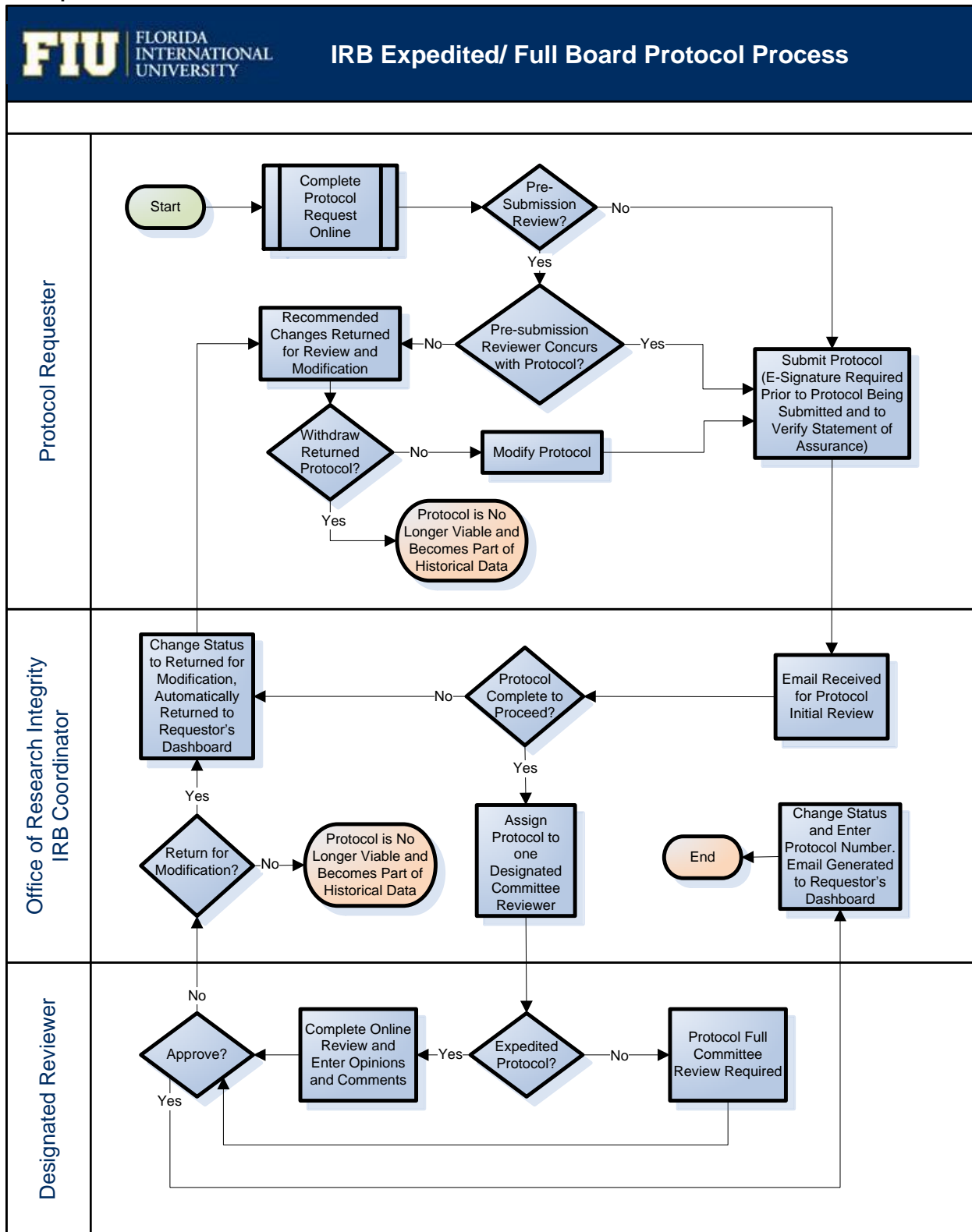


IRB Protocol Application Review Process

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Chapter 1. Business Process Overview



Overview of the IRB Protocol Application Process

When a Principal Investigator submits a protocol application for review it arrives in the “inbox” of the Protocol Administrator or Coordinator, the individual responsible for managing the review process. This individual identifies review type, assigns appropriate reviewers, sets up committee meetings, sets status, and manages feedback to the PI (if applicable).

When a protocol application is submitted there are a number of possible routes it can take through the review process.

- The Coordinator looks at the application to verify that all is in order (e.g., attachments are included, PI e-signature, and valid training certificates).
- The Coordinator assigns the protocol application to one Designated Committee Reviewer for review. The Designated Committee Reviewer determines if it is an Expedited Protocol.
- If it is determined to be an Expedited Protocol, then the Designated Committee Reviewer will complete their online review and enter opinions and corresponding comments prior to approving (unless the protocol requires modifications in which it is then returned to the Coordinator).
- If it is not determined to be an Expedited Protocol, then the Designated Committee Reviewer will assign the protocol for a Full Committee review.
- The reviewers access the application within the system, record comments associated with specific protocol questions and general comments, and are able to submit an opinion on the application.
- When all comments are received, the findings are summarized and the application is returned to the Principal Investigator for modifications.
- If the application is returned to the Principal Investigator for modification, they can review the comment summaries online and make the required changes. The application is then resubmitted and the Coordinator again manages the review process for this new version.
- Once all of the modifications have been addressed (or if there were no modifications needed) the Coordinator will add the application to a committee meeting agenda for further discussion and/or a final decision.

Assumptions

- IRB Member entering protocol application has access to Topaz. If you need to be granted access, please see additional information located at: <http://research.fiu.edu/irb/pages/topaz.html>

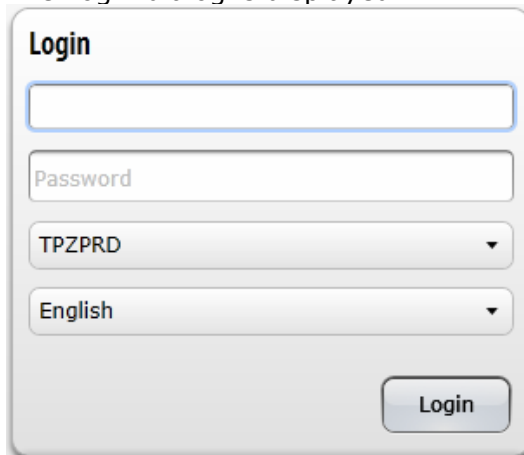
Chapter 2. General Information

This section will explain how to log in and better understand the user interface features throughout the Topaz Protocol Application System. You'll find out how using My Dashboard helps increase your accuracy and efficiency, and how to use the built-in Quick Filter and Filter Settings features to quickly find information.

2.1. STARTING AND LOGGING IN

To access the Topaz Protocol Application System:

1. Navigate to the network location <https://topaz.fiu.edu/TOPAZEnterprise/>. The Login dialog is displayed:



The screenshot shows a login dialog box with the following elements:

- Title: Login
- Text input field (empty)
- Label: Password
- Text input field (empty)
- Dropdown menu: TPZPRD
- Dropdown menu: English
- Button: Login

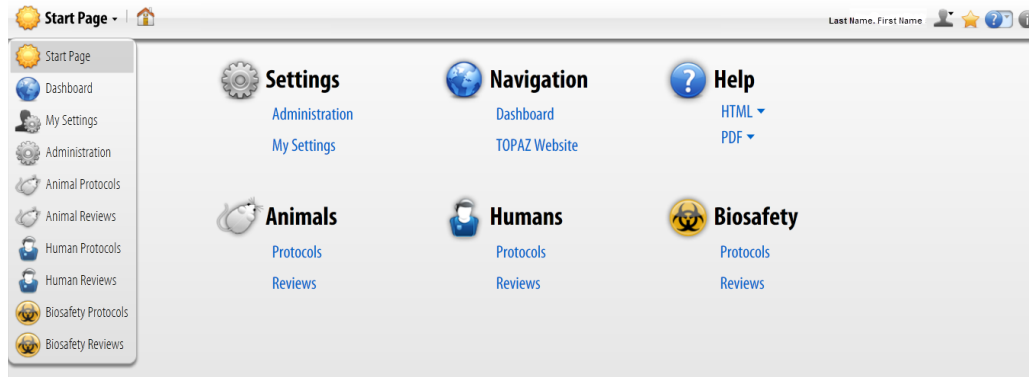
2. Enter the following required login information:

Enter your Panther ID number then enter your corresponding FIU My Accounts Password.

3. Select **Login** at the bottom of the dialog.

2.2. USING NAVIGATION BAR AND MENUS




1. The **Menu** appears:



- The **Start Page** link on the left side of the screen can be selected for a drop-down menu. This menu is available anywhere in the application by clicking the title on the left side of the navigation bar.

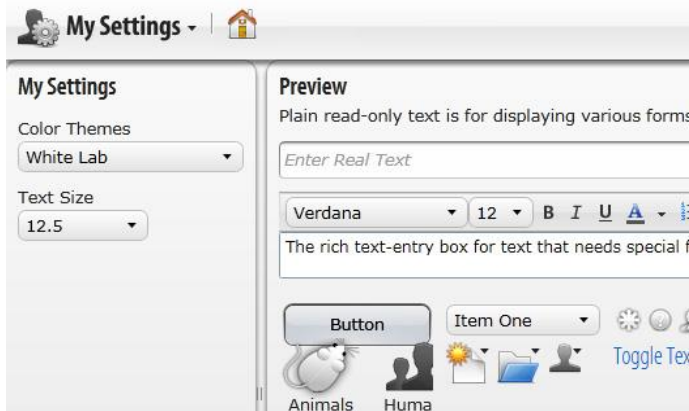
Note: Do not click your browser’s Back button to navigate while using TOPAZ Enterprise. Clicking Back takes you to the last viewed non-application Web page. Failure to SAVE prior to hitting the back button will cause you to lose your unsaved work.

- Select the desired navigation destination:

Field Name	Notes
Menu	This menu allows users to navigate within the application. Depending on your security access this menu maybe different.
House/Star Icon  	Returns you to your home page or default page. The home page can be set by navigating to the page you want to set as your default. Once you are on that page click the star icon on the right to set the page as your home page.
Help	The question mark icon will take you to online help.
Human Silhouette Icon 	Use this icon to log out of the application properly. You <u>cannot</u> change your password since you are using your MyFIU credentials for logging in (LDAP).. The name to the left of the silhouette displays the logged in user.

2.3. USING MY SETTINGS

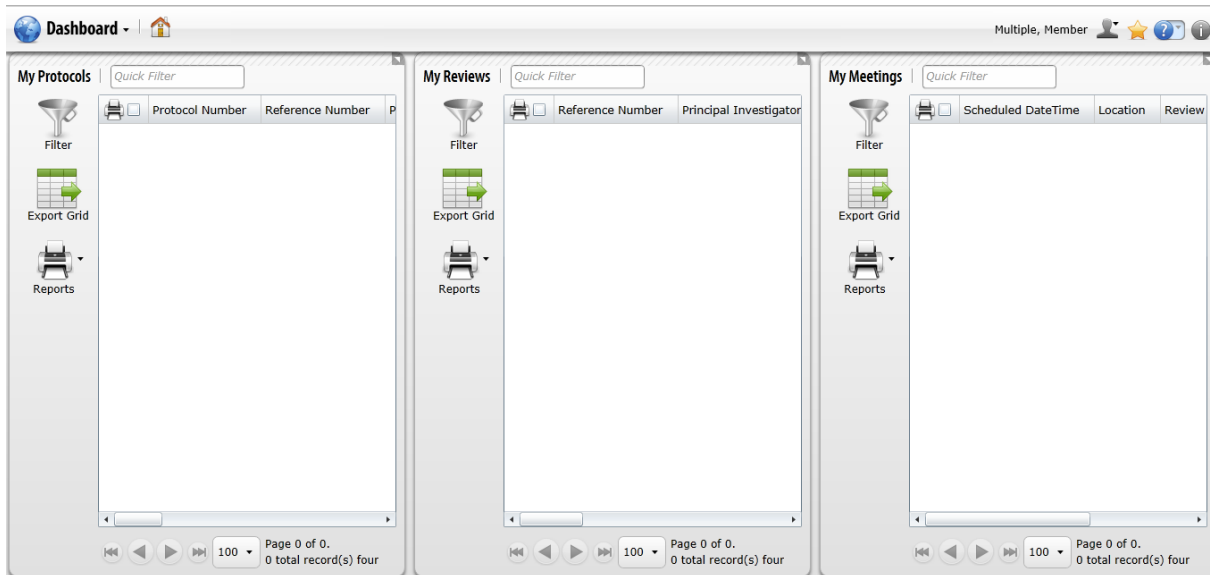
The background color and the size of the text can be controlled within the application. Use the Color Themes drop-down list to select a background theme (“White Lab” is the default). Use the Text Size drop-down list to increase or decrease the text size throughout the application. The Preview panel on the right is simply there to show you how your selected color theme and text sizes will look on various controls within the application.



2.4. USING MY DASHBOARD

My Dashboard provides one-click access to common management tasks and frequently needed information through **My Protocols**.

Note: The changes you make to My Dashboard are not saved. When you navigate away and back again, the default appearance is restored.



My Protocols

My Protocols gives you an at-a-glance overview of your protocols and quick access to view and edit protocol details. To view more information about a particular protocol, mouse over the item in the table to highlight the protocol and click to open the **Protocol** panel.

To help you find information faster, this feature allows you to search the table, to sort by columns in ascending or descending order, and to use filtering.

My Reviews

As a reviewer, **My Reviews** shows your in-progress reviews. To view more information about a particular review, mouse over the item in the table to highlight the review and click to open the **Reviews Main Menu** panel.

To help you find information faster, this feature allows you to search the table and to sort by columns in ascending or descending order.

My Meetings

My Meetings allows you to quickly access all scheduled meetings.

To help you find information faster, this feature allows you to search the table and to sort by columns in ascending or descending order.

Changing the Appearance of My Dashboard

You can customize the appearance of any table on My Dashboard by resizing column widths, changing column order, and reordering the items in a table by sorting columns in ascending or descending order.

Changing Column Width.

In the default view, each column has a default width. You can drag column separators and change the width of columns.

Note: Changing column width does not change the number of columns available to view. A scroll bar appears at the bottom of the table when the table width exceeds the size of the frame.

Changing Column Order

In the default view, columns are arranged in a certain order. You can drag and drop entire columns to rearrange them to your specifications

Sorting Column Contents in Ascending or Descending Order

You can change the order of items in a table by sorting columns in ascending (values lowest to highest, A to Z) or descending (highest to lowest, Z to A) order.

To sort the items in the table in ascending order, select in the column header. The table refreshes in the new order. An upwards pointing arrow appears in the column header cell to indicate the table is sorted in ascending order based on the contents of the column.

To sort the table in descending order, click in the column header again. The table refreshes in the new order and a downwards pointing arrow appears in the column header cell to indicate the table is sorted in descending order based on the contents of the column.

2.5. PROTOCOL PANEL ICONS

Within each type of question there are icons and links that you can use to complete your protocol request. Below is a description of each icon and link that appear on the questions on the Protocol Panel.

Formatting Toolbar - You can select different formatting options such as the design of the font, bullets, or the centering of text.



Required Question - A red asterisk icon indicates that the question requires an answer before the protocol request can be submitted.



Attachment - The attachment icon permits hyperlinks and attachments within questions. Hyperlinks and attachments may consist of Websites and documents. Click on the attachment icon to access the icon for hyperlinks and the icon for document attachments.



Help - Click the help icon to obtain written assistance with answering the question.



Add Images - The add images icon allows the insertion of images into your question.



Delete - The delete icon allows the removal of selected data. Some examples include protocol associates, species, procedures, and rows in table questions.



Hyperlinks -Some questions will contain hyperlinks that will give you access to documents such as standard operating procedures, or access to Websites. These have been added by the facility administrators to provide beneficial information.

2.6. PROTOCOL OUTLINE ICONS

The **outline panel** automatically displays an outline of the form. Use the icons that are available to filter the outline. Click the question title to display it in the Protocol panel. Below is a description of each icon and link that appear on the Protocol Outline.

Required Filter - ALL questions marked by a red asterisk must be answered before you will be allowed to submit your protocol request.



E-Signature Filter - indicates that the item requires an electronic signature.



Unanswered Questions Filter - indicates question which have not been answered.



Changed Questions Filter - indicates that something in the protocol has changed (applies to amendments, renewals, interim reviews, and protocol requests returned for modification.)



Question with Summary Comments - this icon will list all the questions that contain a summary of reviewer comments.



Filter Outline - to filter the outline using a progressive filter type a single letter or word in the open field. This will condense your outline and list specific questions according to your filter.



2.7. RUNNING REPORTS

The following list of reports are available to run from your Dashboard:

Protocol Detail Report allows the user to see all questions on the protocol form.

Protocol Detail Report Answered Questions Only allows the user to only view questions that have currently been answered on protocol form.

Protocol Comparison Report allows the user to view the changes made between two different versions of a protocol. This report can only be used while in the compare mode.

Protocol Review Detail Report allows the user to view all reviewers' comments.

Chapter 3. Protocol Application Review Steps

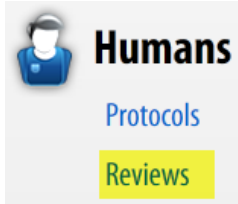
Note: Please reference the Division of Research Topaz website found at <http://research.fiu.edu/compliance/topaz.html> for assistance logging into Topaz.

3.1. REVIEW AND APPROVE SUBMITTED PROTOCOL APPLICATIONS

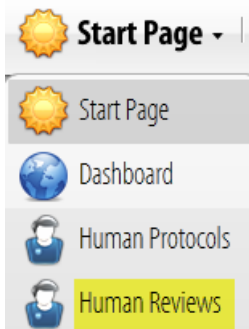
3.1.1. Accessing Reviews Management

1. There are two ways available to access **Reviews Management**. You can access Reviews Management from the system’s start page:

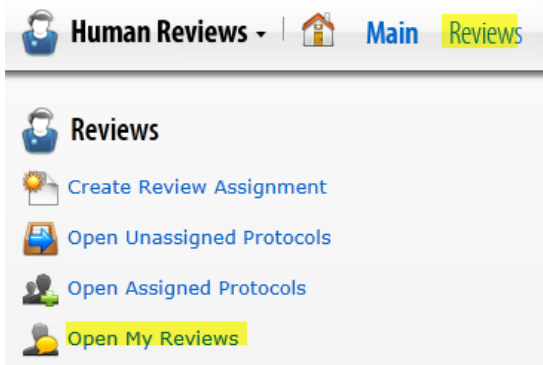
From the **Start Page**, click the **Human Reviews** link.



Alternatively, it can be accessed from the toolbar at any screen, click the **upside down triangle** to access the dropdown menu - click **Human Reviews**.

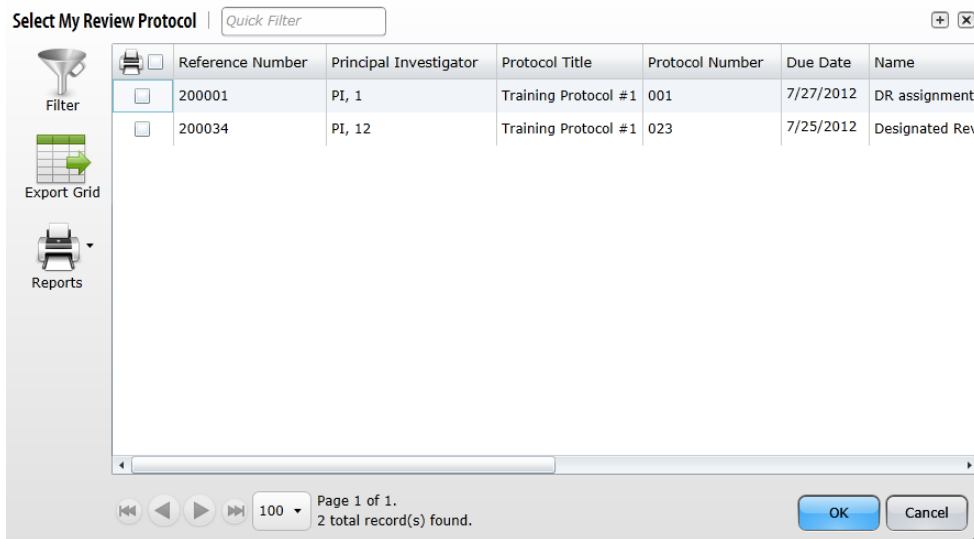


2. After you click Human Reviews from the drop-down menu the **Human Reviews Toolbar** and **Reviews Panel** appears.

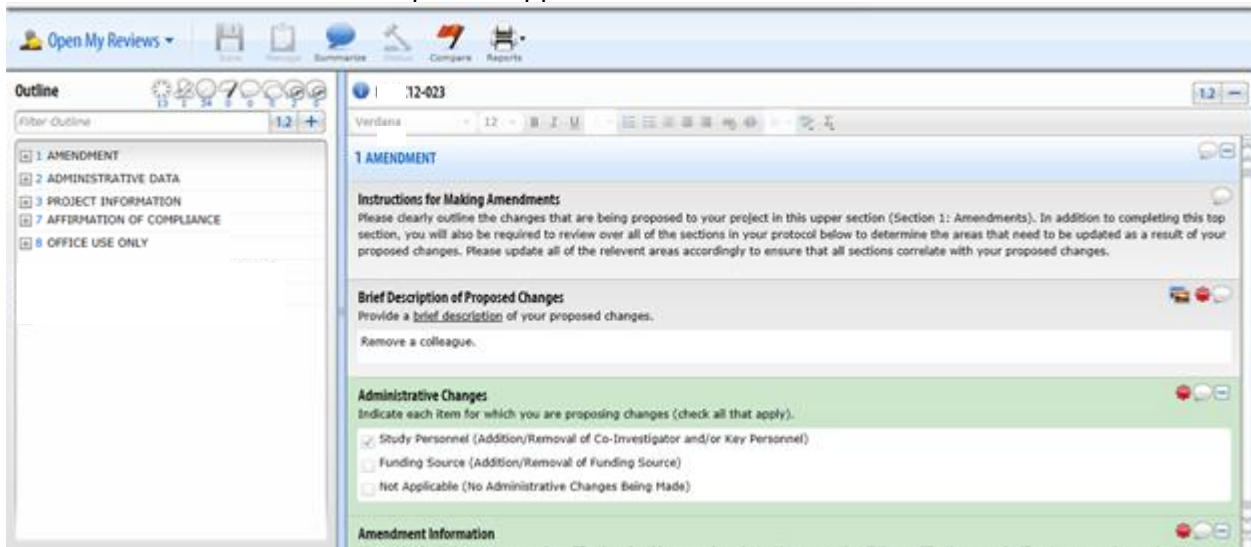


4. Click **Open My Reviews**.

5. The **Select Protocol** panel appears. Select the protocol and click **OK**.



6. The **Protocol** and **Outline** panels appear.



End Procedure.

Note: If this Protocol Application is a resubmission, renewal, or amendment, please reference section 4.1.4 of this guide for comparing the previously submitted Protocol Application before proceeding with the below steps.

3.1.2. Entering Comments on Questions

As you work through the review, you may encounter items that require commentary or read other reviewers' comments when applicable.

To add comments:

1. Click the **Questions Comments** icon to the right of each question.

The **My Comments** entry panel slides up from the bottom to provide a rich-text comment entry for the question.

2. Type in your comments in the displayed rich text box panel.
3. Click **Save**.

Note: If a question contains a review summary from a previous submission, the icon will change to indicate the previous comment.

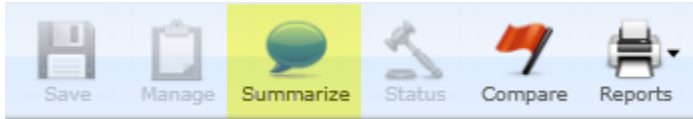
End Procedure

3.1.3. Entering a Vote or an Opinion

Reviewers are allowed to enter a vote or an opinion depending on their reviewer role. Entering a vote or an opinion indicates what you think the status of the protocol request should be. You typically will enter a vote or an opinion only after having reviewed the entire

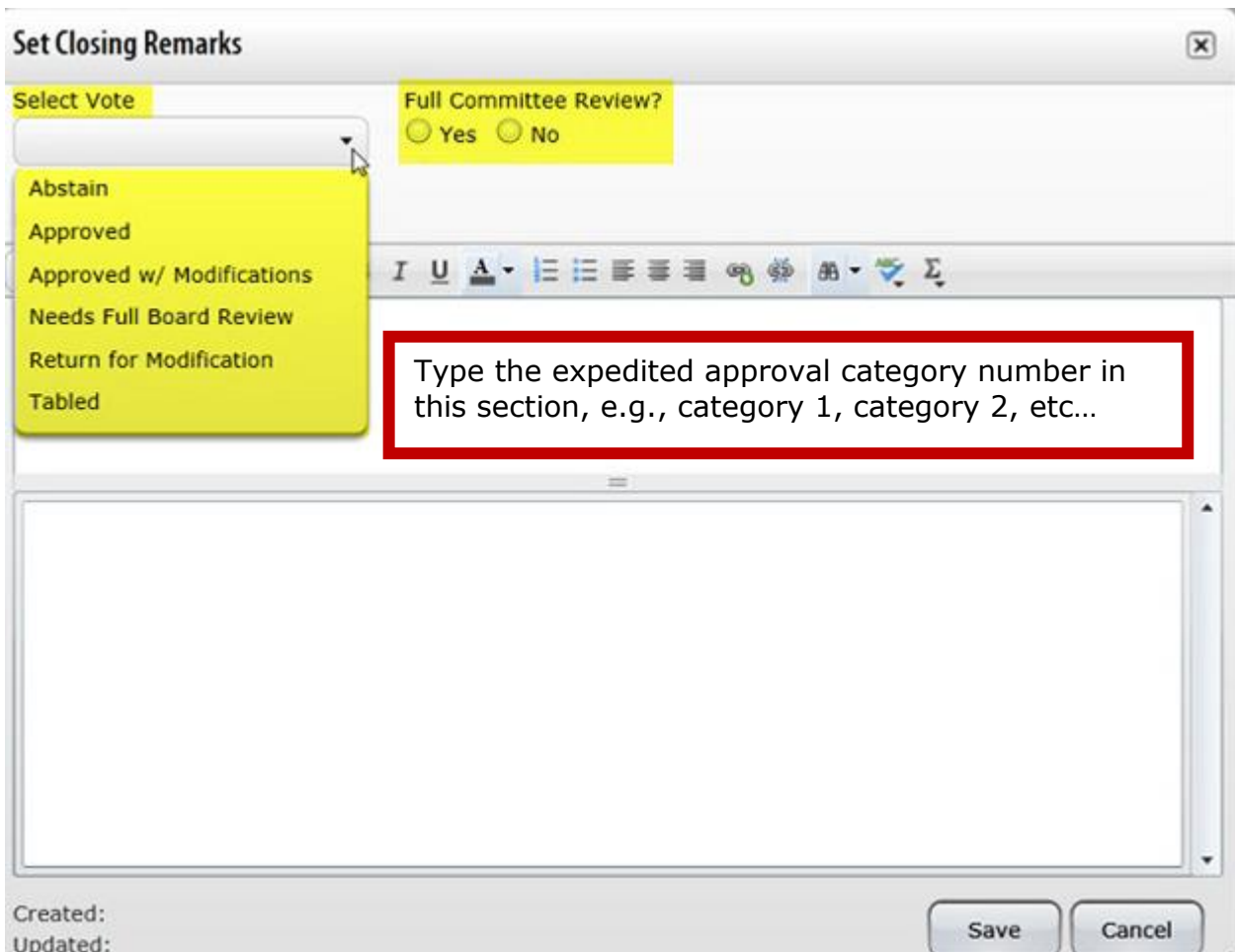
request and entered all of your comments. To enter a vote or an opinion:

1. Select the **Summarize** icon:



The **Set Closing Remarks** panel opens.

Depending on your review assignment, you will be provided with an option to enter a 'Vote' or an 'Opinion'. Below is an example of a 'Vote' used for approving an expedited protocol.



2. Select a vote (or opinion depending on your reviewer role) from the **Select Vote (or Select Opinion)** menu. Selections for a vote include *Abstain*, *Approved*, *Approved w/ Modification*, *Needs Full Board Review*, *Return for Modification*, *Tabled*.

3. Select an option on the **Full Committee Review** section.

4. Type your closing remarks into the text box on the Enter Closing Remarks Section. If approving an expedited protocol, type the expedited approval category number in the indicated section, (e.g., category 1, category 2, etc...).

5. When finished making all entries and selections, click **Save**.

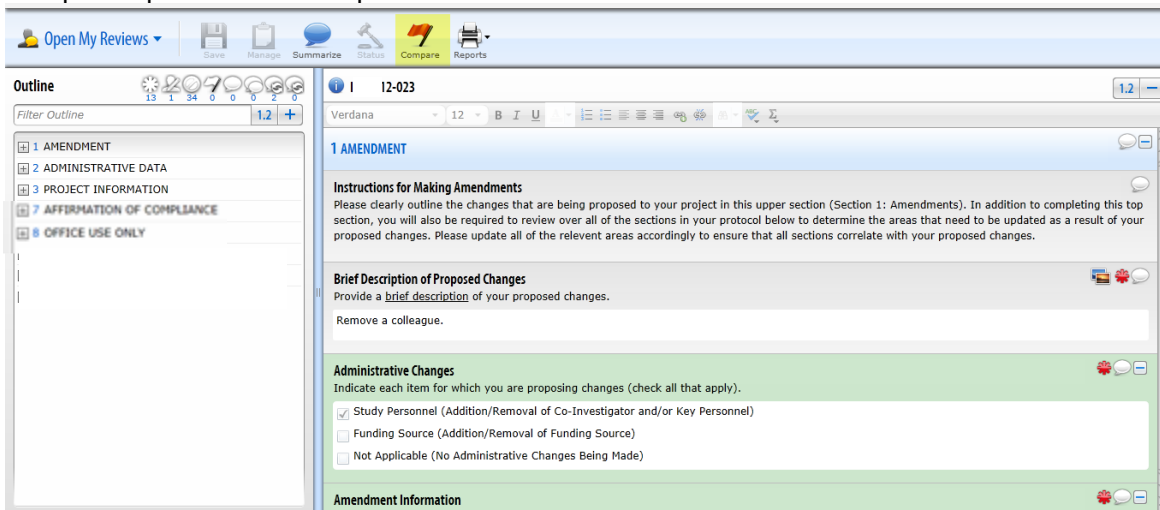
Note: Once **Save** is selected, your comments have been submitted. You will not receive a confirmation message on the screen however you will receive an email confirmation. For the duration of the review assignment, you will still be able to select the **Summarize** icon to submit additional comments if necessary.

End Procedure

3.1.4 Comparing Protocols to Previous Versions

You can compare a current submission to any previous submission associated with the protocol request (some protocol requests may have been returned for modification several times). This feature allows verification that only required modifications were completed.

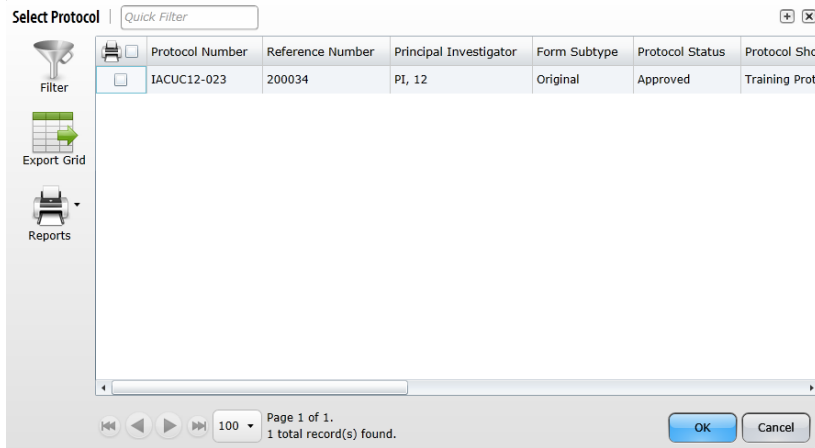
1. Open a protocol to compare.



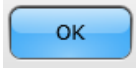
2. Select the **Red Flag** icon to initiate a comparison.



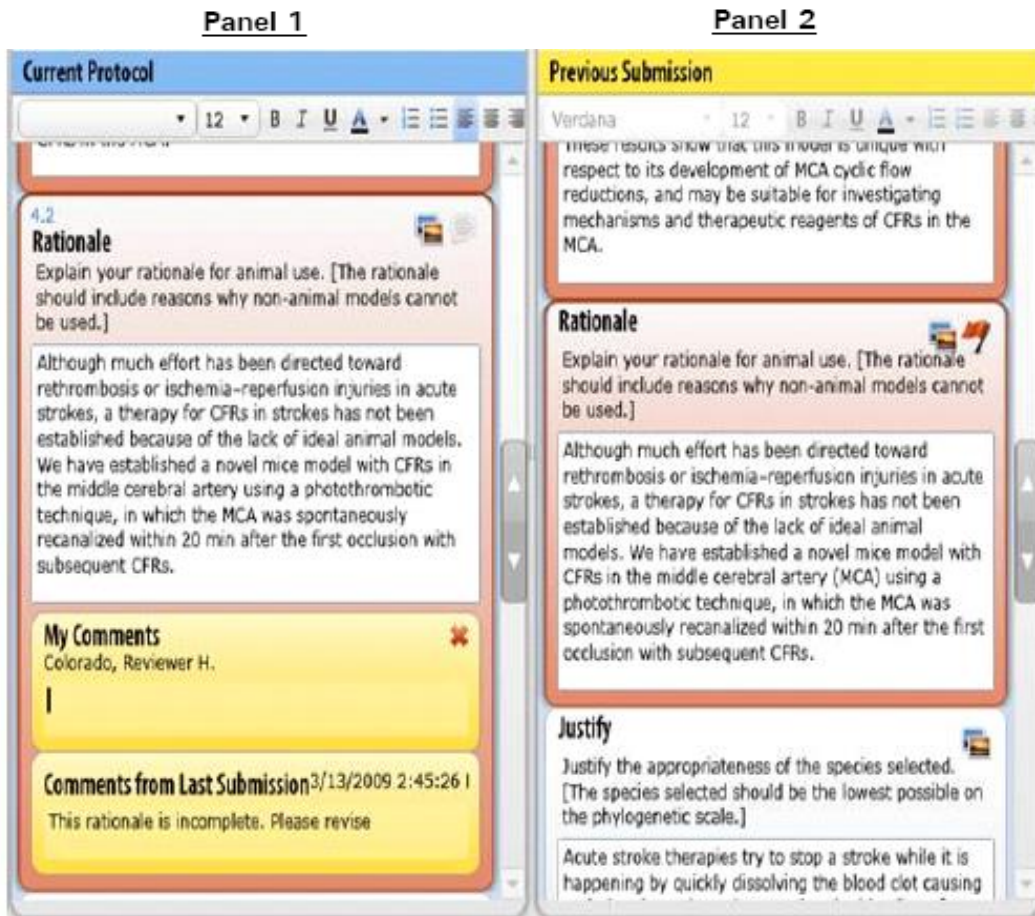
3. The **Select Protocol** panel appears. Select the protocol to be compared.



4. Select the **OK** button to open the protocol request.



5. Two panels open side-by-side. Panel 1 displays the first protocol selection, while panel 2 displays the second protocol.



6. Select the red flag in the Outline panel to filter and identify changed items. This will narrow the outline list, and changed items will be marked in red.



7. Double-click any red item listed in the Outline, and questions will be highlighted in red on the protocol panel.

End Procedure.

3.1.5 **Accessing Read Only Protocols**

You can access read only protocols from the main protocol panel to view and/or compare protocols according to the status of the protocol.

Submitted Protocols

The Submitted Protocols link allows you view and compare submitted request.

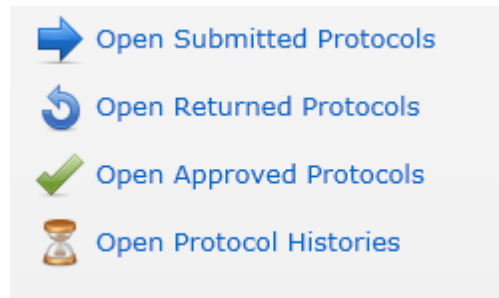
Approved Protocols

The Approved Protocol link allows you to view and compare approved protocols.

Protocol Histories

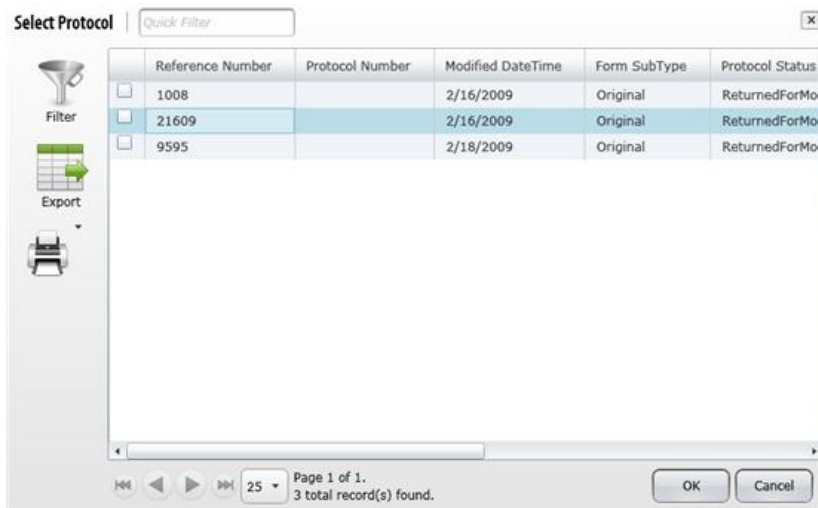
The Protocol Histories link allows you to view all versions of the protocol's lineage: this includes submitted, returned, approved, etc.

1. Select on any one of the following links to open a protocol: **Open Submitted Protocols**, **Open Approved Protocols**, or **Open Protocol Histories**:



Creating Protocol Requests

2. The **Select Protocol** panel appears. Select the protocol to be viewed or compared.



End Procedure.

