates for other participating sites. The REB may need to manually revise the status and expiry date for each site if the study-wide expiry date was corrected.
- d) **Understand the Cascade Effect** If ethics approval for the overall study lapses, approval for all participating sites automatically lapses as well. After correcting the overall study status, the status for each approved site must also be updated accordingly.
- e) **Re-Issue Approval Letters -** Once the expiry date has been corrected, the REB may need to re-issue approval letters, as the expiry date displayed in these letters is automatically pulled from the Sites tab.

1.5 Study Completion

Once a study has been completed at a participating site and ethics approval is no longer required, the site must submit a Participating Site Closure (PSCL) application.

After all participating sites have submitted their respective PSCL applications, the Lead Applicant study team must submit a Study-Wide Closure (SWCL) application to close the overall study file in Stream.

Once the Study-Wide Closure (SWCL) form has been reviewed by the REB and the corresponding approval or acknowledgement letter has been issued, the study status will automatically update to **Completed**.

Important: Before approving or acknowledging the SWCL submission, REB staff must confirm that a Participating Site Closure (PSCL) application has been approved or acknowledged for each participating site.



It is recommended that, upon receiving a SWCL application, the REB first verify that all PSCL applications have been processed before proceeding with the review of the SWCL.

1.6 Suspension of Study-Wide Ethics Approval

If necessary, the REB of Record can suspend ethics approval for a study. When this occurs, the status of both the overall study and all participating sites is automatically updated to **Suspended**.

Upon suspension, email notifications are sent to the Lead Applicant study team, the study team at all participating sites, and the Institutional Representative at each participating site.

1.6.1 Suspending ethics approval for the study:

- a) Navigate to the submission timeline of the CTIA/OSIA for the study and click the **Suspend Study** button on the left side of the page (*Figure 5*).
- b) A pop-up window will appear containing a template suspension letter. REB Staff should carefully revise the letter to ensure it accurately reflects the situation. This includes specifying what research activities must cease, if applicable and what is required of the research team to resolve or address the suspension.
- c) Once the letter has been updated, click the green **Suspend Ethics Approval** button at the bottom of the pop-up window to send the suspension letter.
- d) Once the suspension letter is sent, the overall study status and status of each participating site will update to **Suspended** under the Sites Tab. Research teams at the Lead site and each participating site are notified of the suspension by email. The Institutional Representatives at each institution are also included in this notification.

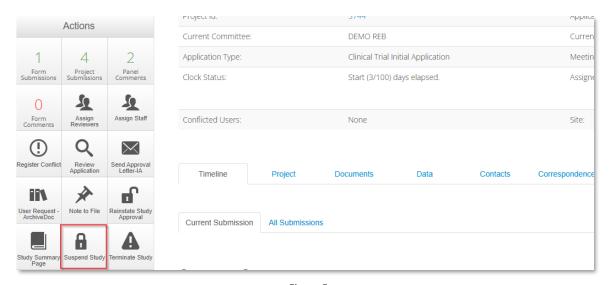


Figure 5

Tip: The 'Suspend Study' button appears in the Action Menu following REB approval of the CTIA/OSIA and remains visible from that point forward.



1.7 Reinstating Study-Wide Ethics Approval After Suspension

Once the research team has resolved the matter to the REB's satisfaction (i.e., by submitting and receiving REB approval of the required form or materials as applicable to the situation), ethics approval can be reinstated by the REB of Record.

1.7.1 Re-instating Study-Wide Ethics Approval:

- a) From the submission timeline of the CTIA/OSIA for the study, click the **Reinstate Study Approval** button from the Action Menu (*Figure 6*) on the left-hand side of the page.
- b) A pop-up window containing the REB letter template will appear on-screen. REB staff should modify the template accordingly and ensure the details of the letter correctly reflect the situation at hand. Once finished editing the letter, press the green **Reinstate Study Approval** button at the bottom right of the window to send the letter.
- c) Once the letter is sent, the "Study-Wide" status automatically changes to **Active**. Steps a) and b) must be repeated for each approved participating site to restore the site's change the status to **Active**.

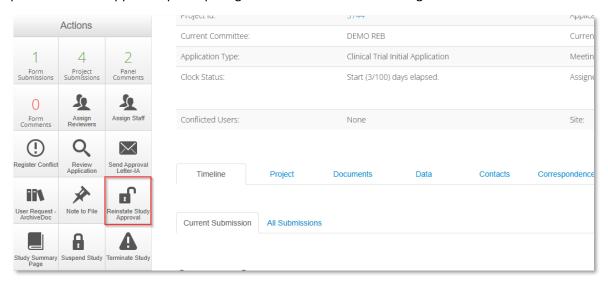


Figure 6

1.8 Termination of Study Ethics Approval

The REB of Record has the authority to terminate study-wide ethics approval. When this happens the status of ethics approval for the overall study and each participating site updates to **Terminated**.

Terminating a study is not the same as a routine study closure or the natural completion of the study. Termination refers specifically to the cessation of ethics approval by the REB of Record, without a request from the study team or sponsor. This action is typically taken in exceptional circumstances—for example, if the applicant has been unresponsive to repeated queries from the REB. In contrast, routine study closure involves a formal request from the study team via a Study-Wide Closure (SWCL) application following the completion of all research activities.

Tip: Terminating a study in is permanent; a terminated study cannot be 'un-terminated'.



1.8.1 Terminating Ethics Approval for a Study:

- a) Go to the Submission Timeline of the CTIA/OSIA for the study you wish to terminate and click the **Terminate Study** button from the Action menu (*Figure 7*).
- b) A pop-up window will open containing a template letter. REB staff should modify the template accordingly and ensure that the details of the letter correctly reflect the situation.
- c) Once the letter is sent, the study status and that of each participating site will automatically update to **Terminated**. The study-wide and participating site research teams are notified via email along with their institution representative.

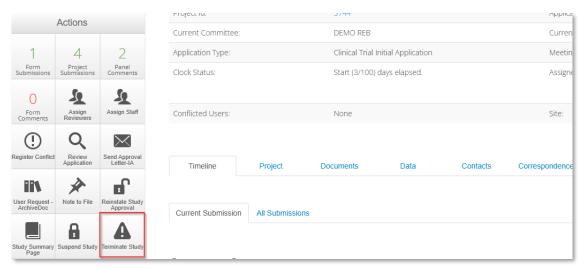


Figure 7

2. Site Expiry Date and Status

2.1 Site Expiry Date

In Stream, the ethics approval expiry date for any participating site is always the same as the study-wide (overall) expiry date, regardless of when the site was initially approved to join the study. As a result, a research site may be required to submit its first Participating Site Continuing Review (PSCR) form less than one year after receiving initial REB approval. When a Participating Site Initial Application (PSIA) is approved, the site's expiry date is automatically populated to match the study-wide expiry date.

If a site experiences a lapse in ethics approval—for example, if the Continuing Review approval letter is not issued before the expiry date—the site's status will automatically change to **Expired**. This allows the REB to easily identify which sites have lapsed and take appropriate follow-up actions.

2.2 Participating Site Status

The status of a participating site reflects the current ethics approval status at that site. Upon creation of a Participating Site Initial Application (PSIA), the site's status in the Sites tab is automatically set to **Pending**. Once the REB approval letter for the PSIA is issued, the site's status automatically changes to **Active**.



If there is a lapse in ethics approval—for example, if the REB approval letter for the Participating Site Continuing Review (PSCR) is not issued before the expiry date—the site's status will automatically change to **Expired**.

2.3 Participating Site Study Completion

When a participating site has completed all study activities and no longer requires ethics approval, the research team must submit a Participating Site Closure (PSCL) application to the REB. This step is required for all sites before the overall study can be closed in Stream. Once the REB approval or acknowledgement letter is issued for the PSCL, the site's status will automatically update to **Completed**.

2.4 Suspension of Ethics Approval for a Participating Site

The REB can suspend ethics approval for a specific site if necessary, using the **Suspend Site** button from the Action Menu, while on the submission timeline of the PSIA for an approved site. The research team members at the site are notified by email of the suspension, along with the institutional representative at the site.

2.4.1 Suspending ethics approval for a Participating Site:

- a) Navigate to the submission timeline of the PSIA of the site you wish to suspend ethics approval for, then click the **Suspend Site** button (*Figure 8*).
- b) A pop-up window will open containing a template letter. REB Staff should revise the letter to ensure that the details of this letter correctly reflect the situation (including specifying what research activities must cease) and what the investigator is required to do in order to resolve/address the suspension. Click the green 'Suspend Ethics Approval' button at the bottom of the pop-up window to send the letter.
- c) Once the suspension letter is issued for a site, the status of the site will automatically update to **Suspended** and members of the research team and institution representative(s) at the site are notified via email.

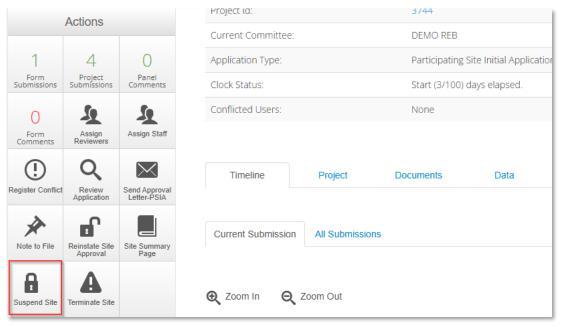


Figure 8



2.5 Reinstating Ethics Approval at a Participating Site After Suspension:

Once the research team has resolved the matter to the REB's satisfaction (e.g., by submission and approval of the material required by the REB or as applicable to the situation), ethics approval can be reinstated.

- a) Navigate to the submission timeline of the PSIA for the site that is to have ethics approval re-instated and press the **Reinstate Site Approval** button from the Action Menu on the left-hand side of the page (Figure 9).
- b) A pop-up window containing the REB letter template will appear on-screen. REB Staff should modify the template accordingly and ensure that the details of the letter correctly reflect the situation at hand.
- c) Once the letter is complete, press the green **Reinstate Site Approval** button at the bottom right of the window to send the letter.

Once the matter leading to suspension has been resolved/addressed to the REB of Record's satisfaction, the REB will follow the above steps as appropriate to the scenario. There are no additional system requirements nor does forms to complete to have the suspension lifted.

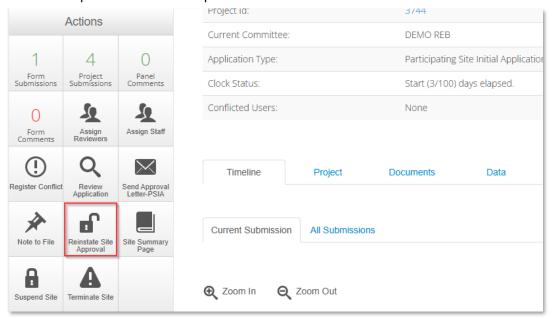


Figure 9

2.6 Termination Ethics Approval at a Participating Site

The REB of Record may terminate ethics approval for a participating site, if necessary. When this occurs the site's ethics approval status automatically updates to **Terminated**. Email notifications regarding the termination are sent to the research team and Institutional Representative(s) at the site.

Termination is not the same as a routine study closure or completion of a study at a site. Terminating a site in Stream is permanent; a terminated site cannot be 'un-terminated'.

Termination refers to the cessation of ethics approval by the REB of Record, without a request from the study team or sponsor. For example, this may occur if a site is unresponsive to REB communications or fails to meet compliance requirements.



2.6.1 Terminating Ethics Approval for a Site:

- a) Navigate to the submission timeline of the PSIA for the site that is to have ethics approval terminated and press the **Terminate Site** button found in the Action Menu on the left-hand side of the page (*Figure 10*).
- b) A pop-up window will open containing template letter. REB Staff should revise the letter to ensure that the details of the letter correctly reflect the situation.
- c) Once the letter is sent, the site's status will automatically update to **Terminated**. The research team is notified via email along with their institution representative.

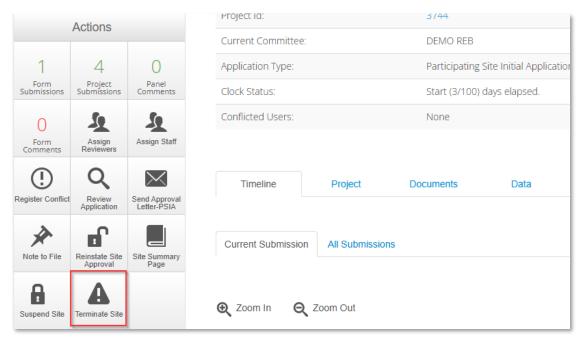


Figure 10

3. Continuing Review

As the ethics expiry date for a study approaches, the REB of Record can expect to receive a Study-Wide Continuing Review (SWCR) submission from the Lead Applicant study team, and a Participating Site Continuing Review (PSCR) submission from each participating site.

The Stream system is configured to allow PSCR forms to be submitted independently of the SWCR form. This means PSCRs can be submitted before or after the SWCR is submitted. This flexibility ensures that each site can complete and obtain sign-off on their PSCR form on time, without waiting for the SWCR submission.

Research teams are instructed to submit both SWCR and PSCR applications before the submission deadline for the applicable full-board meeting date. While PSCR applications typically undergo delegated review, submitting them early ensures the REB has access to all site-level information when reviewing the SWCR. This also allows the REB to escalate the review to a full-board meeting, if necessary.

Tip: The REB of Record must process and approve the SWCR application for the study before approving any of the PSCR applications submitted by the participating sites. When each PSCR application is approved, the ethics approval expiry date will automatically update to match the updated study-wide expiry date.



3.1 Continuing Review Reminders

To help ensure timely submission of continuing review applications, Stream automatically sends reminder emails to research team members based on their roles:

For the overall study, reminders are sent to team members with the following roles:

- Lead Applicant
- Lead Co-Applicant
- Lead Site Study Staff
- Sponsor/CRO

For each participating site, reminders are sent to team members with the following roles:

- Participating Site Principal Investigator
- Participating Site Co-Investigator
- Site Study Staff

These reminders are sent 45, 30, and 15 days prior to the ethics approval expiry date.

3.2 Lapse/Expiration

A lapse occurs when the continuing ethics approval letter is not issued before the ethics approval expiry date. This means that the REB approval letter for the PSCR application at each participating site must be issued before the study expiry date, otherwise the ethics approval at the site will lapse.

If the REB approval letter for the SWCR has not ben issued before the study-wide expiry date, then overall ethics approval for the study will have lapsed and the ethics approval for all research sites is automatically considered to have lapsed as well. The PSCR forms should not be approved until the SWCR form has been approved by the REB of Record, otherwise the expiry date for the site will not get updated. If a lapse in ethics approval does occur, the study-wide status of ethics approval and status of any approved participating sites automatically updates to Expired on the Sites tab.

The Lead Applicant, Sponsor/CRO, and Lead Site Study Staff roles are notified by email of the lapse in ethics approval. If a site has a lapse in ethics approval, the Principal Investigator, Co-Investigator, Site Study Staff, Department Head and Institutional Representative(s) are all notified via email. The email instructs researchers to cease all research-related activities (as applicable) including the enrollment of new participants, and to notify the REB of Record (via Correspondence) 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-wide or site ethics approval remains expired for longer than 10 days, a second email notification is sent (REB Staff are Bcc'd on both emails).

3.3 Reinstating ethics approval following a lapse

To resolve a lapse in ethics approval the Lead Applicant/Principal Investigator must submit a SWCR/PSCR form for review and approval by the REB of Record.



3.3.1 Study ethics approval following a lapse

Prior to issuing the REB approval letter for the SWCR, the REB of Record must update the study-wide expiry date. The steps outlined in <u>Section 1.4 – Correcting the Study-Wide Expiry Date</u> can be followed to re-set the study-wide ethics expiry date. Once the SWCR approval letter is issued, the study status will automatically change to **Active**.

Tip: Approval of the SWCR submission following the lapse does not automatically update each site's expiry date/status. The REB will need to ensure each site has submitted their own PSCR application. Once the REB approves the PSCR application(s), the expiry date/status of the site will automatically be reinstated.

3.3.2 Site ethics approval following a lapse

Once the REB approval letter is issued for the PSCR form, the site's expiry date will automatically update to match the Study-Wide expiry date, and the site's status will change to **Active**.

3.4 Documenting the Duration of a Lapse in Ethics Approval

When issuing the letter to reinstate ethics approval (i.e., following a lapse or suspension), REB staff should revise the template letter (if applicable and in accordance with their SOPs) to reflect the duration of the lapse in ethics approval (the lapse period).