REB User Manual:
Review Process

Stream Helpdesk:
support.ctontario.ca

Contents

1. Pre-screening a Submission

When an application is submitted to the REB of Record in the system, the first step is an administrative pre-screen to assess completeness. For example, the REB will check to ensure all required documents are included in the submission package. During this stage, the status of the submission is **REB Administrative Review**. While at this status the submission is visible to REB Staff via the **REB Submissions** tile of the Work Area.

An additional pre-screening step is done for all Clinical Trial Initial Application (CTIA) and Observational Study Initial Application (OSIA) submissions. This step occurs *before* the application is assigned to the REB of Record and ensures that study includes two or more eligible sites, the correct ICF template(s) was used, and electronic signatures have been obtained from the correct individuals. A similar pre-screen step is done for all Participating Site Initial Application (PSIA) submissions before they are released to the REB of Record. **Note: post-approval submissions are not pre-screened by system administrators.**

When a user with the REB Staff role opens a submission, several actions appear on the left-hand side of the page (*Figure 1*). Some actions move the submission through the REB workflow, and others called **Administrative actions** are used to perform administrative tasks (e.g., making a note to file, comments, assigning a reviewer, etc.)

Actions that move the submission through the REB workflow are called **Workflow actions** (e.g., Application Complete). Once the REB has completed its pre-screen, this action is performed to indicate the submission is complete and ready to proceed. Running this action changes the workflow status of the submission to “Review Type Determination”.

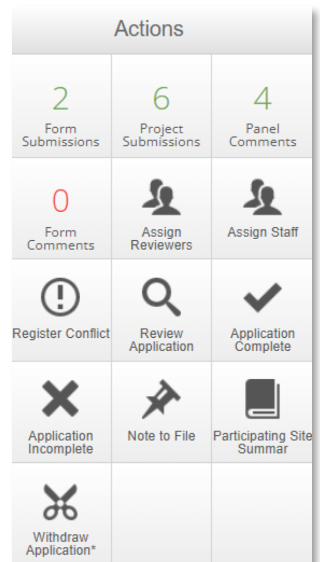


Figure 1

1.1 Application Complete

Once the submission is deemed complete during the administrative review, REB Staff can use the **Application Complete** button to advance the application to the next status of the workflow, called “Review Type Determination”. This opens a pop-up window where you can record a timeline note with the action. Press the green **Application Complete** button (*Figure 2*) at the bottom of the window and then press **Yes** to the question, “Are you sure you want to perform this action?”*****.

The status of the application will change to “Review Type Determination” and then can move forward with selecting the level of review (Full-Board, Delegated or Admin review) as outlined in [Section 2](). While at this status the application will be accessible to REB Staff within the **Assign Review Type** tile of their Work Area.

***All actions include the option to add a Timeline Note. Timeline Notes are optional, but users will always be prompted to press **Yes** and confirm they wish to perform the action before it will be executed. Since both steps are repeated with every action in the system, they will not be mentioned again for the remainder of this guide.

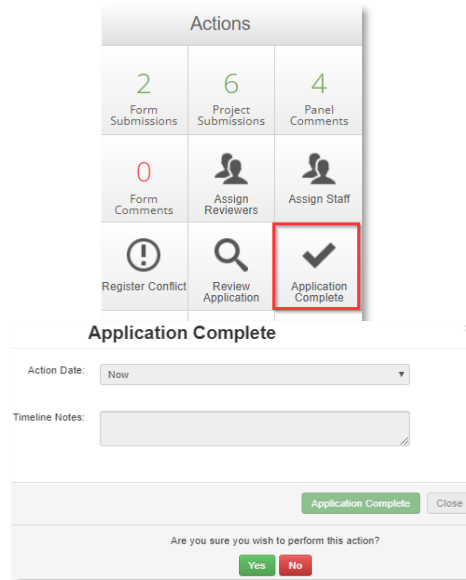


Figure 2 - Application Complete

1.2 Application Incomplete

If, after the administrative pre-screen, the REB determines the submission is incomplete (e.g., a required document is missing or insufficient information has been provided to initiate the review), they may send return it to the study team using the **Application Incomplete** action. Using this action opens the Application Incomplete pop-up window to appear, where the letter template is displayed in a text editor. The REB can enter required changes directly into the text editor or paste from a source outside of the system (i.e., MS Word). The information displayed at the top of the letter, such as the current date, project ID number, study title, etc., is automatically populated with data from the submitted application.

Once the letter is ready to send, click the green **Application Incomplete** button at the bottom of the window (*Figure 3*). This action returns the application to the study team. The study team will receive an email notification notifying them that their application has been sent back by the REB. They can download the REB letter from the History tab of the application.

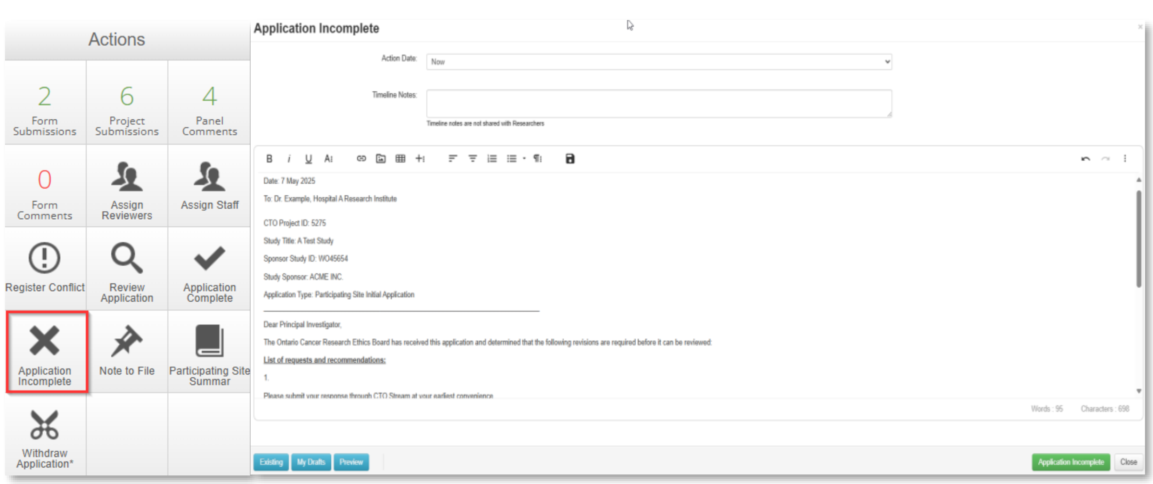


Figure 3 – Application Incomplete

1.3 Application Withdrawal Process

Any application submitted to the REB can be withdrawn, if required (except study or site closure applications). The withdrawal process requires the REB to complete several workflow actions and send the application down the withdrawal pathway of the REB workflow. **The research team must complete the final step of the withdrawal process on the applicant side of the system by performing an applicant action.**

If the application has already been sent back to the study team, they have the option to withdraw it with the **Withdraw Application*** instead of re-submitting. When the study team withdraws their application this way, there is no action required from the REB. After the withdrawal process is complete, an email notification is sent to REB Staff and the study team as confirmation the withdrawal has been completed. The study team cannot subsequently modify and resubmit an application after it has been withdrawn. If the study team has withdrawn an application in error, they can submit a ticket for support via the [Stream Helpdesk].

***Important: Applicants must submit a support ticket if they want to withdraw an amendment. The Withdraw Application button is only available on-demand for amendments to avoid causing project data issues.**

1.3.1 Withdrawing an Application:

To withdraw an application, press the **Withdraw Application** button from the Actions Menu (see *Figure 1*) and then press the green **Withdraw Application** button at the bottom of the Withdraw Application pop-up window.

1.3.2 Archiving Withdrawn Documents:

The next step is to archive the documents attached to the submission using the **Archive Withdrawn Docs** action that is now available in the Actions Menu.

Click **Archive Withdrawn Docs** to make the Archive Withdrawn Docs pop-up window appear. Within the window is a table of all documents attached to the submission. Tick off the checkboxes located in the far-right "Archive" column (*Figure 4*) of the table, for each document. Once all documents have been selected, press the green **Archive Withdrawn Docs** button at the bottom of the window.

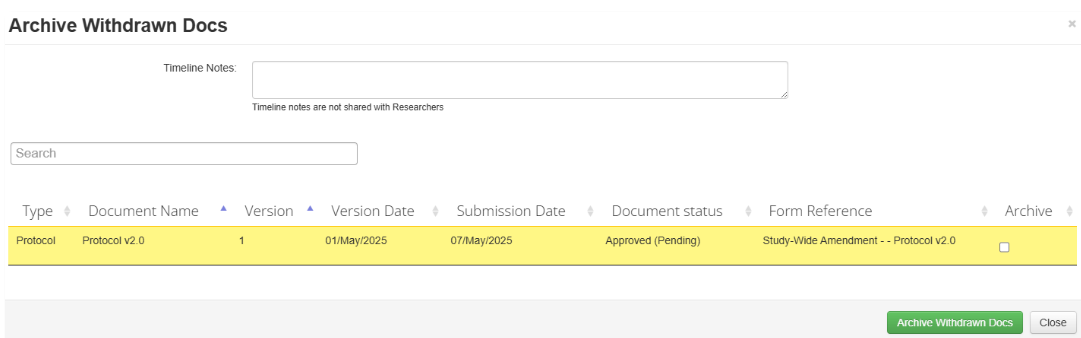


Figure 4 – Archive Withdrawn Docs

1.3.3 Sending the Withdrawal Letter:

Once the submission status changes to "Withdrawn Application – Documents Archived", the final step -drafting and sending the withdrawal letter- can be completed. This final step includes drafting and sending the withdrawal letter.

To draft the letter, click the **Send Withdraw Letter** action. This opens the Withdraw Letter pop-up window where the letter template can be edited before sending. Enter the required changes using the text editor and then press the green **Send Withdraw Letter** button at the bottom of the window to send the letter to the study team.

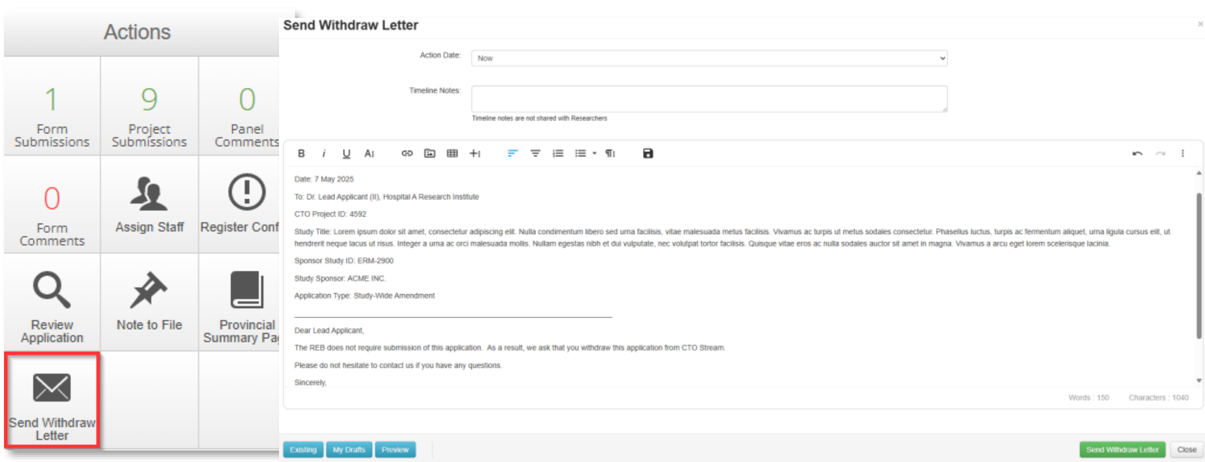


Figure 5 – Send Withdraw Letter

All members of the study team who have a role on the application in the system will receive an email notification indicating that the final step of the withdrawal process can now be completed. At this stage the status of the application changes to “Pending LA/PI Withdrawal” and the **Withdraw Application** action button becomes available to the study team in the Actions Menu when the relevant form is selected in the project tree.

2. Selecting the Level of Review

Once a submission is marked as complete, REB Staff will select the level of review required for the application. During this step the status of the application is “Review Type Determination” and can be accessed from the **Assign Review Type** tile of the Work Area.

Several new workflow actions will become visible which will take the submission down separate pathways of the REB workflow. The actions that you will see at this step are:

1- Admin Review:
For submissions that do not require review by other REB members, allowing REB Staff to administratively acknowledge the submission.

2- Delegated Review:
For submissions that will undergo a delegated/expedited review process.

3- Full Board Review:
For submissions that will be reviewed at a full board meeting.

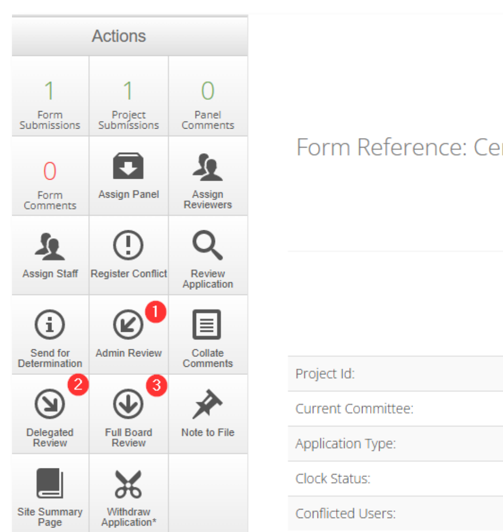


Figure 6 – Review Type Determination

The level of review a submission goes through is not pre-defined even when the same application has been resubmitted by the study team multiple times. This means the REB needs to select the level of review for each individual submission, as required. As an example, the initial submission of an application may undergo a full board review (e.g., a CTIA submission) and decide if subsequent revisions and resubmission can be allowed to undergo delegated review. The responsible REB Staff should always ensure they select the level of review for each submission, in accordance with their SOPs.

2.1 Send Application for Review Type Determination

Some REBs require that submissions be sent to the Chair (or another designated individual) to determine the appropriate level of review (i.e., Delegated or Full Board). In these cases, the Chair must select the review type before the application can advance to the next step of the workflow.

To send an application to the Chair to determine the review type, click the **Send For Determination** button in the Actions Menu (*Figure 7*). A pop-up window listing all the REB members eligible to act as the Review Type Determiner. Locate the appropriate individual (e.g., the Chair) in the table. In the far-right column of their row, use the drop-down menu to select **Review Type Determiner**. Once assigned, the Chair will receive an email notification from the system, informing them that a new submission is awaiting review type review selection.

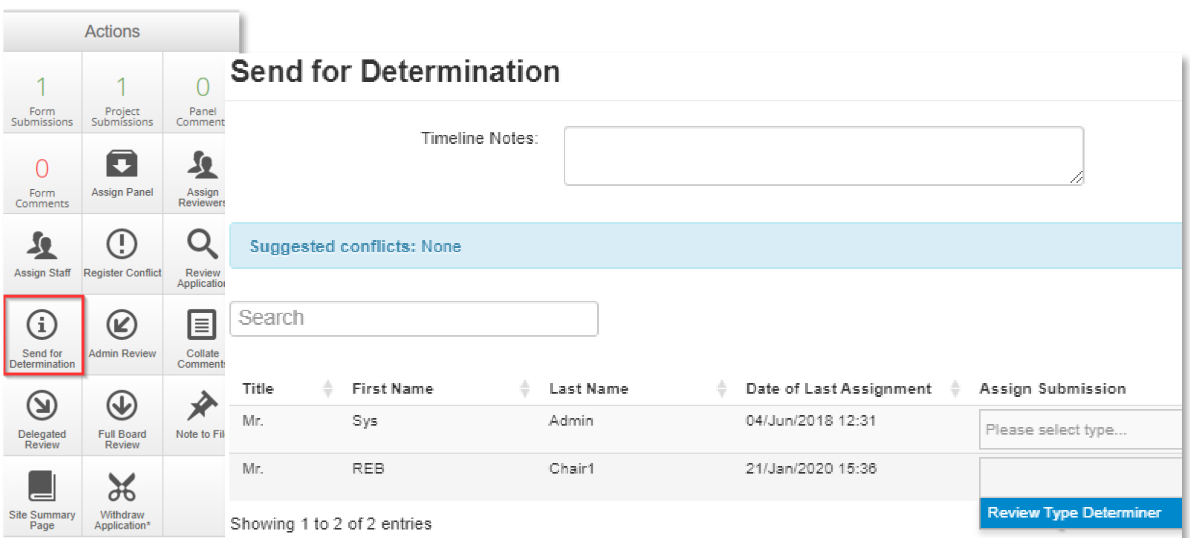


Figure 7 – Send for Review Type Determination

The assigned individual can access the submission from the **Select Review Type** tile of the Work Area. They will select the review type from the Action Menu which corresponds to the level of review required which determines the pathway of the workflow the submission will go down (i.e., full board, delegated or admin).

2.2 Full Board Review

If the application requires review at a full board meeting, the REB Staff (or an assigned individual) can press the **Full Board Review** button (*Figure 6*) in the Actions Menu. This button is available from the Submission Timeline page of the submission. Once the action has been confirmed, the status changes to “Full Board Review”. At this status, the application will also be accessible to REB Staff within **Assign to Meeting** tile of their Work Area.

2.2.1 Assign the Application to a Meeting:

When full board review is selected as the level of review for a submission, the next step of the workflow is to assign the application to an upcoming full board meeting. The full board meeting must have already been created before staff can proceed with this step. For detailed instructions on how to create a meeting in Stream, refer to the Meetings User Guide on the Manuals & Guides page.

Once 'full board' review has been selected, the status of the application changes to "Full Board Review" and a new action becomes visible in the Actions Menu, **Assign to Meeting**. Once the application has been assigned to a meeting, REB members will have access to begin reviewing the application.

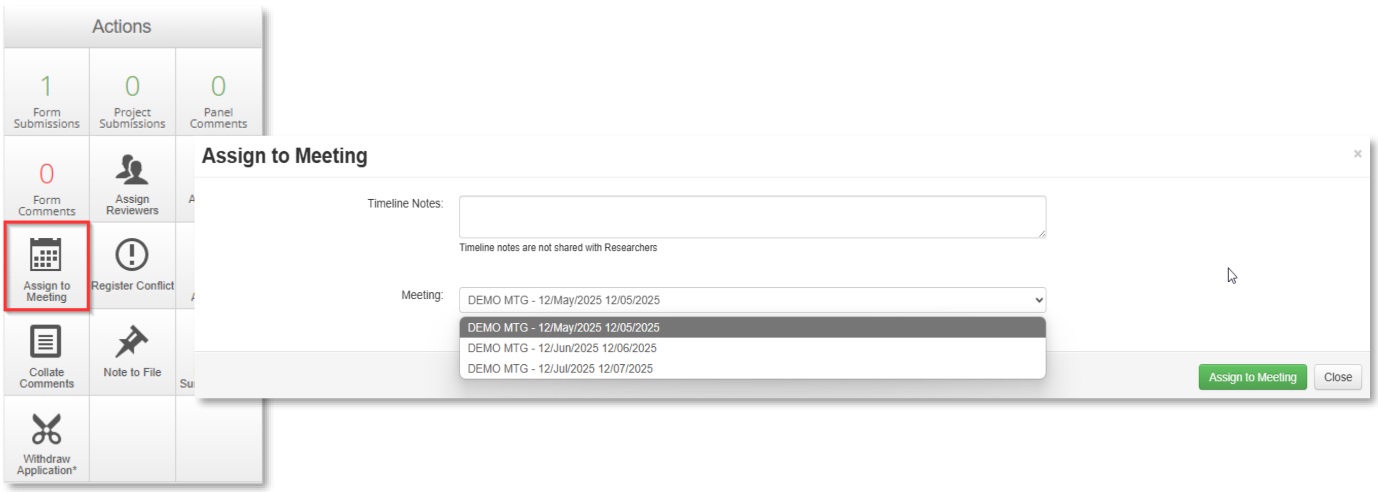


Figure 8 – Assign to Meeting

2.2.2 Recording the end of the full board review:

After the meeting has taken place, the full board review process needs to be marked as complete in the Stream system. This moves the submission to the next step of REB workflow, allowing staff to issue the REB letter.

To record that the meeting and full board review process has concluded, press the **Review Complete** action from the Submission Timeline page. The status of the submission will change to "Decision Pending". At this point, the submission is no longer accessible to REB members.

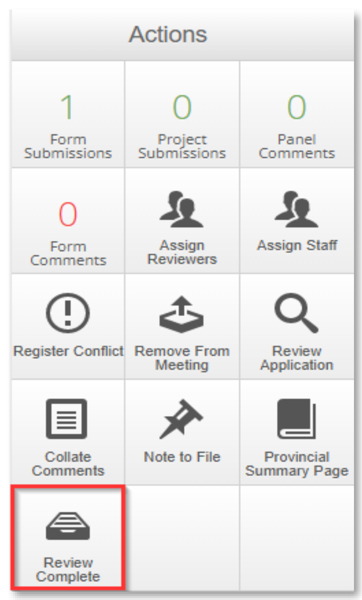


Figure 9 – Review Complete

2.3 Delegated Review

To send a submission down the delegated review pathway, click **Delegated Review** (*Figure 6*), then press the green **Delegated Review** button at the bottom of the pop-up window. The status of the application will change to "Delegated Review". From this status the application is accessible to REB Staff in the **Delegated Review** tile of their Work Area.

2.3.1 Assigning Reviewers:

To assign the reviewer(s) that will conduct the review of the application, press the **Assign Reviewers** button in the Actions Menu. This opens the Assign Reviewers pop-up window which contains a table of all the reviewers that can be assigned. Assign reviewers to the current submission by clicking the drop-down menu in the far-right column of the row containing the reviewer's name (*Figure 10*). Then select the type of reviewer (Primary, Secondary or Other) to assign them as. Multiple reviewers can be assigned at once using the drop-down menus within the row containing the name of the reviewer.

Any time a reviewer is assigned to a submission they automatically receive an email from the system to notify them. Multiple reviewers can be assigned as Primary and Secondary reviewers on the submission. REB Staff can assign a reviewer to the current submission and all future submissions for the project by using the drop-down menu within the "Assign Project and Submission" column.

Submissions undergoing delegated review must have at least one individual assigned as the 'Primary Reviewer'. Only the Primary Reviewer can mark the delegated review as complete and advance the submission to the next step of the REB workflow. The other reviewer types are "**Secondary Reviewer**" and "**Other Reviewer**". These reviewers have access to the application and study documents and can record their recommendation (whether the application should be approved, acknowledged, etc.) but are not able to advance the application to the next step of the workflow.

Tip: REB members only have access to submissions that they have been assigned as a reviewer on. More information about assigning reviewers can be found in the see Assigning Reviewers in Section 4.

2.3.2 Making a Recommendation:

While the submission is at the "Delegated Review" status, REB members assigned as reviewers can make recommendation on whether the submission should be approved, acknowledged, or sent back to the study team for clarifications. This step is called **making a recommendation**. The primary reviewer can also make a recommendation (if required).

REB members can record their recommendation for the submission by going to the submission timeline and selecting the decision in the Actions Menu that corresponds with their recommendation.

The three recommendations that reviewers can choose from are:

Recommend Approval:
The application can be approved as-is, no further changes required.

Recommend Modifications:
The application should be sent back to the research team for changes or clarifications.

Recommend Full Board:
The application as submitted requires further review at a full board meeting.

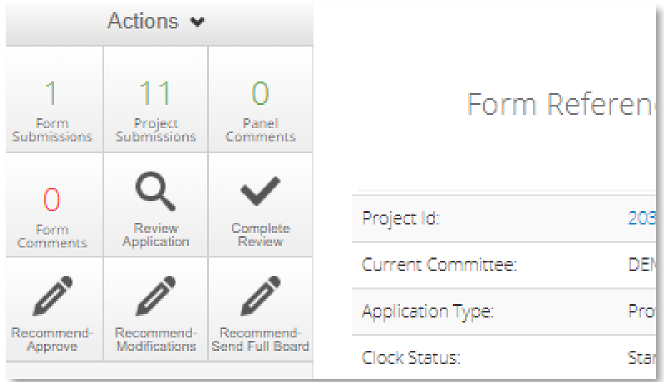


Figure 11 – Reviewer Recommendations

When a reviewer selects 'Recommend – Modifications', they should outline the required changes either through the Timeline Notes field (e.g., when recording the recommendation) or via **comments** on the application so they are visible to REB Staff and other reviewers.

2.3.3 Viewing Recommendations Made by Reviewers:

Any assigned reviewer and REB Staff can view the recommendations made on the submission by the other assigned reviewers. All recommendations are displayed in the list of actions on the Submission Timeline page (*Figure 12*).

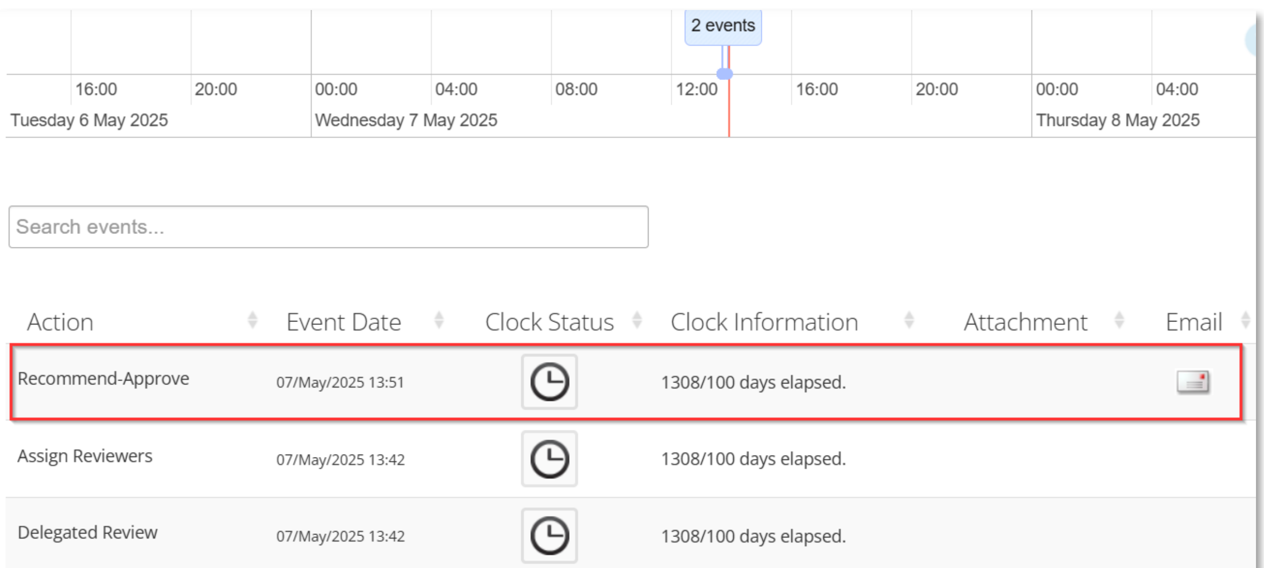


Figure 12 – Viewing Recommendations

Click a recommendation action in the list to see the name of the reviewer who made the recommendation, and any timeline notes they have entered.

2.3.4 Ending a Delegated Review as Primary Reviewer:

When a reviewer is assigned as the Primary Reviewer for a submission, they will indicate when the delegated review process is complete to allow the review decision to be recorded (Approve, Acknowledge, etc.). This is usually done after the Secondary Reviewers and Other Reviewers have entered their recommendations as described in Section 2.3.2 above. The primary reviewer will use the ‘Complete Review’ button, which advances the application to the next step of the REB workflow.

Click the **Complete Review** button in the Actions Menu to end the delegated review process for the submission in the system. After this is done, no additional reviewers can record their recommendation on the application. We recommend the Primary Reviewer waits until all other reviewers have made a recommendation before marking the delegated review complete.

Once the delegated review has been marked as complete, the application’s status changes to “Delegated Review Complete”. At this status, the application will also be accessible to REB Staff within the **Delegated Review** tile of their Work Area. See Section 3 - Post-Review Steps to see the remaining steps of the REB workflow

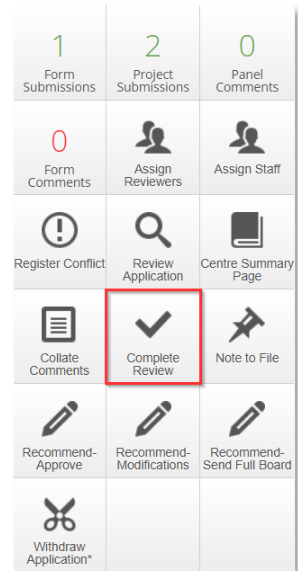


Figure 12 - Complete Review

2.4 Administrative Review

Administrative review is typically selected for applications that do not require full board or delegated review and instead can be reviewed and administratively acknowledged by REB Staff. These could be minimal risk studies or amendments that are administrative in nature. This type of review may also be selected when an application has been re-submitted after previously undergoing a full board or delegated review.

To choose **Administrative Review** as the review type for a submission click the **Admin Review** button, (see *Figure 6* on page 7), then press the green **Admin Review** button at the bottom of the window. The status of the submission will change to “Admin Review”. While at this status the application is accessible to REB Staff in the **Post Decision Steps** tile of their Work Area.

3. Post-Review Steps

Once the submission has been reviewed by the assigned reviewers, the decision needs to be recorded. Ultimately, the application will either be sent back to the study team for changes/clarifications, or it will be advanced through the workflow to the next step, culminating in approval or acknowledgement. This section outlines the steps required to advance the submission through the workflow after the review has been conducted.

3.1 Recording the Decision

Once the submission has been marked as complete, the REB’s decision needs to be recorded in the system. This is done using the workflow actions in the Actions Menu. There are six different actions the REB can use depending on the level of review the application underwent and the type of application. The six decision types available are outlined below in **Table 1**.

TABLE 1 - POST-DECISION STEPS

Approve	The application and associated documents can be approved as submitted – no changes are required
Acknowledge	No changes are required, the application and associated documents are to be acknowledged by the REB
Admin Acknowledge*	Does not require review from the Chair (or other appropriate individual), the application and documents will be reviewed and acknowledged by REB Staff
Modifications Required	The application and/or associated documents require further clarification, changes or corrections before it can be approved by the REB. This action returns the application to the research team unlocked so they can make the required changes and re-submit
Defer to Full Board	The application was assigned to undergo a delegated review, but further consideration resulted in a decision that full board review is actually required (this is only available for applications which have undergone a delegated review).
Defer Decision	The application and/or associated documents require substantive changes or corrections that need to be made before the REB can consider making a decision on the application. The application will be returned to the study team to make the changes, and will need to be re-submitted for REB review
Not Approve	The research study (or post-approval submission) fails to meet the ethical standards for approval and revision is unlikely to enable the REB to reach a positive determination

***This action is only an option if Admin Review was selected as the level of review for the submission. If a previous submission of the application was assigned to a full board meeting, or underwent delegated review, the REB Staff must select "Approve" as the REB's final decision to ensure the proper REB letter template appears for the REB to complete.**

The action buttons that appear in the Actions Menu represent the different decisions the REB can make for the application (i.e., Approve, Defer to Full Board, etc.). The specific buttons that appear will depend on the type of application being reviewed, as well as the level of review that was selected (i.e., full board/delegated). For example, the **Admin Acknowledge** button will not appear in the Action Menu at any point during the review of a Clinical Trial Initial Application (CTIA), Participating Site Initial Application (PSIA).

REB staff will record the REB's review decision on the submission by pressing the corresponding action button. For example, if the REB elected to approve the application as submitted, press the **Approve** button (*Figure 13*) in the Actions Menu to record the decision on the current submission under review. The status of the application will change to "Approved". At this status, the application will also be accessible to REB Staff within the **Post Decision Steps** tile of their Work Area.

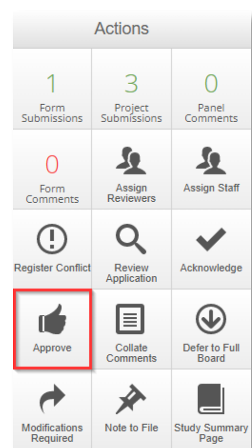


Figure 13 – Approve

3.2 Categorizing the Documents

Applications that the REB has approved, acknowledged, or administratively acknowledged need to go through a step called **Categorizing Documents**. During this step, REB Staff must confirm that the status of all documents on the submission have the correct status (i.e., approved, acknowledged, or received). The status can be changed, as necessary. The status of each document will be displayed in the REB approval/acknowledgement letter. **Note: 'received' documents will not appear in the REB letter.**

Categorizing documents for an application is not applicable when the REB elects to send the application back to the study team for modifications. Instructions on how to properly categorize documents for a submission can be found on below on page 14 of this guide and a description of the different statuses available is provided below in **Table 2**.

TABLE 2 – DOCUMENT STATUSES CATEGORIES

Approved (Pending)	Documents in this category will appear in the 'approved documents' section of the REB approval letter and have a status of "approved" once the review process is complete (e.g., the letter is sent)
Acknowledged (Pending)	Documents in this category will appear in the 'acknowledged documents' section of the REB approval letter and have the status of "acknowledged" once the review process is complete
Received (Pending)	Documents in this category will not appear in the REB approval letter, and will have the status of "Received" once the review process is complete

To categorize documents for a submission click the **Categorize Documents** button in the Actions Menu. This causes a pop-up window to appear, with a table of all documents attached to the submission. The status of the documents has already been pre-determined by the system, but the REB can change this by using the drop-down menu in the row containing the document name. The statuses available in the drop-down menu are: Approved (Pending), Acknowledged (Pending), and Received (Pending) (*Figure 14*).

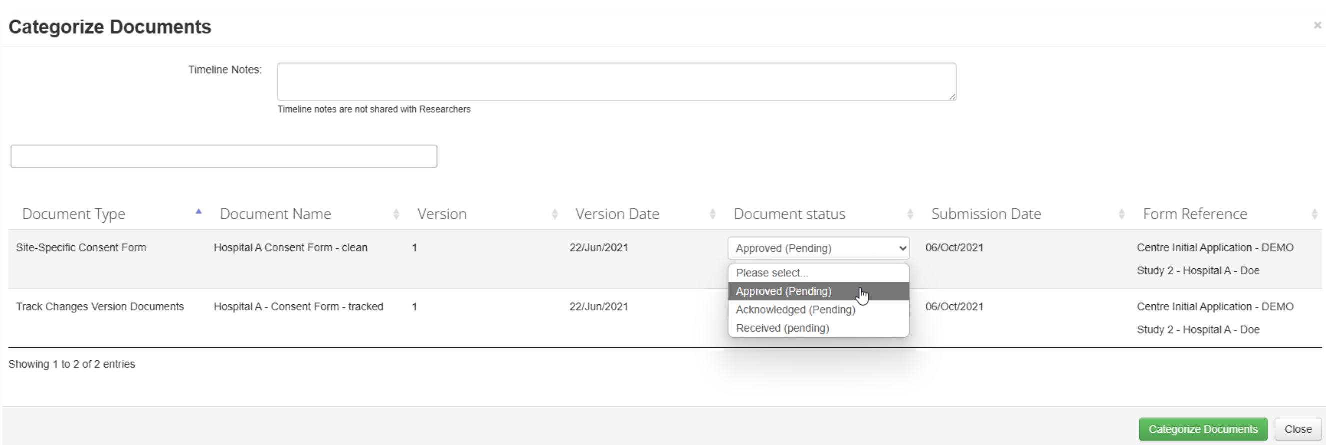


Figure 14 – Categorize Documents

Press the green **Categorize Documents** button at the bottom of the window to complete the action. The status of the submission is now "Approved Pathway-Documents Categorized" (the name of this status depends on whether the application has been approved or acknowledged).

Important: The Categorize Documents step must be completed even if there are no study documents attached to the submission. The submission cannot advance to the next step of the workflow unless the is completed.

3.3 Archiving Documents

The Archive Documents action is only visible for post-approval submissions where there is a possibility that a document on the current submission replaces a previously approved/acknowledged document. It helps to ensure that the study team at each participating site can easily find the latest version of any study document. This step of the workflow is only applicable if the REB has chosen to approve, acknowledge, or administratively acknowledge the submission. Whenever the REB sends an application back to the study team for changes, the status for all documents attached to the submission is automatically updated to "Archived".

Tip: Archiving a document does mean the document is deleted. The archived document can be accessed from the Documents tab on the Project Overview page.

To archive documents on a submission, click the **Archive Documents** button in the Actions Menu which will bring up the Archive Documents pop-up window. Inside the window is list of all documents attached to the submission, displayed in a table. The documents attached to the current submission are highlighted in yellow, while previously approved/acknowledged documents for the project are grey or white.

Use the checkbox in the far-right "Archive" column to archive any document that is being replaced by one of the documents on the current submission (*Figure 15*). Once all applicable documents have been selected, press the green **Archive Documents** button to complete the action.

Important: The archiving step still must be completed if the submission contains no documents, or when there are no documents being replaced.

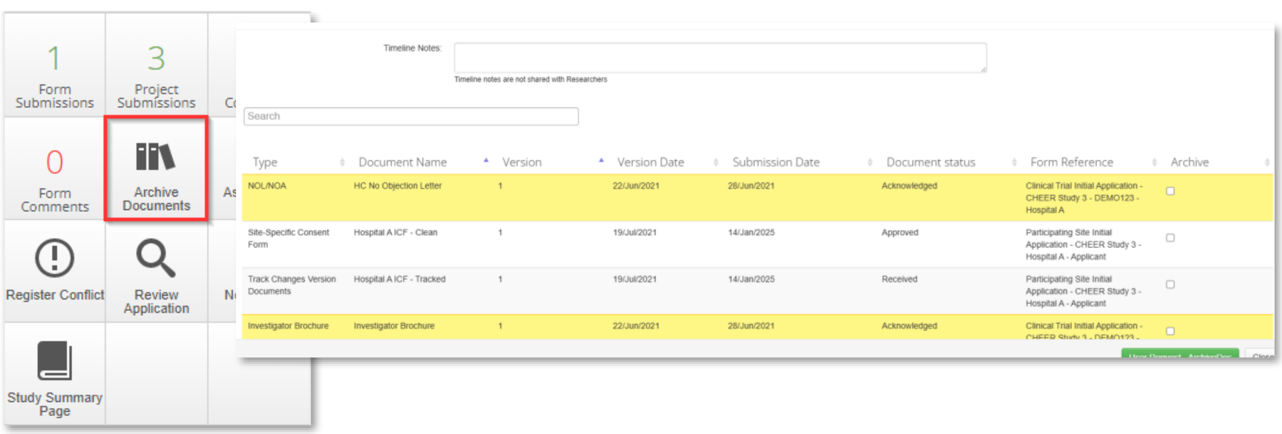


Figure 15 – Archive Documents

Once the Archive Documents step has been completed, the status submission changes to "Approved Pathway – Documents Archived" (or Acknowledged Pathway – Documents Archived). At this status, the application is accessible to REB Staff in the **Post Decision Steps** tile of their Work Area. **Tip: It can be helpful to sort the table by "Type" to make it easier to compare the old and new version of the document (i.e., Investigator Brochure).**

3.4 Setting the Expiry Date

The study-wide ethics approval expiry date is set as part the workflow for Clinical Trial Initial Application (CTIA), or Observational Study Initial Application (OSIA) submissions.

To set the expiry date for the project, click the **Set Expiry Date** button in the Actions Menu to open the Set Expiry Date pop-up window. Here the REB Staff can set the expiry date using the date-picker (*Figure 16).* Once the expiry date has been selected, press the green **Set Expiry Date** button at the bottom of the window to complete the action.

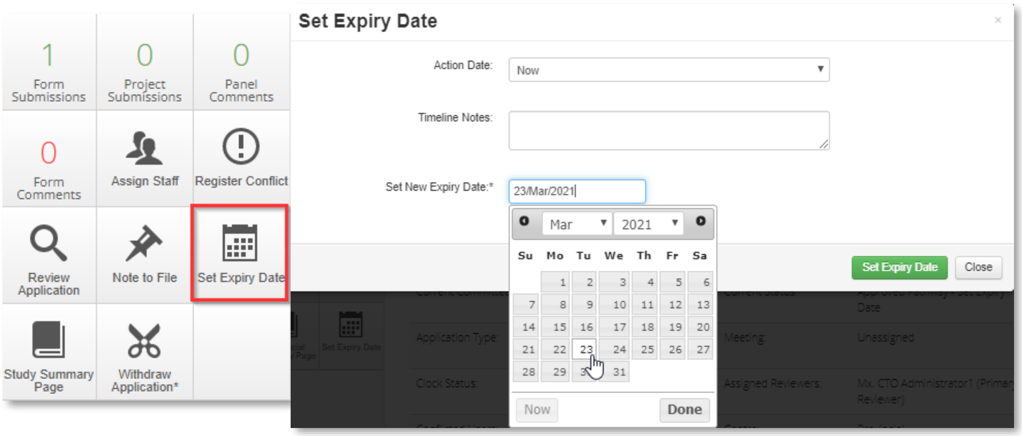


Figure 16 – Set Expiry Date

The status of the CTIA/OSIA (or SWCR) submission will become "Approved Pathway – Expiry Date Set". At this status, the application will also be accessible to REB Staff within the **Post Decision Steps** tile of their Work Area. More information on expiry dates and continuing review can be found in the Ethics Approval Expiry Date, Status and Continuing Review manual posted to the Manuals & Guides page.

3.5 Drafting the REB Approval Letter

This section will illustrate the steps the REB must follow to draft the REB approval letter for the submission, that will ultimately be sent to the study team. In some cases, the drafted letter may need to be sent to the Chair for review before it can be sent to the study team (depending on the SOPs of the REB). The Chair will then determine if any changes are required to the letter, or if it can be sent as-is. The examples shown in this user guide are focused on the approval pathway of the REB workflow, however the same process will be followed when the REB is sending an acknowledgement letter.

To draft the letter for the initial study-wide application (CTIA or OSIA), click the **Draft Approval Letter-IA** button in the Actions Menu. This opens a pop-up window with the REB approval letter template visible inside of the text editor (*Figure 17*). REB users can then edit the template by typing directly into the text editor and use the toolbar at the top of the text editor to make any formatting changes. In most cases the REB letter template will only require minor changes from the REB.

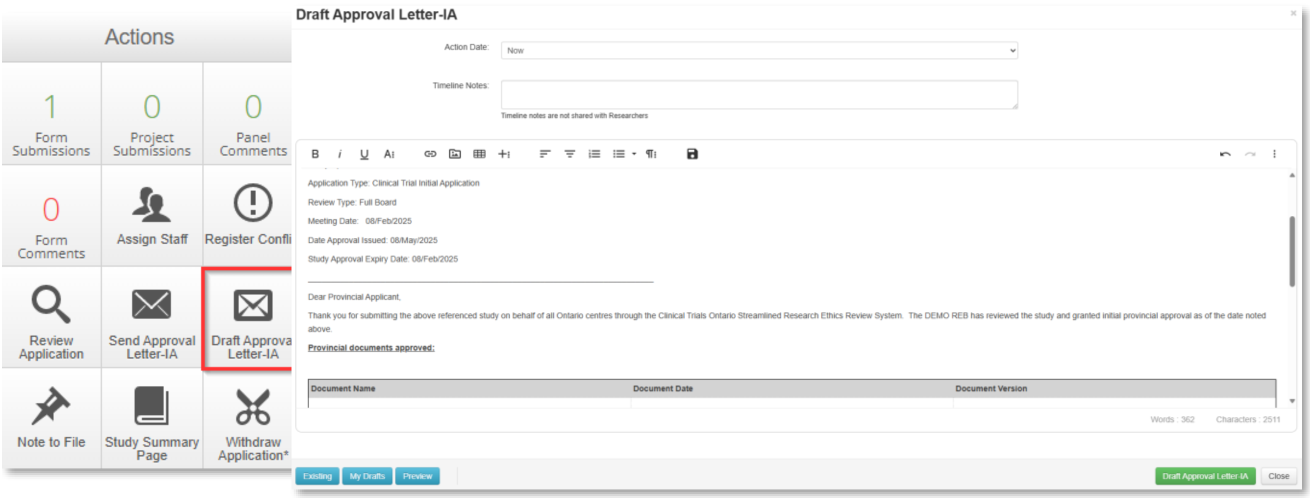


Figure 17 – Draft Approval Letter IA

Some of the information within the letter such as expiry date, document names, document version/date, etc., is automatically populated using data from the submission. If this information is incorrect and needs to be changed, it should only be done on the submission itself and not by manually editing the letter template, otherwise a discrepancy will exist between the contents of the letter and the project data stored in the system.

Tip: Creating a draft of the letter is optional (in according with REB SOPs); REBs that do not require the Chair to review letters can skip the 'Draft Approval Letter' step and use the 'Send Approval Letter' action instead.

3.6 REB Letters Templates

As mentioned previously, some information within the template REB letters is populated automatically with data from the project in Stream. **Table 3** below provides a description of the information that is included:

TABLE 3 – INFORMATION AUTOMATICALLY POPULATED IN REB LETTERS

REVIEW TYPE	Users will always need to modify the letter template to specify whether the application underwent full board, delegated, or administrative review
MEETING DATE	For the CTIA or OSIA submissions, the system will automatically indicate any full board meeting(s) at which the application was reviewed. For all other applications (e.g., Study-Wide Amendments, etc.) the system will only include the full board meeting date if that submission has been reviewed at a full board meeting. If a previous submission of that application was been reviewed at a full board meeting (i.e., not the submission on which the letter is being sent) the REB will need to add the full board meeting date to the letter
DATE APPROVAL ISSUED	This is the date and time when the decision to approve/acknowledge/administratively acknowledge was recorded on the submission in the system (e.g., the date and time the button was pushed in the system). Users may wish to remove the time
SPONSOR STUDY ID	This field may be blank (e.g., if a study ID was not specified by the Lead Applicant team) and can be deleted from the template if empty

3.7 Save a Drafted Letter

Users can save a copy of the draft of the letter they are working on by pressing the **Save** button, a computer disk icon within the toolbar of the text editor (*Figure 19*). The saved draft can be re-opened at any time by pressing the blue **My Drafts** button at bottom-left corner of the text editor window. Saved drafts are only visible to the user who created them.

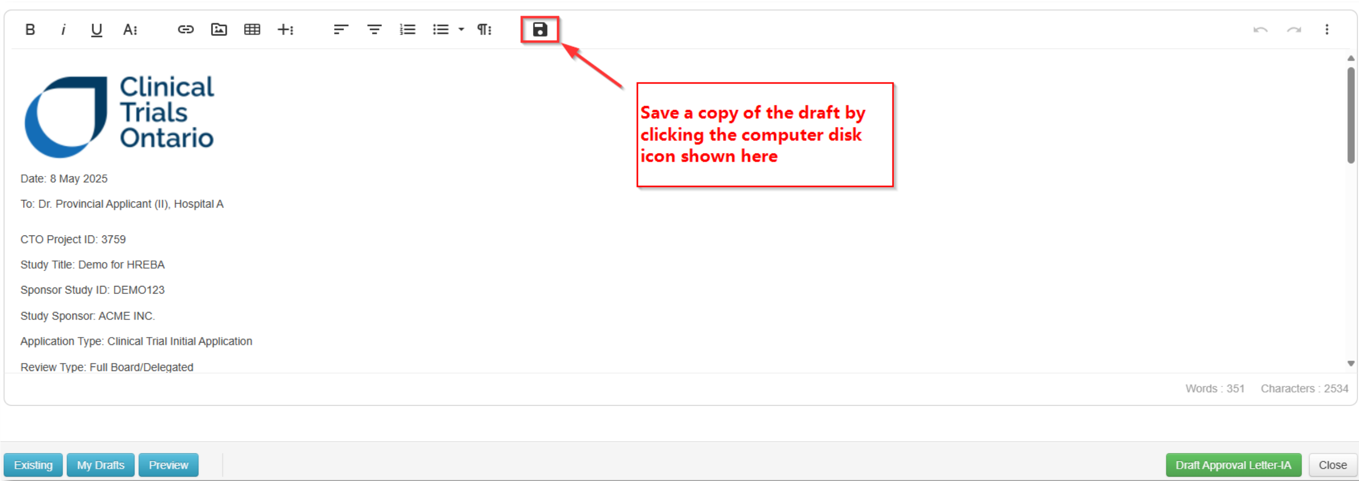


Figure 19 – Save Draft of REB Letter

When the drafted letter is ready, press the green **Draft Approval Letter – IA** button at the bottom of the pop-up window to advance the application to the next step of the workflow.

3.7.1 My Drafts:

To save a draft of the letter to My Drafts, click the **computer disk icon** in the tool bar of the text editor. A save field will appear on-screen (*Figure 20*) and a name can be entered for the letter draft (20-character maximum limit). Press the green **Save** button to complete the save. **Note: the saved draft of the letter is not accessible to any other users.**

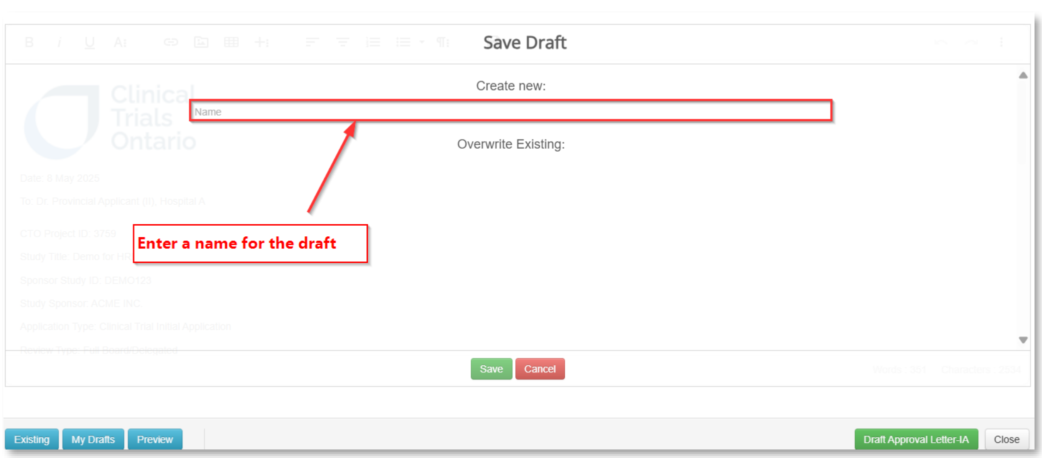


Figure 20 – Name the Draft of the REB Letter

3.7.2 Draft Letter:

Once satisfied with drafted letter press the green **Draft Approval Letter** button at the bottom of the pop-up window. The status of the submission will become Approval Letter Drafted and the REB letter can be sent to the REB Chair (or other appropriate individual) for review, using the Letter Review process (if required).

3.7.3 Changing a Drafted Letter:

Once a draft of the letter has been created it can be viewed by any other REB users who have access to the submission in the system. The letter is saved as an attachment on the **Draft Approval Letter-IA** action and displayed along with the other actions previously executed on the submission, on the Submission Timeline page.

To change the drafted letter, click the **Draft Approval letter-IA** action that is still visible in the Actions menu to bring up the draft letter template. To load the existing draft, click the blue **Existing** button at the bottom-left corner of the window (*Figure 17*). This will cause the pop-up window to split in two halves, with a list of all the existing letter drafts on the right.

Select the desired draft on the right side of the screen and then press the **Overwrite** button located in the middle section of the page (*Figure 21*). This replaces the template with the existing saved draft of the letter. The other option, called **Append**, will insert the drafted letter at the end of the template letter.

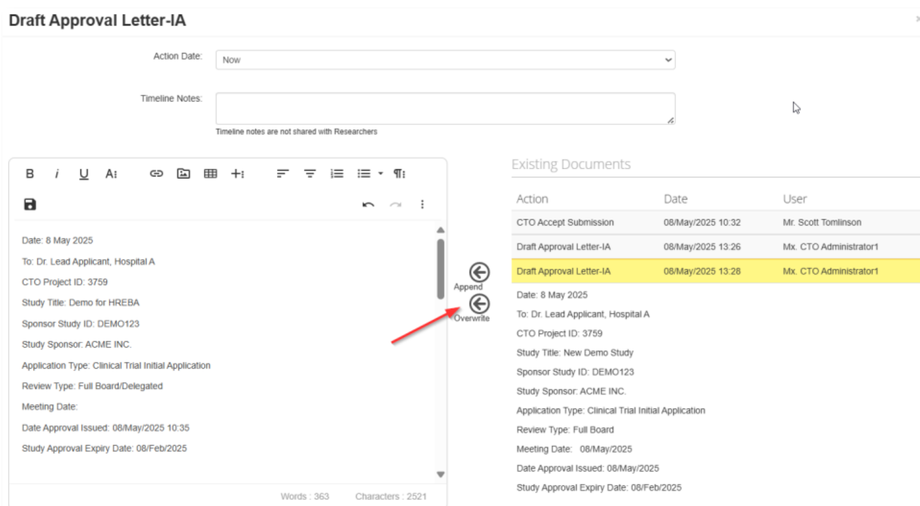


Figure 21 – Overwrite or Append Drafted Letter

3.8 Letter Review

Prior to sending the REB letter for an application to the research team, the REB operations personnel may first need to send the letter to the REB Chair for review and 'approval'. The Chair then can choose to make changes to the letter themselves directly or list the changes in a separate document. This guide refers to the 'Chair' as the Letter Reviewer, however we recognize this may not be the case for every REB office. The system allows for anyone with a role with the REB in Stream to be assigned as Letter Reviewer.

3.8.1 Letter Review vs No Letter Review

Once the REB letter has been drafted (i.e., an approval letter), two buttons will appear in the Actions Menu called **No Letter Review** and **Letter Review** (*Figure 22*). If required, the latter can be used to send a drafted letter to the Chair to review (according to SOPs).

If the Chair does not need to review letters prior to them being sent to the research team (according to REB's SOPs), the REB operations personnel can press **No Letter Review** to skip the chair review pathway.

Tip: The letter review is completely optional but has been pre-built and is available to facilitate compliance with REB SOPs, as required. Some REBs may choose to do letter review outside of the system (i.e., by email).

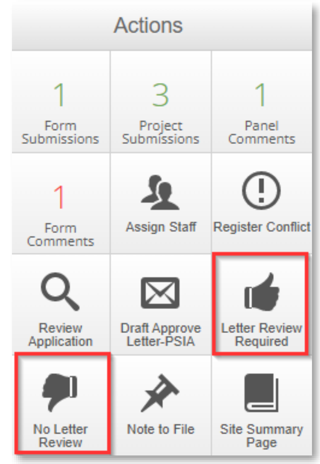


Figure 22 – Letter Review

3.8.2 Assigning the Letter Reviewer

When the **Letter Review Required** option is selected, the buttons displayed in the Action menu change to reveal a button called **Assign Letter Reviewer**. Press this button to show the Assign Letter Reviewer pop-up window, then select the Chair (or appropriate person according to SOP) as the Letter Reviewer in the **Assign Submission** column (*Figure 23*).

The Chair will receive an email from the system to let them know they've been assigned a letter to review and/or associated documents. This email contains a link to bring the reviewer directly to the submission timeline of the application. The application where the letter was drafted can also be found in the **For My Review** tile of the Chair's Work Area.

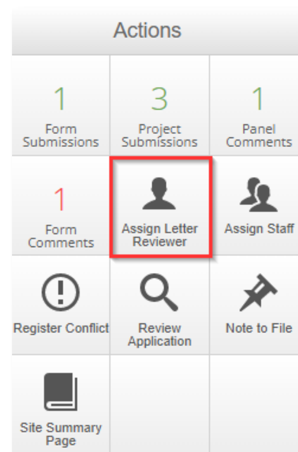
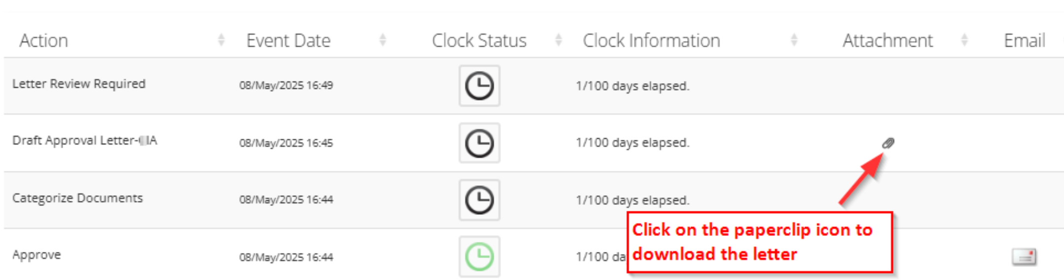


Figure 23 – Assign Letter Reviewer

3.8.3 Reviewing the drafted Letter

As previously mentioned, any time an individual is assigned as a Letter Reviewer they receive an email from the system. A link within the email can be used to take them directly to the Submission Timeline of the application which the letter was drafted on. The letter can be downloaded from the Timeline Tab by clicking on the **paper clip icon**, displayed in the same row as the Draft Approval Letter action (timeline actions are sorted by event date, by default). Click the green **Download** button to download the letter in .PDF format.



Action	Event Date	Clock Status	Clock Information	Attachment	Email
Letter Review Required	08/May/2025 16:49		1/100 days elapsed.		
Draft Approval Letter-[illegible]IA	08/May/2025 16:45		1/100 days elapsed.		
Categorize Documents	08/May/2025 16:44		1/100 days elapsed.		
Approve	08/May/2025 16:44		1/100 da		

Figure 24 – Review Drafted Letter

3.8.4 No Changes Required

If the Letter Reviewer determines no changes to the letter are necessary, they should select **No Change Required** in the Actions Menu (*Figure 25*). This progresses the submission to the next step of the workflow and allows the REB operations personnel to send the drafted letter as-is.

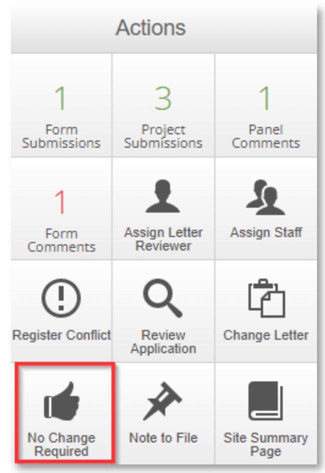


Figure 25 – No Change Required

3.8.5 Changes Required

If changes to the letter are necessary, the Letter Reviewer will press the **Change Letter** button in the Action Menu, then choose from one of the following two methods for inputting the required changes: type their changes in point-form directly into the text editor or follow the instructions in the pop-up window to add their changes directly into the drafted letter in *Figure 26* below.

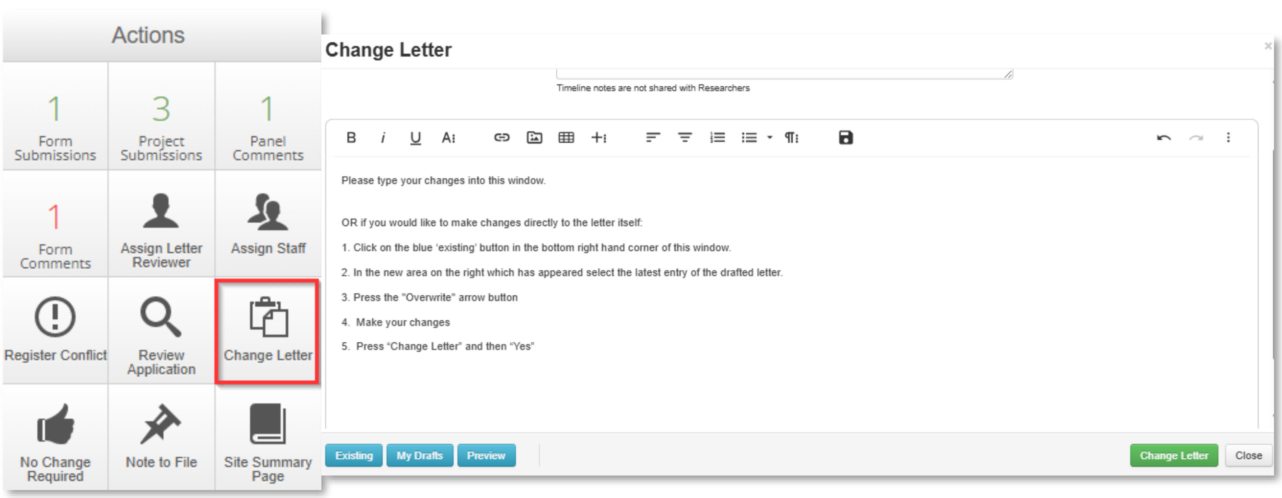


Figure 26 – Change Letter

3.9 Sending the Letter

The final step in the workflow is sending the approval or acknowledgement letter to the study team. To do this, click **Send Approval Letter-IA** action. A pop-up window will appear with the approval template letter visible inside a text editor (*Figure 27*). Edit the letter directly in the editor or overwrite it with an existing draft by following the process described in Section 3.7 - My Drafts. You can see a preview the letter in PDF format before sending by clicking the blue **Preview** button located to the right of the **My Drafts** button.

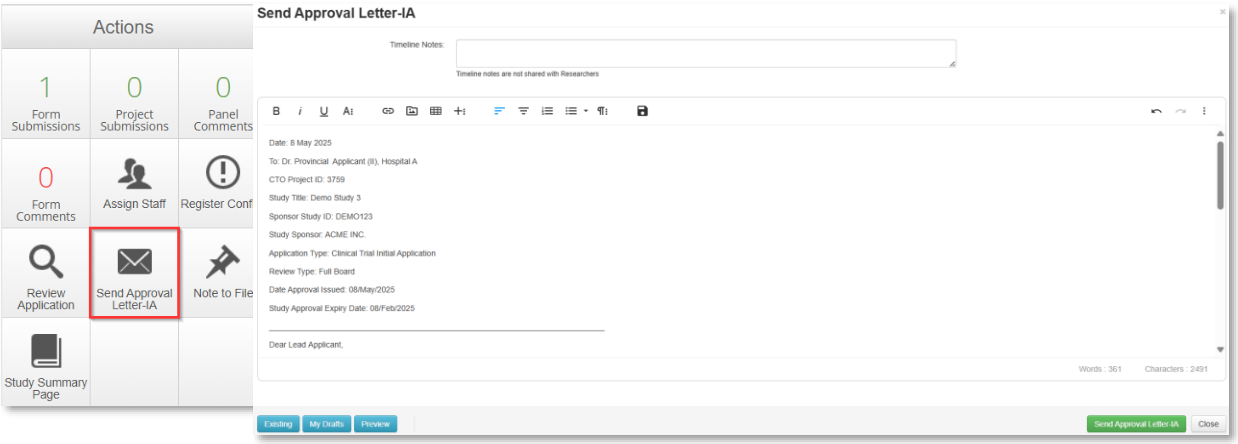


Figure 27 – Send Approval Letter

3.10 Going Back a Step in the Review Process

During the review of a submission if an action button is pressed in error and the application has moved to the wrong status, please submit a support ticket to the Stream Helpdesk and provide the review reference number of the submission, as well as the status the application should to go back to. A system administrator can create an **UNDO** button, which is a customized action to revert the status of the submission back to a requested status.

4. Administrative Actions

Administrative actions also appear within the Actions Menu during many steps of the REB workflow. Unlike the workflow actions discussed previously, administrative actions do not change the status of a submission within the REB workflow. Instead, REB users can use these to perform administrative tasks on a submission like assigning a reviewer, registering a conflict or creating a note to file, etc. The various Administrative actions are described over the next several pages.

4.1 Assign Staff

There are several different 'types' of reviewers that can be assigned to submissions in Stream. Assigning reviewers helps direct the workflow through a specific individual (i.e., the Chair) as well as distribute the workload of submissions the REB receives through the system. One type of reviewer is called **Review Staff** who are assigned by the REB Manager after they have accepted the study on behalf of the REB of Record. REB operations personnel who get assigned as Review Staff will be responsible for conducting the initial review of the submission, assessing for completeness, and then assigning REB Members as required.

Review staff can be assigned to just the current submission under review, or to the current submission plus all future submissions for the project. Review Staff can access submissions to which they're assigned from the **My studies** tile of their Work Area. Only users with the REB Director/Manager and/or REB Staff system roles have access to the **Assign Staff** button in the Actions Menu.

Tip: REB users with 'REB Staff' role can access any submission (once study accepted by the REB Manager) from the administrative review tiles of their Work Area, regardless of if whether they have been assigned as Review Staff.

To assign a Review Staff, click **Assign Staff** in the Actions Menu to open the Assign Staff pop-up window. Inside is a table of all users from the REB that can be assigned as Review Staff.

To assign **Review Staff** to the current submission only, click on the drop-down in the far-right column (called **Assign Submission**) in the row containing the REB member you want to assign. Or assign the user to the current submission and all future submissions using the drop-down in the **Assign Project and Submission** column.

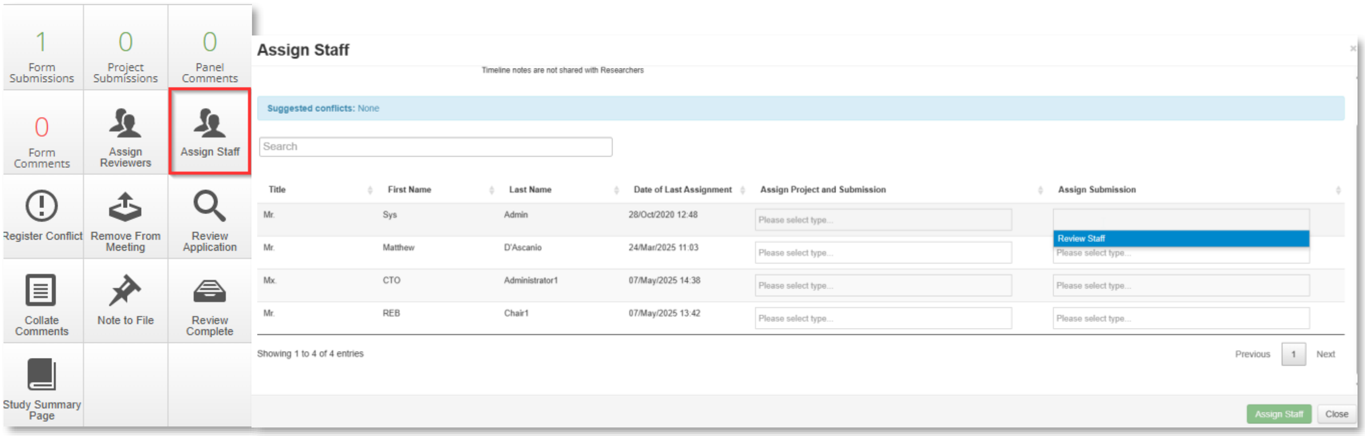


Figure 28– Assign Review Staff

Once all Review Staff have been selected, click the green **Assign Staff** button at the bottom of the window. This action will be recorded on the Submission Timeline page including the name of the user who performed the action, and the reviewers that were assigned (if applicable).

4.2 Assigning Reviewers

Several additional reviewer types exist which are typically reserved for REB Members or the REB Chair. These include **Primary, Secondary, or Other** reviewers. Like **Review Staff**, these types of reviewers can be assigned to only the current submission, or the current submission plus all future submissions for the project. Assigned reviewers can access their submissions from the **For my Review** tile of their Work Area. However, access is available after the level of review has been selected and before the REB's decision (i.e., approved, acknowledged) has been recorded for the submission.

The **Assign Reviewers** action is an example of an **administrative action** meaning it does not change the status of the submission in the workflow. Note: assigning reviewers is optional, except for when the submission is undergoing delegated review. In that case, at least one user must be assigned as the **Primary Reviewer** (see Section 2.3 above).

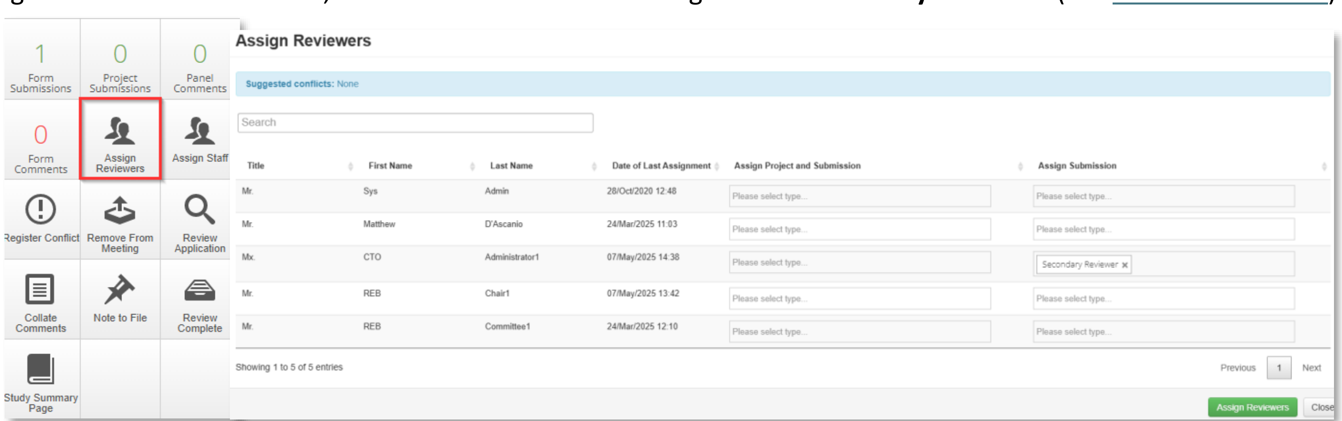


Figure 29 – Assign Reviewers

Tip: The 'Assign Reviewers' action is recorded on the Submission Timeline page and includes details about the user who performed the action, and any user(s) assigned as reviewer(s).

Click **Assign Reviewers** in the Actions Menu to assign a reviewer to the submission. This will cause the Assign Reviewers pop-up window to appear with a list of all the REB members that can be assigned to the submission displayed within a table. To Assign a reviewer to only the current submission, click the drop-down menu in the far-right column that contains the REB member's name and then select the type of reviewer (Primary, Secondary, or Other). To assign a reviewer to the current and all future submissions for the project, click the drop-down menu in the column under the heading, **Assign Project and Submission**.

4.3 Removing Assigned Reviewers or Staff

Assigned Review Staff and other reviewers can be removed (or un-assigned) from a submission at any time by pressing the **Assign Staff** or '**Assign Reviewers'** button, respectively. Click the '**X'** button that appears next to the current reviewer type they have been assigned. Once done removing reviewers, press the green button at the bottom right-hand corner of the window.

Note: Deselecting reviewers and simply closing the window without pressing the green 'Assign Staff/Reviewers' button will not complete the action; it will only close the pop-up window.

4.4 Assigning Review Type Determiner

In some cases, REB Staff may need to send the submission to the Chair to determine the level of review. The process of assigning a user to determine the review type is like assigning a reviewer or staff but is done before the level of review has been selected, while the status of the submission is "Review Type Determination". From here the **Send for Determination** button will be visible in the Actions Menu and REB Staff can use it to make a user (i.e., the Chair) the **Review Type Determiner** (the REB member who will determine the review type) for the submission.

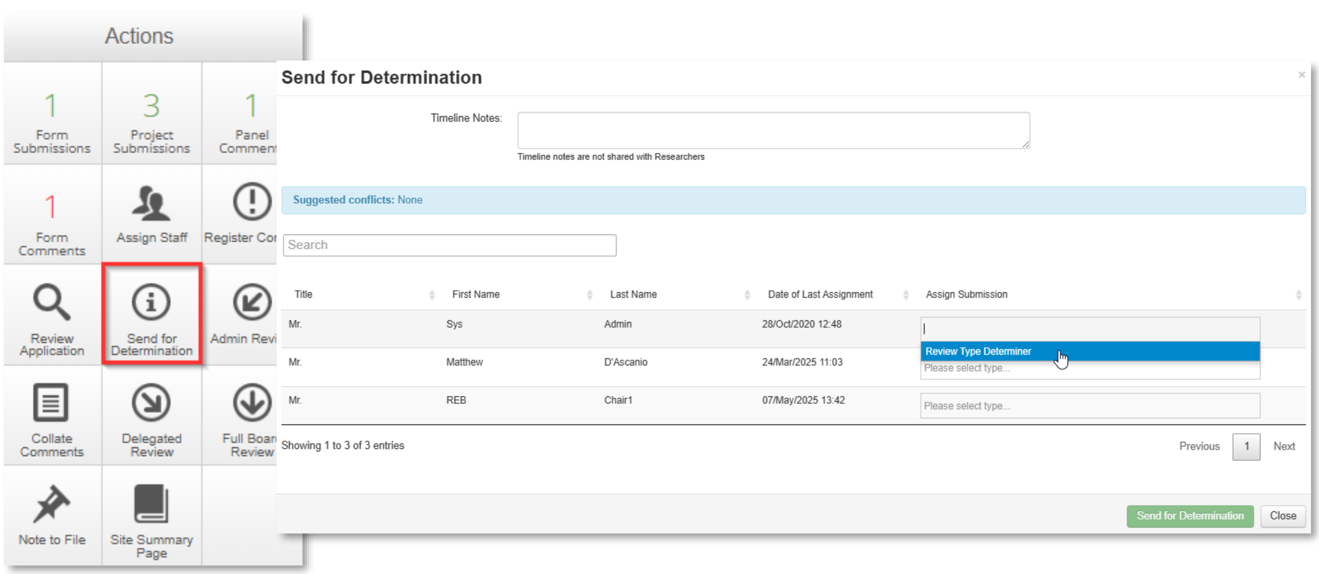


Figure 30 – Review Type Determination

Press the **Send for Determination** button to open a pop-up window from which the Chair or other REB members can be selected to determine the level of review for the submission.

The assigned user will receive an email with a link to the submission. If the chair is assigned it will also be accessible to them in the **Select Review Type** tile in their Work Area. The REB Staff will receive an email once the level of review has been selected.

4.5 Conflict of Interest

If one or more member(s) of the REB has a conflict of interest for the submission under review, the REB can register a conflict on the submission in the system to restrict access to the submission or the entire study. Registering a conflict means the submissions for the study will no longer be visible to the conflicted user in the system.   Use the Conflict of Interest action to restrict a user from accessing any application(s) for which they have a conflict with the research being conducted.

To record a conflict, click the **Register Conflict** button in the Actions Menu to open the Register Conflict pop-up window. Any REB members or REB Staff with a potential conflict will be displayed in the blue bar as "suggested conflicts" (*Figure 31*).

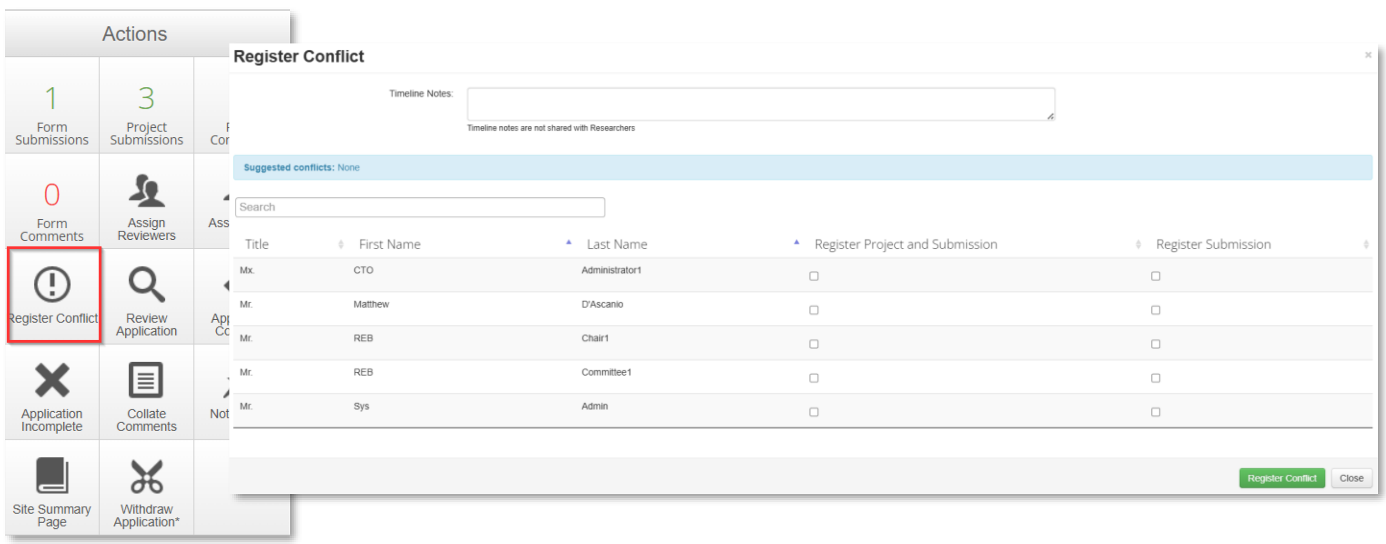


Figure 31 – Register Conflict

Tick off the checkbox for any users that have a conflict to either register a conflict for the entire project or just the current submission. Press the green **Register Conflict** button at the bottom of the window.

4.6 Review Application

To view the submitted application and associated documents, click the **Review Application** button (denoted with a magnifying glass icon) in the Actions Menu. This opens the Navigation page, where a table of contents is displayed, allowing the REB user to select a section to review. For more information about viewing applications see the Navigating Stream user manual, posted to the [Manuals & Guides](#) page.

4.7 Collating Comments

The **Collate Comments** button enables REB users to combine all the comments made within the application by other staff and REB members (form and panel comments) into a single document. This feature creates a single document containing all reviewer comments which can later be inserted into the review letter template by REB Staff.

Click **Collate Comments** in the Actions Menu. This opens a pop-up window containing two tables. One displays all **Form Comments** and the other displays all **Panel Comments** made on the submission.

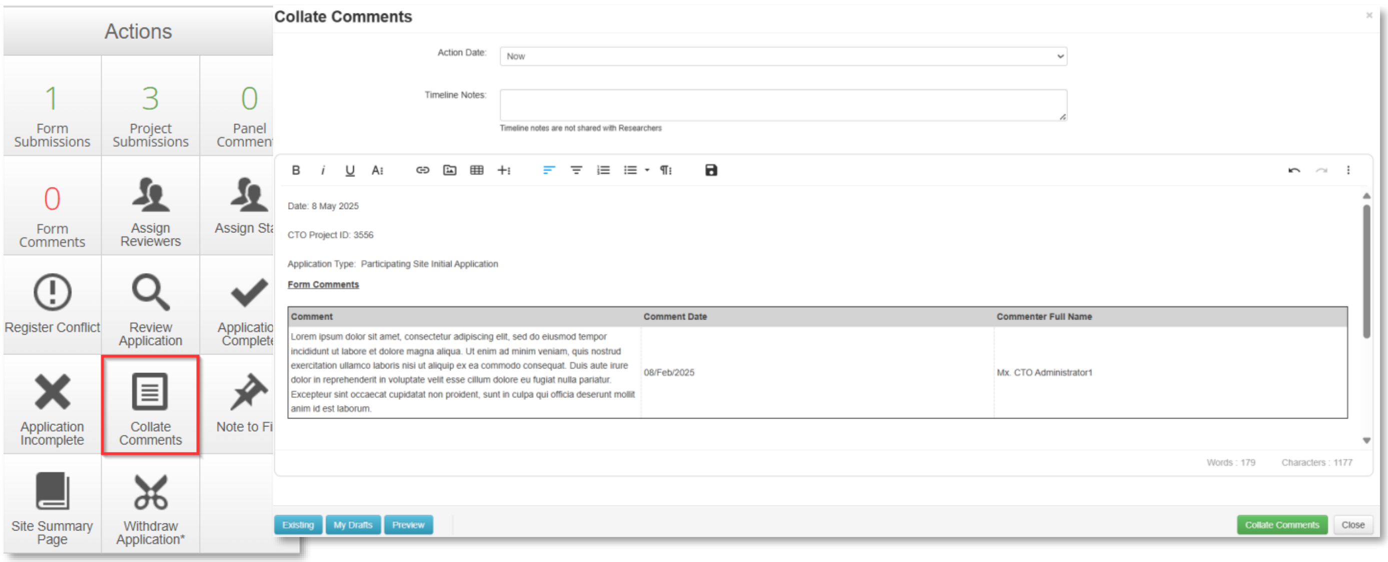


Figure 32 – Collate Comments

Users can edit, delete, or add comments to the letter (including the tables) by typing the changes directly into the text editor. Use the toolbar at the top of the text editor to make any required changes to the tables.

Once finished editing the comments click the green **Collate Comments** button at the bottom of the window. The action will be recorded to the Submission Timeline page, along with the list of other actions previously completed on the submission, where it can be downloaded by any REB users with access to the submission. During the draft letter step of the workflow, the collated comments document can be appended to the letter. A draft of the collated comments can also be saved and then re-opened at anytime later using the **My Drafts** button (just like when saving a draft of a letter).

5. Other Review Features

5.1 Comments

While reviewing a submission assigned reviewers may want to leave a comment, question or reference note for the other REB members to view. There are two types of comments reviewers can make on submissions:

Panel Comments:
Comments related to/about a specific question within the application

Form Comments:
Comments related to/about the submission overall

Note: Comments made by REB members, REB Staff, or the Chair are visible to all REB members but are <u>never visible to applicants</u>. The user making the comment also can edit or delete their comment at any time.

5.1.1 Form Comments:

To add a new form comment to the application, go to the Submission Timeline page, the navigation page, or into any section of the form. The Actions Menu on all three pages will have the **Form Comments** button visible. A red number on the button shows the number of form comments previously made on the submission by other REB users. Add a comment by clicking the **Form Comments** button, causing the Form Comments pop-up window to appear. At the top of the window is a **+Add Comment** button (*Figure 33*). Click the button and a pop-up window will appear where the comments can be typed into the text box. Once finished press the green **Save** button to save the comment.

To edit a comment click the **Form Comment** button, then click on the comment you want to edit. Only the user who created the comment can edit or delete it.

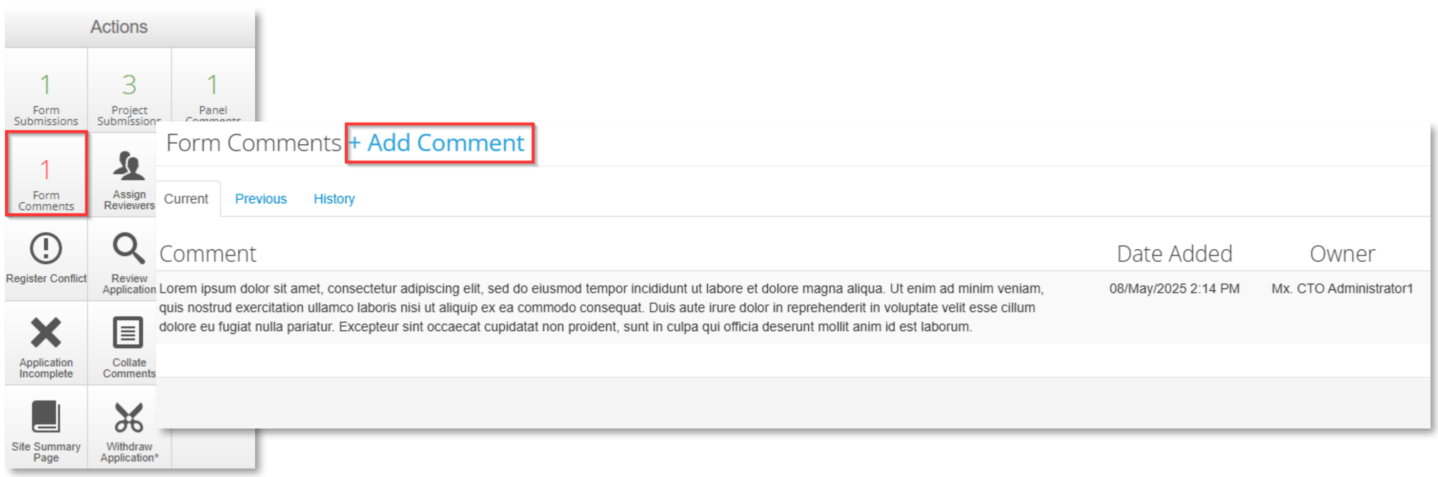


Figure 33 – Form Comments

5.1.2 Panel Comments:

Panel Comment can only be made while you are inside a section of the form. Specifically, the section of the form containing the question you want to leave a comment on. While inside a section of the form, click the **Panel Comment** button that is visible in the Actions Menu. A red number displayed on the front of the button shows the total number of panel comments made across all submission versions of the application.

To make a new panel comment click the **New Comment** button. The page will become greyed-out, but questions on the form will still be visible. Click anywhere on the white part of a question (anywhere within the blue box shown in *Figure 34*).

A pop-up window will appear where the comment can be typed into the text box. Click the green **Save** button at the bottom of the window to save the comment.

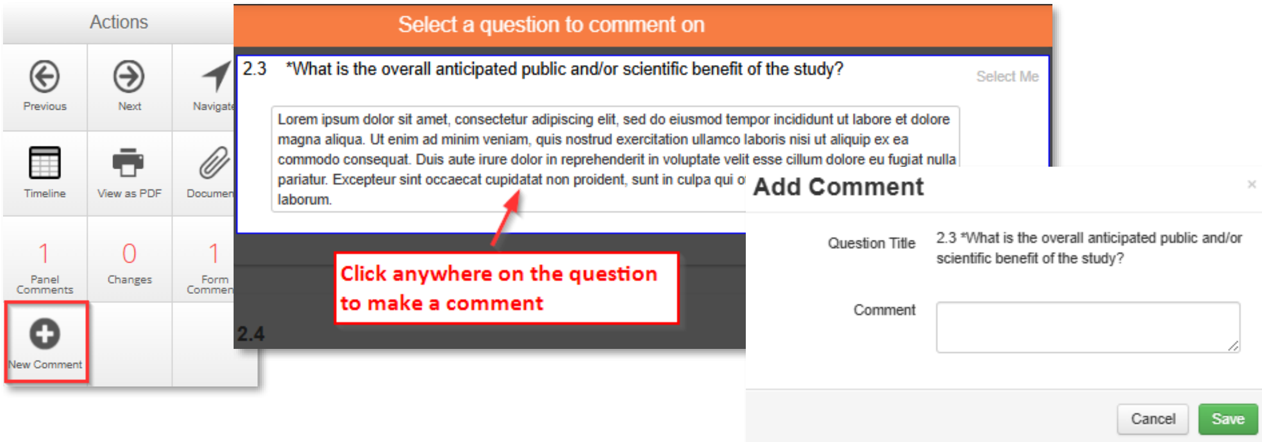


Figure 34– Add a Panel Comment

The user who made the panel comment can edit it at any time. To edit the panel comment, click the **Panel Comment** button in the Actions Menu from within the application form or directly from the timeline view.

Click the blue **Edit** button to the right of the comment you wish to edit. Only the user who created the comment can edit it. Once finished editing the comment, press the green **Save** button to save the changes. The user who created the comment is also the only one who can delete it, using the red **Delete** button.

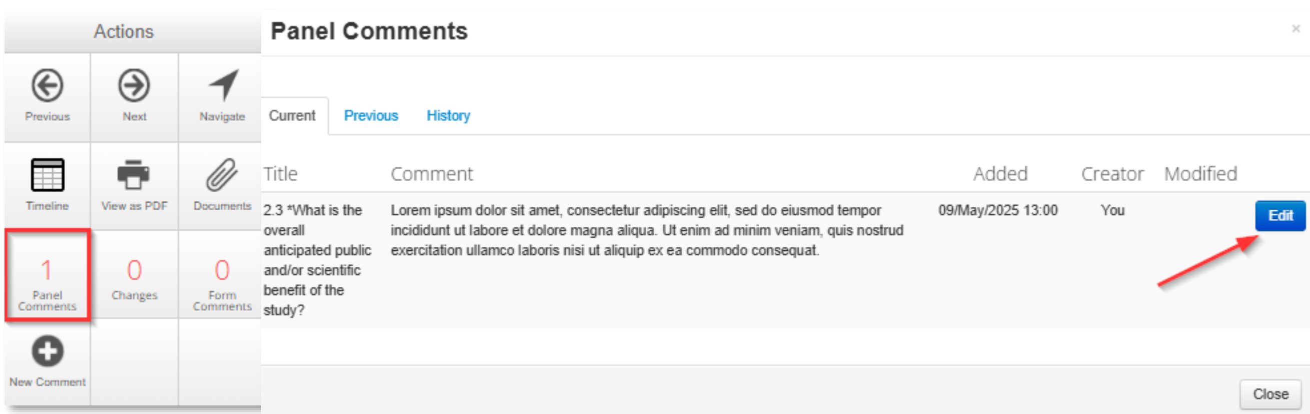


Figure 35 – Edit Panel Comment

5.2 Editing Document Identifiers after Submission

When applicants upload a document to their application, they must include a document name. Document date and document version number are not mandatory fields, therefore they may be left blank. If a situation arises where the study team makes a typo when entering this information, the REB can edit the document name, version date, or version number for any documents included in the submission they are reviewing

To do this, the REB can go to the Documents tab on and then click on the row containing the name of the document in the table. A pop-up window will appear where the Document Name, Version Date, and Version number are editable. Typically this is only done when an error is detected by the REB Staff or at the request of the study team.

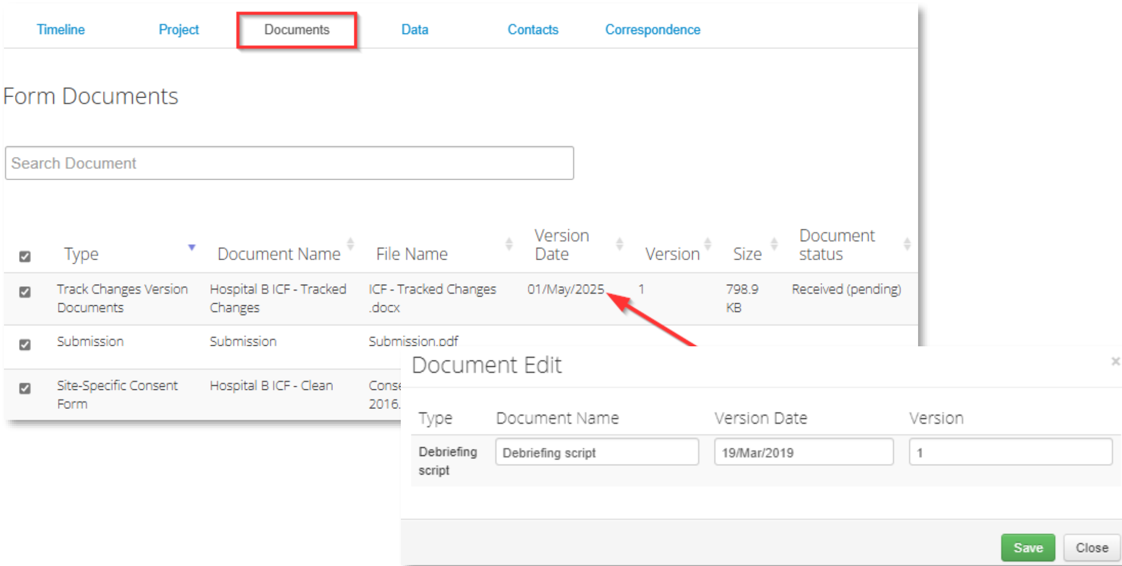


Figure 36 –Editing Document Name, Version Date, Version Number

Tip: Do not manually change the document information directly within letter template. Doing so will create a discrepancy between the document approved by the REB and the project document data within Stream. More details on this can be found in the Navigating Stream user manual, available for download on the [Manuals & Guides] page.