wcg™ velos

eCompliance User Guide

Table of Contents

1 About This Guide 4

1.1 Who Should Use It? 4

2 eCompliance 6

2.1 Example Workflow 8

2.2 Overview of Roles 9

2.3 Navigating Compliance and Permissions 10

2.4 Study Team Member Functionalities 16

2.4.1 Protocols 16

2.4.2 Protocol Build and Submission 16

2.4.3 Protocol Modification Requests 27

2.4.4 Viewing Final Outcome Documentation 30

2.4.5 Protocol Amendments after Initial or Amended Submission 33

2.5 eCompliance Administrators Functionalities 38

2.5.1 Assigning a Modification 39

2.5.2 Assigning a Reviewer and Setting a Meeting 41

2.5.3 Post Review Processing 45

2.5.4 Navigating to Manage Meetings Functions 48

2.5.5 Final Outcome Processing 52

2.6 Reviewers Functionalities 55

2.6.1 Navigating to Reviewers Area 56

2.6.2 Managing Reviews 57

2.7 Board Committee Members Functionalities 60

2.7.1 Review Reviewer's Forms 62

2.7.2 View Meeting Details and Meeting Topics 63
3 Appendix A: Technical Information 65
3.1 Revision History 65
3.2 Related Software 65
3.3 Minimum Workstation Requirements 65

1 About This Guide

This document presents the following topics:

- eCompliance may be used as a stand-alone tool for internal reviews, using the client's internal review boards.
- The eCompliance module allows permissioned study team users to develop and submit new protocols and/or amendments to the designated review committees.
- eCompliance is typically used by Institutions to manage their regulatory workflows and processes including documentation, such as attachments and forms.
- Creating foundational account elements such as organizations, groups, users, quick links, and account forms.
- A study team will have a central location for managing a study from development to completion.

1.1 Who Should Use It?

This guide is intended for study team members, eCompliance Administrators, Reviewers and Board Committee Members. While eResearch is not a role-based system, functionalities within eCompliance are grouped together by "roles". The permissioned roles in eCompliance, enables a user with the assigned role to initiate and complete their specific tasks.

Study Team Members, Reviewers, and Board Committee Members will only be able to view and create or edit study data if added to a study as part of the study team and given permissioned access.

This guide assumes users have a knowledge of managing patient data, clinical trial management systems, and clinical trial regulatory requirements.

2 eCompliance

eCompliance is an add-on module for Velos eResearch or may be used as a stand-alone tool for internal reviews, using the client's internal review boards. This module in particular is configured to the client's needs, and therefore each use case is unique. This section in the user guide is describing what is possible in eCompliance at a high level. Specifics of a client's environment can be obtained from the client's project manager.

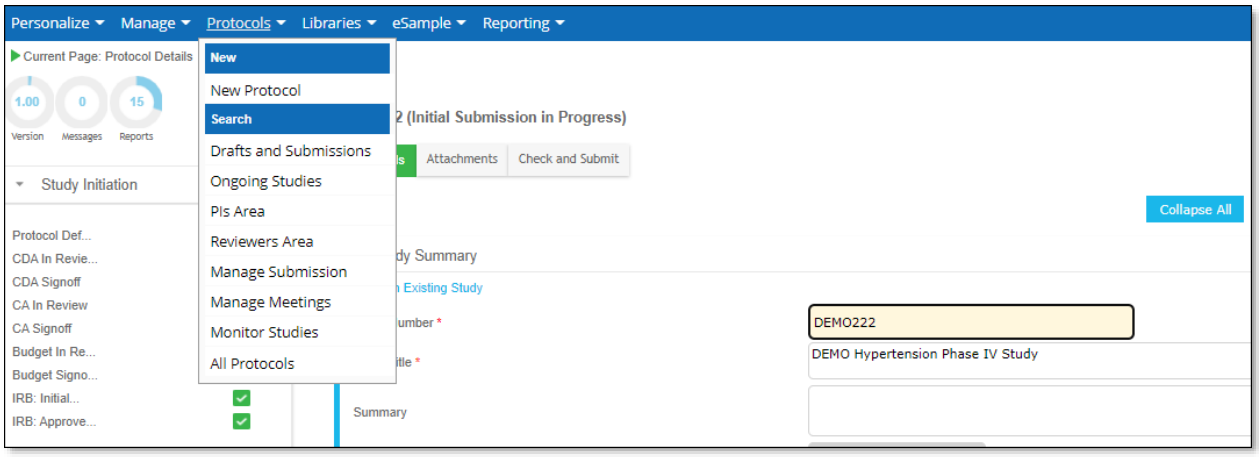
The eCompliance module allows permissioned study team users to develop and submit new protocols and/or amendments to the designated review committees. eCompliance is typically used by Institutions to manage all of their regulatory workflows and processes including documentation, such as attachments and forms. A study team will have a central location for managing a study from development to completion. eCompliance requires various users within groups to complete required tasks.

Please be aware that each client's eCompliance build is unique, therefore the user roles and process steps in this section are being used as examples.

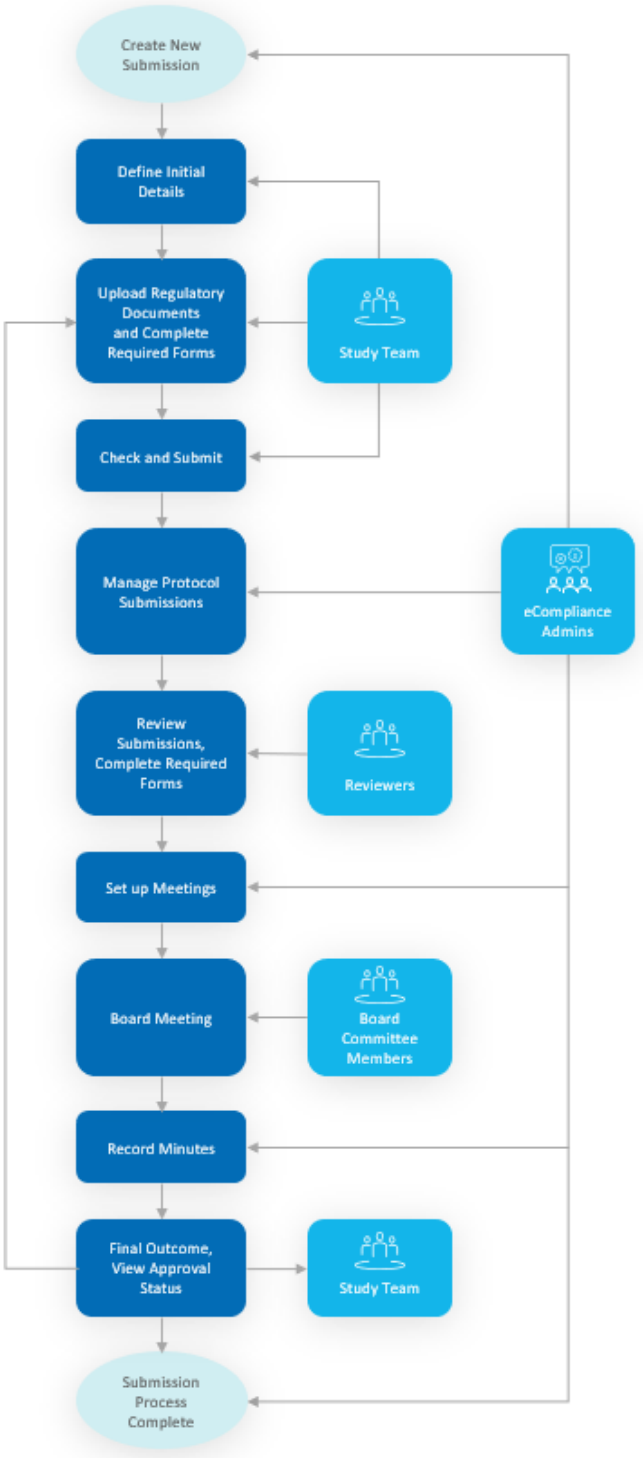
Note: In Study Management, the Study Details page will be viewed instead of a Study Summary page. For environments that have both eCompliance and eResearch, the Study Summary tab will be in LIND (non-editable) mode by default. mainly because all such changes need to be done within eCompliance since it may impact the review processes. Please submit a request to Velos Support to switch between viewing the Study Summary page instead of the Study Details page, if needed.

Within this section of the guide, topics are broken down by eCompliance user roles:

- Study Team Members
- eCompliance Administrators (eCompliance Admins)
- Reviewers
- Board Committee Members



2.1 Example Workflow



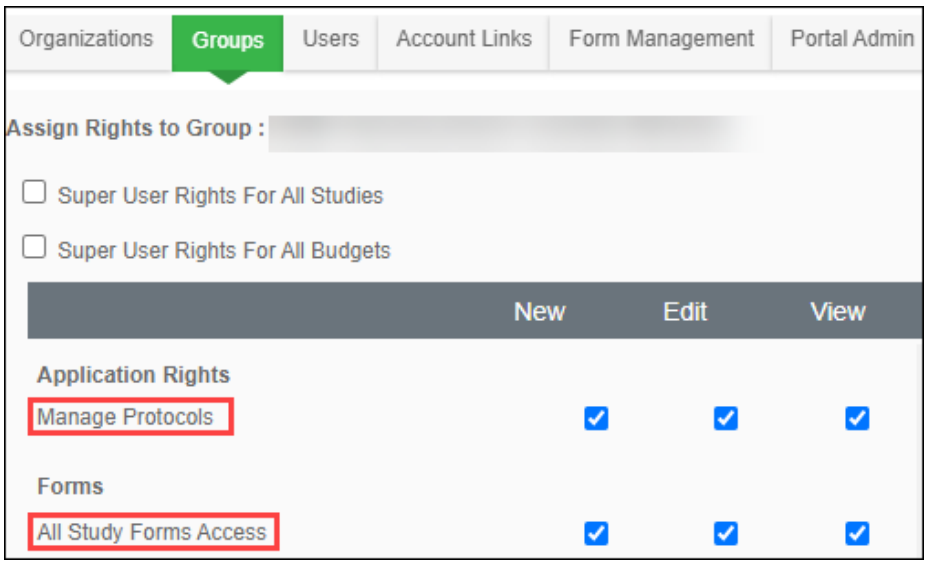
2.2 Overview of Roles

While eResearch is not a role-based system, functionalities within eCompliance are grouped together by “roles”. The permissioned roles in eCompliance, enables a user with the assigned role to initiate and complete their specific tasks.

Details of the role-based functionality in eCompliance is described in the following table:

Role Name	Responsibilities
Study Team Members	Create New Protocol Submissions: ▪ Define Initial Details ▪ Upload Regulatory Documents ▪ Submit using Check and Submit Modify Submissions, as requested View Final Outcomes and Documents Initiate Amendments, if requested
eCompliance Administrators	Manage Protocol Submissions: ▪ Update Submission Statuses ▪ Assign Study Team Member(s) for Modifications, as necessary ▪ Assign Reviewer(s) ▪ Setup Board Meetings ▪ Create Meeting Topics ▪ Take Meeting Notes ▪ Assign Final Outcome Statuses
Reviewers	Review Assigned Submissions: ▪ Complete Reviewer Forms
Board Committee Members	Review Submissions View Meeting Topics and Details Attend Meetings: ▪ Vote on Final Outcome

Note: Study Team Members, Reviewers, and Board Committee Members will only be able to view and create or edit study data if added to a study as part of the study team and given permissioned access (as shown in the image below). Additionally, Reviewers and Board Committee Members require permissioned access to Study Team Forms view and/or complete these forms in the Reviewers Area. Depending on the access needed, a group may have View, Edit, and/or New rights, as shown below.

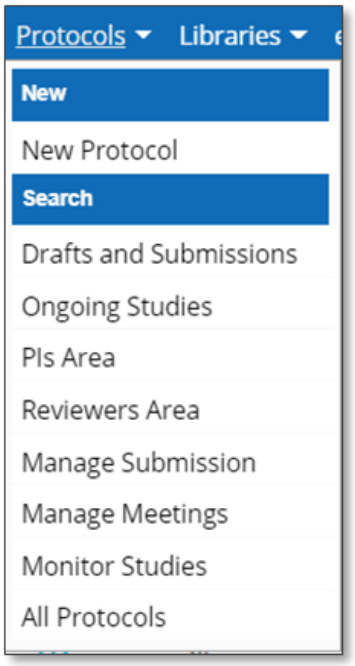


2.3 Navigating Compliance and Permissions

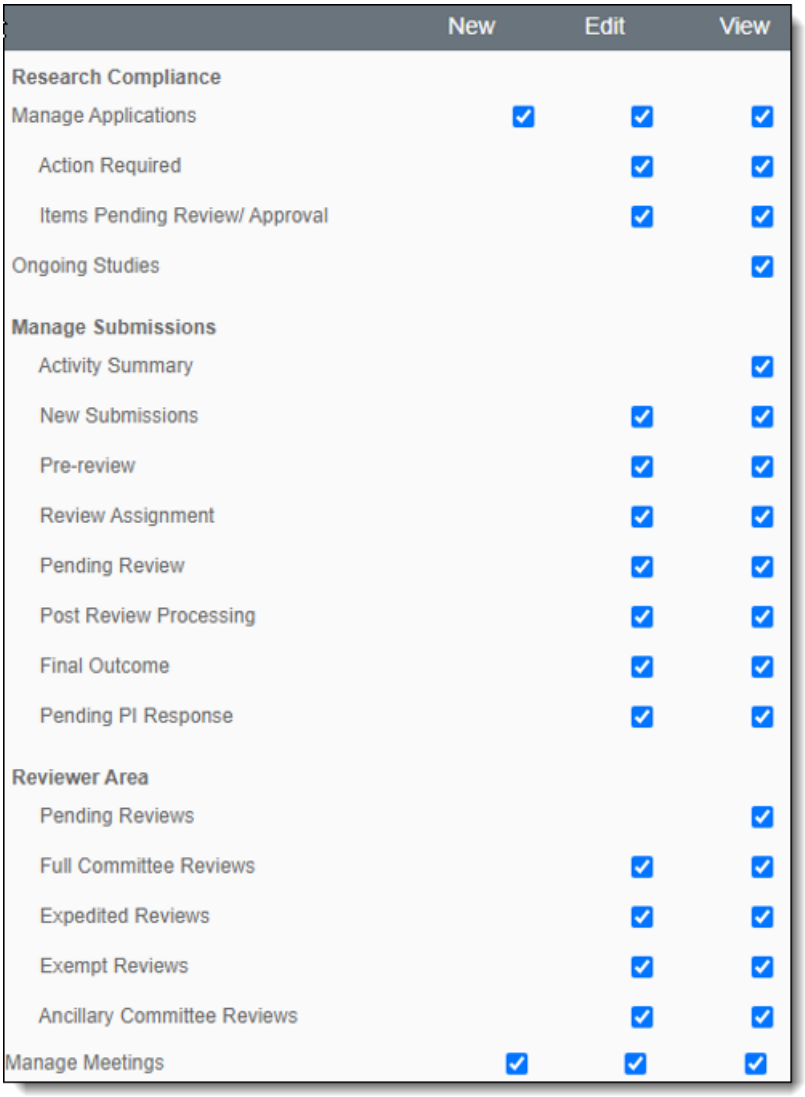
Within eCompliance, the core functionalities are found under the Protocols tab in the main navigation bar. At any point, users may use the Protocol heading in the main navigation bar and select the appropriate page or topic to navigate to for eCompliance. In order for each area of the Protocols dropdown to populate for a role, each group assigned in eResearch must be permissioned specific access rights in the eCompliance areas of Group Rights.

Note: The following are suggested permissioned access rights to navigate in eCompliance for the role examples created for this user guide.

1. eCompliance Admins will have access to all areas with white backgrounds in the Protocols dropdown, as shown below.

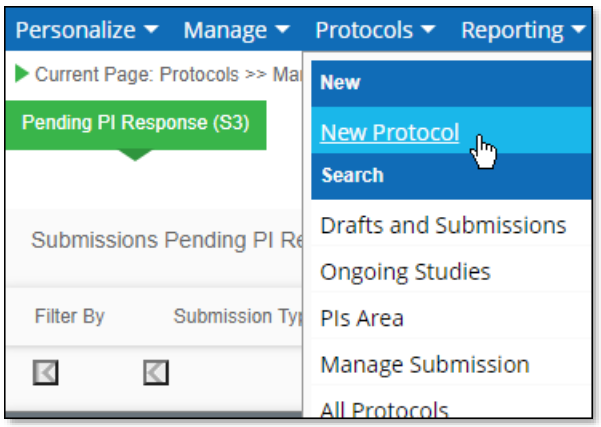


a. In order to have access to all areas in eCompliance as an eCompliance Admin, this group of users must have the following eCompliance rights.

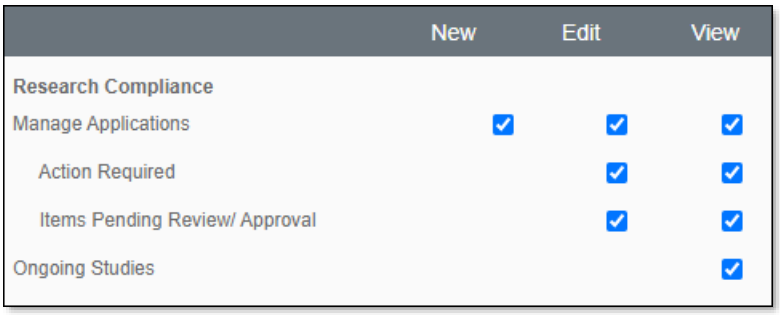


	New	Edit	View
Research Compliance			
Manage Applications	☑	☑	☑
Action Required		☑	☑
Items Pending Review/ Approval		☑	☑
Ongoing Studies			☑
Manage Submissions			
Activity Summary			☑
New Submissions		☑	☑
Pre-review		☑	☑
Review Assignment		☑	☑
Pending Review		☑	☑
Post Review Processing		☑	☑
Final Outcome		☑	☑
Pending PI Response		☑	☑
Reviewer Area			
Pending Reviews			☑
Full Committee Reviews		☑	☑
Expedited Reviews		☑	☑
Exempt Reviews		☑	☑
Ancillary Committee Reviews		☑	☑
Manage Meetings	☑	☑	☑

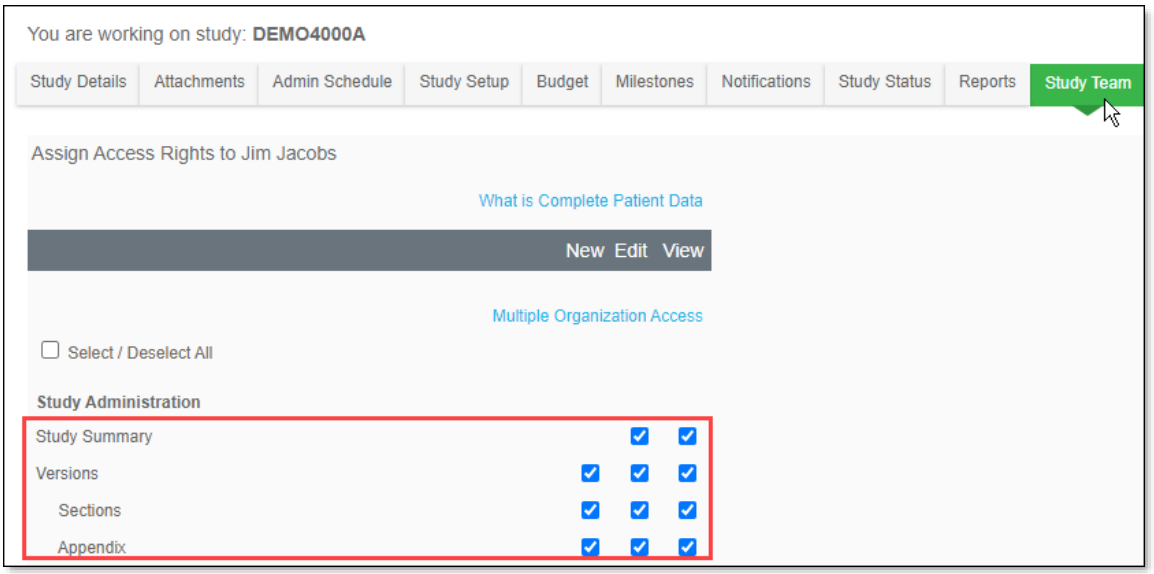
2. Study Team Members will have access to only the following areas in the Protocols dropdown, including New Protocol, Drafts and Submissions, Ongoing Studies, and PIs Area.



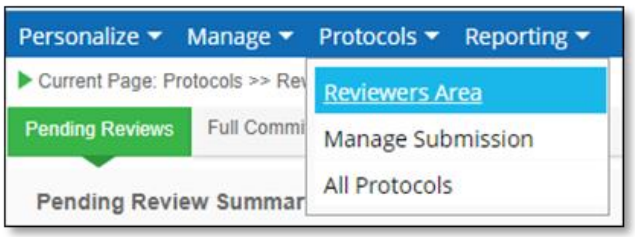
a. In order to have access to the areas in eCompliance as a Study Team Member, this group of users must have the following eCompliance rights.



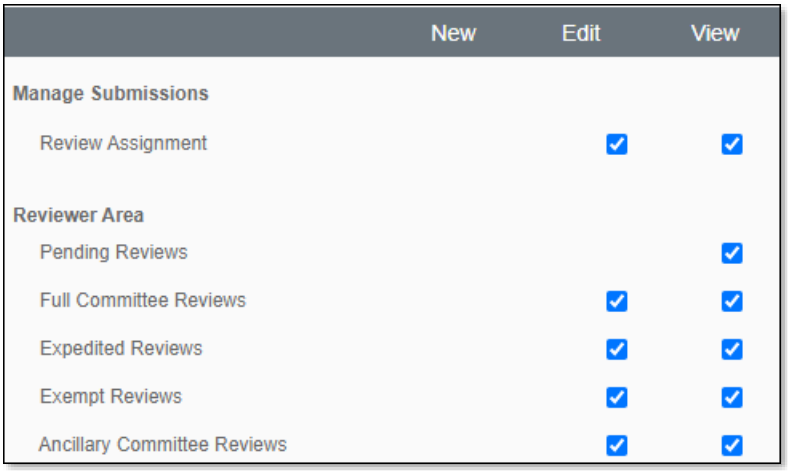
b. Additionally, to be able to add new, edit, and view in a submission's Study Summary/Details and Versions/Attachments tabs, the study level access rights for the study team member must be checked.



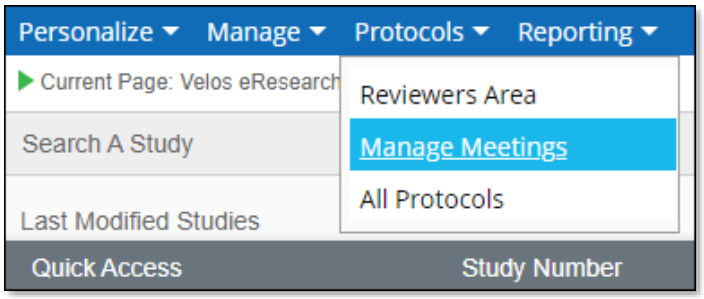
3. Reviewers will have access to only the following areas in the Protocols dropdown, including Reviewers Area and Manage Submissions.



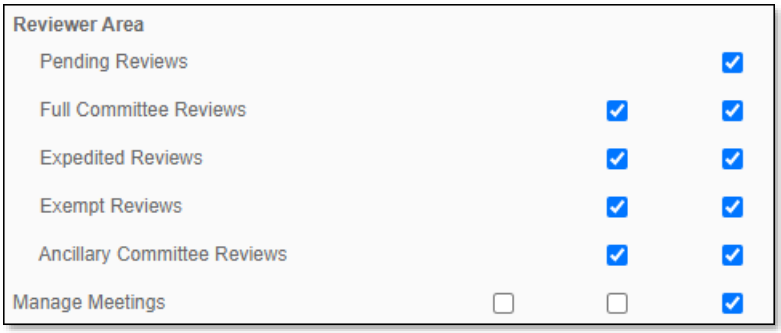
a. In order to have access to the areas in eCompliance as a Reviewer, this group of users must have the following eCompliance rights.



4. Board Committee Members will have only the following access to areas in the Protocols dropdown, including the Reviewers Area and Mange Meetings.



a. In order to have access to the areas in eCompliance as a Board Committee Member, this group of users must have the following eCompliance rights.



2.4 Study Team Member Functionalities

Study Team Members, such as Coordinators or PIs, may be tasked with creating and defining new Protocols. With eCompliance, this step replaces creating a new study and defining study details, as study details are documented during the protocol creation process.

Study Team Members with eCompliance begin with creating a new protocol, and then continue with steps such as defining the Initial Details tab, uploading Attachments, and submitting the protocol and attachments to the review board in the Check and Submit tab.

Note: eCompliance Administrators must ensure the study team member is assigned to the study team and that access rights are set as per the **Navigating Compliance and Permissions** section.

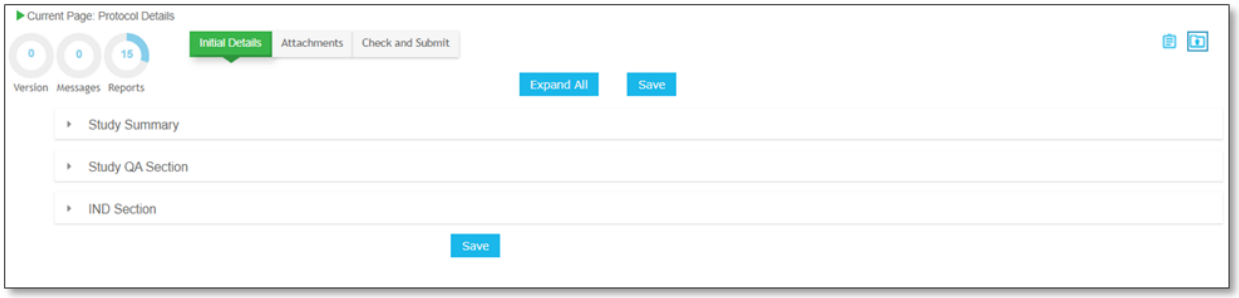
2.4.1 Protocols

Within eCompliance, the creation of a new protocol uses three default tabs: Study Details, Attachments, and Check and Submit tab.

2.4.2 Protocol Build and Submission

eCompliance allows for permissioned Study Team Members to build and submit protocols within eResearch. Typically, these duties are completed by members of the Study Team, such as PIs, Coordinators, or Protocol Managers.

Creation of a new study will be done through New Protocols instead of New Studies. For instructions on building a Protocol, see **Create a New Submission**. For instructions on Protocol submission, see **Check and Submit Tab**.



Warning: With eCompliance enabled, it is highly recommended that new studies are initiated using eCompliance and not by using New Studies under the Manage dropdown in the navigation bar.

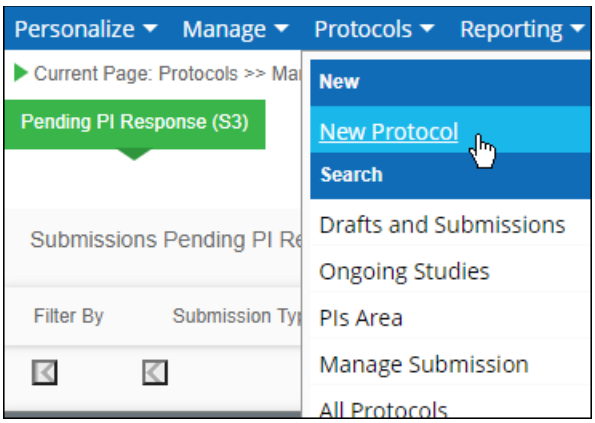
2.4.2.1 Initial Details Tab

On the Initial Details tab, permissioned users define basic study details that begin the process of building a protocol.

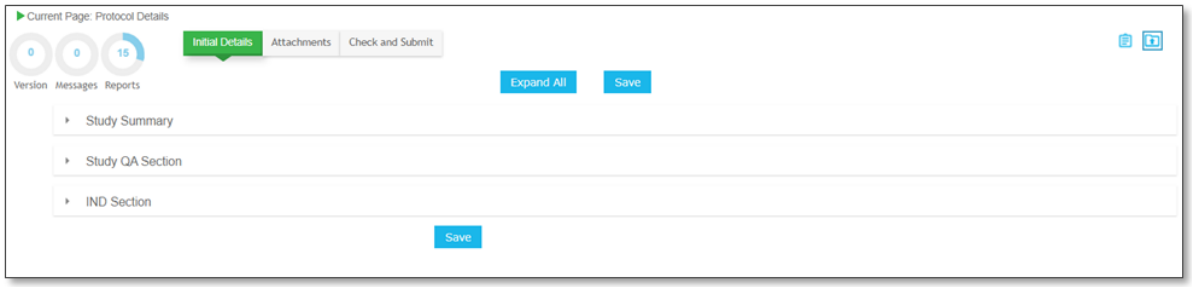
Note: The details entered on the Initial Details tab will appear on the Study Summary / Study Details tab of a study.

To navigate to the Initial Details tab:

1. From the main navigation bar, hover over **Protocols** and under the heading "New", click **New Protocol**.



The Protocol page displays:

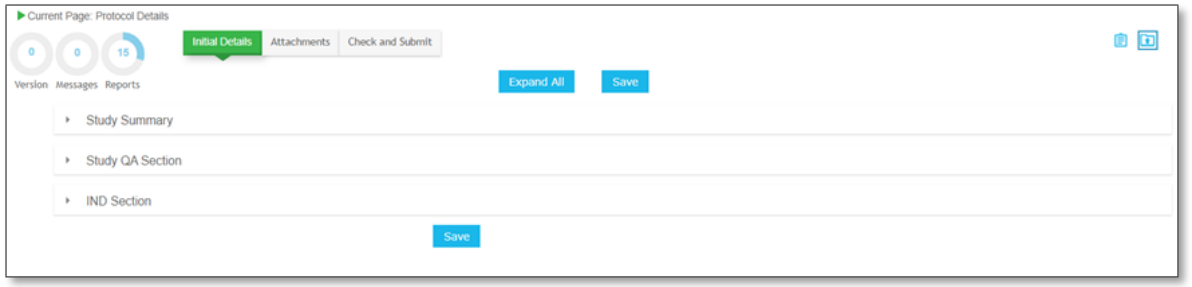


2.4.2.2 Create a New Submission

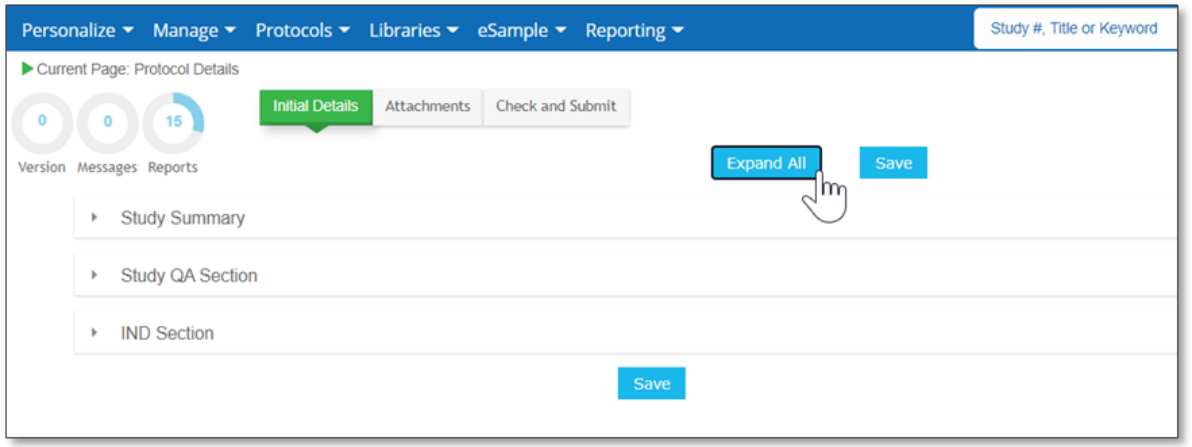
Creating a new protocol submission is the first step in eCompliance.

To create a new protocol:

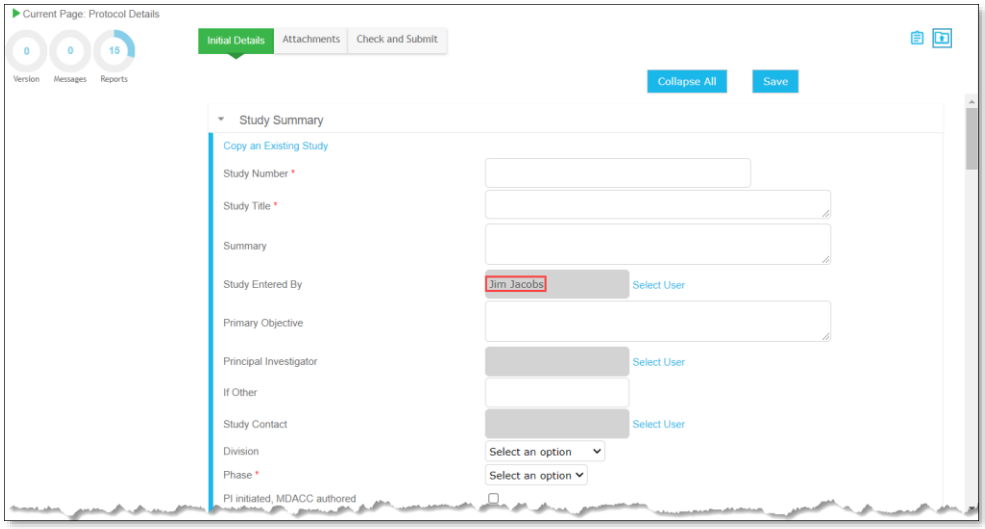
1. Navigate to the Initial Details page.



2. Click **Expand All** to expand the Initial Details sections.



The sections expand, displaying available fields with the Study Team Member field populated with the username of the user entering data.



Note: The Study Details page will be the default tab instead of a Study Summary page in most eCompliance environments. Please submit a request to Velos Support to switch Lind Mode to Y/On, to view the Study Summary page instead of the Study Details page, if needed. Additionally, fields may vary based on your institution's requirements and eResearch settings.

For details on how to complete the available fields, use the table below:

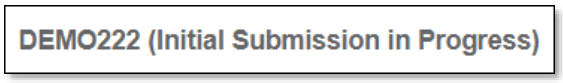
Section Name	Description
Study Information	Users can Copy an Existing Study, update assigned users, select a Principal Investigator, and select a Study Contact. In the Enterprise version, the study information can also include: ▪ If the Principal Investigator was a major author/initiator of this study ▪ If the study is CTRP Reportable ▪ If the study is an FDA Regulated Study
Study Definition	Users can modify the Study Number, Study Title, enter a Primary Objective, enter a Summary for the study, and enter an NCT Number (or import from ClinicalTrials.gov using an NCT number lookup, if interface has been added). **Note:** NCT######## must be listed before the 8-digit number.

Section Name	Description
Study Details	Users may enter a study Agent/Device, select a Division from the dropdown, select a Therapeutic Area, enter a Study Duration, select a Duration from a dropdown, and enter the total sample size. In the Enterprise version, the following fields are also available: ▪ Disease Site ▪ Specific Sites ▪ National Sample Size ▪ Estimated Begin Date **Note:** The Division controls the values for the Therapeutic Area field.
Study Design	Users may select a study Phase from the dropdown menu, select a Research Type from the dropdown, select what the study is Linked to, or select Coverage Analysis Required from the dropdown. In the Enterprise version, the following fields are also available: ▪ Study Scope ▪ Study Type ▪ Study Linked To (must be a study in eResearch) ▪ Blinding ▪ Randomization
Sponsor Information	Users may enter or select a Sponsor Type, enter a Sponsor ID, enter a Primary Contact, or enter a Sponsor Name. In the Enterprise version, the following fields are also available: ▪ If Other (sponsor type) ▪ Other Contact ▪ NIH Grant
Keywords	Keywords are an Enterprise Only feature which allows permissioned users to associate keywords for study searches.
More Study Details	More Study Details are Enterprise Only fields that include the following: ▪ Short Protocol Number ▪ IRB Number ▪ Other Number ▪ Specify Name for Other Number

Note: Division is a required field as to complete as it allows you to populate the Department required field.

3. Complete the fields to define the Initial Details tab as appropriate and click **Save** to submit.

The Initial Details are saved. Once saved, the Initial Details page will include a note that the protocol submission is “In Progress”.

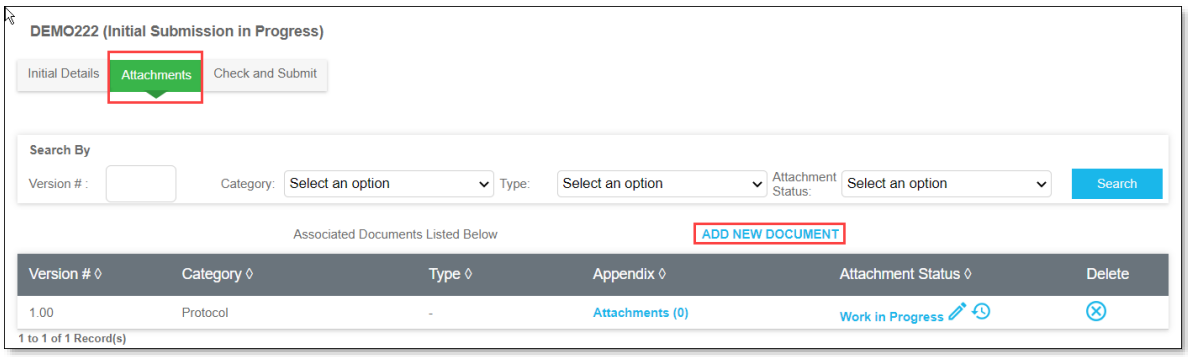


2.4.2.3 Attachments Tab

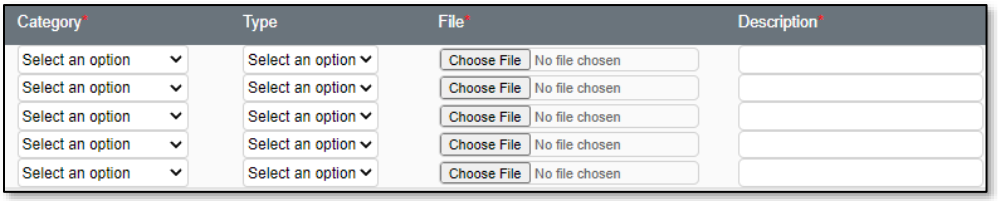
Once Protocol creation has begun and the Initial Details tab completed, users can use the Attachments tab. The Attachments tab is where permissioned users may upload and manage files from outside the application that are associated to a study. In eCompliance, documents that must be attached are those documents that need to be submitted for review by the review board. Usually, at minimum, a protocol needs to be uploaded.

To add a New Study Document/Attachment:

1. From the Attachments tab, select Add New Document.



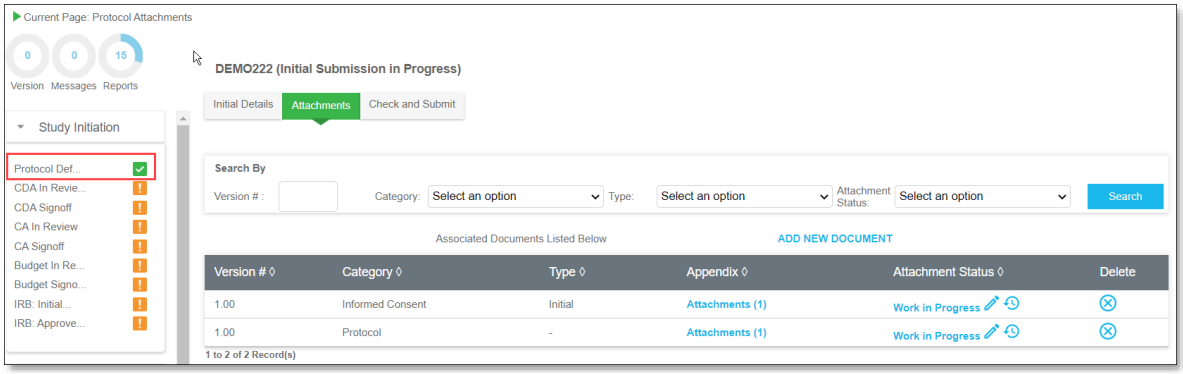
The Add New Version/Document window open



Note:
1. Multiple documents can be uploaded at once by adding each document as a line item.
2. Only PDF, Word, Excel, PowerPoint, and Text formats are accepted in the system as Documents.
3. Version Numbers will be auto-generated and numeric.

2. Enter in the appropriate document information for the document version and save with your e-Signature.

3. Below is an example of what may be viewed after adding documents in Attachments.



Note:
1. If the protocol document is added, the Study Checklists will appear and the Protocol Definition green checkmark will appear to show Done status.
2. To change the Attachment Status, click on the Edit icon in the Attachment Status column.
3. History of the attachment can be viewed by clicking the History icon under the Attachment column.
4. An attachment can be deleted by clicking the Delete icon in the Delete column.
5. By clicking the Attachments link under the Appendix column, the document can be accessed for viewing, editing, or deleting.

2.4.2.4 Check and Submit Tab

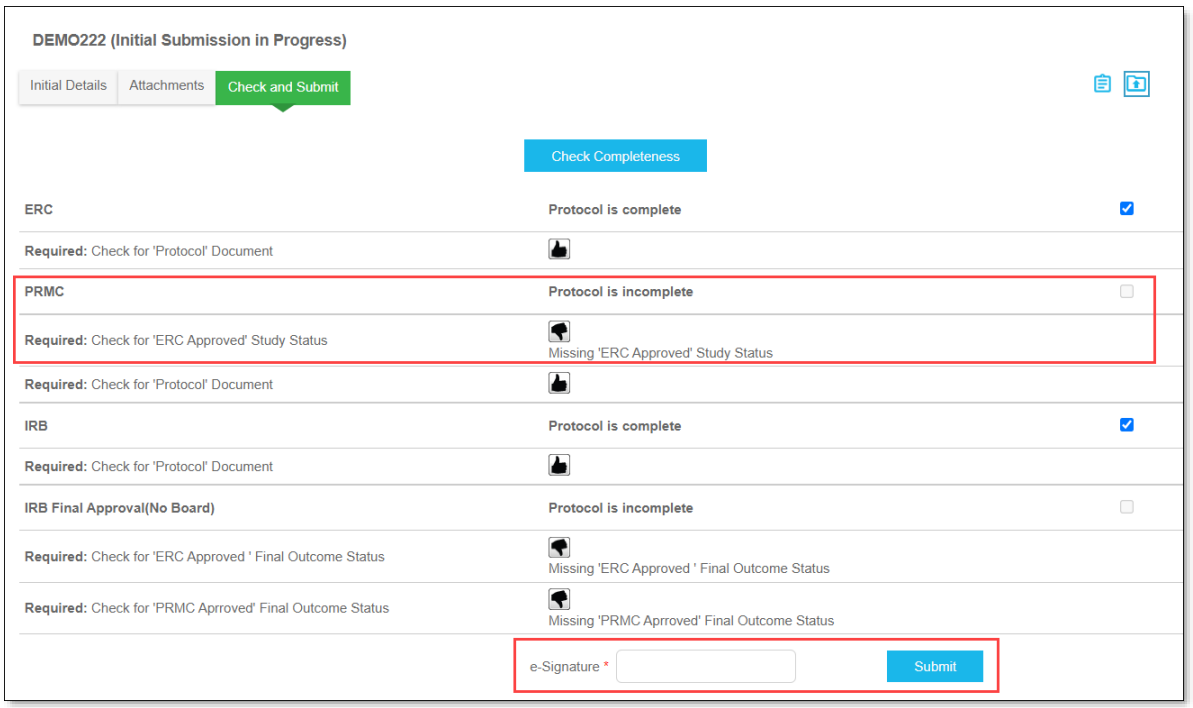
The Check and Submit tab allows permissioned users to verify that all requirements for the designated review committees are complete. Once the appropriate requirements are met, the protocol can be submitted for review by the eCompliance Admins, Reviewers, and Board Committee Members. The requirements here will be rules dictated and set by the client and configured by the WCG Velos teams as part of initial eCompliance setup.

When setting up groups and users for eCompliance, clients must work with Velos Support to ensure eCompliance backend permissions are applied. This will affect what board review types can be viewed by Study Team Members in the Check and Submit page.

To verify requirements and submit the protocol submission:

1. From the Attachments, tab, click the **Check and Submit** tab, then click **Check Completeness** to confirm all requirements have been met.

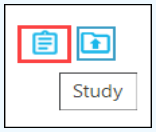
The page refreshes and displays items for the review committee.



a. If there is a "Fail" status, proceed to the appropriate Protocol tabs or Study page to complete the requirements, except for Final Approval statuses, as these are managed by the eCompliance Admin.

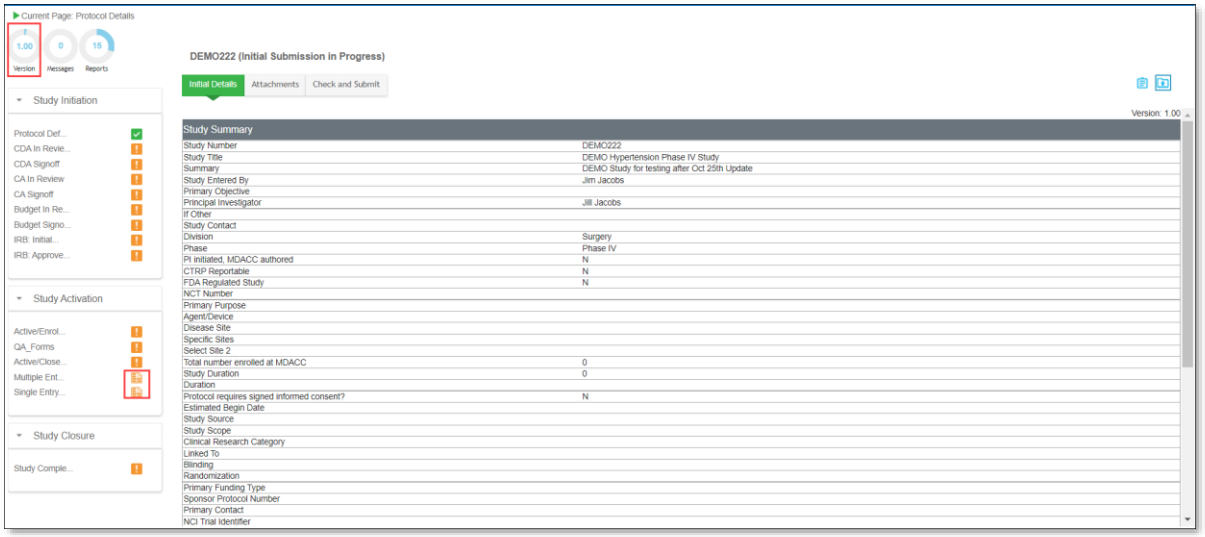
   i. For the example, in the image above, the Check and Submit tab indicates the Protocol details are incomplete for the PRMC and that the 'ERC Approved" Study Status must occur before submitting for this Board Review. To complete the above requirements in the example, return to the Study's Study Status tab and update the ERC status as requested.

Note: Depending on the "Fail" status, the request may be to make an update from the Initial Details tab, Attachments tab, or to update a Study Status from the Study page. Click the **Study** icon to access the Study page.



2. Once the Check and Submit indicates the Protocol is complete and all requirements, except the Final Approvals, have a “Pass” status, the protocol can be submitting by entering your e-Signature and clicking **Submit**.

When the Protocol is submitted, the Study Details tab will be locked down and users will be unable to edit, as seen below:



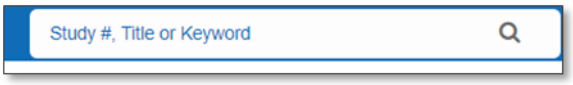
Note:
1. The number field in the circle for Version will show 1.00. This links to a pop-up showing the Submission Type of New Application.
2. If the Study Checklists in the left-hand column did not appear after adding documents in the Attachments tab then they will appear after Check and Submit. If there are any forms attached to any of the statuses, the icon will appear with lines through it as highlighted by a red box in the image above.

2.4.2.5 Access an In-Progress Protocol

If at any point during the Protocol Build and Submission process you need to return to the Initial Details, Attachments, or Check and Submit tabs, follow the instructions below.

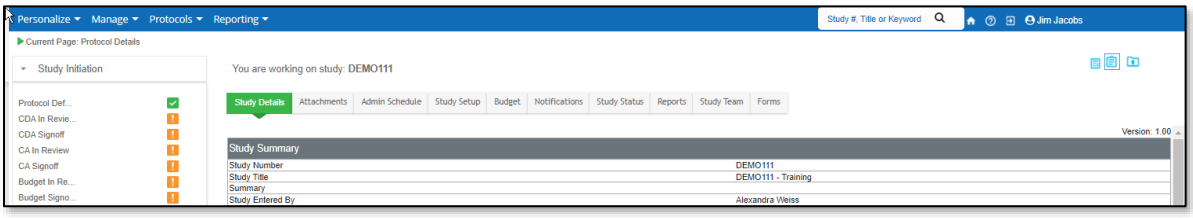
To access an in-progress Protocol Submission:

1. From the default homepage, search for the study in the homepage navigation bar.



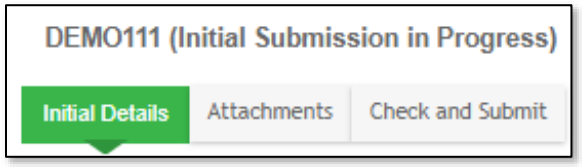
2. From the default homepage, search for the study in the homepage navigation bar.
3. From the search results, select the study using the clipboard icon.

The Study Details / Study Summary page displays:



4. On the Study Details / Study Summary page, click the **Protocol** icon.

The Protocol page displays:



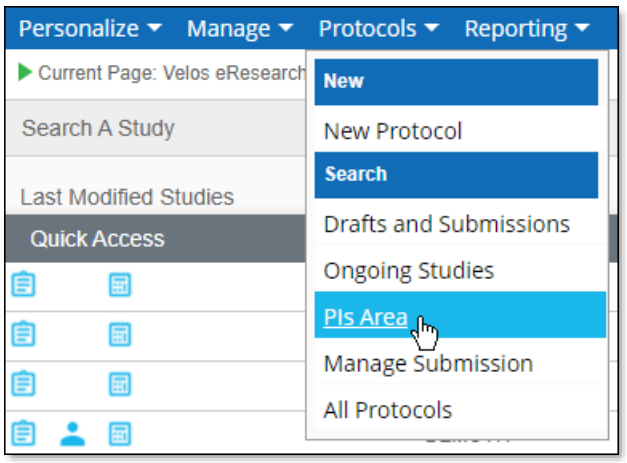
2.4.3 Protocol Modification Requests

Study Team Members may respond to an eCompliance Admin's / Board Committee Members' modification request. Typically, when a review committee has a modification request the study team will receive a notification from the system, as per configuration. If a modification request is made, a specific status will display on the Study Status tab of a selected study, indicating a request has been made for the protocol. This request will be entered by the eCompliance Admin. When the modification required status is added to the Study Status page, the sections on the Study Details tab will be enabled.

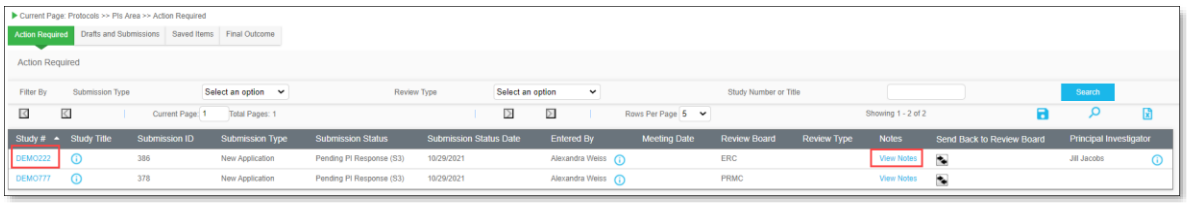
Note: In order to perform a modification, the eCompliance Administrator must place the protocol in Pending PI Response, so that a Study Team Member may update the Summary and Attachments tabs, as needed. Making a modification prior to approval by the board review is a different action than amending a protocol after approval by the board review, which is further explained in **Protocol Amendments after Initial or Amended Submission.**

To modify the protocol and submit modification requirements:

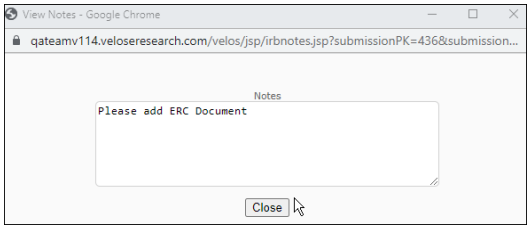
1. From the navigation bar, under the Protocols heading, click **PIs Area**.



2. From the PIs Area, either click the **View Notes** link to view the modification request.

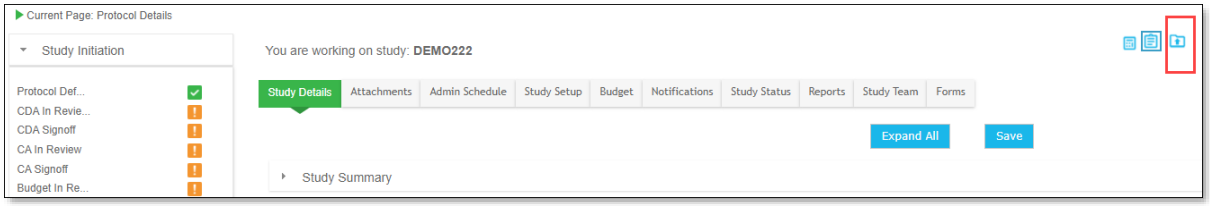


a. The notes page will appear. Click **Close** after reading.

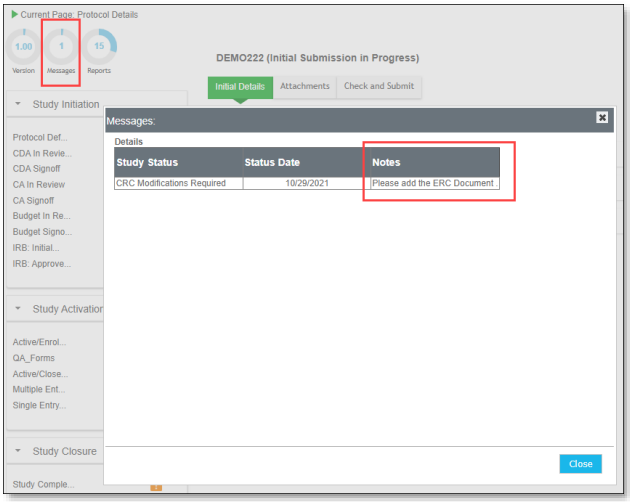


-OR-

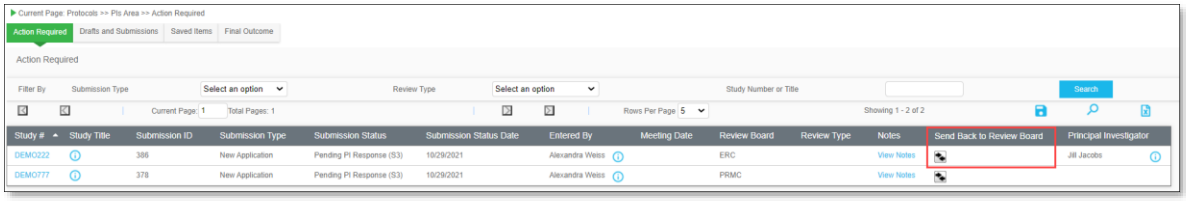
Click the Study # link for the protocol, then click the Protocol link.



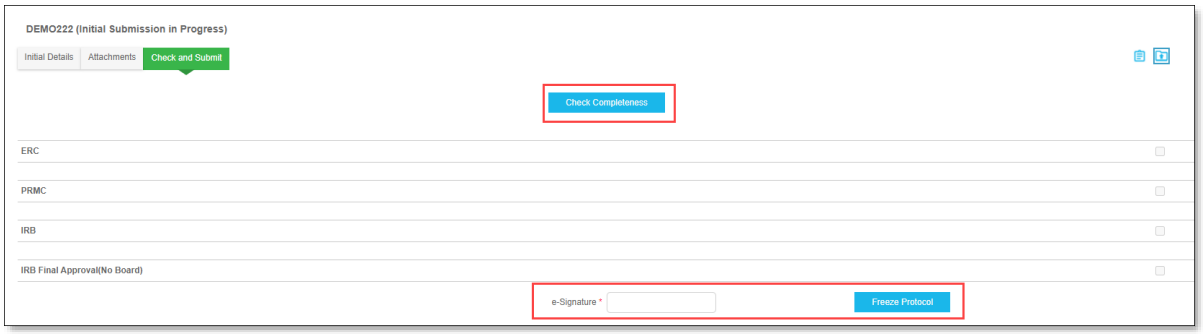
b. Next, click the number inside the circle above Messages to view the pop-up note and click **Close** after reading.



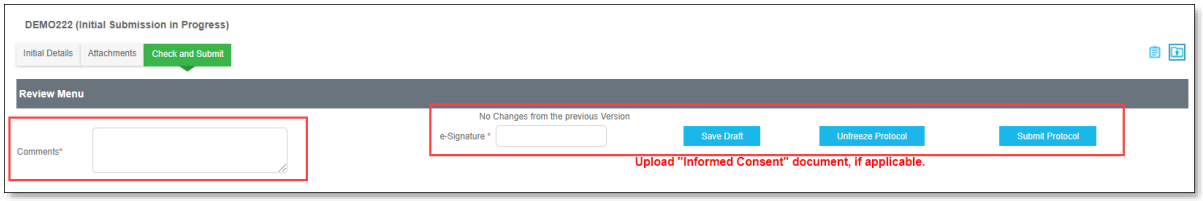
3. After addressing the request, from the PIs Area click the Action icon under the Send Back to Review Board header.



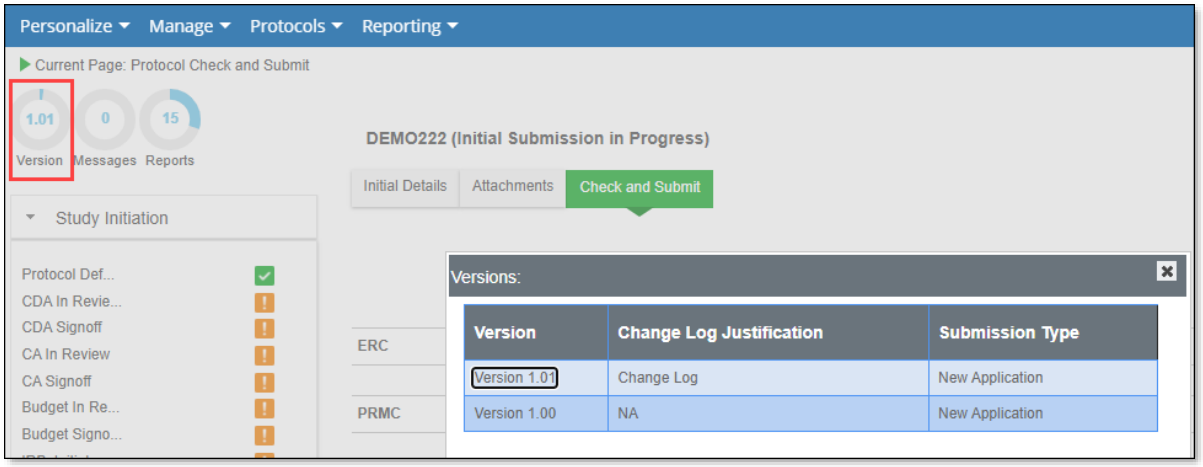
4. The Study Team Member will be returned to the Check and Submit screen. Click **Check Completeness**, enter e-Signature, and click **Freeze Protocol**.



5. Enter an applicable comment, enter e-Signature, and then click either **Save Draft**, **Unfreeze Protocol,** or **Submit Protocol**.



In this example, Submit Protocol was selected and the Version number now shows 1.01. The submission has been modified and may continue with the review process.



2.4.4 Viewing Final Outcome Documentation

Study Team members can view the final outcome documentation from the PIs Area, if configured for the review board type.

In order to view an Outcome Letter, the following criteria must apply:

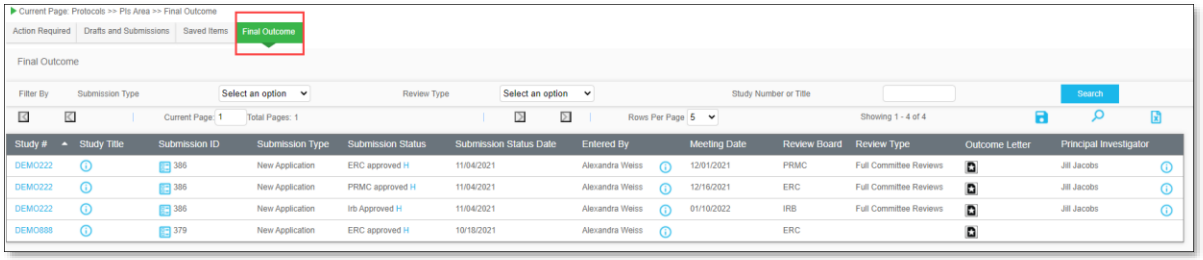
- The Submission Type must be New Application
- The Submission Status must be Conditional Approval, ERC Approved, PRMC Approved, or IRB Approved
- The Review Type must be Full Committee Review, Expedited Review, Exempt Review, or Ancillary Review

If a combination of these criteria is not met, such as if there was no board review, then clicking on the Outcome Letter icon will show the following error message.

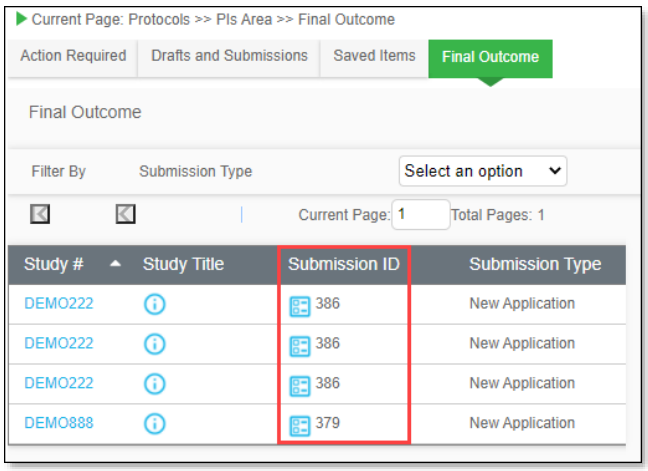
An error occurred while generating PDF

To view final outcome documentation from the PIs Area:

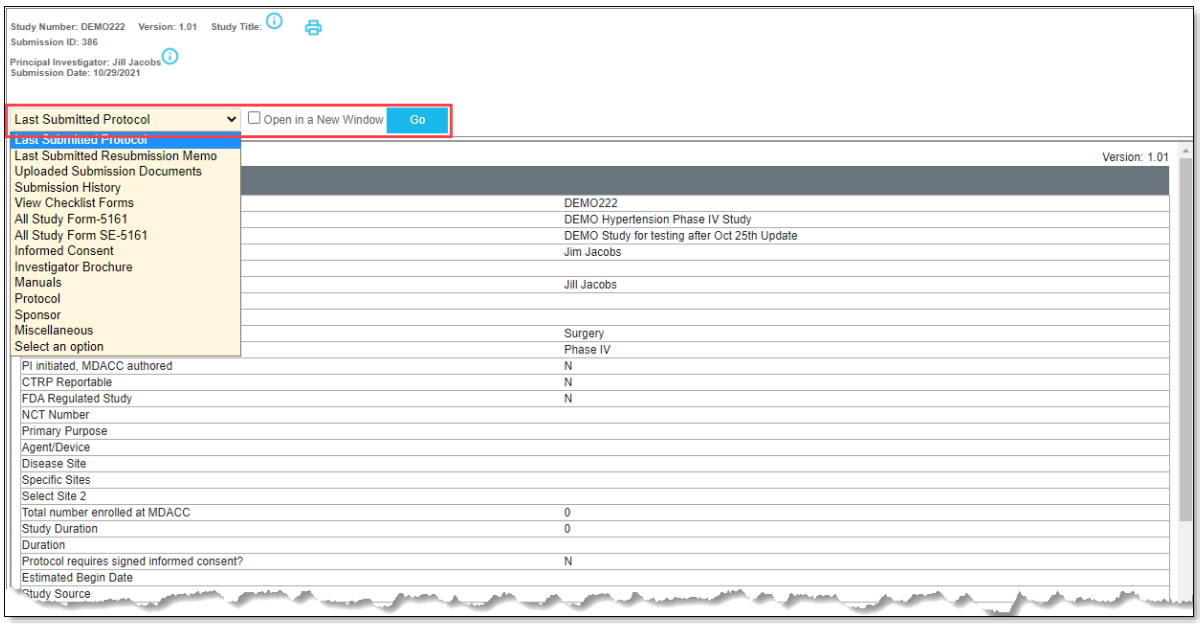
1. Click the **Final Outcome** tab.



2. To view the submission package, click the **Submission Package** button under the Submission ID header for the applicable study.

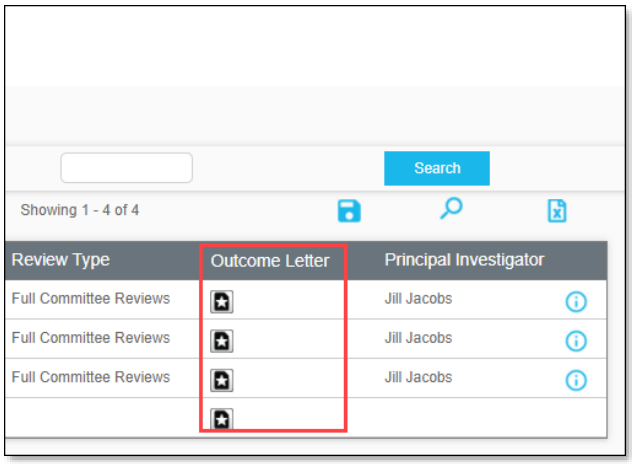


The submission package will appear.

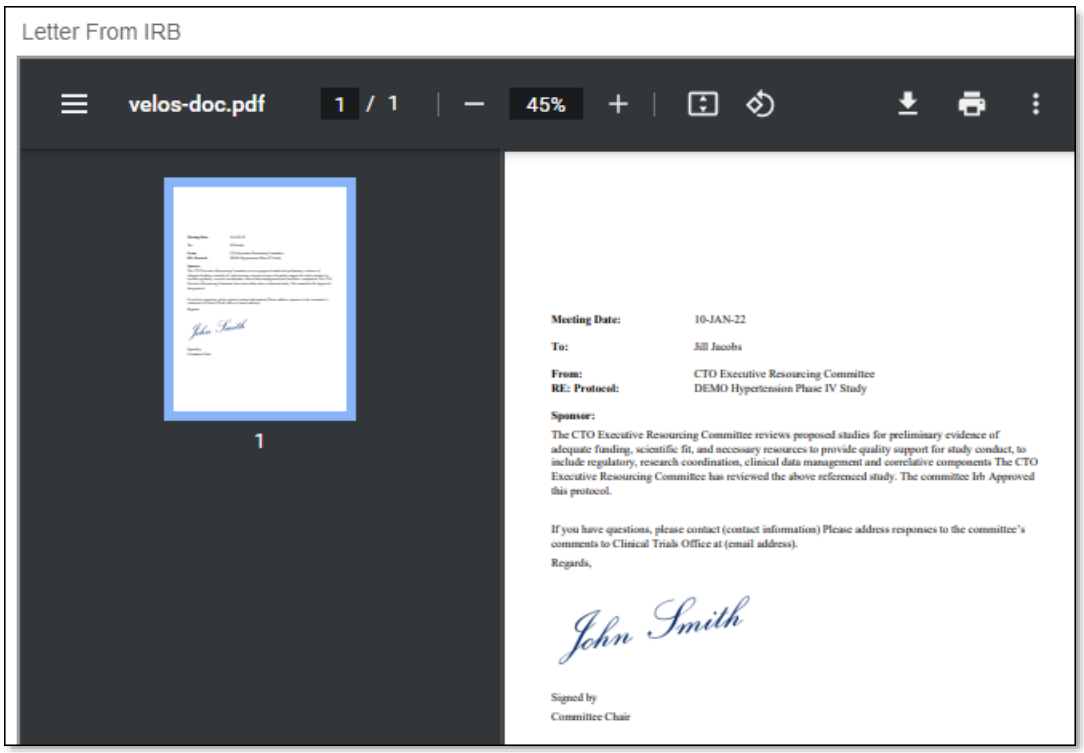


a. Use the dropdown and click **Go** to view each document in the package.

3. To view the outcome letter, click the **Outcome Letter** button under the Outcome Letter header for the applicable study.



The outcome letter will appear.



a. Use the functions to download and print as needed.

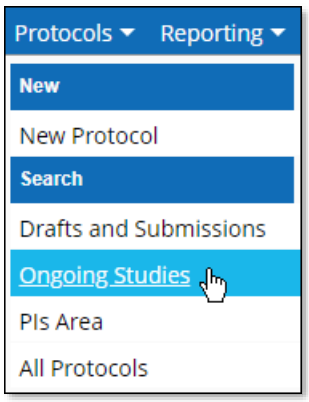
2.4.5 Protocol Amendments after Initial or Amended Submission

If changes need to be made to a Protocol Submission after it is in Final Outcome, an amendment must be made by a Study Team Member and then the Protocol must be resubmitted.

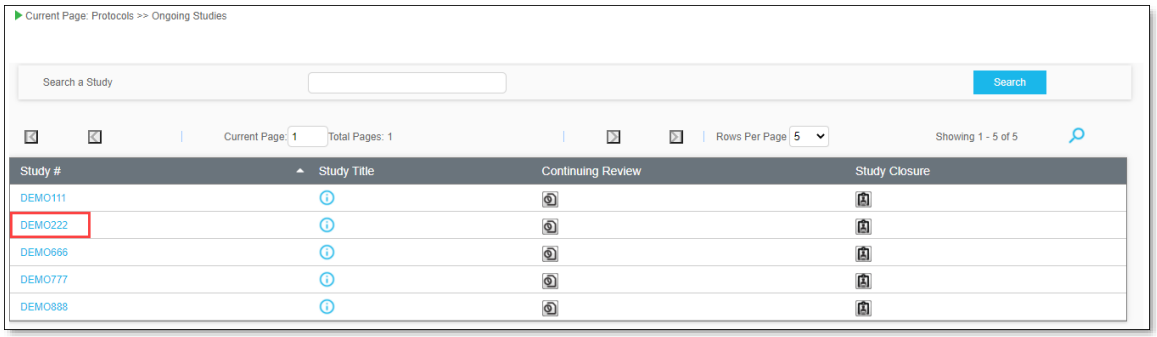
Note: eCompliance Administrators must ensure the study team member is assigned to the study team and that access rights are set as per the **Navigating Compliance and Permissions** section, in order to have full capabilities in this section.

To make an amendment to a protocol and resubmit:

1. From the navigation bar, under Protocols, select **Ongoing Studies**.

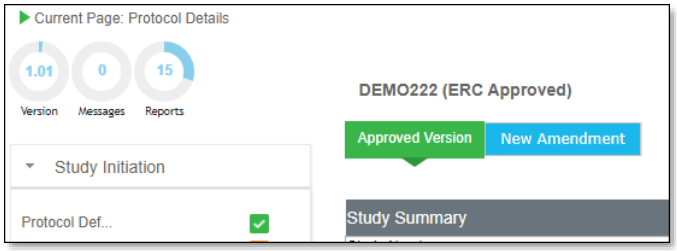


2. From the Ongoing Studies page, click on a Study # to access the Study Details tab.

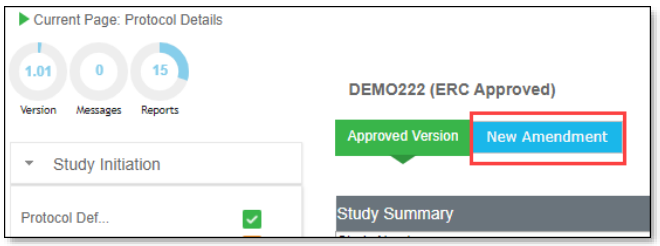


3. On the Study Details tab, click the **Protocol** link.

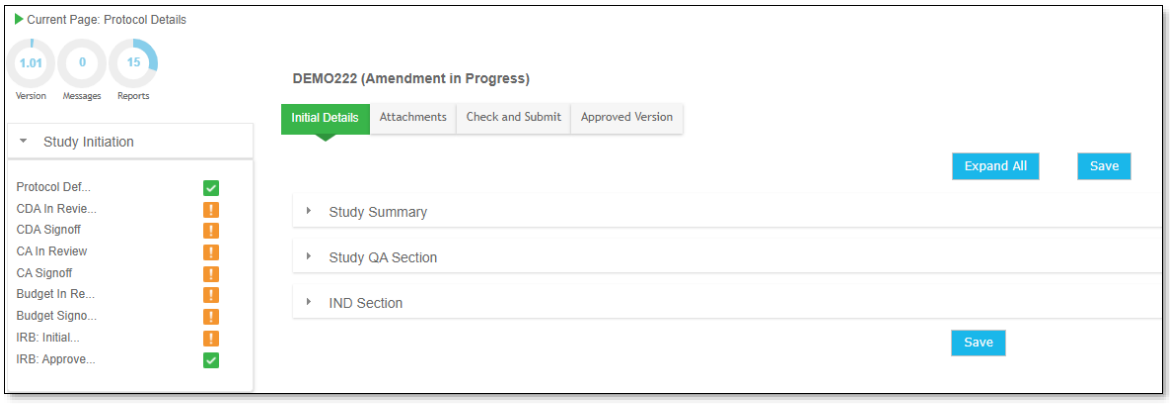
The Protocol Details page displays with the Approved Version tab open:



4. Click the **New Amendment** tab.



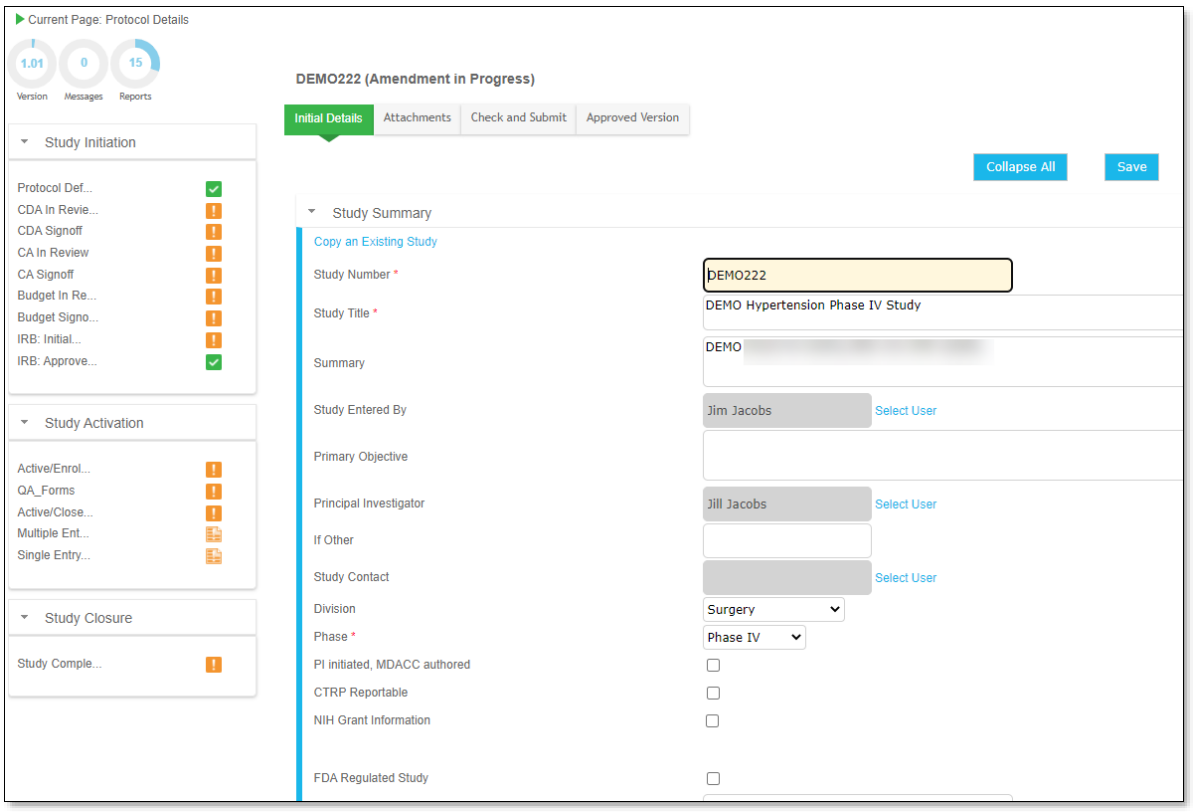
The page refreshes and displays the Initial Details of the protocol, now able to be modified:



Note:

1. When a New Amendment is being processed, the status next to the protocol will change to display “Amendment in Progress” over the tabs.
2. The Approved Version tab is added when an amendment is being made. This tab will be added to the previous protocol build view to include what information was previously approved.

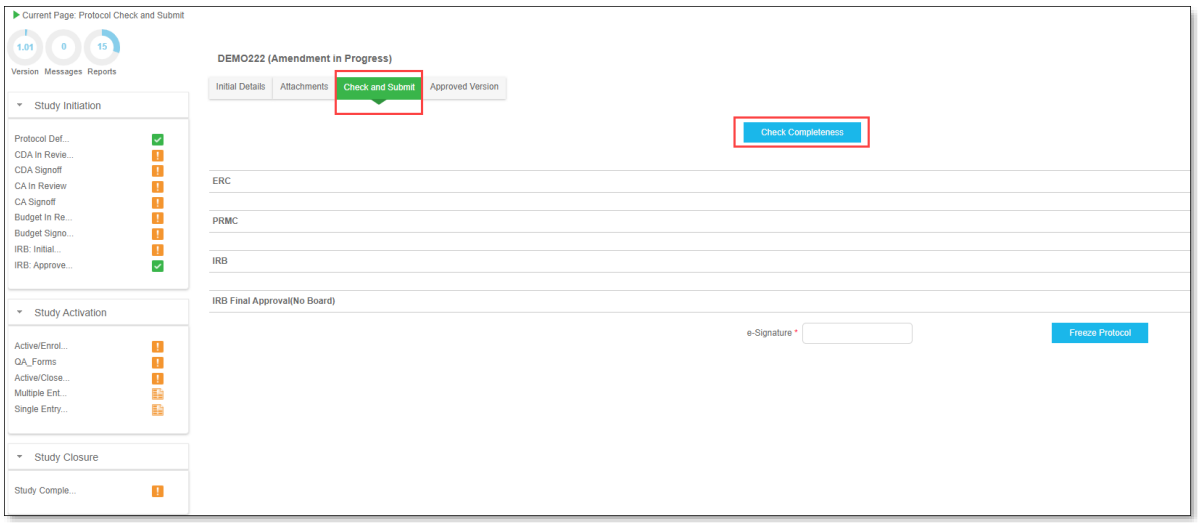
5. Expand the sections and modify sections as needed.



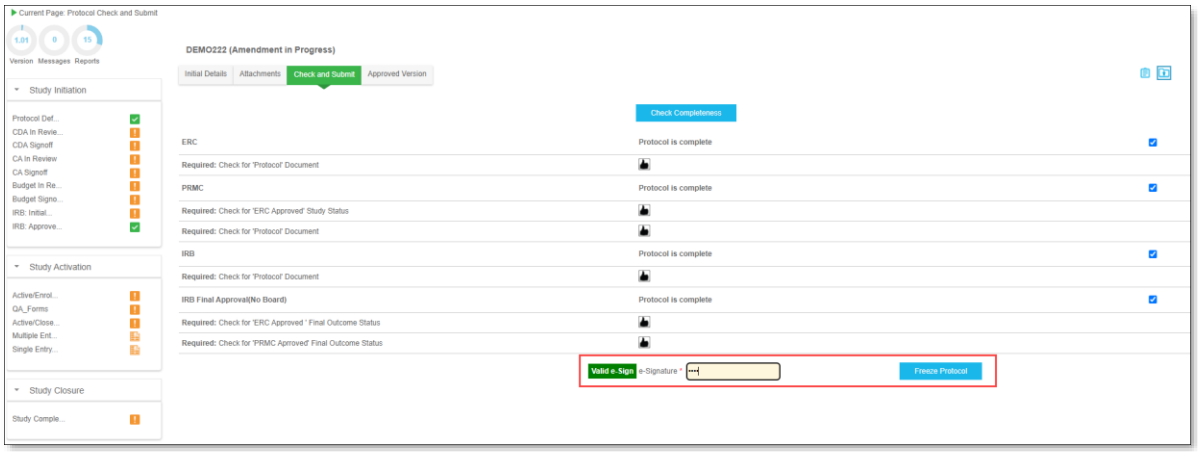
6. Once changes are complete, click **Save** to save any changes made.

7. Continue to the **Attachments** tab, making changes as needed.

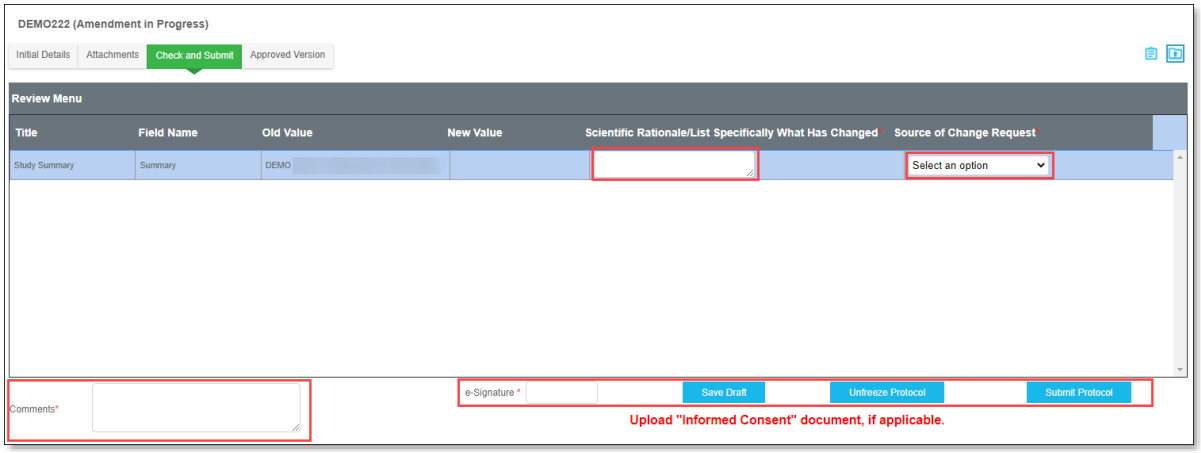
8. Click the **Check and Submit** tab, then click **Check Completeness**.



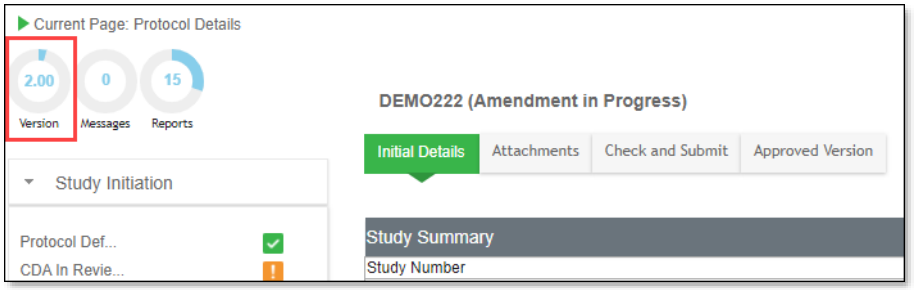
9. If all board review items are approved, as indicated by a thumbs up, then enter your e-Signature and click **Freeze Protocol**.



10. Enter the Scientific Rationale, Source of Change from the dropdown, Comments, e-Signature, and click either **Save Draft**, **Unfreeze Protocols**, or **Submit Protocol**.



In this example, Submit Protocol was clicked. The submission has updated to the next major version number.



2.5 eCompliance Administrators Functionalities

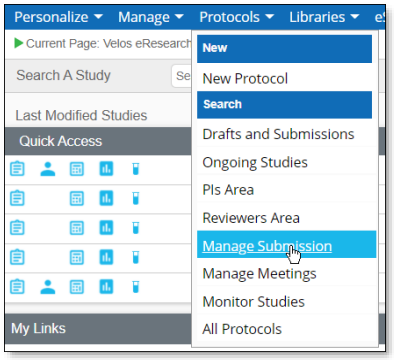
Once the newly created Protocol is successfully submitted by a Study Team Member, users tasked with being eCompliance Admins will then begin their tasks within eCompliance. As eCompliance is highly configurable, steps may vary. For this guides purposes, the eC Admin is going to request a modification by a Study Team Member prior to review by a Board Committee Member and also request a Reviewer to review a board protocol submission, prior to the assigned board review.

2.5.1 Assigning a Modification

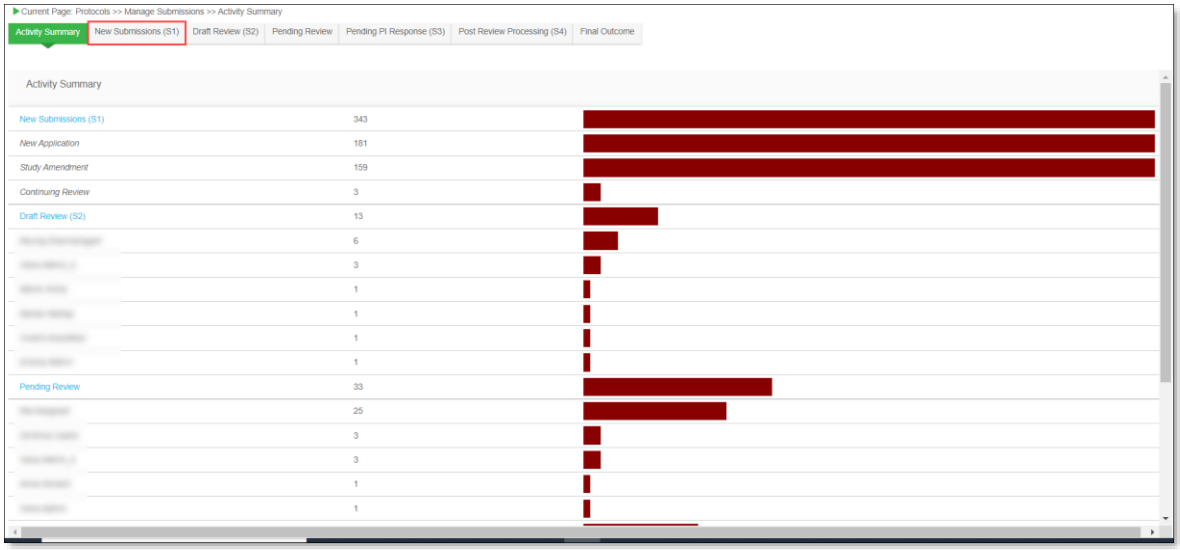
eCompliance Admins may assign modifications to the Protocol before a Reviewer reviews, after a Reviewer reviews, or after a Board Committee Member reviews. Modifications will be requested by using Notes.

To add modification requests for Study Team Members:

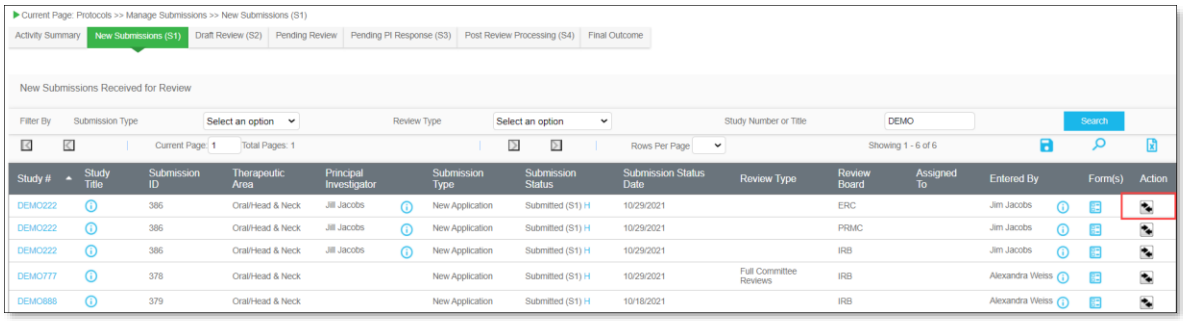
1. Click **Manage Submission** under the Protocols dropdown in the Navigation bar.



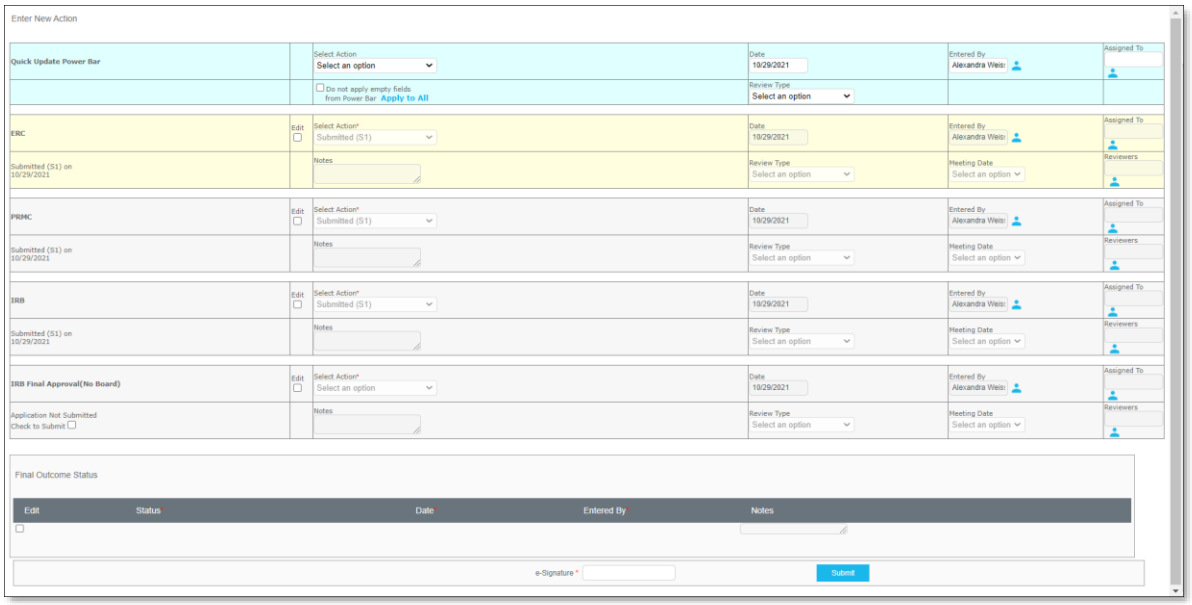
2. For New Submissions, click the **New Submissions** tab, otherwise, for any other submission statuses, click the appropriate tab.



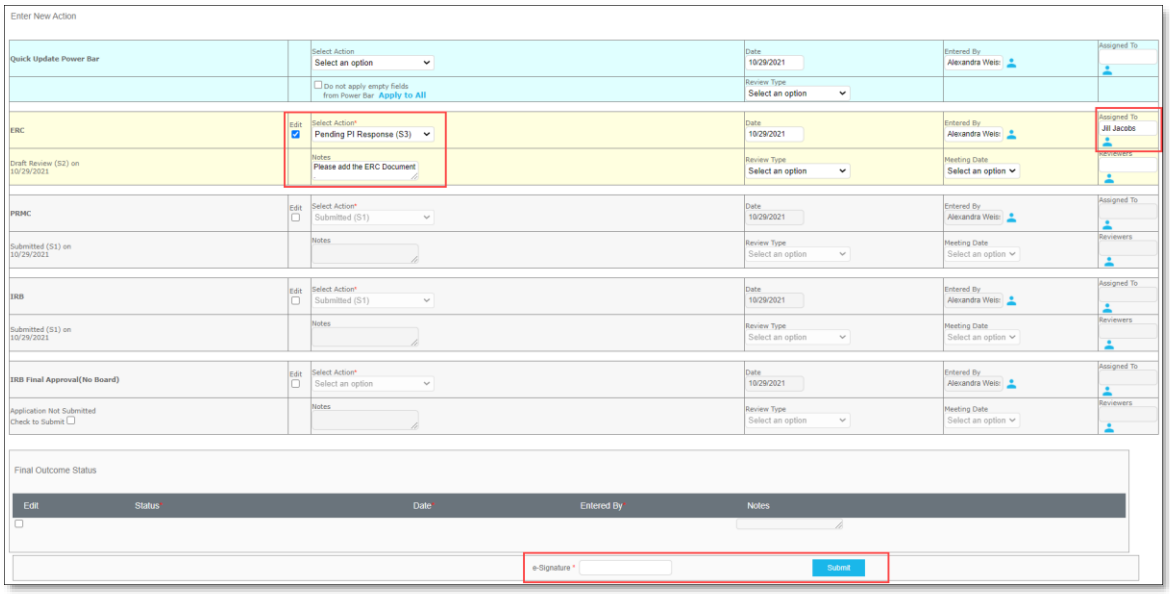
3. From the New Submission tab, or other tab, enter search criteria and click Search if needed, and then click the Actions button for the applicable Study # identifying the protocol that requires modification.



The Enter New Action pop-up will appear.



4. Place a checkmark under the Edit box for any Review Board Protocol Submissions that require an update, select the action from the Select Action dropdown, enter a Note as applicable. Select a Study Team Member to populate the Assigned To field by clicking on the Person icon under that field and then selecting a user.



Note:
1. In this example the Pending PI Response (S3) was selected, as this is a New Submission that has not been reviewed by a Reviewer or the ERC Board Committee Members and requires a PI to follow-up. Other options may be selected depending on your process steps.
2. Notes in the note field should describe what needs to be updated.

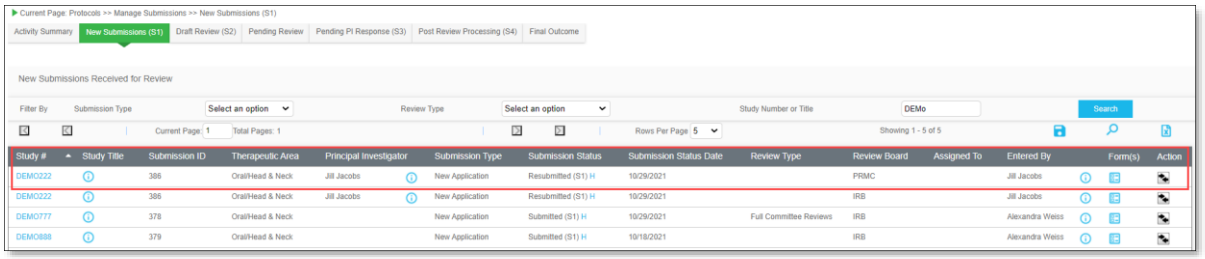
5. Enter your e-Signature and click **Submit**. The modification request will now appear in the 'Assigned To' Study Team Member's queue. Refer to **Protocol Modification Requests** to view how a Study Team Member views and responds to a modification request.

2.5.2 Assigning a Reviewer and Setting a Meeting

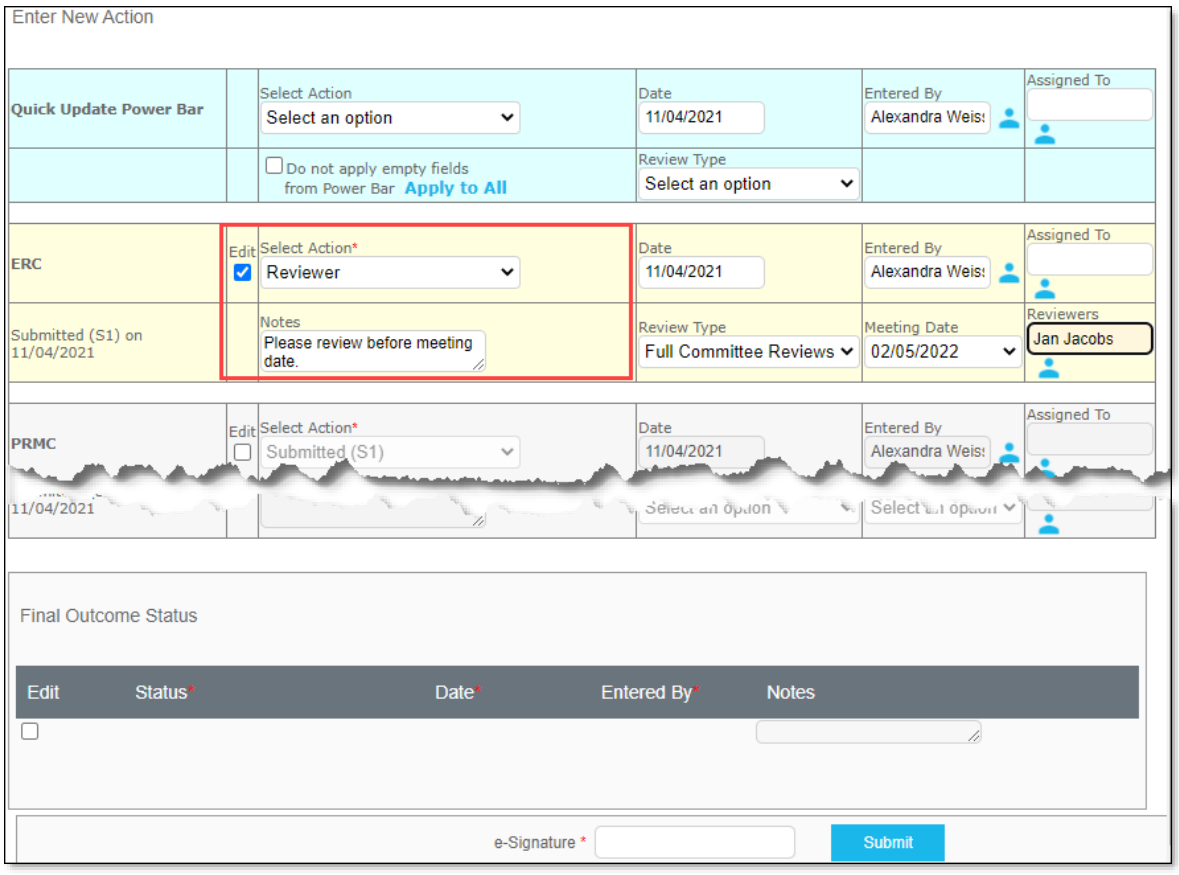
Reviewers can be assigned to review certain Protocol submissions before Board Committee Members perform their reviews. Reviewers can have different role names for different clients and different responsibilities. Reviewers review assigned board information and then complete the applicable Form(s).

To assign a Reviewer to a Review Board Protocol Submission:

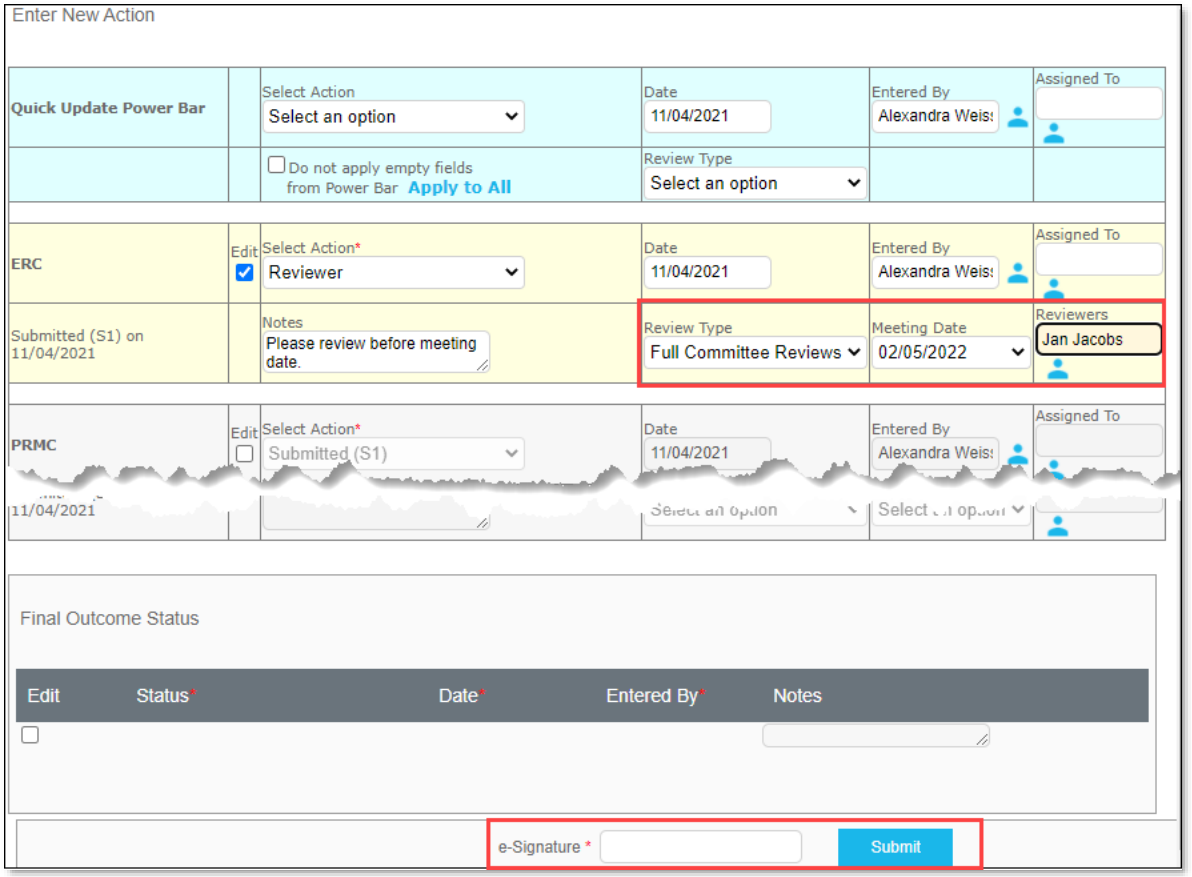
1. From the Manage Submissions' page, locate the applicable protocol Study # and Review Board for review and then click the **Action** button.



2. In the Enter New Actions pop-up, check the checkbox under **Edit for the Review Board** entry to assign, change the Select Action in the dropdown to **Reviewer** (or other applicable status), and enter Notes as applicable.



3. Add the Review Type from the dropdown, select the Meeting Date from the dropdown, and select one or more Reviewers by clicking on the person icon and submitting.



4. Enter your e-Signature and click **Submit** to assign the review.

Note:
1. If assigning more than one Review Board type for review, the Quick Update Power Bar can be used. Populate the fields and then click Apply to All.
2. To add meeting dates to the dropdown, refer to Add a Meeting Date.

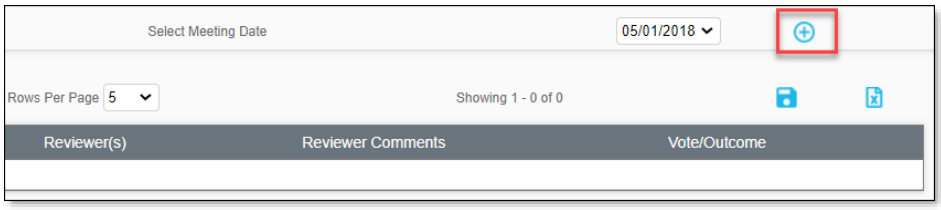
2.5.2.1 Add a Meeting Date

Dates can be added for Review Board meetings. These new dates will populate in the actions screens Meeting Date field.

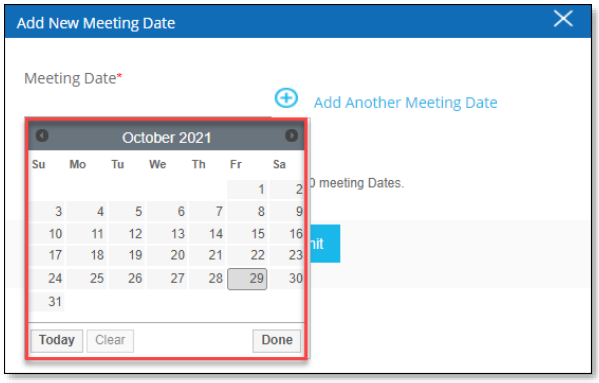
Note: This section applies to eResearch Version 12.0.

To add a Meeting Date:

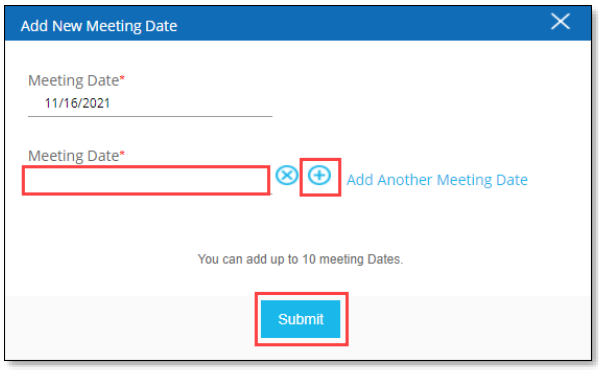
1. From the Manage Meetings page, for the specific selected review board, click the plus sign to the right of the Select Meeting Date field.



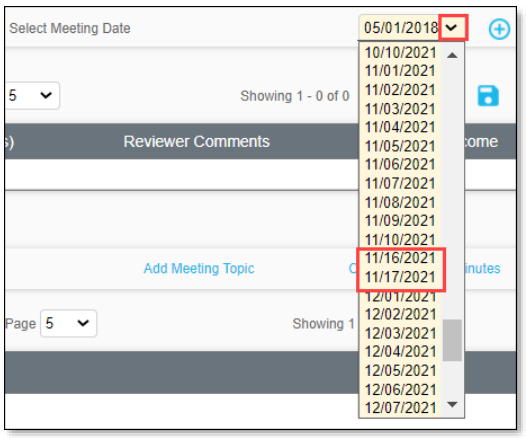
2. Click in the date field and use the Date Picker to select a date in the future.



3. Add up to ten dates at one time by clicking the **plus** sign, picking additional dates, and then click **Submit**.



4. The new date(s) will now appear in the Select Meeting Date dropdown.

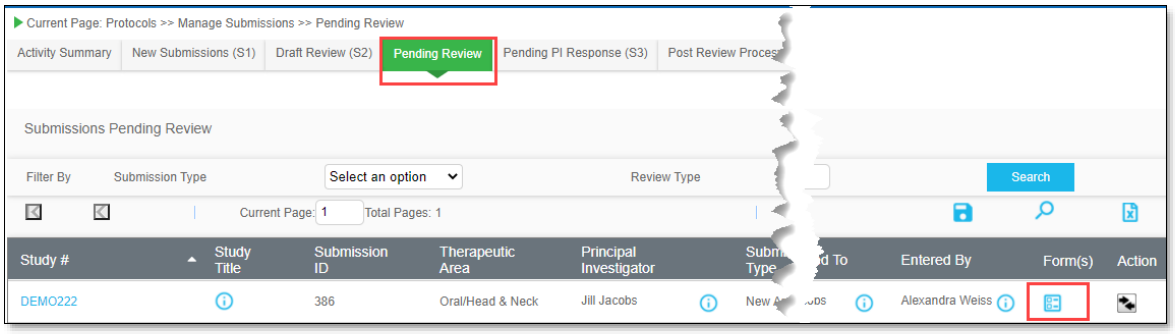


2.5.3 Post Review Processing

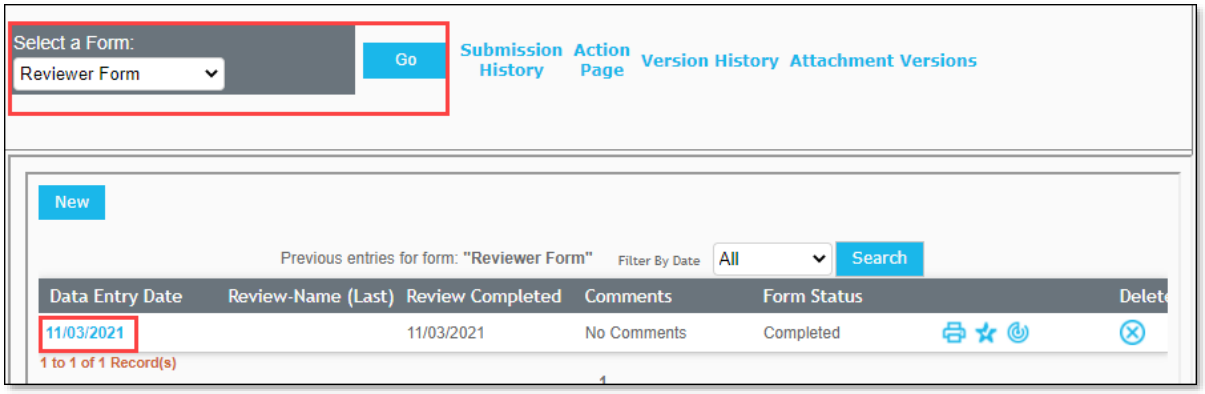
After a Reviewer has completed their assigned review, an eCompliance Admin may review the completed Reviewer Form and then assign the Action for the Review Board to Post Review Processing.

To review the Reviewer's Form and assign the next Action step:

1. From the **Pending Review** tab of the Manage Submissions page, click the **Forms** button for the applicable Study #.



2. Use the Select a Form dropdown to view all form entries and click the Data Entry Date to view each form.

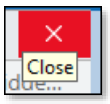


Note:

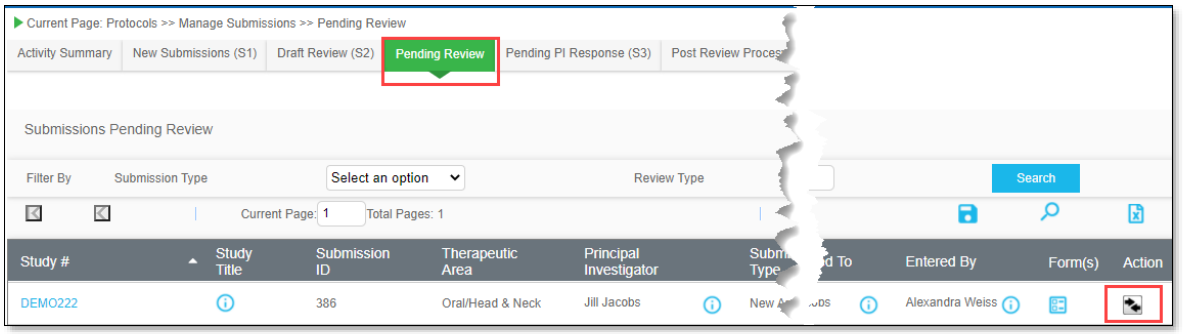
1. Submission History Link- Provides the Submission Status Date, the Submission Status, and Notes
2. Action Page Link – Works the same as the Actions tab from the Manage Submissions page
3. Version History Link – Shows the version history of the Protocol Submission and the associated Change Log Justification if a change was made
4. Attachment Versions Link – Shows the version history of all attachments to the Protocol Submission along with links to the document and the Attachment Status

3. As per your processes, make updates and/or change the Form Status, add your e-Signature and click **Submit**.

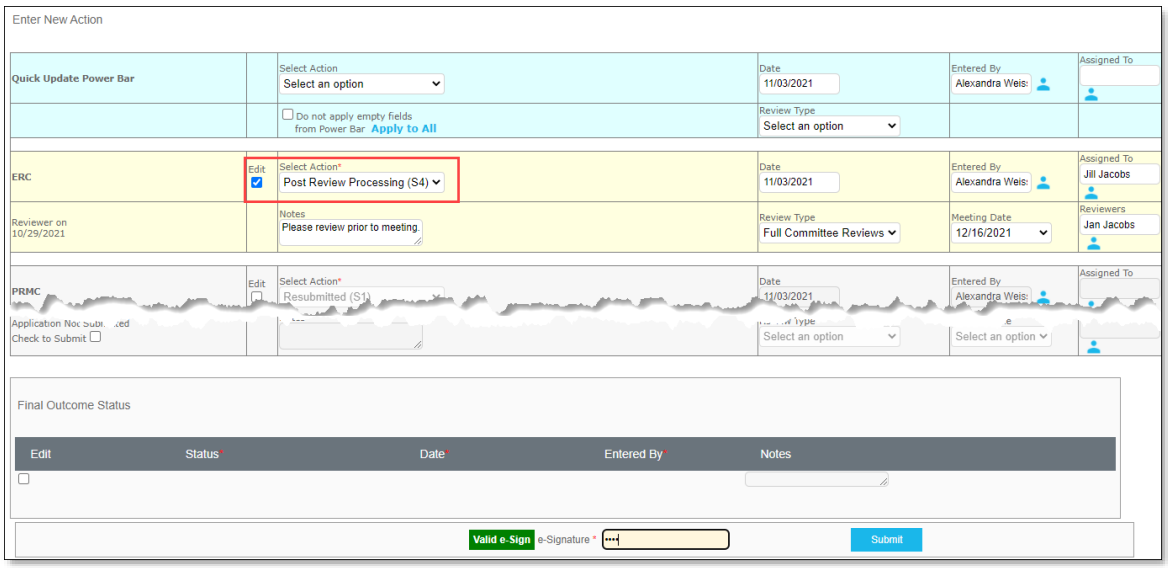
4. Click **X** to close the pop-up.



5. Click the **Actions** button for the Study #.

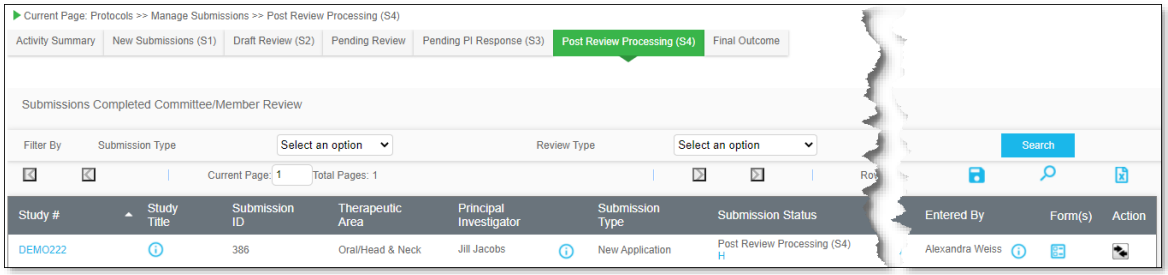


6. In this example, to proceed with processing, the eCompliance Admin will assign a Review Board to Post Review Processing (S4) by checking the checkbox under **Edit** for the applicable Review Board and then selecting **Post Review Processing** (S4) from the Select Action dropdown.



7. Complete by entering e-Signature and clicking **Submit**.

   The Protocol is now in Post Review Processing and is ready for the Review Board meeting.

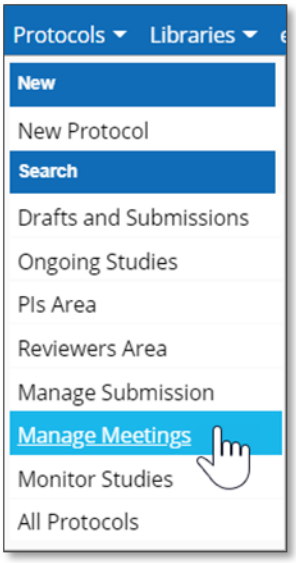


2.5.4 Navigating to Manage Meetings Functions

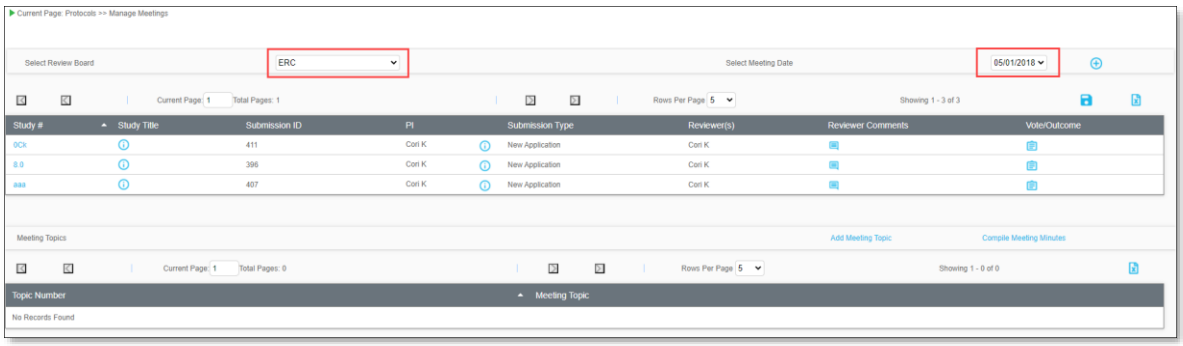
Admins can navigate to the Manage Meetings page to add meeting dates, add or edit meeting topics, or add meeting minutes. Refer to **Add Meeting Minutes** for more details.

To navigate to the Manage Meetings page:

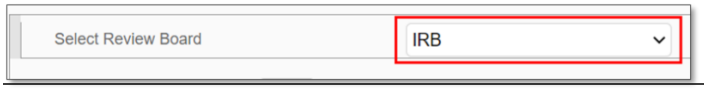
1. From the navigation bar, hover over **Protocols** and select **Manage Meetings**.



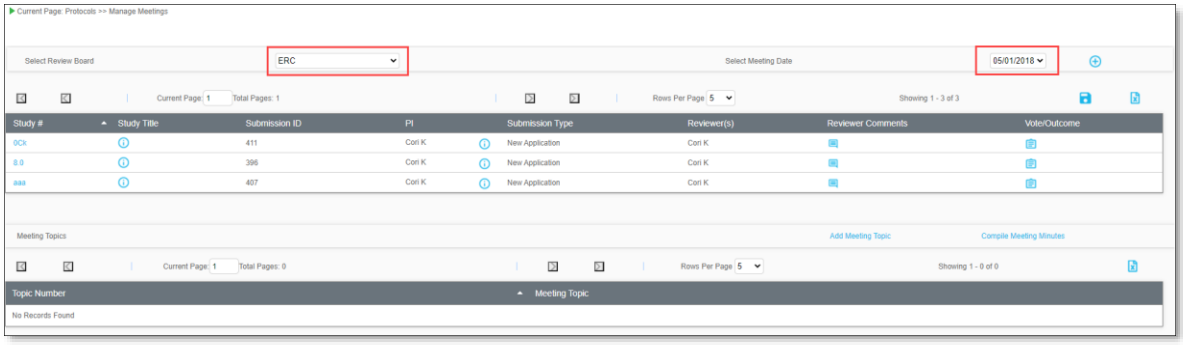
The Manage Meetings page displays:



2. Click the **Select Review Board** dropdown menu to display the desired Review Board to manage meetings for.

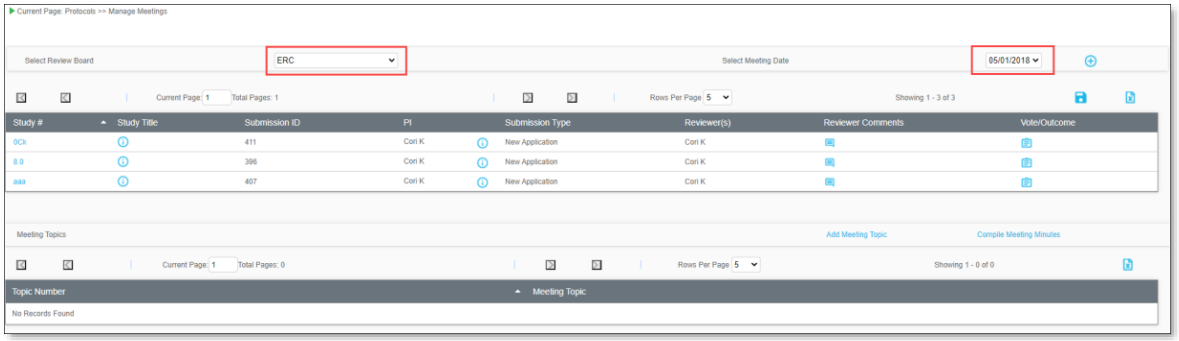


3. Select the date from the Select Meeting Date dropdown for the Review Board meeting.



Note: This date can be found by returning to **Manage Submissions** and looking in the Actions area for the Review Board meeting date.

The meeting for the Review Board displays along with any Meeting Topics that may be available.

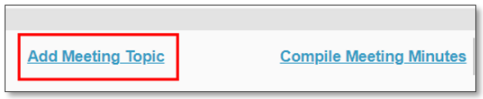


2.5.4.1 Add a New Meeting Topic

eCompliance Admins can schedule meeting topics for a Review Board within eCompliance, prior to a meeting.

To add a new Meeting Topic:

1. From the Manage Meetings page for the appropriate Review Board, click the **Add Meeting Topic** link.



The Meeting Topic window opens:

2. Add a meeting Topic Number, define the Topic(s) briefly, and then e_Sign and click **Submit**.

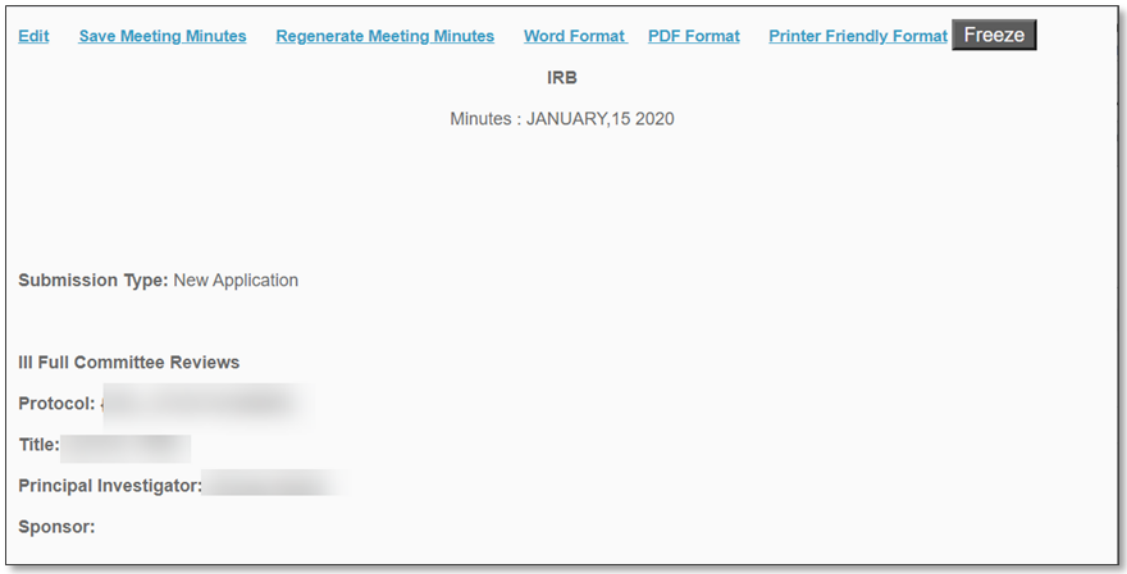
2.5.4.2 Add Meeting Minutes

The Meeting Minutes page will only be accessible to those with permissioned access to the Manage Meetings page, including eCompliance Admins, who have should have full permission, and Board Committee Members, who should have view only permission, typically. All meetings for the type of Review Board for the selected date will appear in the Meeting Minutes page. When edits are made to the minutes, in the system, only permissioned users will view the data. To document meeting minutes, an eCompliance Admin may export or print the Meeting Minutes page, update, and save locally.

To add Meeting Minutes:

1. From the Manage Meetings page for the desired Review Board and Date, click the **Compile Meeting Minutes** link.

The Meeting Minutes window displays:



2. Click the **Edit** button to revise the Meeting Minutes page and then click **Save Meeting Minutes**, to update the form.

Note: The Edit option is only for updating basic data in the system. Export the form for adding minutes for a specific meeting.

-OR-

Click either **Word Format** or **PDF Format** to download and save the Meeting Minutes form locally, or click **Printer Friendly Format** to print a copy of the form.

3. After adding minutes during the meeting, save the meeting minutes and share with Board Committee Review members as per procedures.

Warning: Using Regenerate Meeting Minutes will bring the template back to the default state and erases all updates made by editing.

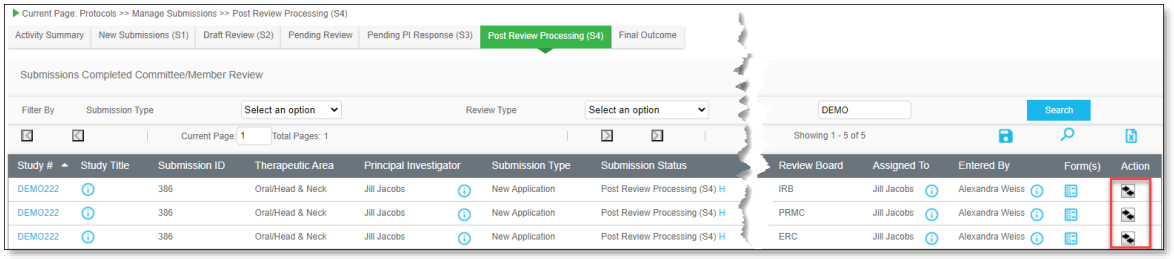
2.5.5 Final Outcome Processing

After a meeting is held, the Final Outcome determination must be submitted from the Manage Submissions page. This will lock the submission. Any revisions to this submission will be processed as an amendment to the protocol. See **Protocol Amendments after Initial or Amended Submission**.

Note: Outcome letters can be configured for each type of outcome status and by review board type with client specific templates during implementation.

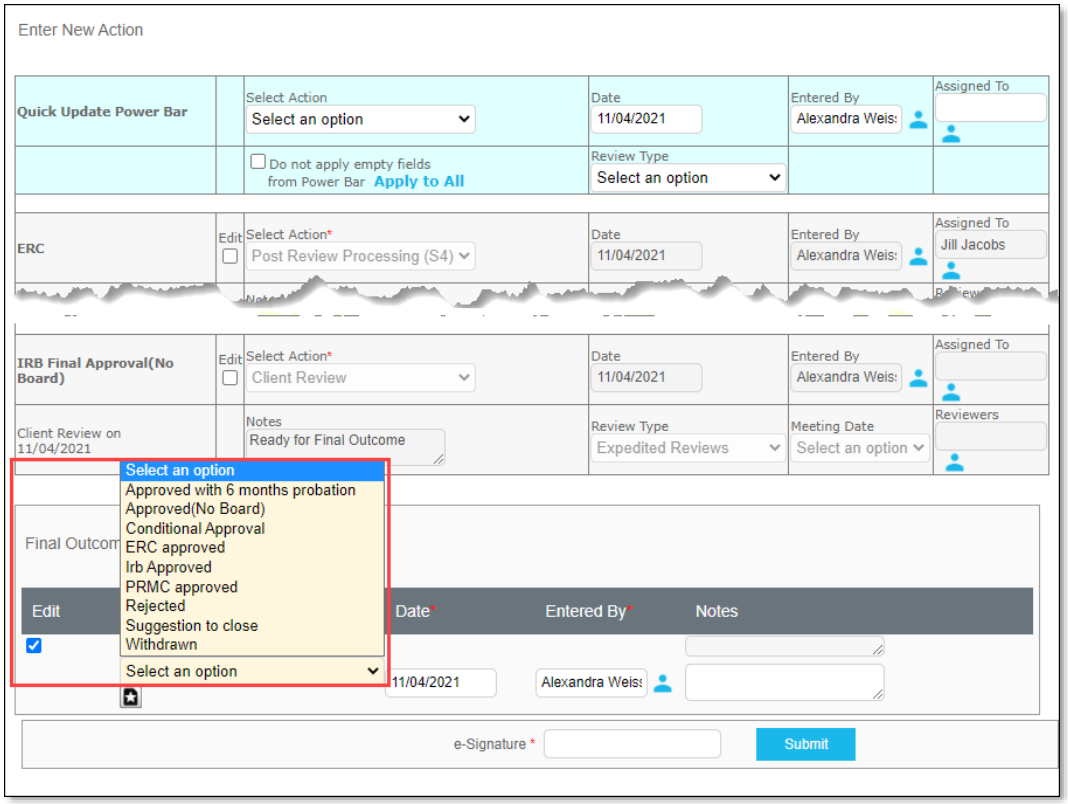
To update the Final Outcome for a Protocol Submission:

1. From the **Manage Submissions** page and the **Post Review Processing (S4)** tab, click an **Action** button for a specific Study #.

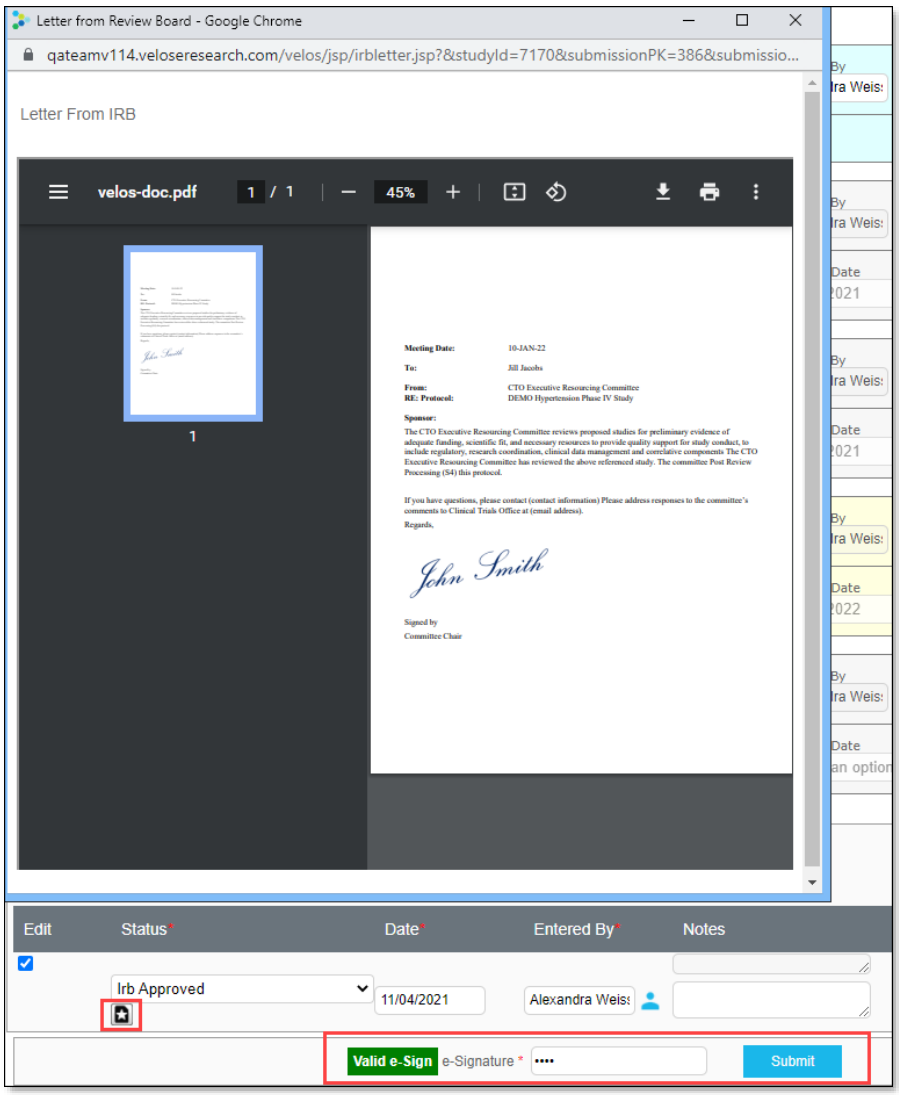


Warning: This step should only be performed after each Review Board type for that Study # is in the Post Review Processing (S4) Submission Status, Review Board meetings have been held, and all outstanding reviews and notes have been addressed.

2. Check the **Edit** checkbox for the Final Outcome Status area and select a status from the dropdown.

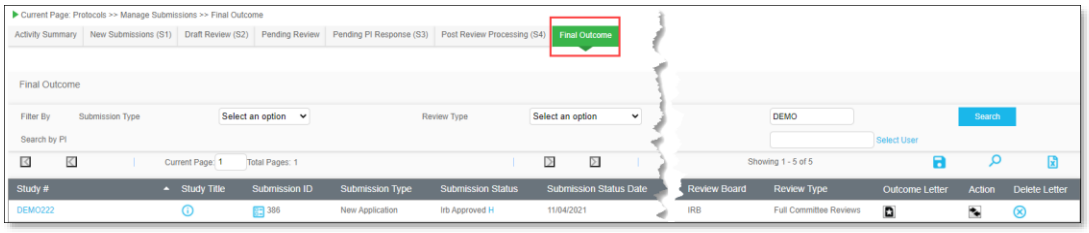


3. Click the newly populated Outcome Letter button to view, review, and download, as needed.

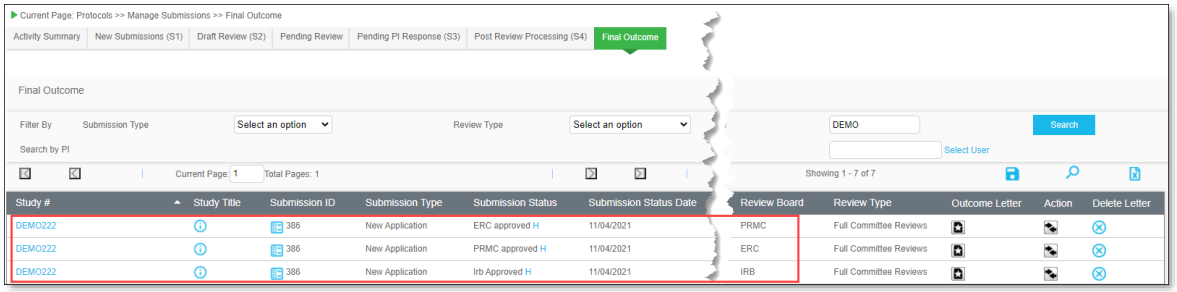


4. Enter your e-Signature and click **Submit** to confirm Final Outcome Submission Status.

   The submission will now appear in the Final Outcome tab.



5. Repeat this step for each Review Board type, as applicable, for completion of the initial Protocol Submission.

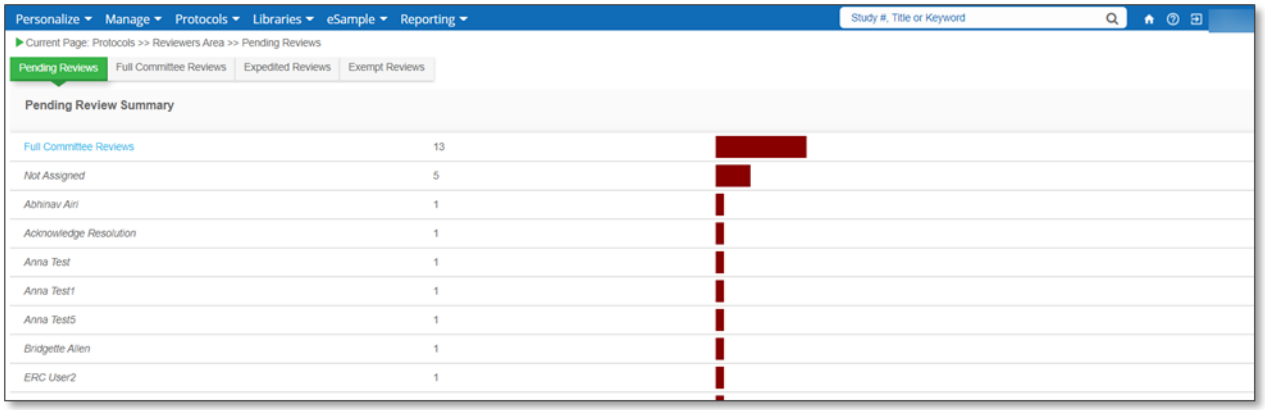


When all applicable Review Board types are in the Final Outcome step, the submission is completely approved.

Note: If the submission requires an amendment after Final Outcome, a Study Team Member must initiate the change to the protocol submission. Refer to **Protocol Amendments after Initial or Amended Submission.**

2.6 Reviewers Functionalities

Reviewers for eCompliance are typically tasked with managing submissions, which can be broadly classified into Full Committee Reviews, Expedited Reviews, and Exempt Reviews.



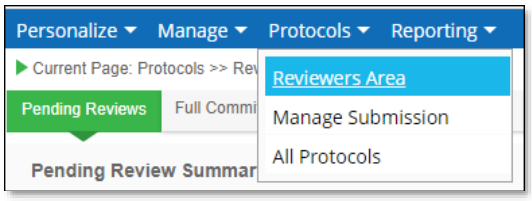
Note: If the submission cannot be viewed in the Reviewers Area, the eCompliance Administrator should ensure that the submission status is Reviewer, as well as to ensure that the user is added to as a Super User to Forms for access rights to view, edit, and add new forms.

2.6.1 Navigating to Reviewers Area

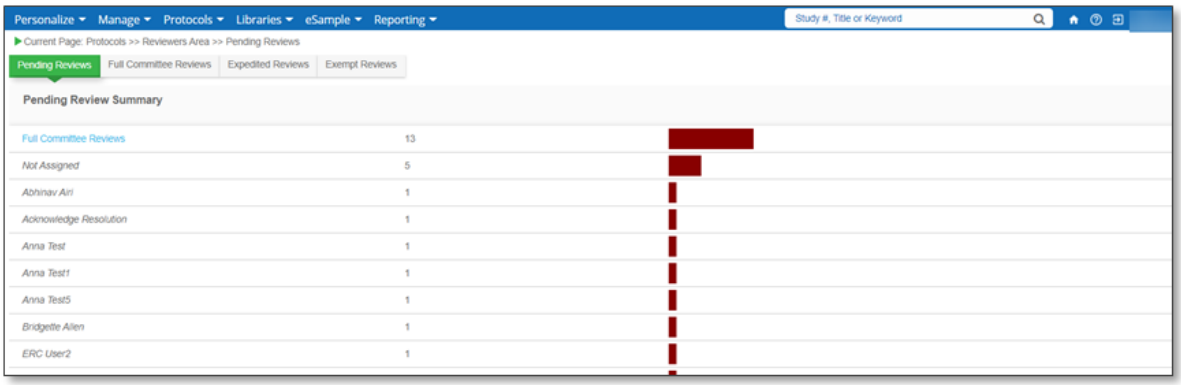
Reviewers review assigned Protocol Submissions for specific Review Boards and complete Reviewer Forms from the Reviewer's tabs, which includes the Pending Reviews tab, which is further broken down into: Full Committee Reviews, Expedited Reviews, and Exempt Reviews tabs.

To navigate to the Reviewer's area:

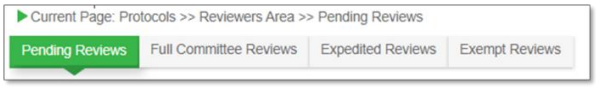
1. From the navigation bar, click **Protocols** and select **Reviewers Area**.



The Reviewers Area displays:



2. Using the available tabs, navigate to the desired type of review as appropriate.

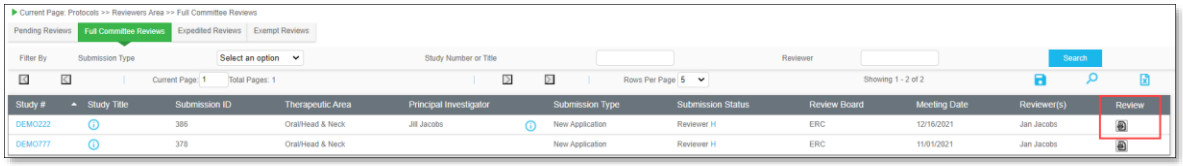


2.6.2 Managing Reviews

Once at the Reviewer's tabs, Reviewer's may manage the various forms of reviews available. This section covers how Reviewers can review submissions assigned to them. Note that Expedited and Exempt Reviews are only for Chair or Co-chairs or designees and Exempt Reviews are usually just a chart Review.

To review submissions:

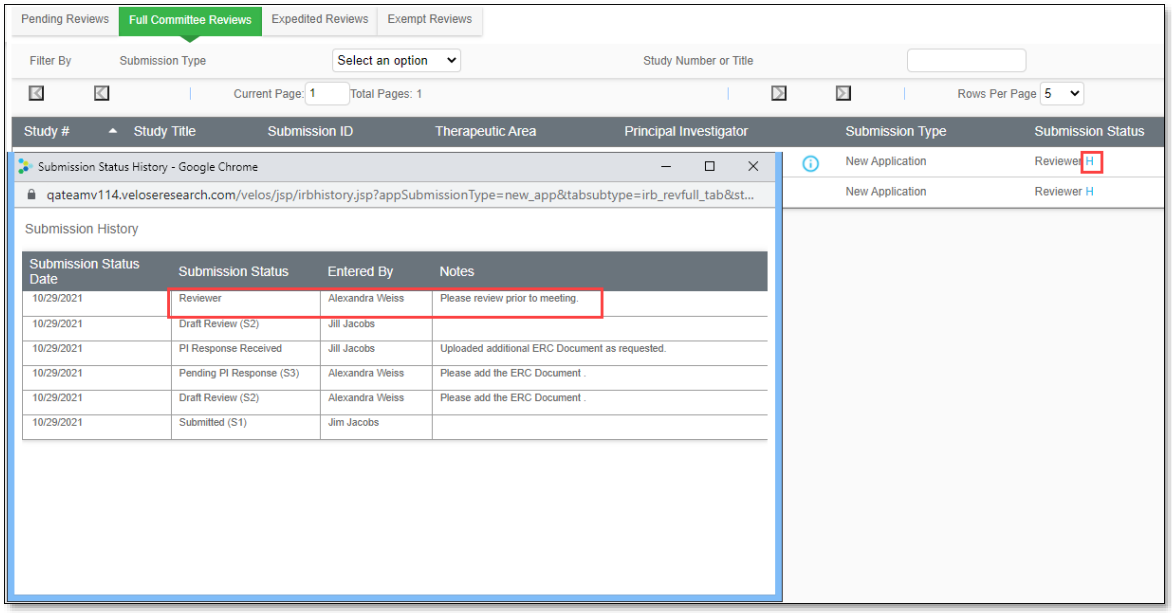
1. From the Reviewer's Area, navigate to the applicable Reviewer's Area tab.



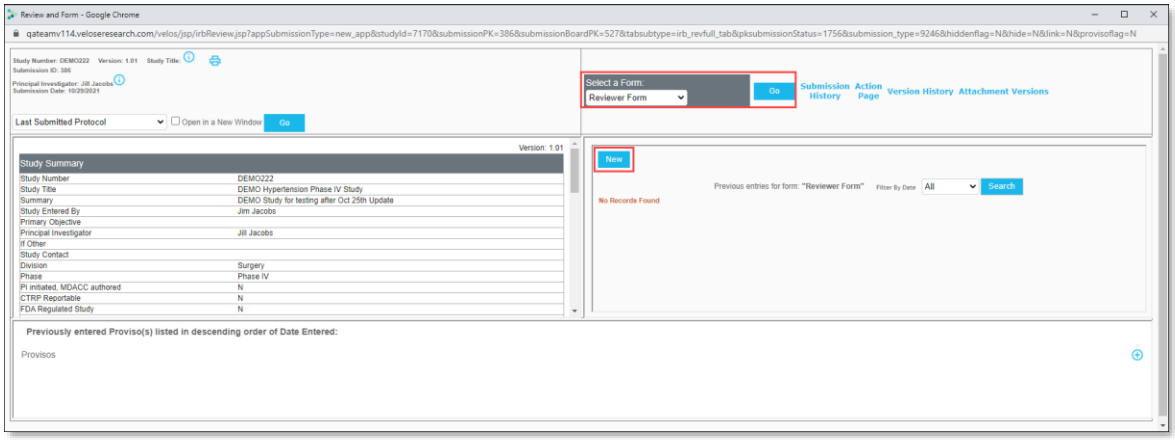
On the Reviews page, Reviewers can view the following details:

Column Name	Description
Study #	Lists the Study number defined on the Initial Details / Study Details tab.
Study Title	Hover over the information icon to display the study number.
Submission ID	Lists the Submission ID.
Therapeutic Area	Lists the Therapeutic Area, if defined.
Principal Investigator	Lists the Principal Investigator.
Submission Type	Lists the Submission Type of the Protocol.
Submission Status	Click the H to view the Submission Status history.
Review Board	Lists the Review Board.
Meeting Date	Lists the Meeting Date.
Reviewer(s)	Lists the Reviewer(s).
Review	Click the Review icon to complete the review.

2. Review the assigned Protocol as per a Note left in the Submission History by the eCompliance Admin by clicking the History icon under the Submission Status header.

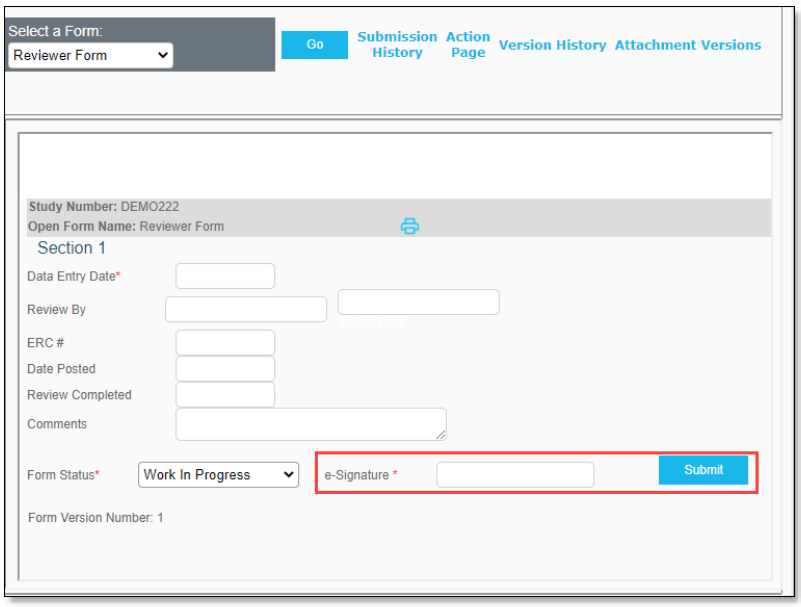


3. Click the **Review** icon and then select a form from the Select a Form dropdown and click **Go**.

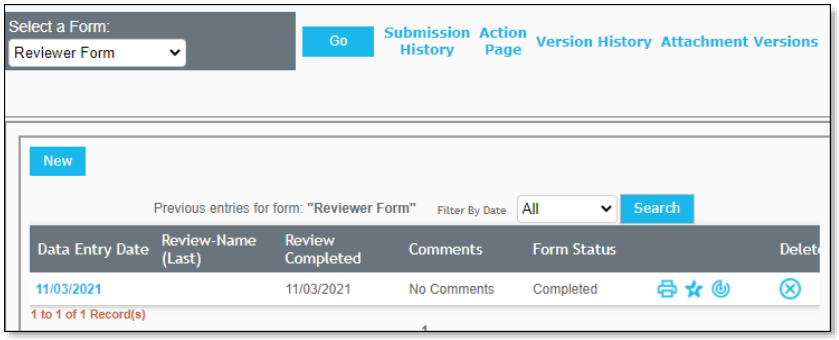


4. Review existing forms, if there are any.
5. Add a new form to confirm review, by clicking **New**.

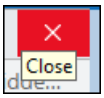
6. Complete the form, enter your e-Signature and click **Submit**.



The completed from appears under the New button.



7. Use the **Select a Form** dropdown to complete any other applicable forms or form reviews.
8. Click **X** to close the window.

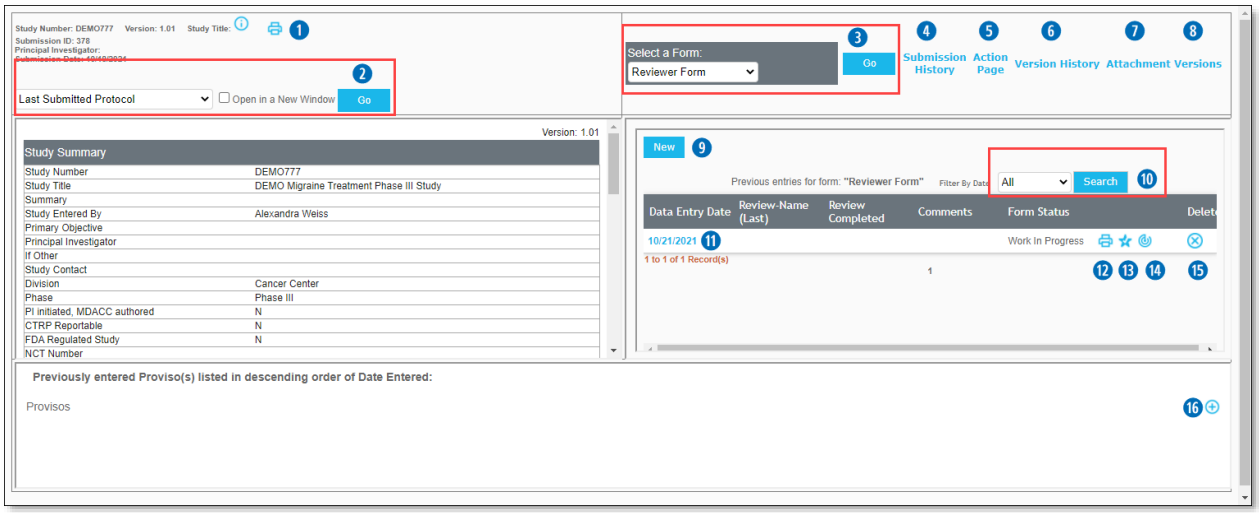


2.7 Board Committee Members Functionalities

Board Committee Members are eCompliance users who are tasked with voting on submission outcomes. They require “View” permissions to the Manage Meeting tab to view meetings and meeting outcomes / notes, as well as full access to the Reviewers Area to review study information. Refer to **Navigating to Reviewers Area** on how to access and view study information.

Note: If the submission cannot be viewed in the Reviewers Area, the eCompliance Administrator should ensure that the submission status is Reviewer, as well as to ensure that the user is added to as a Super User to Forms for access rights to view, edit, and add new forms.

The following functionalities may be available in the Reviewer’s Area:

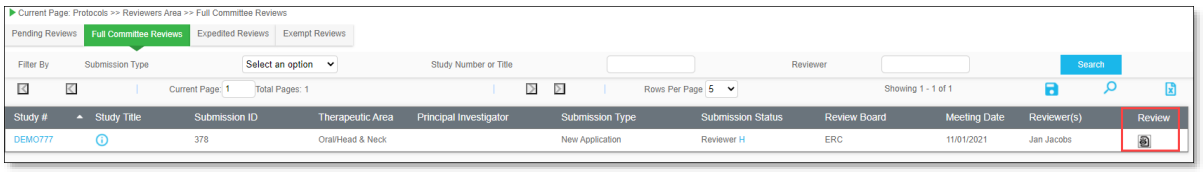


1. Print Button– Click to print the information shown in the left-hand window
2. Select Dropdown and Go Button– Select a dropdown option and click Go to view a document or submission data in the left-hand window
3. Select a Form Dropdown and Go Button– Select a form from the dropdown and click Go for a Reviewer's Form type to view, edit, or create a new form, as permissioned
4. Submission History Link– Provides the Submission Status Date, the Submission Status, and Notes for a submission. This may not be available to access depending on your permissions.
5. Action Page Link– Works the same as the Actions tab from the Manage Submissions page for eCompliance Admins
6. Version History Link– Shows the version history of the Protocol Submission and the associated Change Log Justification if a change was made
7. Attachment Versions Link– Shows the version history of all attachments to the Protocol Submission along with links to the document and the Attachment Status
8. New Button– Click to create a new form. This may not be available to access depending on your permissions
9. Filter By Date Dropdown and Go Button– Select a date timeframe from the dropdown and click Go to filter the forms, if needed
10. Data Entry Date Link– Click to view the completed form. An Add/Edit Queries button will be available to use to add a new query to the form, if needed
11. Print Button– Click to print a specific form
12. Audit Button– Click to view an audit trail for a specific form, in a new window
13. Track Changes Button– Click to view tracked changes to a specific form, in a new window
14. Delete Button– Click to delete a form entry, if needed
15. Add New Proviso Button– Click to add a new proviso

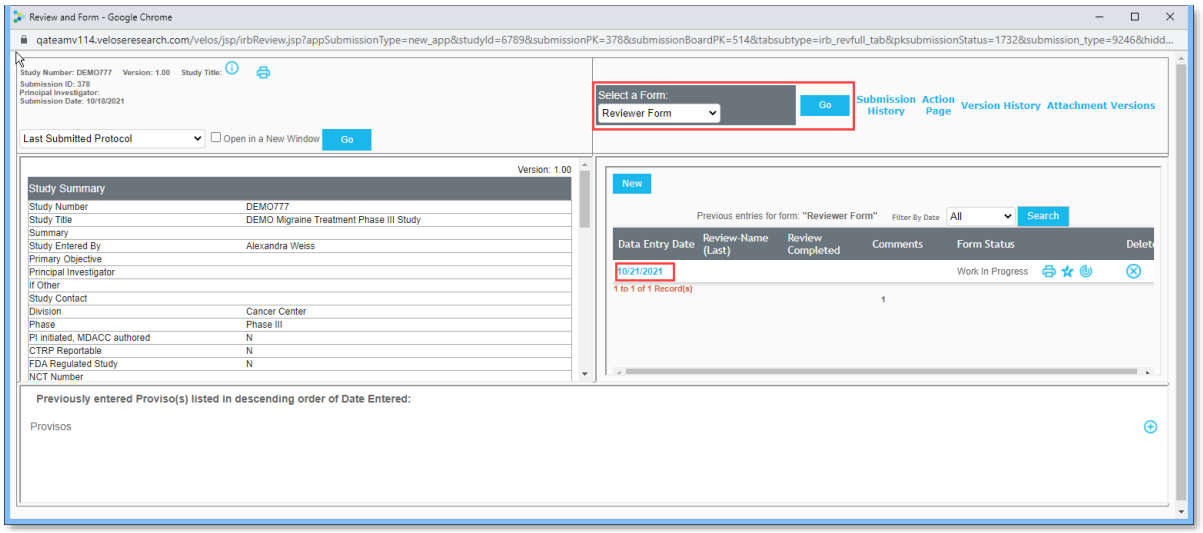
2.7.1 Review Reviewer's Forms

After navigating to the applicable submission in the Reviewers Area, to review a Reviewer's Form:

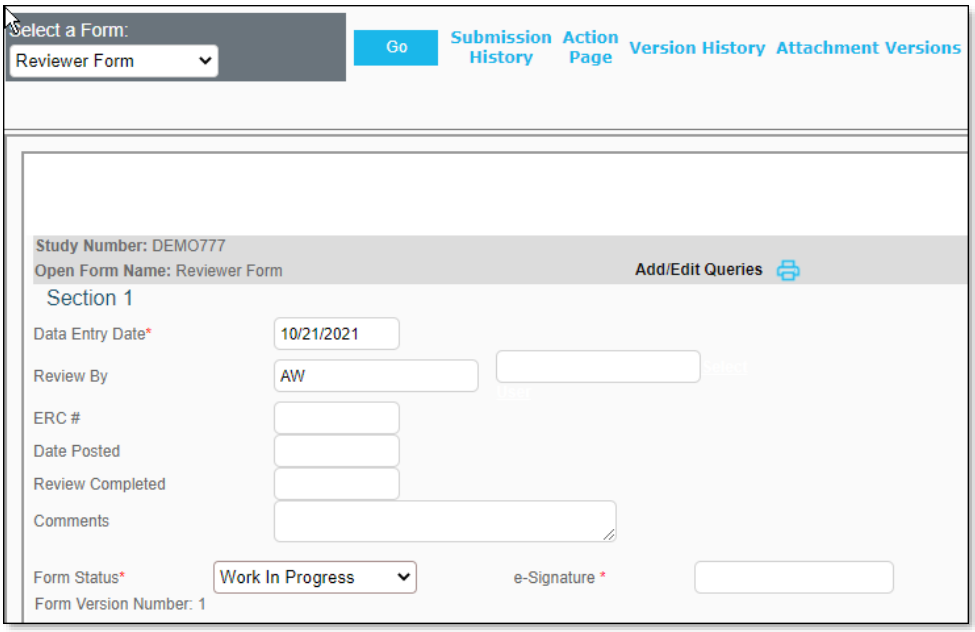
1. Click the **Review** button for a Study #.



2. Select a type of form from the Select a Form dropdown and click **Go**.



3. Click the date link under the Data Entry Date header to view the form.
    a. If permissioned, update and/or change the Form Status from the dropdown and then enter your e-Signature and click **Submit**. In this example, the Board Committee member only has View access and cannot edit.



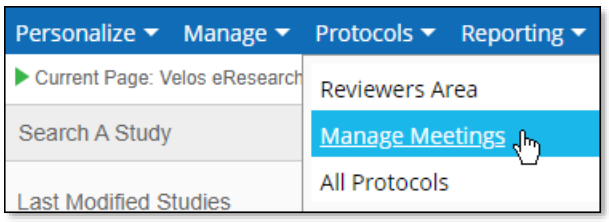
4. Complete reviewing all forms in the Select a Form dropdown before clicking **X** to close the pop-up window.

2.7.2 View Meeting Details and Meeting Topics

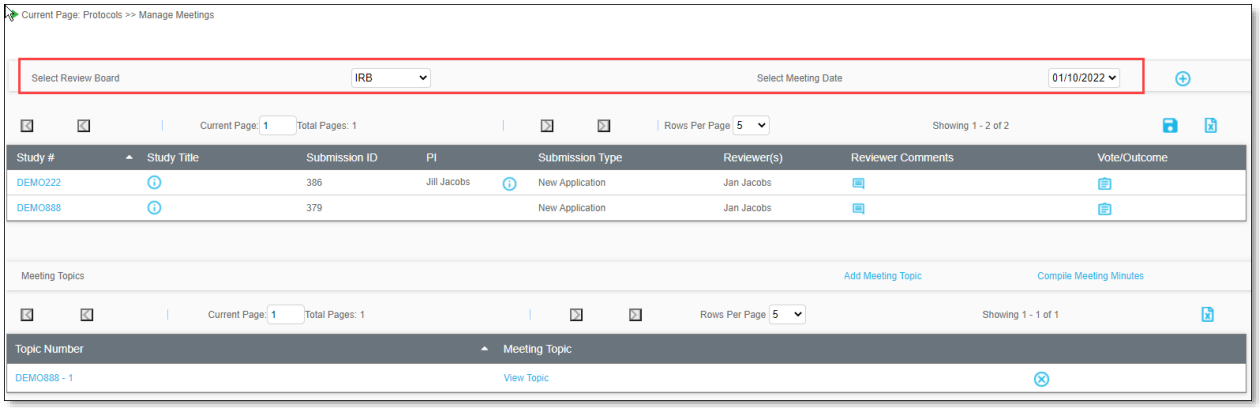
Prior to a meeting, Board Committee Members should review the Meeting Topics and meeting details for an upcoming Review Board meeting that they may be attending.

To view meeting details and Meeting Topics:

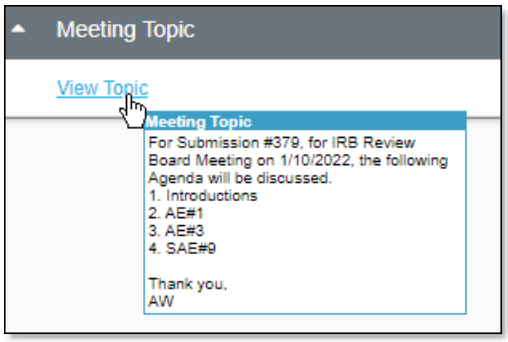
1. Click **Manage Meetings** under the Protocols dropdown in the navigation bar.



2. Click the applicable Review Board in the Select Review Board dropdown and click the applicable Meeting Date in the Select a Meeting Date dropdown.



3. Hover over the **View Topic** link to view information which the eCompliance Admin provided about the upcoming meeting.



Note: Depending on permissions, the Topic Number link may be unavailable to access. Other links and buttons may also be unavailable in which you will see an “Access or Edit Permission Denied” pop-up after clicking.

3 Appendix A: Technical Information

3.1 Revision History

Version	Section	Description of Changes
1	N/A, first version	1. This initial version was exported from the eResearch user guide for 12.1. Refer to the eResearch user guide's Revision History for any prior changes to this free-standing user guide.
2	Fixed Styles Minimum Workstation Requirements	1. Fixed Styles 2. Internet Explorer is no longer supported and Microsoft Edge is now a supported browser.

3.2 Related Software

Software	Version
Velos eResearch	13.0

3.3 Minimum Workstation Requirements

Browser	Version	Screen Resolutions
Google Chrome	104	1280x1024 1360x768
Firefox	104	
Edge	104	